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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92066392
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Attachments	ERBE Opposition to Covidien Renewed Motion for Summary Judgment.pdf(399279 bytes) 2019.09.30 Declaration of John Day (FINAL).pdf(133326 bytes) Day Ex. 1 - Highly Confidential Placeholder.pdf(60151 bytes) Day Ex. 2 - Highly Confidential Placeholder.pdf(60157 bytes) Day Ex. 3.pdf(3320039 bytes) Day Ex. 4 - Highly Confidential Placeholder.pdf(60157 bytes) Day Ex. 5.pdf(4720959 bytes) Day Ex. 6.pdf(4636108 bytes) Day Ex. 7.pdf(155579 bytes) Day Ex. 8 - Highly Confidential Placeholder.pdf(60263 bytes) Day Ex. 9 - Highly Confidential Placeholder.pdf(60183 bytes) 2019.09.30 Mullarkey Declaration (FINAL).pdf(85131 bytes) Placeholder Ex. A - Erbe 30(b)(6) John Day Excerpts - Highly Confidential.pdf(4422 bytes) Ex. B - E-SOFT-000001-15.pdf(4626330 bytes) Ex. C - E-SOFT_000110-17.pdf(862021 bytes) Ex. D - E-SOFT_000118-21.pdf(793134 bytes) Ex. E - E-SOFT_000122-27.pdf(785552 bytes) Ex. F - E-SOFT_000144-79.pdf(3123596 bytes) Ex. G - E-SOFT_000180-211.pdf(2741198 bytes) Ex. H - E-SOFT_000212-35.pdf(3687628 bytes) Ex. I - E-SOFT_000349.pdf(713866 bytes) Ex. J - E-SOFT_000350-51.pdf(805148 bytes) Ex. K - E-SOFT_000352-53.pdf(1369642 bytes) Ex. L - E-SOFT_000360.pdf(788521 bytes) Ex. M - E-SOFT_000361-62.pdf(613877 bytes) Ex. N - E-SOFT_001273.pdf(500638 bytes) Ex. O - E-SOFT_001274.pdf(506919 bytes) Placeholder Ex. P - E-SOFT_001640-48 Highly Confidential.pdf(4424 bytes) Placeholder Ex. Q - E-SOFT_001653-54 Highly Confidential.pdf(4431 bytes) Placeholder Ex. R - E-SOFT_001686-87 Highly Confidential.pdf(4425 bytes)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

COVIDIEN LP, Petitioner, v. ERBE ELEKTROMEDIZIN GMBH, Registrant.	Cancellation No. 92066392 Registration Nos. 4,236,231and 4,686,396 Mark: SOFT COAG

REGISTRANT'S OPPOSITION TO PETITIONER'S RENEWED MOTION FOR SUMMARY JUDGMENT

Dated: September 30, 2019

Respectfully submitted,

POLSINELLI PC

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Registrant Erbe Elektromedizin GmBH's ("Erbe" or "Registrant") hereby opposes Petitioner Covidien LP's ("Petitioner" or "Covidien") motion for summary judgment.

INTRODUCTION

Covidien has petitioned to cancel two ERBE registrations for the mark SOFT COAG (the "SOFT COAG mark"): U.S. Registration No. 4236231 for "medical instruments, namely, electrosurgical coagulation component of an electrosurgical generator system that operates at constant voltage" in International Class 10; and U.S. Registration No. 4686396 for "Computer software for use in electrosurgical generator systems to maintain constant voltage during fluid coagulation; high-frequency apparatus and measuring instruments, namely, electrosurgical generator systems comprised of computer software used to maintain constant voltage for in vivo use; software-programmable microprocessors" in International Class 9, "Electrosurgical generator systems comprising surgical instruments and apparatus and components thereof that operate at constant voltage; electrosurgical generator systems comprising high frequency surgical apparatus and instruments for medical purposes" in International Class 10, and "Development, programming and implementation of software for use in electrosurgical generator systems to maintain constant voltage; technical support services, namely, troubleshooting of computer software problems in electrosurgical generator systems" in International Class 42 (the "SOFT COAG registrations").

Covidien's petition alleges that SOFT COAG is a generic term and, alternatively, that SOFT COAG is descriptive of Erbe's goods and services and has not acquired distinctiveness. Both genericness and acquired distinctiveness are questions of fact, disfavoring summary judgment. *See In re Reed Elsevier Props., Inc.,* 482 F.3d 1376, 1378 (Fed. Cir. 2007); *In re Loew's Theatres, Inc.,* 769 F.2d 764, 769-70, 226 USPQ 865, 869 (Fed. Cir. 1985).

Contrary to Covidien's assertions, the facts presented in the record do not support a conclusion that the SOFT COAG mark is generic. The determination of whether a mark is generic involves a two-step analysis: (1) What is the genus of goods or services at issue? And (2) Is the term sought to be registered understood by the relevant public primarily to refer to that genus of goods or services? *H. Marvin Ginn Corp. v. Int'l Ass'n of Fire Chiefs, Inc.*, 782 F.2d 987, 990, 228 USPQ 528, 530 (Fed. Cir. 1986); *In re Trek 2000 Int'l Ltd.,* 97 U.S.P.Q.2d 1106 (T.T.AB. 2010). A proper analysis clearly shows that purchasers of electrosurgical gerenators understand that SOFT COAG refers not to the genus – electrosurgical generators – but to the species, Erbe's electrosurgical generators.

Similarly, the facts presented in the record clearly demonstrate that SOFT COAG has acquired distinctiveness through Erbe's substantially exclusive and continuous use in commerce of its SOFT COAG mark for more than five years before the date of its Affidavit of Acquired Distinctiveness and actual evidence of acquired distinctiveness. TMEP §1212.

Moreover, there is a myriad of genuine issues of material fact as to whether Erbe's SOFT COAG mark is generic, merely descriptive without secondary meaning, and whether the mark has acquired distinctiveness. Thus, Covidien's motion for summary judgment must be denied in its entirety.

ERBE'S STATEMENT OF UNCONTESTED FACTS

Since at least 1994, Erbe has used its SOFT COAG trademark to identify a mode available on its electrosurgical generator systems in the United States. Declaration of John Day ("Day Declaration") ¶7. The SOFT COAG mode is Erbe's proprietary low, constant voltage waveform in Erbe's electrosurgical generators. Day Declaration ¶10 and Day Declaration Exhibit

("Day Ex.") 1; Mullarkey Decl. Ex. A[1] (June 25, 2018 30(b)(6) Deposition of Erbe at 112:20-113:6); *see also* Day Ex. 1 at E-SOFT_001629 (Erbe describes SOFT COAG as a "constant voltage regulated, unmodulated, power limited electrosurgical coagulation."). The waveform is proprietary because the algorithms used to keep the voltage constant have never been disclosed. Day Declaration ¶10; Mullarkey Ex. A at 112:20-113:17. Specifically, Erbe's SOFT COAG mode never exceeds 200 volts peak during application, the voltage remains constant (ensuring reproducible, consistent tissue effect with each activation) and the current/power automatically adjusts lower as internal microprocessors diagnose increasing tissue dehydration/desiccation. Day Declaration ¶11 and Day Ex. 2. Controlled constant voltage not exceeding 200Vp prevents micro-electric arc formation at target tissue and ensures reproducible, consistent tissue effect. Day Declaration ¶11 and Day Ex. 2.

Constant voltage never exceeds 200 volts peak when the Erbe electrosurgical generator is operating in the SOFT COAG mode. Day Declaration ¶12 and Day Ex. 3. Thus, no sparks are capable of being produced between the coagulation electrode and the tissue. Day Declaration ¶12 and Day Ex. 3; Mullarkey Ex. A at 71:18-72:5. Sparks can lead to cutting effect and carbonization of target tissue. In fact, Erbe has occasionally referred to its SOFT COAG mode as NSC ("no spark coagulation"). Day Declaration ¶13; E-SOFT-001850-1933 at E-SOFT-001871. At other times, Erbe has described its SOFT COAG mode as constant voltage regulated, unmodulated, power limited electrosurgical coagulation. Day Declaration ¶13 and Day Ex. 4.

When utilizing Erbe's SOFT COAG mode, coagulated tissue appears to have a uniform, off-white color without any black spots which would indicate that sparks had been created or that

[1] Lettered exhibits A-Z are to the Declaration of Daniel P. Mullarkey submitted herewith. Confidential exhibits are filed under seal.

cutting or charring of tissue has occurred. Day Declaration ¶14. This uniform tissue effect, which demonstrates minimal tissue damage and allows for increased postoperative healing has been observed only after coagulation procedures utilizing Erbe's SOFT COAG mode, which some clinicians referred to the effect as "soft coagulation." Day Declaration ¶14; see also Bukrinsky Ex. 9 at E-SOFT-005027 ("[Use of the Erbe] Soft coag [mode] provides no carbonization and minimizes necrosis, with increased benefits for postoperative healing.").

Contrary to Covidien's contention, "soft coagulation" is not a medical procedure, and nothing in Covidien's brief supports this incorrect assertion. *See* Declaration of Katie Bukrinsky Exhibits ("Burkinsky Exs.") 43-55. Instead, electrosurgical generators are used by clinicians in therapeutic endoscopy for a variety of procedures to cut or coagulate tissue and/or vascular structures. Day Declaration ¶15 and Day Ex. 5; *See also , e.g.*, Burkinsky Ex. 22 at E-SOFT-00005346 (describing "electrical energy from the snare tip [] converted to thermal energy, [] lead[ing] to tissue desiccation and vessel coagulation."). Surgeons have the option to select a "mode" on an electrosurgical generator based on the voltage they need, at any given point, within the procedure. Burkinsky Ex. 22 at E-SOFT-00005346 (Selecting SOFT COAG mode during EMR procedure).

Erbe's SOFT COAG mode is designed to be used in therapeutic endoscopy and flexible endoscopic surgery where there is need for precision and reproducibility in tight spaces involving hollow organs. Day Declaration ¶¶15-16 and Day Ex. 5; Mullarkey Ex. A at 38:19-39:1. The SOFT COAG mode of Erbe's electrosurgical generators are rarely used in open or laparoscopic surgery, since coagulation mode progresses too slowly and has proven to be ineffective in treating active bleeds. Day Declaration ¶15. Recognizing that it had an innovative and effective new voltage methodology, constant low voltage, Erbe branded the mode SOFT

COAG. Mullarkey Ex. B; Day Declaration ¶18. While SOFT COAG is suggestive, there is no recognized meaning for "soft" in electrosurgical procedures. *See* Day Declaration ¶19. *Compare* Bukrinsky Exs. 38, 39, and 41, defining "soft coag" as "generally assured with voltages below 200 peak volts Cov-SOFT02331; Cov-SOFT02370 and "soft coag" being "characterized in that the amplitude of the RF voltage required…is less than 200 Volts… Cov-SOFT02395 with Ex. 42, which cites to ERBE's brochures, defining "SOFT COAG" as "190 Vp **constant voltage** waveform…" (Cov-SOFT02291) (emphasis added).

Contrary to Petitioner's assertions, trade journals and publications do not use "SOFT COAG" generically. Day Declaration ¶¶18-20. Indeed, Covidien's own evidence supporting its incorrect assertion are referring to a mode on the Erbe generator. *See, e.g.,* Burkinsky Ex. 22 at E-SOFT-00005346 (in methods section of article, authors note the use of Erbe's VIO 300D electrosurgical generator); Bukrinsky Ex. 44 at Cov-SOFT01092 (noting that Erbe's "VIO 300D system was set to soft coagulation."); Bukrinsky Ex. 45 at Cov-SOFT00603 (noting use of Olympus device, which is licensed from Erbe). Further, the vast majority of journals and publications use the term soft coagulation to describe the tissue effect achieved when a coagulation procedure has been done with an Erbe electrosurgical generator operating in the SOFT COAG mode. Day Declaration ¶20 and Day Ex. 6 (including E-SOFT-001574-80 (Olympus machine using Erbe technology).

Similarly, there is little evidence that competitors in the **United States** use the term SOFT COAG to refer to a coagulation mode. Indeed, Erbe has sought to protect its trademark rights in SOFT COAG since at least 2003. Day Declaration ¶25. In the 2000's Olympus and Karl Storz used SOFT COAG to identify a mode of an electrosurgical generator sold in the United States. Day Declaration ¶ 25. However, Erbe was the Original Equipment Manufacturer

("OEM") of those electrosurgical generator systems. Day Declaration ¶25 and Day Ex. 8. So not only were these uses authorized, but the consuming public properly attributed SOFT COAG trademark and its inherent goodwill to a single source – Erbe.

Erbe has also successfully enforced its trademark rights against third party competitors. *See, e.g., Erbe Elektromedizin GmbH et al v. Genii, Inc.*, D.Minn. 0:13-cv-03190-JNE-SER; E-SOFT_000972-77 (settlement agreement). Genii ceased use of the SOFT COAG mark for its coagulation mode in response to Erbe's request. Day Declaration ¶26 and Day Ex. 9. Finally, much of the competitor "evidence" refers to machines that are not sold in the United States. *See* Day Declaration ¶28.

Erbe has extensively marketed and promoted its electrosurgical generators consisting of the SOFT COAG mode. *See, e.g.*, Mullarkey Exs. B-S. Erbe's electrosurgical generators are marketed to and used in "thoracic procedures, urology procedures, thoracic, gastrointestinal, pulmonology, and colorectal procedures." Mullarkey Ex. A at 38:22-39:1. Doctors in the aforementioned fields trust Erbe's SOFT COAG mode for delicate procedures. *Id.*

While Valley Lab had a "SOFT COAG" mode that was discontinued in the 1990s, that mode was very different from Erbe's SOFT COAG mode. Day Declaration ¶29; Mullarkey Ex. A at 56:8-17). As shown in Buysse Exhibits C-E, the SOFT COAG mode of these Valleylab electrosurgical generators operated at a 9000 volts peak-to-peak, more than 40 times that of the SOFT COAG mode of Covidien's FT10 electrosurgical generators, the resulting tissue effects were anything but "soft". Day Declaration ¶29.

Erbe has sold a substantial number of electrosurgical generators and its SOFT COAG mode drives sales of Erbe's electrosurgical generators. Mullarkey Ex. A at 183:7-10. Further, doctors have come to know Erbe as the source of the very important SOFT COAG mode.

Mullarkey Ex. A at 185:24-186:1); *see also* Burkinsky Ex. 22 at E-SOFT-00005346 (in methods section of article, authors note the use of Erbe's VIO 300D electrosurgical generator); Bukrinsky Ex. 44 at Cov-SOFT01092 (noting that Erbe's "VIO 300D system was set to soft coagulation."); Bukrinsky Ex. 45 at Cov-SOFT00603 (noting use of Olympus device, which is licensed from Erbe).

On November 6, 2012, U.S. Registration No. 4,236,231 for the SOFT COAG trademark registered on the Principal Register based on a claim of acquired distinctiveness. Erbe filed a 2(f) declaration along with two supporting affidavits. *See* Bukrinsky Exs. 14 and 15. The USPTO reviewed and accepted these affidavits and the 2(f) claim of acquired distinctiveness. In support Erbe affirmed the substantially exclusive use of SOFT COAG, an annual spend of approximately $50,000 to produce literature that discusses the SOFT COAG mode of its generators, distribution of thousands of pieces of the literature distributed by mail to the relevant public, and promotion of the SOFT COAG mode on its website which received 10,000 visitors per month at the time of the declaration. At the time, Erbe also described the importance of reaching relevant consumers through tradeshows, presentations and trainings and stated an annual spend of $700,000 to attend trade shows, an annual spend of $20,000 to produce promotional and training materials, and an annual spend of $10,000 to produce self-study booklets that include the SOFT COAG mode. Between 2003 and 2012, Erbe gave nearly 30,000 in-service demonstrations for customers of its electrosurgical generators having the SOFT COAG mode. In that same time period, Erbe sold approximately 7000 electrosurgical generators having the SOFT COAG mode, sales that totaled in excess of $80,000,000 in revenue.

For the years 2013-2017, Erbe "estimates that it spent $1.8 million, $1.8 million, $1.99 million, $2.2 million, and $2.4 million respectively to promote generators having a SOFT COAG

mode. For example, Registrant has promoted the SOFT COAG mark by giving hundreds of presentations in the United States about the SOFT COAG mode of its electrosurgical generators. Bukrinsky Ex. 1 (Erbe's Response to Interrog. 21) at p.4). Indeed, Erbe's extensive promotional efforts have led to sales exceeding $160 million in the U.S. Mullarkey Ex. T; Bukrinsky Ex. 1 (Erbe's Response to Interrog. 21) at p.4.

A. Certain of Covidien's Facts are Factually Incorrect

1. Contrary to Covidien's assertions, there is no recognized definition for "soft coagulation." Instead, Petitioner misstates Mr. Day's Rule 30(b)(6) testimony. Contrast with Covidien's Uncontested Statement of Fact ("CUSF") ¶ 4 in which Covidien asserts "soft coagulation" is a technique or common medical procedure. Also contrast with CUSF ¶ 32 in which Covidien asserts that IEC calls "soft" a coagulation type. *See* CUSF ¶37.

2. Soft Coagulation is not a medical procedure. Day Declaration ¶ 19.

3. According to Covidien's own records, Valley Lab did not sell any Force SS45 generators with a "soft coag" mode after 1995.

4. According to Covidien's own records, Valley Lab sold only one Force 4B generator with a "soft coag" mode between 1996 and 2003, and sold only a handful of generators between 2004 and 2009.

B. Examples of Some Undisputed Facts that Contradict Covidien's "Undisputed" Facts

1. Other than Covidien, the only third party currently using "soft coag" to designate a mode on electrosurgical generator is Olympus.

2. Olympus began using "soft coag" after Covidien filed the cancellation proceeding. Day Declaration ¶ 28.

3. Erbe made the Olympus generators that had a SOFT COAG mode in the early 2000's, and Olympus issued press releases that its generators were using Erbe's technology. Day Declaration ¶ 25.

4. Similarly, in the early 2000's Erbe was the Original Equipment Manufacturer ("OEM") of the Karl Storz generators that used SOFT COAG to designate a mode on an electrosurgical generator using Erbe's proprietary technology. Day Declaration ¶ 25.

5. Almost every scientific journal that discussed "soft coagulation" attributed the effect to the use of the SOFT COAG mode of an Erbe electrosurgical generator. Day Declaration ¶ 20.

6. The SOFT COAG mode of Erbe's generators and the SOFT COAG mode of Covidien's FT10 generator are not the same, the modes achieve coagulation in different ways, and the effect of the coagulation procedure is not the same.

C. Coviden's "Undisputed Facts" are so Misleading as to be False

Most of the 42 undisputed facts asserted by Covidien are so incomplete that they are misleading and themselves create several important factual disputes. Consequently, Covidien's renewed motion for summary judgment must be denied.

1. Electrosurgical generators are relatively expensive medical devices. Advertising through trade journals and written publications are not effective marketing avenues for electrosurgical generators as suggested by Covidien. Instead, specialty related trademarks, e.g., Digestive Disease Week, regional and national meetings and conducting workshops regarding how to obtain the best clinic results for patients are the most effective forms of advertising. Day Declaration ¶¶ 9-10.

2. Covidien refers to a "soft coag" mode used by its predecessor Valley Lab. However, Erbe's SOFT COAG mode is vastly different from that Valley Lab mode. The Valley Lab "soft coag" mode was anything but "soft" in that it operated at 9000 volts, more than 40 times that of Erbe's SOFT COAG mode. Day Declaration ¶29. Further, Covidien's own "soft coag" mode, discovered by Erbe in 2017, differs from Erbe's proprietary mode. Specifically, the user manual graphs from Covidien's own user manuals show that voltages are greater than 200 volts peak. *See* Mullarkey Ex. A at 66:21-23; Buysse Exhibit E. Thus Covidien's own use of its "soft coag" mode differs from its established "definition" that "soft coagulation" is defined as less than 200 volts peak.

3. Covidien asserts that various Valleylab electrosurgical generators that included a "soft coag" mode were sold through 2005. Not only is this "fact" inaccurate, see supra at Sec. A ¶¶ 2 and 3, and Day Declaration ¶ 29. Covidien provided no documentary evidence of these sales or of its claims of the commercial success for its electrosurgical generators with a "soft coag" mode. Instead, Covidien merely cites to a self-serving employee declaration. *See* McCarthy 12.13 (Affidavits from friendly employers given little weight.).

4. While Covidien asserts that some Erbe documents fail to properly show trademark use of "SOFT COAG," many Erbe brochures discuss the innovative features of this mode showing proper trademark use. *See, e.g.,* Bukrinsky Ex. 7; Bukrinsky Ex. 9 (which describes "ERBE's famous Soft coag" at E-SOFT-005027). Further, Petitioner takes a narrow set of Erbe's brochures and incorrectly implies that the documents it cites encompass the totality of Erbe's advertising/marketing brochures. Again, Erbe's brochures/marketing literature discuss Erbe's trademark "SOFT COAG" mode. *See, e.g.*, Bukrinsky Ex. 7; Bukrinsky Ex. 9 (which describes "ERBE's famous Soft coag" at E-SOFT-005027); Bukrinsky Ex. 5; Bukrinsky Ex. 6;

Mullarkey Ex. U (utilizing the ™ symbol); Mullarkey Ex. V (describing Erbe's "Proprietary Monopolar" SOFT COAG setting at E-SOFT-005036); Mullarkey Ex. W (describing Erbe's "SOFT COAG – Proprietary Monopolar and Bipolar" setting at E-SOFT-005035); Mullarkey Ex. X (Discussing "proprietary voltage control" at E-SOFT-005127).

5. Covidien overstates Erbe's "interchangeable" use of "SOFT COAG" and "Soft coagulation." The exhibits cited to support this allegation are all dated before Erbe applied for, and received, a trademark for its proprietary "SOFT COAG" technology. Erbe corrected its use before Covidien adopted "soft coag" and thus the earlier more descriptive use is irrelevant to the current inquiry. However, even at that time "soft coag" and "soft coagulation" were merely suggestive terms for gentle coagulation.

6. The alleged third-party uses cited in Petitioner's motion heavily relies on electrosurgical generators sold outside the U.S. In fact many of those generators submitted as evidence by Covidien are barred from sale in the United States until the FDA approves the generators. Day Declaration ¶28.

7. Even the patents submitted as evidence create factual disputes. The patents fail to agree on a common definition for "soft coag" and therefore creating doubt that the phrase has a generic meaning. Bukrinsky Exs. 38, 39, and 41, defining "soft coag" as "generally assured with voltages below 200 peak volts Cov-SOFT02331; Cov-SOFT02370 and "soft coag" being "characterized in that the amplitude of the RF voltage required…is less than 200 Volts… Cov-SOFT02395 with Ex. 42, which cites to Erbe's brochures, defining "SOFT COAG" as "190 Vp **constant voltage** waveform…" (Cov-SOFT02291) (emphasis added).

8. Finally, Petitioner's assertion that Erbe "admits that 'soft coagulation' is a non-proprietary medical procedure" is wholly unsupported by the testimony cited. The testimony merely states that Erbe's SOFT COAG is a proprietary trademark – and nothing more.

LEGAL STANDARD

Summary judgment is only appropriate when there is no genuine dispute of material fact. *See* Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); O*pryland USA Inc. v. Great American Music Show Inc.*, 970 F.2d 847, 23 USPQ2d 1471 (Fed. Cir. 1992). The onus is on the moving party to demonstrate the absence of any material fact. *Id.* The evidence must be viewed in a light most favorable to the nonmoving party, and all reasonable inferences are to be drawn in the nonmovant's favor. *Lloyd's Food Products, Inc. v. Eli's, Inc.*, 987 F.2d 766, 25 USPQ2d 2027, 2029 (Fed. Cir. 1993).

"A party asserting that a fact cannot be or is genuinely disputed must support the assertion by (A) citing to particular parts of materials in the record ...; or (B) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1). A factual dispute is genuine if, on the evidence of record, a reasonable fact finder could resolve the matter in favor of the non-movant. *Opryland*, 23 USPQ2d at 1472 (Fed. Cir. 1992); *Olde Tyme Foods, Inc. v. Roundy's, Inc.*, 961 F.2d 200, 22 USPQ2d 1542, 1544 (Fed. Cir. 1992). In deciding a motion for summary judgment, the Board may not resolve any factual dispute; it may only determine whether a genuine dispute of material fact exists. *See, e.g., Meyers v. Brooks Shoe Inc.*, 912 F.2d 1459, 16 USPQ2d 1055, 1056 (Fed. Cir. 1990). Further, the non-movant must be given the benefit of all reasonable doubt as to whether a genuine dispute as to material facts exist, and the evidentiary record on summary judgment and all inferences to be drawn from the

undisputed facts must be viewed in the light most favorable to the non-movant. *Opryland*, 23 USPQ2d at 1472.

Covidien argues that SOFT COAG is generic or otherwise has not acquired distinctiveness. These are both fact intensive determinations. A federally registered mark is entitled to a strong presumption of validity, "includ[ing] the specific presumption that the trademark is not generic." *Coca-Cola Co. v. Overland, Inc.*, 692 F.2d 1250, 1254 (9th Cir. 1982) (citing 15 U.S.C. § 1115(a)). Genericness "involves a two-step inquiry: First, what is the genus of goods or services at issue? Second, is the term sought to be registered ... understood by the relevant public primarily to refer to that genus of goods or services?" *Marvin Ginn v. International Ass'c of Fire Chiefs*, 228 USPQ, 528, 530 (Fed. Cir. 1986); *see also Princeton Vanguard, LLC v. Frito-Lay North America, Inc.*, 786 F.3d 960, 969, 114 USPQ.2d 1827, 1830 (Fed. Cir. 2015) ("there is only one legal standard for genericness: the two-part test set forth in *Marvin Ginn*"). Similarly, Covidien must establish that at the time the SOFT COAG registration issued, the registered mark was merely descriptive. *See Alcatraz Media Inc. v. Chesapeak Marine Tours Inc.*, 107 USPQ2d 1750, 1764 (TTAB 2013). If Covidien can establish mere descriptiveness at the time of registration, the burden shifts to Erbe to establish that "prior to issuance of the registration, the registered mark had acquired secondary meaning in the sense that its primary significance was that of a source indicator of goods emanating from registrant." *Id.* (quoting *Neapco Inc. v. Dana Corp.*, 12 USPQ2d 1746, 1747 (TTAB 1989). If the burden shifts, there are several factors that need to be assessed to determine whether Erbe acquired distinctiveness such as substantial and extensive exclusive use, sufficient advertising and sales figures, unsolicited media coverage, successful enforcement efforts, and other factors that the Board may find relevant.

ARGUMENT

A. Erbe's "SOFT COAG" Mark is Not Generic

The Board's test to determines genericness turns upon the **primary significance** that the wording would have to the relevant public (i.e., whether the primary significance is source identifying). TMEP § 1209.01(c)(i) (emphasis added). There is no dispute as to the first inquiry, the genus of the goods is that defined in Erbe's registrations. *See In re Cordua Rests., Inc.*, 823 F.3d 594, 602, 118 USPQ2d 1632, 1636 (Fed. Cir. 2016). Here, it is undisputed that Erbe's trademark covers, *inter alia*, electrosurgical generators. Thus, electrosurgical generators are the genus of goods. However, there are factual disputes as to whether the evidence suggests the relevant public finds SOFT COAG generic.

1. The Relevant Public are Highly Educated Physicians and Hospital Personnel

Covidien's factual predicate stems from a misbelief that "soft coagulation" is a procedure performed by a surgeon. This is simply incorrect. Covidien failed to define "relevant public," and in this case the relevant public is a subset of consumers, namely physicians and hospital personnel. ("Relevant Public"). "The critical issue in genericness cases is whether members of the relevant public primarily use or understand the term sought to be protected to refer to the genus of goods or services in question." *H. Marvin Ginn*, 782 F.2d at 989-90. "[T]he relevant public's perception is the primary consideration in determining whether a term is generic." *Princeton Vanguard,* 786 F.3d at 969. None of the evidence submitted by Covidien establishes that the Relevant Public understands "soft coagulation" to mean a procedure performed by a surgeon. There is no medical dictionary definition for "soft coagulation." Further, there is no supporting material from any physician or relevant hospital personnel that establishes "soft coagulation" is a procedure. Instead, the evidence establishes that surgeons perform electrosurgical procedures to coagulate tissue using various modes on an electrosurgical

generator. For delicate procedures and to avoid rupturing surrounding tissue, advancements have been made in the way coagulation can be achieved. One such advancement is Erbe's SOFT COAG mode on its electrosurgical generator. Physicians have a keen understanding of what SOFT COAG means and it is a specific to a mode on Erbe's electrosurgical generator. The evidence of record, including that submitted by Covidien, largely supports Erbe's position, when viewed by physicians and hospital personnel, the relevant public.

2. There are Factual Disputes Whether SOFT COAG is Generic

Covidien makes several assertions as fact, all of which are disputed and not supported by the record. First, Covidien grossly overstates the "undisputed" nature of "soft coagulation" as a common medical procedure. Second, Covidien relies on use of "soft coag" outside of the United States in support of its multiple use position. Finally, Covidien's assertion that Erbe and third parties use SOFT COAG and "soft coagulation" interchangeably is largely based on inappropriate descriptive use that Erbe has since corrected and articles that are relying on the Erbe generator. There is little to no support that SOFT COAG is generic and it is certainly not something that can be decided on summary judgment.

a. *Dictionary Definition*

Noticeably absent from Covidien's statement of facts is any mention of "soft coagulation" or "soft coag" in a dictionary. Despite claiming it is a common medical procedure throughout its brief, Covidien's loan evidence for a dictionary type definition is through an IEC standards definition of "coagulation" that includes various "types" of coagulation, one of which is "soft." There is no context in support of the IEC definition of "coagulation." For example, the IEC document may be referring to Erbe's SOFT COAG mode. Further, the Board should only consider evidence of the mark as a whole and no definition for "soft coag" or "soft coagulation" exists. *See Princeton Vanguard,* 114 USPQ2d at 1832 (stating evidence should include use of the

mark as whole in the record). As a matter of law, the Federal Circuit has held, the Board must consider the term *as a whole* and not merely by its constituent parts. *See e.g., In re Am. Fertifility Soc.*, 188 F.3d 1341, 1347-48 (Fed. Cir. 1999). A standards document defining coagulation and noting various types without context is not a substitute for a dictionary definition for an allegedly common medical procedure known as "soft coagulation" or "soft coag." Further and noticeably absent from Covidien's brief is any discussion of the meaning of "soft" as applied to the goods at issue. In other words, Covidien rightly does not argue that this is a case of two generic terms used together while maintaining the genericness of those terms. *Compare In re Mecca Grade Growlers, LLC*, 125 USPQ2d 1950, *12 (TTAB 2018) ("a proposed mark is generic if 'it can be shown that the public understands the individual terms to be generic, and joining of those terms into one compound work provides no additional meaning'") (quoting *Princeton Vanguard, LLC*, 786 F.3d 960 (internal citations omitted). Therefore without any substantive evidence of a definition of "a common medical procedure" the use of SOFT COAG cannot be generic. The absence of a dictionary definition favors Erbe.

b. *Third Party Manufacturer Use*

While Covidien states Erbe admits that third party manufacturers use "soft coag", it fails to mention that those third party uses all take place outside of the United States. Day Declaration at ¶28. An argument that "soft coag" is generic outside the United States is insufficient to find genericness within the United States. *See V&V Food Products, Inc. v. Cacique Cheese Co., Inc.*, 683 F.Supp. 662, 669-670 (finding "the perception of CHIHUAHUA as a generic term for cheese in Mexico does not undermine the validity of…[the] federal registration in the United States. In determining whether a term is generic for purposes of United States trademark law, it is irrelevant how the mark is used outside the United States") (citing *Anheuser-Busch Inc. v. Stroh Brewery Co.*, 750 F.2d 631, 642 (8th Cir. 1984)). Before Covidien's infringing adoption of

"soft coag" in 2017, Erbe was the only manufacturer in the United States that used SOFT COAG.[2] The third party manufacturer use submitted by Covidien is entirely irrelevant.

Also, Covidien assets Olympus has been using "soft coag" continuously since 2008. However, Erbe was the OEM for Olympus's generators that included the SOFT COAG mode. In this respect, the relevant purchasing public, physicians and hospital personnel understood and were well aware that the Olympus generators included the Erbe proprietary SOFT COAG mode. Finally, there are numerous factual issues as to whether the Valley Lab generator was sold to consumers at any relevant time. Therefore whether the third party manufacturer use is relevant skews in favor of Erbe and certainly does not support a ruling in Covidien's favor on summary judgment.

c. *Leading Publications Mostly Reference Erbe*

There is a substantial amount of evidence indicating that publications primarily use SOFT COAG and "soft coagulation" to refer to Erbe and its proprietary mode, which takes SOFT COAG outside of the generic finding or, at a minimum, raises a factual dispute that is not ripe for summary judgment. *See In re Merrill Lynch*, 828 F.2d 1567, 1571, 4 USPQ.2d 1141 (Fed. Cir. 1987) (finding CASH MANAGEMENT ACCOUNT non-generic when a substantial number of publications indicated that the source was the appellant). Covidien asserts in its CUSF ¶ 36 several articles that it alleges use SOFT COAG and/or "soft coagulation" generically. However, a review of these publications indicates that they almost all are *primarily* discussing Erbe's SOFT COAG mode. For example, in Bukrinsky Exs. 43, 44, 53, 54 (which is the exact same document as Ex. 44), and 55, researchers used Erbe's electrosurgical generators in their study. Ex. 43 at Cov-SOFT00999 "…an electrosurgical unit (ICC-200; ERBE…)"; Bukrinsky Exs. 44

[2] Olympus adopted "soft coag" for a mode in 2018.

and 54 at Cov-SOFT01092 "The VIO 300D system was set to soft coagulation mode..."; Bukrinsky Ex. 53 at Cov-SOFT00587 "…using the VIO soft coagulation system (VIO300D; ERBE…)"; Ex. 55 at Cov-SOFT00515 "soft coagulation was performed used an electrosurgical unit (ICC200, ERBE…)." Further, Bukrinsky Exs. 45 and 52 utilized Olympus's electrosurgical generator, which is manufactured by Erbe. Ex. 45 at Cov-SOFT00603 "The electrosurgical generator used was the Olympus PSD-2…"; Ex. 52 at Cov-SOFT01103 "The electrosurgical generator used was the Olympus ESG 100…" Further, there are numerous other articles omitted by Covidien that clearly reference Erbe and proper use of SOFT COAG. Day Declaration ¶20 ("Trade journals and publications do not use the term SOFT COAG generically. In fact, the vast majority of journals and publications use the term soft coagulation to describe the tissue effect achieved when a coagulation procedure has been done with an Erbe electrosurgical generator operating in the SOFT COAG mode. Day Ex. 6; E-SOFT-001574-80 (Olympus machine using Erbe technology). There is a substantial amount of evidence that establishes the *primary* significance of SOFT COAG is a source identifier for Erbe and not a generic use.

d. *The Patent Evidence is Insufficient to Support Genericness*

Covidien is unable to supply any definition of "soft coag" or "soft coagulation" and its patent argument only supports Erbe's position. None of the patents cited agree on a definition for "Soft coag" or "soft coagulation." Further, this is not evidence of consumer recognition by the relevant public or even use in commerce. Finally, there is no context supplied in Covidien's brief and it is not clear if the patents are referencing Erbe's SOFT COAG mode. In view of the other evidence, this is not sufficient to support of finding of genericness on summary judgment.

The overwhelming evidence establishes that Erbe developed a highly successful proprietary method for coagulation and branded it SOFT COAG. Since the adoption by Erbe, third party competitors have attempted to replicate the proprietary method, but in failing to do so,

have instead adopted an identical trademark to trade off of Erbe's goodwill. There is simply not enough support in the record to find that the primary significance of SOFT COAG is generic and it is certainly not ripe for summary judgment.

B. Erbe's SOFT COAG Mark has Acquired Distinctiveness

1. The "SOFT COAG" Mark Identifies Erbe's Electrosurgical Generator Mode

The evidence of record indicates that Erbe is the source of electrosurgical generators utilizing the SOFT COAG mode at the date of federal registration on the Principal Register. In order to obtain its registration, Erbe submitted evidence of acquired distinctiveness along with a 2(f) declaration (and not simply a claim of five years of substantially exclusive use). In other words, the Trademark Office created a strong presumption that Erbe had acquired distinctiveness in SOFT COAG on November 6, 2012. While COAG strongly implies "coagulation" as it is applied to electrosurgical generators, the term "soft" is subtly suggestive of a gentle coagulation. This is in sharp contrast to the more harsh coagulation of typical electrosurgical generator voltage settings. Recognizing the suggestive nature of SOFT COAG, Erbe made a claim of acquired distinctiveness in order to obtain registration for SOFT COAG. The Trademark Office accepted the 2(f) claim and supporting affidavit and registered SOFT COAG on the Principal Register. It is Covidien's burden to rebut this strong presumption, which it has failed to do.

2. Erbe Has Extensively Used SOFT COAG as Mark

Considering the highly specialized industry Erbe's electrosurgical generators service, Erbe's advertising and sales support a finding of acquired distinctiveness. Covidien fails to show evidence to the contrary. Here, Erbe has continuously, substantially, and almost exclusively used its mark "SOFT COAG" in connection with the constant voltage mode of its electrosurgical generators. Erbe has done so since at least 1994. The evidence submitted at the time of registration more than supports this finding, especially considering the suggestive nature of the

mark. SOFT COAG is not a highly descriptive mark that would require more substantial evidence of acquired distinctiveness. *See In re Greenliant Systems Ltd.*, 97 USPQ2d 1078, 1085 (TTAB 2010) ("Highly descriptive terms... are less likely to be perceived as trademarks and more likely to be useful to competing sellers than are less descriptive terms. More substantial evidence of acquired distinctiveness thus will ordinarily be required to establish that such terms truly function as source-indicators"). Instead, "soft" implies a non-harsh coagulation. Terms such as "gentle" or "smooth" or "quiet" or "tender" among others could all be used to "describe" the type of coagulation Erbe's generator achieves in its SOFT COAG mode. This mark certainly falls on the less descriptive portion of the spectrum and simply because Covidien erroneously asserts genericness does not make it "highly descriptive." Even if found highly descriptive, the evidence submitted more than satisfies the requirement to show acquired distinctiveness or at least that there is a factual dispute precluding summary judgment.

3. Covidien's "substantially exclusive" rebuttal is Fraught with Factual Disputes

Covidien asserts questionable "undisputed facts" for its position that Erbe's use has never been "substantially exclusive." Most of this argument relies upon statements that Valley Labs first adopted and used "soft coag" for an electrosurgical generator mode, those generators were sold until 2005, and that some of those generators are still in use. Covidien also asserts that its own adoption of "soft coag" in 2015 also supports rebutting Erbe's claim of acquired distinctiveness. Covidien also relies on use of SOFT COAG by Olympus in 2008 to support its position, but Erbe made those generators. Finally, and discussed above in the generic section, Covidien relies on alleged use by several manufacturers including, Bovie, ConMed, Ackermann, Aesuclap, Alsa Apparecchi, EMED, HEBU, Integra, Kavandish, KLS Martin, Lamidey Noury,

and Soring to support its position, but none of these generators are sold in the United State or even approved for sale in the United States.

a. ***Valley Labs Use***

Erbe does not dispute that Valley Labs first used a "soft coag" mode for an electrosurgical generator. However, that mode would not be confused with Erbe's proprietary SOFT COAG mode. This is due to the fact that Valley Lab's device had a peak to peak voltage that was significantly more than 200V peak. *See* Buysse Ex. C at Cov-SOFT00202 (showing peak to peak voltage of 9000V for the "Soft Coag" mode). The relevant public would not use the Valley Labs mode to conduct "soft coagulation" as Covidien attempts to define it. The mode has an entirely different effect and Covidien admits that sales of the generators ceased in 2005. Further, Covidien admits that most of the sales of the generators occurred in the 1980's and 1990's. None of these facts rebuts Erbe's 2(f) declaration describing substantially exclusive use starting in 2003. Covidien states that some of these generators are still in-use but there is no indication of how many units or if "soft coag" is promoted or known to the relevant public. This evidence is simply insufficient on summary judgment to rebut the strong presumption of acquired distinctiveness.

b. ***Covidien's later infringing adoption has no bearing on Erbe's claim of substantially exclusive use***

Covidien's theory its own infringement helps its case is certainly novel. According to Covidien it adopted the "soft coag" mode in 2015. The cancellation proceeding was filed in June 2017 shortly after Erbe raised its infringement concerns when it first became aware of Covidien's infringing use. Day Declaration ¶¶21-22; 27. Erbe closely polices its SOFT COAG trademark. This is a proprietary mode and the infringement by a third party could have disastrous effects if the relevant public is confused as to the source of a "soft coag" mode on a

electrosurgical generator. Just as in the case with Covidien, Erbe has previously enforced its trademark rights against a competitor and successfully obtained an agreement in which the competitor ceased use of the trademark. Day Declaration ¶26. Covidien cites to *Roselux Chem Co. v. Parsons Ammonia Co*. in support of its position that its alleged adoption two years prior to this proceeding "alone should have been sufficient to support a finding of lack of distinctiveness." 299 F.2d 855 (CCPA 1962). Even a cursory reading of *Roselux* makes it clear that the Opposer in the Opposition matter had been using the trademark for two years prior to the Applicant's application. Further, numerous other third parties were also using the trademark at the time of application. *See Id.* at 860-63. There is no analogy to Covidien's position. Erbe filed a 2(f) declaration in support of a registration in 2012 and alleging use back to at least as early as 2003. Covidien is admitting it did not use the "soft coag" mark until 2015, at least three years after Erbe's registration issued and more than twelve years after Erbe at least began using the mark in United States commerce. Any reliance on *Roselux* is misplaced at best.

c. *Erbe provided OEM generators for Karl Storz and Olumpus*

Covidien also refers to Olympus's use of "soft coag" in 2008. However, this use as applied to Erbe's proprietary SOFT COAG mode inures to Erbe's benefit. The Relevant Public was well aware that the SOFT COAG mode found on both Olympus and Karl Storz generators were that of Erbe. To Erbe's knowledge Karl Storz no longer sells generators that include a "soft coag" mode. However, Olympus recently, in 2018, started advertising and selling generators that include "soft coag." This use started well after Erbe acquired distinctiveness in the SOFT COAG mode.

d. *None of the Other Third Party Use Occurs in the United States*

Covidien re-raises its third party use argument to argue no acquired distinctiveness. However, the same principle applies in acquired distinctiveness as it does in genericness.

Trademark rights are territorial in nature. Use outside the United States does not affect whether a trademark owner has acquired distinctiveness and this use should not be relied upon.

The evidence suggests that Erbe has been the substantially exclusive user of SOFT COAG since at least 1994 and it was certainly so in 2012 when it obtained its federal registration. Its efforts since that time to enforce its rights only strengthen that position. The facts weigh strongly in favor of Erbe and certainly do not favor summary judgment.

4. Erbe's SOFT COAG mark has Acquired Distinctiveness

Covidien attempts to dismiss Erbe's use of SOFT COAG as improper and therefore it cannot have acquired distinctiveness. This erroneous attempt is supported by its argument that Erbe's SOFT COAG mark is highly descriptive. However, except for its "generic" argument based on third party use, there is no support in the record that "soft" is highly descriptive for a coagulation type and therefore Covidien has the higher burden of persuasion. Covidien's argument and support fail to meet this burden.

Covidien does not attempt to describe how the Relevant Public encounters related trademarks for electrosurgical generators. Instead, Covidien immediately attacks a lack of advertising or use in magazines. The Relevant Public, Physicians and hospital personnel, purchase and become aware of these products through extensive training programs and at trade shows. These highly sophisticated purchasers do not encounter trademark use in the same traditional sense as the general public might. The generators are expensive medical devices and purchasers belong to a relatively small, closed marketplace. Therefore it is not cost effective to advertise a specific mode of a generator in traditional ways such as magazine or journal advertisements. Covidien's assertion that advertising related to brochures, instructions manuals, training materials and trade shows is deficient compared to "magazines or written publications" is simply not correct and entirely unsupported. On the contrary, Erbe extensively advertises its

SOFT COAG mode when it gives presentations and training to physicians and hospital personnel. In fact, training on the proprietary SOFT COAG mode is extremely important and this training reinforces Erbe's trademark rights. Further, simply because other modes are available on an Erbe generator does not mean that the proprietary SOFT COAG mode lacks acquired distinctiveness. It is the mode that is extensively advertised through the training programs and drives the revenue of the generators. These are all factual disputes that are not appropriate for summary judgment.

C. Erbe Uses SOFT COAG as a Trademark

Contrary to Covidien's assertion, Erbe uses SOFT COAG as a trademark. Simply because Covidien has failed to define the relevant public and describe how the relevant public encounter trademarks, in this case physicians and hospital personnel, does not render Erbe's use of SOFT COAG in a non-trademark sense. Physicians and hospital personnel receive extensive training and presentations on the use of the generators and especially Erbe's proprietary SOFT COAG mode. These trainings and presentations are reinforced every time a member of the hospital staff uses the SOFT COAG mode. It is in fact extensively used as a trademark.

DATED this 30th day of September, 2019.

Respectfully submitted,
POLSINELLI PC

By: */s/ Philip G. Hampton, II/*

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ERBE Elektromedizin GmbH

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

COVIDIEN LP, Petitioner, v. ERBE ELEKTROMEDIZIN GMBH, Registrant.	Cancellation No. 92066392 Registration Nos. 4,236,231and 4,686,396 Mark: SOFT COAG

DECLARATION OF JOHN DAY

I, John Day, do hereby declare under penalty of perjury as follows:

1. I am over eighteen years of age and competent to make the following statements. I have personal knowledge of the facts set forth in this Declaration and, if called to testify as a witness, I can testify to these facts in a court of law or in an administrative agency, including the Trademark Trial and Appeal Board ("TTAB").

2. From around 1992 to 1997, I was employed at Valleylab, Inc. ("Valleylab") as a Territory Sales Manager. During my tenure at Valleylab, I was involved and dealt with electrosurgical generators, including the Valleylab Force 48 and SSE4 electrosurgical generators.

3. I have been employed at Erbe Elektromedizin GmbH ("Erbe") since January 1998. My roles and job title has changed during the course of my employment at Erbe. In January 1998, I was a product manager at Erbe. In 2000, I was promoted to Regional Sales Director. In 2001, I was promoted to Vice President of Marketing, which is the job I currently hold.

4. As Vice President of Marketing, I oversee strategic planning, new business development, assistance with patents and trademarks, and am indirectly responsible for all tradeshows and workshops at the national, regional, and local levels at Erbe. I also train and lecture to hospital

personnel about electrosurgical waveforms. Further, as part of my job, I often give lectures ranging from small labs, to courses and on occasion, formal "Grand Rounds". I regularly interact with hospital personnel and physicians who utilize electrosurgical generators.

5. My job responsibilities have allowed me to be involved with electrosurgical generators in some capacity for over 27 years. I am knowledgeable about Erbe's and other manufacturers' generators. This includes being knowledgeable about the different modes available on certain electrosurgical generators and electrosurgical waveforms.

6. Thus, my experience provides me with intimate knowledge about customers, their use of electrosurgical generators, and how the industry understands the term "SOFT COAG."

7. Since at least 1994, Erbe has used its SOFT COAG trademark to identify a mode available on its electrosurgical generator systems in the United States.

8. Electrosurgical generators are relatively expensive medical devices since the potential purchasers of these devices are part of a relatively small, closed marketplace, it is not cost effective to advertise a specific mode of an electrosurgical generator in traditional ways, e.g., through magazine or journal advertisements or through direct mail.

9. Instead, Erbe, like most manufacturers of electrosurgical generators, advertises extensively at tradeshows, such as Digestive Disease Week, directed to limited medical/surgical subspecialties, such as gastroenterology. Erbe also advertises its electrosurgical generators and its available modes by attending and displaying at regional and national meetings and conducting workshops regarding techniques that can be used with various generator modes (e.g., SOFT COAG) to obtain specific tissue effects (e.g., soft coagulation).

10. The SOFT COAG mode is Erbe's proprietary low, constant voltage waveform in Erbe's electrosurgical generators. Exhibit 1 to the Declaration of John Day ("Day Ex. 1"). The

waveform is proprietary because the algorithms used to keep the voltage constant have never been disclosed. (June 25, 2018 30(b)(6) Deposition of Erbe (Erbe Dep. Tr.) at 112:20-113:17).

11. Specifically, when the SOFT COAG has been selected, the voltage remains constant, never exceeding 200 volts peak, and the current/power automatically adjusts lower as tissue dehydration occurs and circuit impedance rises. Day Ex. 2; Erbe Dep. Tr. at 112:20-113:6. Controlled constant voltage not exceeding 200Vp prevents micro-electric arc formation at target tissue and ensures reproducible, consistent tissue effect.

12. Moreover, since the constant voltage never exceeds 200 volts peak, when the Erbe electrosurgical generator is operating in the SOFT COAG mode, no sparks are capable of being produced between the coagulation electrode and the tissue. Day Ex. 3; Erbe Dep. Tr. at 71:18-72:5. Sparks can lead to cutting effect and carbonization of target tissue.

13. Erbe has occasionally referred to its SOFT COAG mode as NSC ("no spark coagulation"). Day Ex. 4. At other times, Erbe has described its SOFT COAG mode as constant voltage regulated, unmodulated, power limited electrosurgical coagulation. *Id.*

14. Because no sparks are created and no cutting or charring of tissue occurs during coagulation with Erbe's SOFT COAG mode, tissues appear to have a uniform, off-white color with without any black spots. This tissue effect, which for years was only noticed after coagulation procedures utilizing Erbe's SOFT COAG mode, is what some clinicians refer to as "soft coagulation."

15. Erbe's SOFT COAG mode is designed to be used in therapeutic endoscopy and flexible endoscopic surgery where there is need for precision and reproducibility in tight spaces involving hollow organs. Day Ex. 5; Erbe Dep. Tr. at 38:19-39:1. In fact, the SOFT COAG mode of Erbe's electrosurgical generators are rarely used in open or laparoscopic surgery, since

coagulation mode progresses too slowly and has proven to be ineffective in treating active bleeds.

16. Because key opinion leaders ("KOLs") in flexible endoscopy procedures discuss the superior results they obtain from using the SOFT COAG mode in their public presentations, Erbe representatives field calls on a weekly basis from clinicians seeking more information about the SOFT COAG mode and the resulting tissue effect, soft coagulation.

17. Consequently, Erbe extensively markets to surgeons using flexible endoscopes as well as to therapeutic endoscopists, including gastroenterologists and pulmonary interventionists, where precision is required to coagulate tissue and vascular structures within the confines of hollow organs and tight anatomical spaces. Doctors and surgeons performing thoracic, gastrointestinal, pulmonology, and colorectal procedures often request Erbe electrosurgical generators since they trust the Erbe SOFT COAG mode to provide the requisite tissue coagulation within the very tight spaces.

18. Erbe's electrosurgical generator systems have gained prominence in therapeutic endoscopy and flexible endoscopic surgery because they incorporate the SOFT COAG mode.

19. There is no recognized meaning for "soft" with regard to procedures performed with electrosurgical generators; electrosurgical procedures involve either the cutting or the coagulation of tissue and/or vascular structures. I have never encountered "soft coagulation" as a mode on any electrosurgical generator. Instead, I have encountered "soft coagulation" as a term coined by some to describe the tissue effect that is observed when a medical procedure utilizes the proprietary Erbe SOFT COAG coagulation mode. *See* ¶14.

20. Trade journals and publications do not use the term SOFT COAG generically. In fact, the vast majority of journals and publications use the term soft coagulation to describe the tissue

effect achieved when a coagulation procedure has been done with an Erbe electrosurgical generator operating in the SOFT COAG mode. Day Ex. 6; E-SOFT-001574-80 (Olympus machine using Erbe technology).

21. Until I received the email from Mr. Gregory Seitz on May 19, 2017 (Day Ex. 7), Erbe was unaware of Covidien's interest in actually using its SOFT COAG mode in GI applications, as Covidien had never shown its FT10 generator at any of the major GI tradeshows or national/regional meetings. And while Covidien's sales in the U.S. dwarf those of Erbe, the FT10 electrosurgical generator is almost never use in flexible endoscopy procedures. In fact, I have never seen any scientific articles discussing flexible endoscopy procedures in which a mode of an FT10 electrosurgical generator was used, nor have I ever heard any KOL discuss using the Covidien FT10 generator.

22. Only after reviewing Mr. Seitz's email, did I raise the issue that Covidien's use of soft coag as an identifier of a generator mode could cause confusion within the marketplace. I was concerned that Covidien would attempt to enter the flexible endoscopy market by trading off on the renown of the SOFT COAG mode of Erbe's electrosurgical generators.

23. Because soft coagulation is a specific tissue effect observed after using Erbe's proprietary SOFT COAG mode in flexible endoscopic surgical procedures or therapeutic endoscopic procedures, I disagree with Mr. Buysse's assertion that "[H]undreds of surgeons and researchers in the United States perform the Soft Coagulation technique using Medtronic's generators, Erbe's generators, and the generators of third parties."

24. Similarly, I disagree that "[D]octors, surgeons, researchers and other purchasers and users of electrosurgical generators use the terms Soft Coag and Soft Coagulation interchangeably to refer to … a mode on any manufacturer's generator … that allow the user to perform the Soft

Coagulation procedure," since soft coagulation describes a particular result achieved by using the Erbe SOFT COAG mode.

25. Erbe has sought to protect its trademark rights in SOFT COAG since at least 2003. In the 2000's Olympus and Karl Storz used SOFT COAG to identify a mode of an electrosurgical generator sold in the United States. However, Erbe was the Original Equipment Manufacturer ("OEM") of those electrosurgical generator systems. Day Ex. 8. So not only were these uses authorized, but the consuming public properly attributed SOFT COAG trademark and its inherent goodwill to a single source – Erbe.

26. Erbe U.S. Trademark Registration No. 4,236,231 from the USPTO in 2012. In 2014, Erbe sued Genii for trademark infringement after it identified a SOFT COAG coagulation mode on its newly unveiled electrosurgical generator. To settle the lawsuit, Genii agree to cease using a SOFT COAG mark. Day Ex. 9.

27. On July 11, 2016, Erbe sent Medtronic, Covidien's parent a cease and desist letter regarding use of SOFT COAG as a mode on the FT10 electrosurgical generator. After receiving a follow-up letter from Erbe on January 30, 2017, counsel for Covidien responded claiming that Covidien was only using the mark descriptively. Covidien then instituted the current cancellation proceeding.

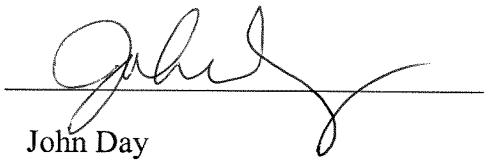
28. The only other significant purveyor of electrosurgical generators in the U.S. that uses SOFT COAG to identify a coagulation mode is Olympus that released its new generator system just last year. The competitor "evidence" presented by Covidien regarding the use in the United States of SOFT COAG to identify a mode of an electrosurgical generator is irrelevant, since almost all of those generators are not sold in the United States. In fact, most of the generator

systems cited by Covidien have not even been cleared for sale in the U.S. by the FDA. Erbe Dep. Tr. at 21:15-22:4.

29. Mr. Buysse also discussed certain obsolete Valleylab electrosurgical generators – the SSE4 and Force 4 – that each had a SOFT COAG coagulation mode. However, not only do I believe that Valleylab stopped selling these generators in the 1990s, but even according to Mr. Buysse's erroneous definition of "soft", the resulting tissue effects were anything but "soft". As shown in Buysse Exhibits C-E, the SOFT COAG mode of these Valleylab electrosurgical generators operated at a 9000 volts peak-to-peak, more than 40 times that of the SOFT COAG mode of Covidien's FT10 electrosurgical generators.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: September 30, 2019



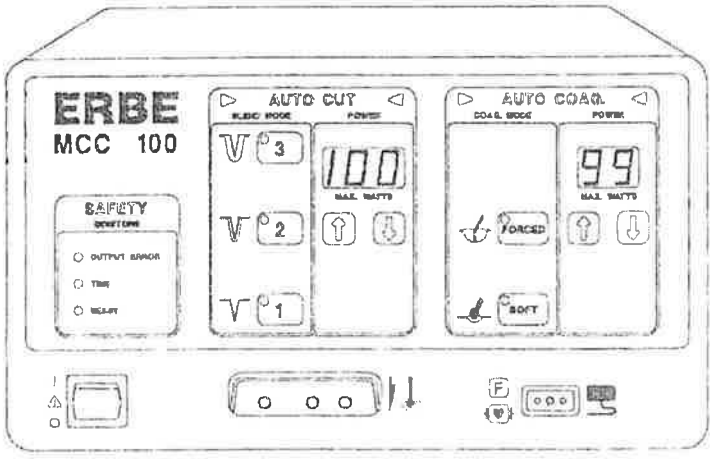
John Day

Day Exhibit 1 – Highly Confidential

Day Exhibit 2 – Highly Confidential

Day Exhibit 3

ERBE



MCC 100

Operating Instructions

06.1992

E-SOFT-001850

ELECTROSURGICAL UNIT

TYPE NO.: 10129-000

OPERATING INSTRUCTIONS

EFFECTIVE DATE: JUNE, 1992

Printed by: ERBE ELEKTROMEDIZIN, Tübingen
Printed in Germany

CONTENTS

1 INTRODUCTION

The MCC 100 is a Microprocessor controlled high frequency electrosurgical unit for cutting and/or coagulation of biological tissue with 100 watts rated output power.It is designed and manufactured to be reliable, safe and easy to operate.

This Manual is your written guide to the model MCC 100 unit. Read the entire manual carefully before operating the unit. Recommended settings are given only as guidlines, not to restrict the surgeon. However, before trying other settings, the surgeon and support personnel should be experienced with the unit and familiar with the new settings.

The Warnings and Notes contained in this Manual are important and must be followed. They are set apart throughout the text and are also in the Warning section of this Manual.

If you have questions or require additional information, please contact your local Service Representative or the Technical Service Department at:

2 WARNINGS

WARNING
Hazardous electrical output.
This equipment is for use only by qualified, medical personnel.

CAUTION
HF surgery may present a hazard to patients with pacemakers.
Consult qualified medical personnel.

CAUTION
Sparking at the active electrode is a common occurrence.
DO NOT perform procedures if flammable or explosive media are present, i.e., flammable anesthetics, bio-intestinal gases, etc.

CAUTION
Electric shock hazard, do not remove top cover.
Refer servicing to qualified personnel.

WARNING
Never increase the power beyond the normal settings without first checking both the actice and the neutral electrodes and their connections.

WARNING
Burns to the surgeon's hands are possible in most clinical situations if a monopolar active electrode istouched to a metal instrument held in the surgeon's hand.

PRECAUTION
The surgeon's staff should be aware that the electrosurgical generator can malfunction for reasons such as random component failure or defective active or neutral electrodes as well as the relevant cables.
A standby generator and relevant accessories are recommended if generator or accessory malfunction is a significant risk to the patient.

To insure safe and dependable operation the electrosurgical generator and the relevant accessories should be periodically checked for wear and tear.

3 PHYSICAL FUNDAMENTALS OF HIGH-FREQUENCY SURGERY

For more than 50 years, high-frequency (HF) surgery has been used to cut and/or coagulate biological tissue using the intrinsic thermal effect of electric current. In order to prevent endogenous effects of the electric current, such as electrolysis and stimulation of nerves and muscles, an alternating current with a frequency of at least 300 kHz must be used for HF surgery.

The requirements imposed today on HF surgery differ, depending on the specialist area concerned.

When HF surgery is used to cut parenchymal organs, the surgeon also expects efficient hemostasis either as a result of coagulation to a greater or lesser depth as the cut is being made or through partial coagulation of the bleeding vessels once the cut has been completed. The latter case also applies when using a scalpel, scissors or ultrasound to cut the tissue.

In both cases, the efficiency with which bleeding can be stopped depends on the intensity of thermal coagulation the greater the depth of coagulation inside the tissue, the greater the hemostatic effect. At the same time, however, it must also be ensured that not more tissue suffers thermal damage during cutting or coagulation than is absolutely essential in order to obtain sufficient hemostasis.

Both when cutting and during partial coagulation, the surgeon should therefore always seek to obtain the optimum depth of coagulation for the specific tissue concerned; this can never be more than a compromise between the most effective hemostasis with the disadvantage of deep coagulation necroses and the least possible coagulation necrosis with the disadvantage of time-consuming partial coagulation.

Unfortunately, at present we do not have any scientifically substantiated knowledge of the optimum depth of coagulation during cuttting and/or partial coagulation of the different tissue types and vessels. It may generally be said that the depth of coagulation required for efficient hemostasis is proportional to the lumen of the vessel concerned.

If the surgeon does not wish to leave the depth of coagulation during cutting or partial coagulation to chance, he must know not only the optimum depth of coagulation for each specific tissue type, but also the relevant physical parameters determining the depth of coagulation during cutting and/or partial coagulation.

3.1 CUTTING

Biological tissue can only be cut when the voltage between the cutting electrode and the tissue to be cut is sufficiently high to produce electric arcs between the cutting electrode and the tissue, effectively concentrating the HF electric current onto specific points of the tissue (Fig. a+b).

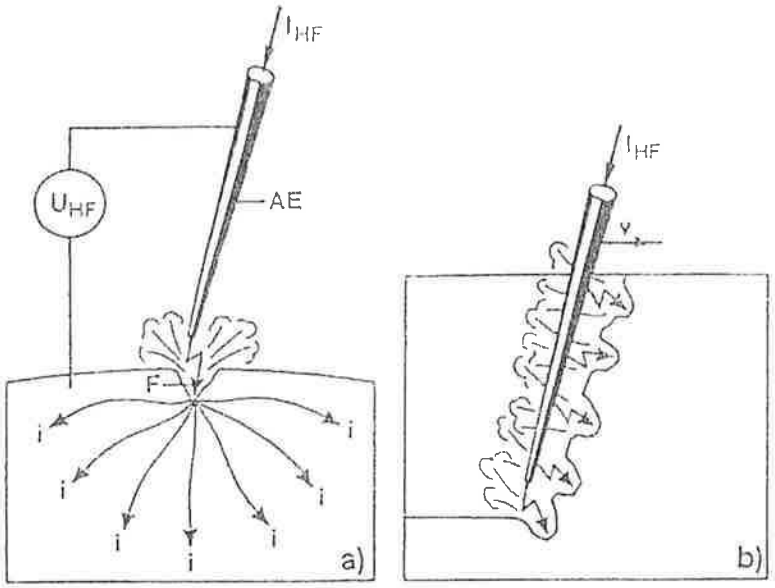


Fig. a: If the voltage U between active electrode AE and tissue G is sufficiently high, electric arcs F may be produced, concentrating the entire current I onto a single point so that the tissue at that point is immediately evaporated.

Fig. b: A cut is produced when electric arcs contact the tissue near the active electrode and cause it to evaporate.

The temperatures produced at those points at which the electric arcs contact the tissue like microscopic flashes of lightning are so high that the tissue is immediately evaporated or burned away. As the active electrode passes through the tissue, electric arcs are stochastically produced wherever the distance between the electrode and the tissue is sufficiently small, producing a cut.

A voltage of approximately 200 V_p is required in order to produce the electric arc between a metal electrode and biological tissue. If the voltage is less than 200 V_p, the electric arcs cannot be triggered, and the tissue cannot be cut. If it is greater than 200 V_p, the electric arcs increase in proportion to the voltage. Experience has shown that the depth of coagulation (k) along the cut increases with increasing voltage and length or intensity of the electric arc (Diagram 1).

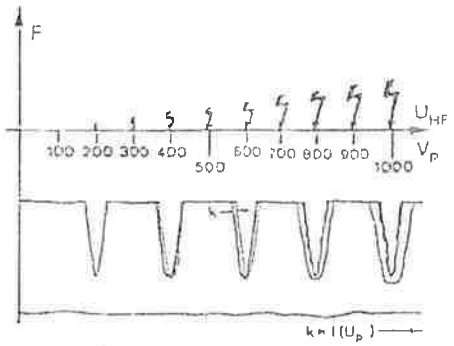


Diagram 1: Schematic illustration of the relationship between the intensity of the electric arcs F and hence of the coagulation depth k on the voltage U.

This relationship between the depth of coagulation and the voltage or intensity of the electric arcs between the active electrode and biological tissue has been used for decades in the practical application of conventional HF surgical equipment; unmodulated voltages with a relatively small peak value U_p are used to produce cuts with the least possible coagulation necrosis, while voltages with greater or lesser amplitude modulation and a relatively high peak value U_p are used for cuts with a greater or lesser depth of coagulation (Diagram 2).

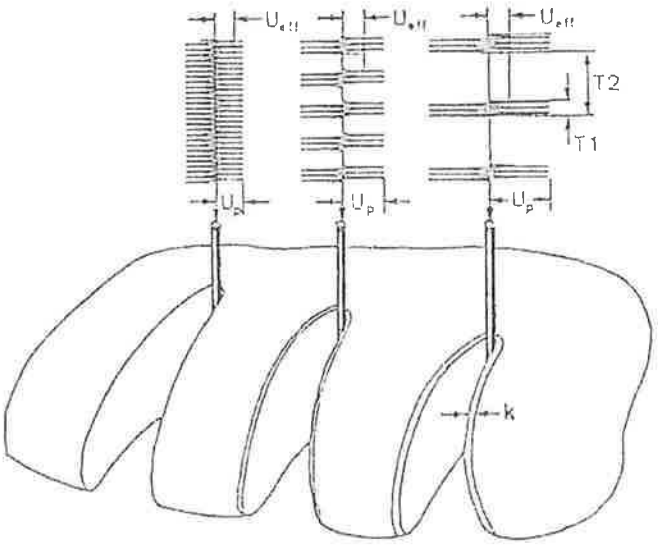


Diagram 2: As a rule, the amplitude U_p and amplitude modulation $T_2:T_1$ of the HF voltage can be varied on conventional surgical equipment. The depth of the coagulation k increases with increasing peak value U_p and constant root-mean-square value U_{rms} of the voltage U.

The HF surgical equipment used for this purpose up until around 1980 included a tube generator and a spark-gap generator. The tube generator produces largely unmodulated HF voltages for cuts with little coagulation, the spark-gap generator producing strongly amplitude-modulated HF voltages for cuts with intensive coagulation. The HF output power of the two generators could be adjusted relatively accurately but separately for each unit. The depth of coagulation along the cut edges could then be varied to a greater or lesser degree by mixing the HF voltages of the two generators.

Semiconductor-based HF surgical equipment has been built since 1970. The only difference with regard to cutting properties is that the depth of coagulation is no longer varied by mixing unmodulated HF voltage produced by a tube generator with a modulated HF voltage produced by a spark-gap generator, but by adjusting the amplitude and degree of modulation of the HF voltage. As in HF surgical equipment with tube and spark-gap generators, the controls for adjusting the degree of modulation are still marked "Mix" or "Blend" on a number of units with transistorized generators. The purpose of the "Mix" or "Blend" function is to allow the operator to determine the quality of the cut, i.e. the depth of coagulation, in advance by adjusting the settings on the HF surgical equipment (Diagram 2).

One problem with regard to the adjustability, reproducibility and constancy of the depth of coagulation common to all conventional HF surgical equipment is the greater or lesser generator impedance R_i making the HF output voltage U_a more or less dependent on the HF output current I_a (Diagram 3).
The greater the generator impedance R_i, the more the HF output U_a depends on the HF output current I_a. Conventional HF surgical equipment has a generator impedance of between 200 and 1000 ohm.

$$U_a = U_o - R_i \times I_a$$

$$U_a = \frac{U_o}{R_i + R_a} \times R_a$$

The output voltage U_a and hence also the intensity of the electric arcs and ultimately the depth of coagulation vary considerably, since the load resistance R_a and current I_a vary from one cut to the next and also during each cutting process as a result of fluctuations in the cutting depth, cutting rate and inhomogeneity of the tissue.

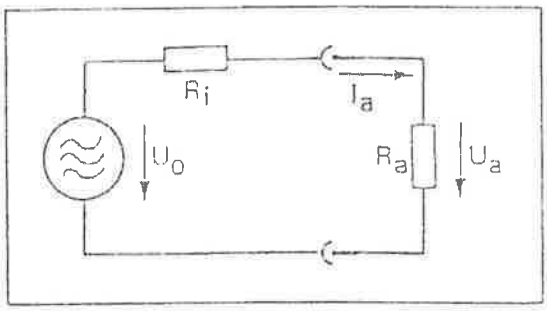


Diagram 3: **HF output voltage U_a as a function of the output current I_a and load resistance R_a.**

Diagram 4 shows the fluctuations in current I_a and voltage U_a, occurring during a single cut as a result of the inevitable fluctuations in cutting rate, cutting depth and inhomogeneity of the tissue.

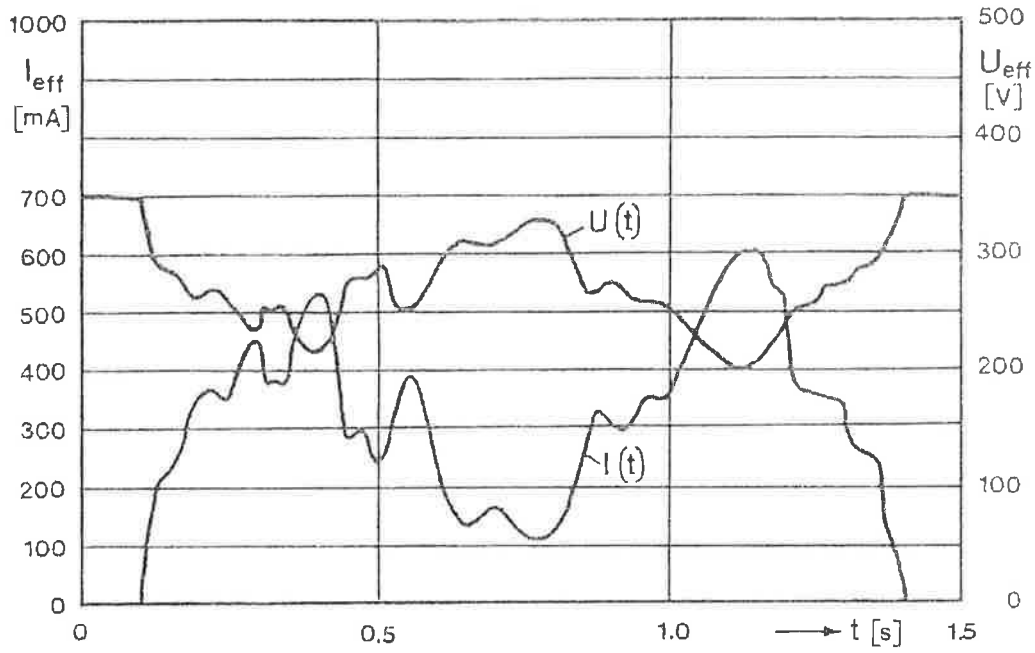


Diagram 4: Fluctuations in current I_a (t) and voltage U_a (t) during a single cut produced in 1.3 seconds. The HF generator has an impedance of 300 ohm.

Diagram 5 illustrates the effects of the fluctuations in the current I_a on the output voltage U_a, intensity of the electric arc F and coagulation depth k in a conventional HF surgical unit with an impedance of 300 ohm. The voltage suitable for cutting biological tissue ranges between not less than 200 V_p and not more than 500 V_p. If it drops below 200 V_p, the tissue cannot be cut since electric arcs cannot be generated between the cutting electrode and the tissue. If it rises above 500 V_p, the electric arcs become so intense that the tissue is increasingly carbonized and the cutting electrodes may be damaged.

Parameters 1 to 10 represent the individual equipment power stages that can be set. Stage 1 cannot be used for cutting. Stage 2 can be used to produce cuts with a slight depth of coagulation up to a maximum of 200 mA.

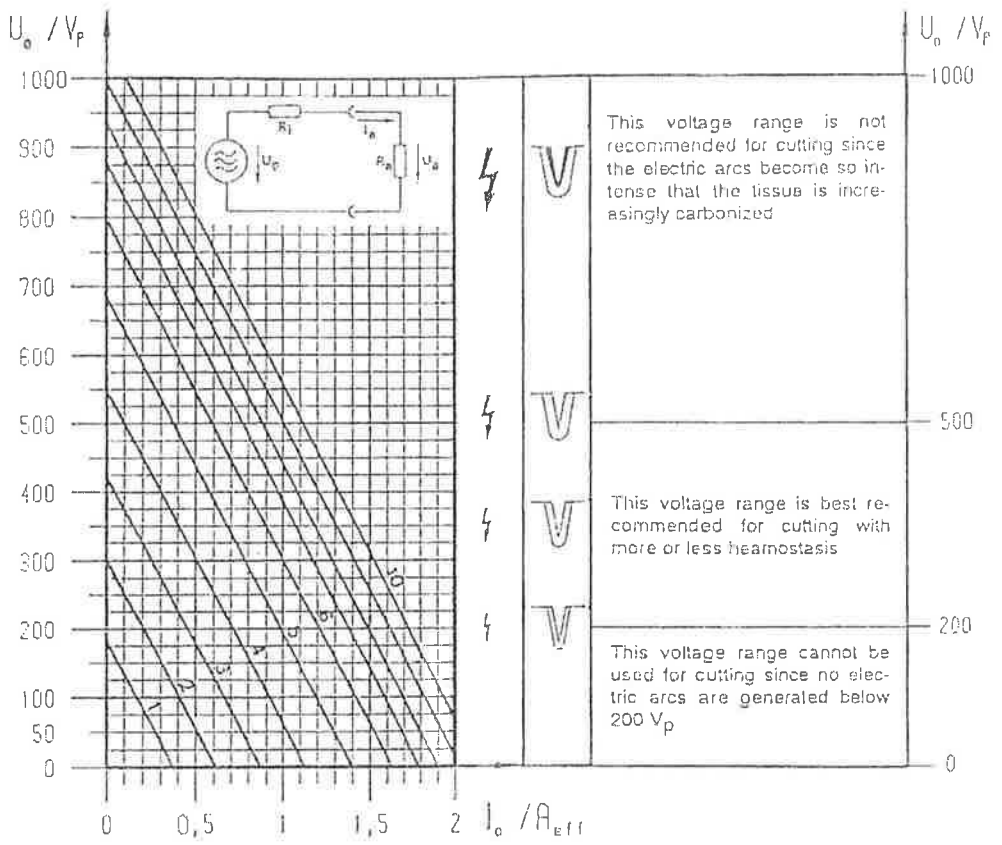


Diagram 5: Relationship between HF output voltage U_a and HF output current I_a of a conventional HF surgical unit with an impedance of R_i = 300 ohm and various power settings between 1 and 10.

Cuts up to 600 mA can be obtained with stage 4, although the depth of coagulation varies considerably.

From stage 6 upwards, the risk of tissue carbonization increases if the cut is produced too slowly, the cutting angle is too shallow and/or the cutting electrode is too thin.

For this reason, practical application of conventional HF surgical equipment demands that the depth of coagulation should depend not only on the setting of the HF output power and degree of modulation, but also on the thickness of the electrode, as well as on the cutting rate and depth. This relationship increases with the impedance of the HF generator.

The following rules must therefore be taken into account when using conventional HF surgical equipment:

A slight depth of coagulation is obtained by

- using the thinnest possible cutting electrodes
- using the smallest possible unmodulated HF voltage
- cutting as rapidly as possible, the full depth of the cut being obtained in a single pass rather than in a number of shallow passes.

Deeper coagulation is obtained by

- using the thickest possible cutting electrodes
- using the highest possible HF voltage; amplitude modulation is only advisable if a suitably thick cutting electrode cannot be used.
- cutting as slowly as possible.

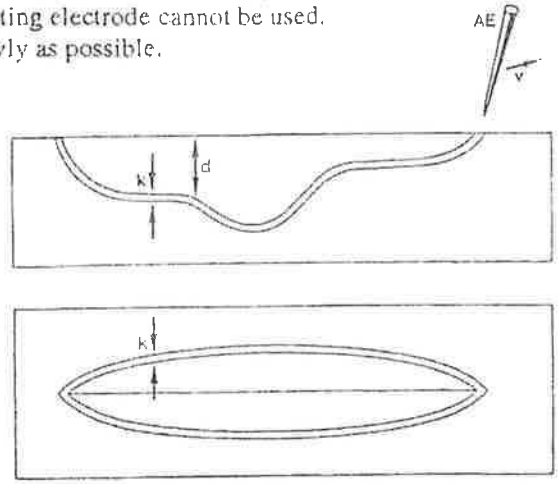


Fig. 6a: **Schematic illustration of the relatively constant depth of coagulation k despite the irregular cutting depth d and cutting rate v.**

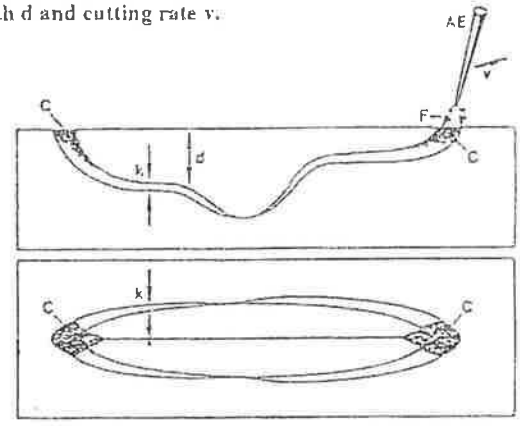


Fig. 6b: **Schematic illustration of the irregular coagulation depth k due to the irregular depth d of the cut despite a uniform cutting rate v, resulting in carbonization C of the tissue at the beginning and end of the cut produced by the intense electric arcs F.**

HF surgical equipment incorporating automatic control circuits has been available since 1985. These control circuits ensure that the intensity of the electric arcs and/or the peak value U_p of the HF output voltage are kept constant. This makes the depth of coagulation relatively independent of the cutting rate and depth, as well as of the magnitude of the HF output current I_a (Diagram 6 and Fig. 6a, 6b).

As in Diagram 5, the optimum HF cutting voltage range between 200 V_p and 500 V_p has again been marked.

Parameters 1 to 5 represent the individual adjustable HF voltages and the individual adjustable intensities of the electric arc between cutting electrode and tissue. Automatic control of the HF output voltage U_a or automatic control of the electric arc intensity ensures that the depth of coagulation remains constant for each setting, regardless of the magnitude of the HF output current I_a.

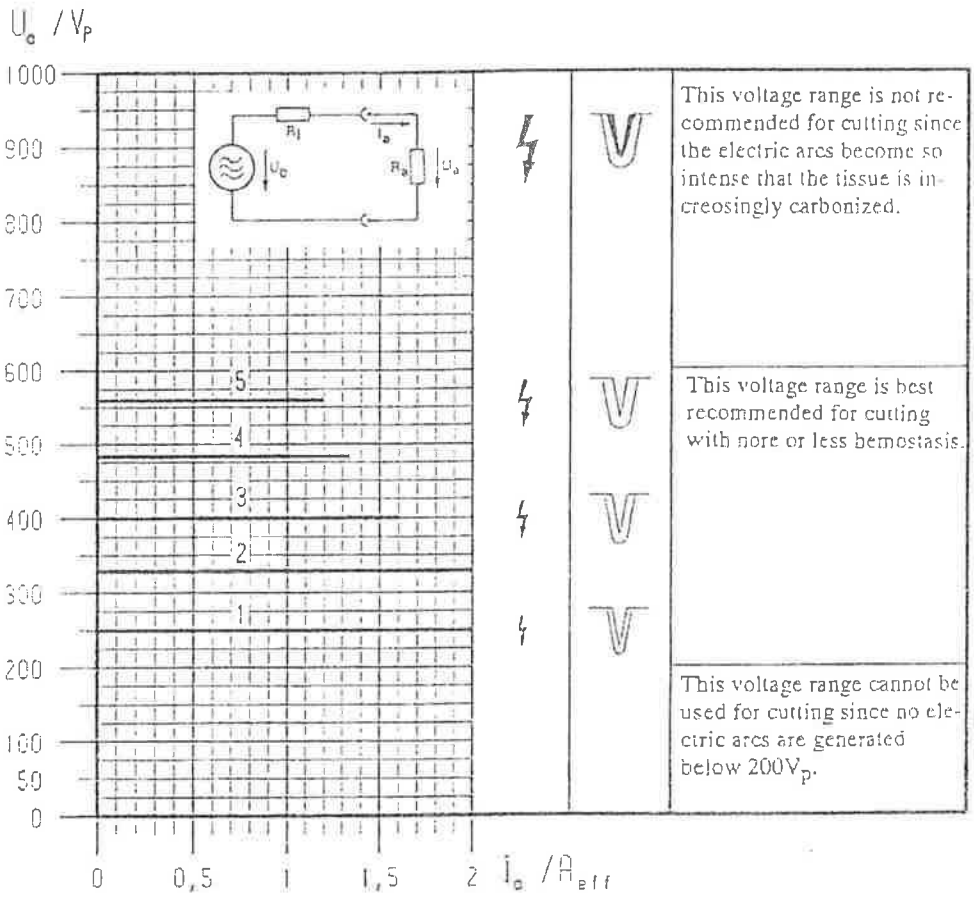


Diagram 6: Non-dependent relationship between HF output voltage Ua and HF output current I_a in a HF surgical unit with automatic voltage control and different settings 1 to 5 of the HF output voltage.

Cutting biological tissue using HF equipment as compared with other cutting or separating methods offers the following advantages, particularly when using equipment with automatic control:

1. The cut edges are thermally coagulated to a greater or lesser depth as the cut is produced. This ensures that at least the smaller vessels inevitably opened as a result of the cutting process are sealed off. Larger vessels can be sealed through partial thermal coagulation.

2. The use of suitable cutting electrodes, such as needle-type electrodes, gives the operator considerable freedom with regard to both the direction and depth of cutting.

3. All soft tissues can be cut without mechanical resistance or mechanical stress on the tissue. However, this also means that larger vessels can be cut or even separated without any perceptible mechanical resistance; this risk is particularly high when cutting parenchymal organs, such as the liver.

4. The use of HF surgical equipment automatically regulating the intensity of the electric arcs and/or amplitude of the HF voltage between cutting electrode and tissue and thus determining the quality of each and every cut guarantees a high degree of elasticity during the cutting process while maintaining a largely constant cutting quality; in other words, the operator can move the cutting electrode through the tissue as quickly or slowly as desired and at any angle without affecting the depth of coagulation to any major extent and without changing the settings on the HF surgical equipment. This makes it possible to produce highly dynamic cuts.

3.2 COAGULATION

Biological tissue can only be coagulated by thermal means if the requisite temperature of approximately 70°C has been built up. Although this effect appears very simple, the problems associated with utilizing the effect to obtain specific denaturation of the tissue or specific hemostasis are extremely complex.

Specific denaturation of the tissue or specific hemostasis means that no more tissue is coagulated than is absolutely required in order to achieve the intended purpose. This requirement is difficult to satisfy, for it is virtually impossible to introduce heat energy into the tissue in such a way that the tissue to be coagulated is heated to the temperature required for coagulation as uniformly as possible without causing thermal damage to the adjacent tissue. The following critical temperatures must be noted:

Up to approximately 40°C :
No significant cell damage.

Above approximately 40°C :
Reversible cell damage, depending on the duration of exposure (according to BENDER and SCHRAMM, 1968).

Above 49°C:
Irreversible cell damage = denaturation (according to BENDER and SCHRAMM, 1968).

Above approximately 70°C:
Coagulation (Latin: coagulatio = clotting). Collagens are converted to glucose.

Above approximately 100°C:
Phase transition from liquid to vapor of the intra- and extracellular water. The tissue rapidly dries out = desiccation (Latin: ex sico = dehydration). Glucose has an adhesive effect after dehydration.

Above approximately 200°C:
Carbonization (Latin: carbo = coal; medical: pathological burns of the 4the degree).

If the temperature of approximately 50°C required for denaturation is not obtained or if the temperature of approximately 70°C required for coagulation is exceeded, additional problems may arise as the coagulum containing glucose dehydrates and carbonizes.

When using HF alternating electric current for endogenous heating of biological tissue, the tissue temperature T increases until it reaches approximately 100°C or the boiling point of the tissue liquids in a manner roughly proportional to the specific electric flow Δt and square of the root-mean-square value of the electric current density i in the tissue concerned:

$$\Delta T = f\,(r,\ \Delta t,\ i^2_{rms})$$

The temperature rises at different rates at the various points on account of the inhomogeneity of the electrical and thermal tissue properties and, above all, of the irregular current density distribution within the tissue. As a rule, the density of the electric current is largest in the effective contact area between coagulation electrode and tissue, decreasing with the distance from this contact area (Fig. 7).

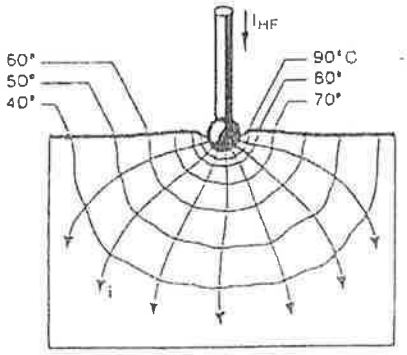


Fig. 7: **Typical temperature profile obtained during monopolar coagulation.**

On the one hand, this constitutes a problem with regard to controlling the physical size of the coagulation zone, but is simultaneously also the physical prerequisite for ensuring that monopolar coagulation does not continue to any random depth. Fig. a and b schematically illustrate the basic principles underlying the endogenous thermal effects during monopolar and bipolar coagulation over time.

3.2.1 Physical magnitude of temperature-dependent effects over time

When the HF generator is switched on at time t_1, a current I flows through a monopolar (Fig. a) or bipolar (Fig. b) coagulation electrode into the tissue where it is dispersed to a greater or lesser degree, the current density i decreasing with the distance from the contact surface. Since the rise in tissue temperature is proportional to the square of the current density, the temperature near the contact points increases very much more rapidly than in the deeper tissue layers.

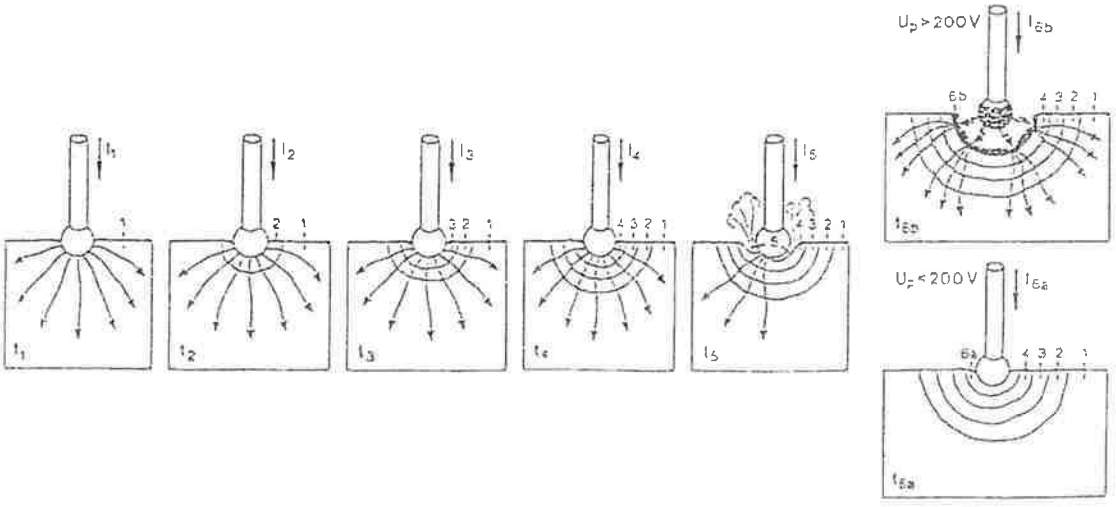


Fig. a: **Illustration of the monopolar coagulation process over time.**
A) Typical Soft Coagulation process.
B) Typical Forced or Spray Coagulation process.

The following zones are produced as the temperature increases during monopolar or bipolar coagulation process:

Zone 1: No noticeable increase in temperature

Zone 2: Irreversible cell damage due to thermal effects

Zone 3: Coagulation zone

Zone 4: Desiccation zone (thermal dehydration)

Zone 5: Vapor zone

Zone 6a: Dehydrated tissue incapable of conducting electric current may adhere to the coagulation electrode (due to the conversion of collagens to glucose in zone 3 and dehydration in zone 4)

Zone 6b: Carbonization zone.

The current I can only flow through the tissue unimpeded, and the tissue temperature can only increase until the boiling point of the tissue liquids near the contact surface has been reached, as illustrated for time t_5 , this produces a vapor layer 5 between coagulation electrode and tissue, impeding the current flow to various degrees, depending on the magnitude of the voltage between cogulation electrode and tissue. If the voltage has a peak value of less than 200 V_p, the electrically insulating effect of the resultant vapor layer slows down the coagulation process when the boiling point has been reached until the tissue layer 6a near the electrode has dried out to such an extent that virtually no more current can flow. If the current I is not switched off and the coagulation process halted by time t_4 at the latest, the coagulum may adhere to the coagulation electrode as of time t_5 (Diagram 7).

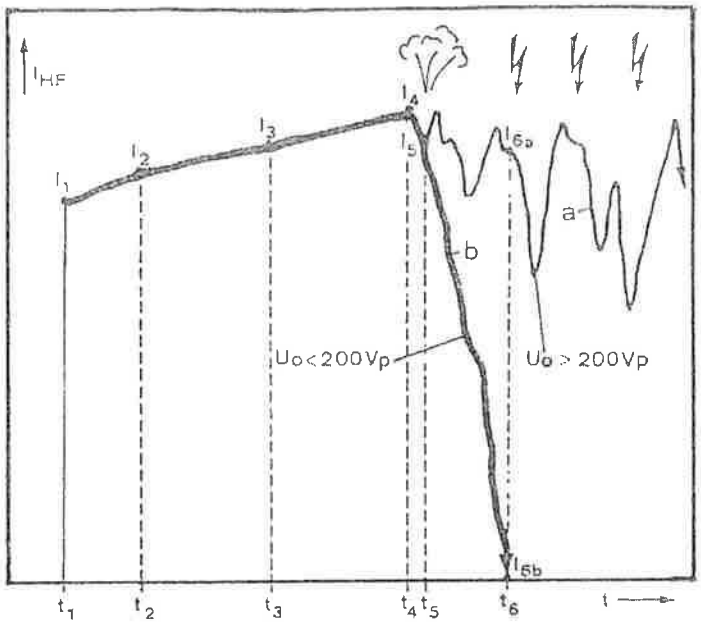


Diagram 7: Typical change over time t in the intensity of the HF current I during monopolar and bipolar coagulation. Although the rate of coagulation up to time t_5 varies with different HF voltages, it is basically always the same. From time t_5 onwards, the current I decreases towards zero if U_p < 200 V, or electric arcs carbonizing the coagulum are produced if U_p > 200 V.

This yields the following general rule:
The coagulum can be prevented from adhering to the coagulation electrode if the current I is switched off as soon as vapor emerges from the tissue.

If the voltage has a peak value of more than 200 V_p, the vapor layer 5 and dried-out tissue layer 6a are punctured by electric arcs causing the coagulation process to continue either until the HF generator is switched off or until the thickness of the dried-out tissue layer is so great that it cannot be punctured by any further electric arcs at the voltage set. The electric arcs produced between the coagulation electrode and the tissue cause the tissue 6b to carbonize, producing not only the unpleasant smell of burning flesh, but also strongly contaminating the coagulation electrode.

This yields the following general rule:
If the coagulation electrode is to make electrically conducting contact with the tissue to be coagulated, voltages greater than 200 V_p should only be used in exceptional cases in which relatively large coagulation zones must be produced by relatively small electrodes within a relatively short period of time, and the risk of carbonization of the coagulum is tolerable.

The physical size of the coagulation zone can be determined both by the application technique and by the coagulation rate. In this context, it is appropriate to differentiate between three coagulation modes, namely soft coagulation, forced coagulation and spray coagulation (Fig. a, b, c).

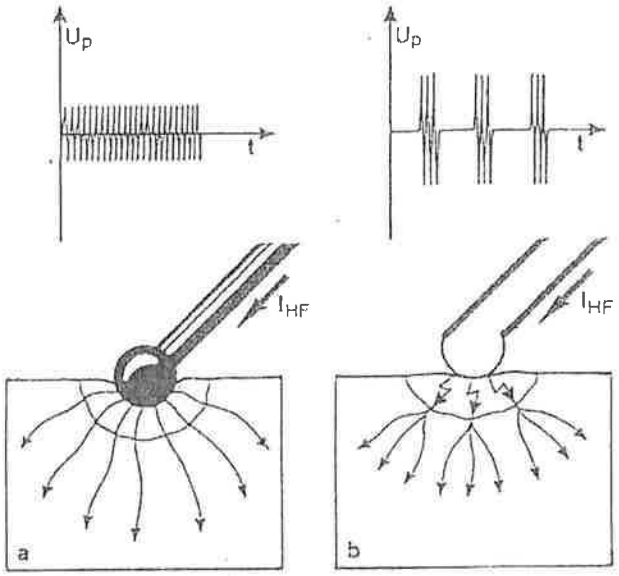


Fig.: a) Soft coagulation b) Forced coagulation

Soft coagulation, also known as No Sparking Coagulation (NSC), (Fig. a) is characterized by the fact that no electric arcs are produced between the coagulation electrode and the tissue during the entire coagulation process to prevent the tissue from becoming carbonized. Unmodulated HF voltages with a peak value below the trigger voltage for electric arcs between coagulation electrode and tissue are recommended for soft coagulation.

Soft coagulation is recommended for all cases in which monopolar or bipolar coagulation electrodes are brought in direct contact with the tissue to be coagulated.

Forced coagulation, also known as Pin Point Coagulation (PP), (Fig. b) is characterized by the fact that electric arcs are intentionally generated between the coagulation electrode and the tissue in order to obtain deeper coagulation than could be achieved with soft coagulation, particularly when using thinner or smaller electrodes. The risk of tissue carbonization must be tolerated here. Modulated HF voltages with a peak value sufficiently high to produce electric arcs of the required length, but with a root-mean-square value sufficiently small to prevent cutting effects during this coagulation mode are recommended for forced coagulation.

Forced coagulation can only be recommended when thin or small electrodes are to be used to obtain relatively deep coagulation. One such case, for example, would be the transurethral resection with rinsing fluid, the thin cutting electrode also being used for coagulation. Since there are no empirical data available as to the specific advantages and disadvantages of forced coagulation for parenchymal organs, this coagulation mode will not be considered further here.

3.2.2 Controlling the physical size of the coagulation zone by varying the application technique for soft coagulation.

The physical size of the coagulation zone for soft coagulation depends above all on the distribution of the current density within the tissue to be coagulated. The current density distribution, on the other hand, is primarily dependent on the technique with which the HF current I is applied. Basically, a distinction is made between monopolar and bipolar application techniques; these are then further differentiated according to monopolar and bipolar surface application, monopolar and bipolar puncture application and monopolar and bipolar spread application.

Since the extent of coagulation primarily depends on the current density distribution within the tissue, the size of the effective contact surface between tissue and electrode has a decisive effect on the development and maximum size of the coagulation zone obtained; the smaller the effective contact surface, the more inhomogeneous the current density distribution near the contact surface.

This yields the following general rule: The greater the effective contact area, the larger or deeper the coagulation zone. The physical size of the coagulum depends on the effective contact area and not on the available contact area.

3.2.3 Controlling the physical size of the coagulation zone by varying the soft coagulation rate.

With soft coagulation, the coagulation rate remains roughly proportional to the square of the HF current I or the square of the HF voltage U until the boiling point has been reached. As already described in detail, the temperature increases most rapidly near the point of contact between electrode and tissue, producing a temperature gradient from the contact surface into the tissue. The resultant flow of heat w from the boundary layer between coagulation electrode and tissue towards the deeper tissue layers can be used to control the depth of coagulation. If the HF current or voltage is set so that the amount of heat produced near the coagulation electrode is only marginally greater than that conducted into the deeper tissue layers per unit time, the resultant temperature gradient from the electrode towards the tissue will be flatter and the depth of coagulation correspondingly larger than in the case of more rapid coagulation using a higher HF current or voltage (Fig.).

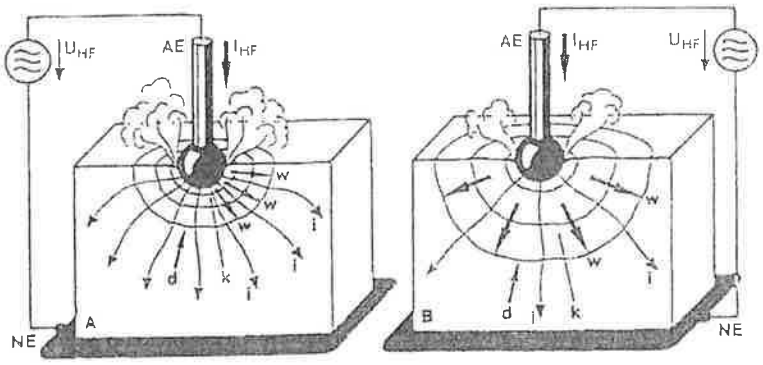


Fig.: **The physical size of the coagulum before coagulation is terminated by a vapor layer between electrode and tissue is roughly reciprocal to the voltage U and current I. The lower the HF voltage U, the more slowly vapor is created, which hinders the current flow and therefore allows the heat w to flow longer into the deeper tissue layers.**
A - Relatively high voltage U_{HF}
B - Relatively low voltage U_{HF}

This yields the following rule: The HF voltage U must not be too high if a relatively small coagulation electrode or relatively small effective contact area is to be used to obtain the maximum possible depth of coagulation d. For the higher the HF voltage, the more rapidly an electrically insulating vapor layer will be created between the coagulation electrode and the tissue, ending the coagulation process prematurely. The heat w produced near the coagulation electrode can flow into the deeper tissue layers if a lower HF voltage is used.

In this context, it is often found that high HF voltages are used to obtain great coagulation depths by force, intense electric arcs carbonizing the tissue and contaminating the coagulation electrode in the process. (This does not apply to coagulation during transurethral resection where the coagulation is performed in water and this other conditions apply).

However, the coagulation time can only be used as a reliable means of controlling the coagulation depth if the HF surgical equipment used for this purpose has the required characteristics. This applies not only to the ability to define the HF voltage setting, but also the constancy of the set HF voltage over the entire relevant current range. Since the effective contact area between coagulation electrode and tissue can vary considerably from one coagulation to the next, the HF current required for a defined coagulation time will also vary from one coagulation to the next. A constant current density i independent of the coagulation electrode and tissue can only be guaranteed if the root-mean-square value of the HF voltage U_a used for coagulation remains constant (Diagram 9).

The HF output voltage U_a of a HF generator with a generator impedance of R_i = 350 ohm is plotted as a function of the HF output current I_a for different settings 1 to 10 in Diagram 8. For each of the settings 1 to 10, the HF output voltageU_a decreases as the reciprocal value of the effective contact area A_{eff} and current I_a. Consequently, the more the effective contact areas Aeff varies during an operation, the more difficult it becomes to determine the depth of coagulation d that can be achieved by varying the settings on the HF generator.

If the equipment is set to values for which peak voltages greater than 200 V_p are obtained for $I_a = 0$, electric arcs may be produced between the coagulation electrode and tissue, carbonizing the tissue when using smaller effective contact areas.

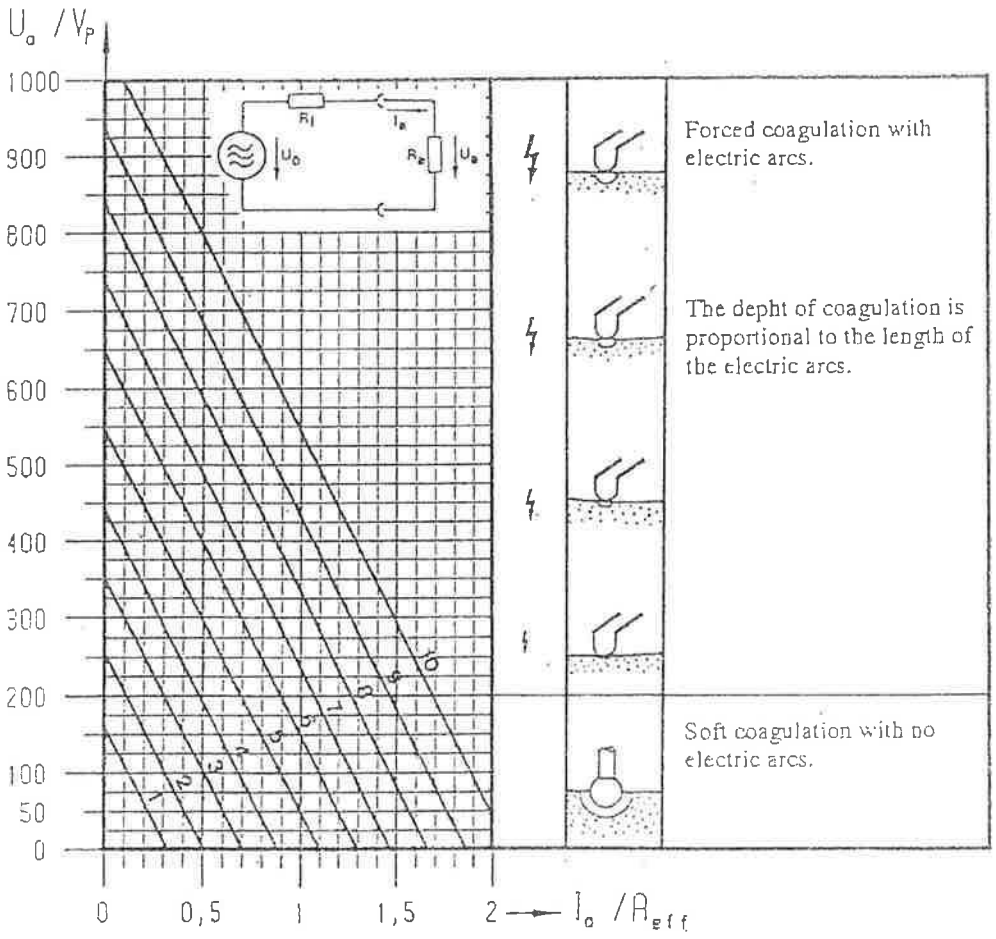


Diagram 8: Relationship between the HF output voltage U_a and HF output current I_a of a conventional HF surgical unit with an input impedance R_i = 350 ohm and power settings between 1 and 10.

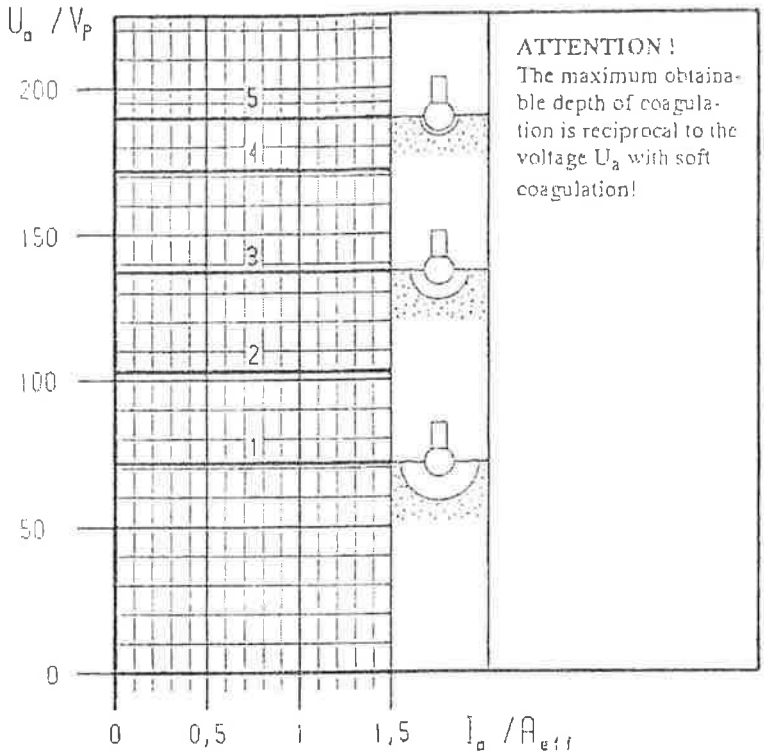


Diagram 9: Non-dependent relationship between the HF output voltage U_a and the HF output current I_a of a HF surgical unit with automatic voltage control for soft coagulation, settings 1 to 5.

Diagram 9 illustrates the relationship between the HF output voltage U_a of a HF generator with automatic voltage control and the HF output current I_a for different settings 1 to 5 of the HF output voltage U_a. The automatic voltage control function ensures that the HF output voltage U_a remains constant regardless of the current I_a and effective contact area. As a result, the coagulation depth that can be obtained for each setting remains largely independent of the effective contact area.

This yields the following general rule for soft coagulation: The settability and reproducibility of the soft coagulation depth increases as the HF generator impedance decreases. A HF generator with automatic voltage control is ideal for this purpose.

Soft coagulation can only be used to the optimum extent if the coagulation process is stopped when the vapor phase occurs at time t_4, as illustrated in Diagram 7. The coagulation zone effectively ceases to increase from this time onwards, since vapor formation considerably reduces the current flow. If this particular moment is disregarded or missed, the coagulum, which now contains glucose, will dry out (desiccate) and possibly adhere to the coagulation electrode. When the electrode is then removed from the tissue, the coagulum may be torn away, resulting in inadequate hemostasis.

This yields the following general rule for soft coagulation: In order to avoid this adhesive effect, soft coagulation should be stopped as soon as vapor emerges from the coagulation zone.

HF surgical equipment has now been developed which automatically ends the coagulation process at time t_5 as soon as the vapor phase has been achieved, as illustrated in Diagram 7.

5 RISKS AND SAFETY DURING HF SURGERY

High-frequency surgery always entails certain risks for the patient, the staff and the surroundings. In order to avoid these risks in practice, the surgeon and his assistants must be aware of their existence and follow certain rules to prevent damage or injury. These risks are described below, together with the rules to be followed in order to prevent damage or injury.

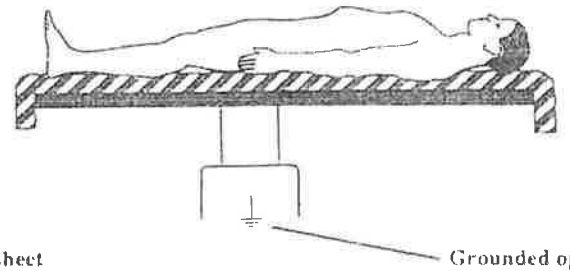
5.1 Accidental burns due to HF leakage current

The patient inevitably conducts HF electrical voltages to ground during HF surgery. If he comes in contact with electrically conductive objects during surgery, a HF current may flow between that object and the patient which may in turn cause thermal necroses.
Not only metal objects conduct electricity: damp and above all wet fabrics are also highly conductive.

The rules for application of high-frequency surgical equipment include the following requirements:

- The patient's entire body, including all extremities, must be insulated against all grounded metal parts of the operating table during HF surgery.

- Since elastic sheets on the operating table have a certain degree of conductivity in order to discharge any electric charges, they cannot always guarantee simultaneous HF insulation between the patient and any metal parts of the table. Such HF insulation can be achieved by using a sufficient number of additional intermediate layers (sheets).



Positioning the patient

- A waterproof sheet must be used to prevent the intermediate layers providing HF insulation from becoming soaked if moisture, perspiration, etc. is to be expected during the operation.

- Absorbent sheets must be placed between the patient and the waterproof sheet in order to prevent any accumulation of moisture below the patient.

- Additional sheets must be placed between any areas where considerable perspiration is to be expected, between limbs in contact with the torso or where skin-to-skin contact is unavoidable (e.g. between arm and torso, between the legs, below the breasts).

- **The following conditions must be satisfied if the patient is connected to the HF surgical equipment and also to a monitor, e.g. ECG:**

- If both units are operated with grounded neutral electrodes, the grounded ECG cable must be connected to the neutral electrode of the HF surgical unit.

- The active surgical electrode must not be placed in the vicinity of the ECG electrodes (minimum distance 15 cm) .

- The use of needle electrodes or injection cannula is not recommended; the metal cone must never rest on the skin; the same applies for the monitor cables.

- Drain urine with a catheter.

5.2 Accidental burns due to improper useof electrosurgery

Preference should generally be given to bipolar coagulation techniques rather than monopolar coagulation. This applies in particular when coagulating long organs in which the HF current flows through long stretches with invariable or increasingly narrow cross-sections.

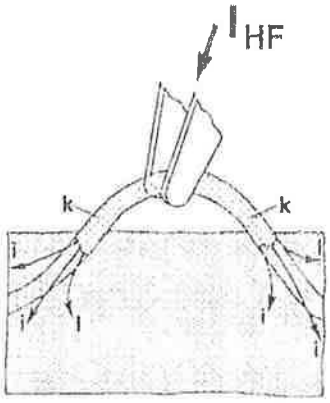


Fig.:If the high-frequency current I_{HF} flows through long tissue parts with the same cross-section when using monopolar techniques, the entire length k will be coagulated.

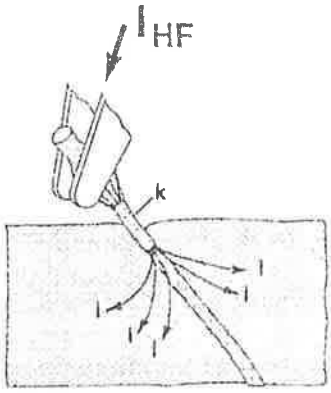


Fig.: If the high-frequency current flows through constrictions in the tissue when using monopolar techniques, the coagulation k starts at the point of constriction and not at the point at which the coagulation electrode touches the tissue.

5.3 Accidental burns due to improper use of the neutral electrode

If the neutral electrode is not applied correctly or is not used at all, there is a very high risk of accidental burns both at the point of application of the neutral electrode and at other points on the patient`s body.

The following rules must therefore be observed when applying the neutral electrode:

- The effective contact area and the value of the electrical conductance between neutral electrode and patient must be adequate for the HF output and intensity of the HF current used.

  The effective contact area in this case is the area of the neutral electrode in electrically conductive contact with the patient's skin during HF surgery.

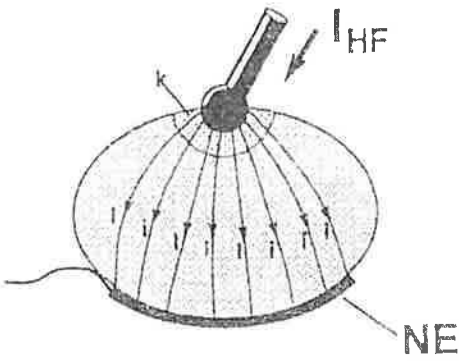


Fig.: The current density at the neutral electrode is only negligibly small if it makes full electrical contact with the patient's skin.

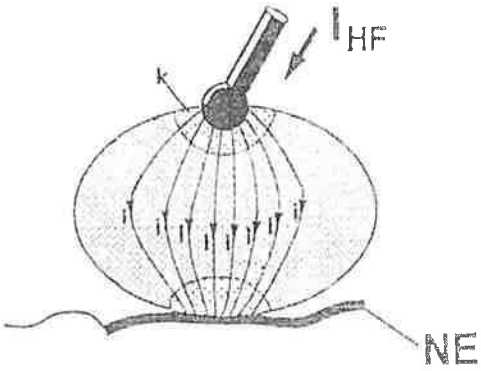


Fig.: If the neutral electrode makes only partial contactwith the patient's skin, the current density at this effectively small point can becom extremely large and burn the tissue.

Many years of experience have shown that neutral electrodes should be selected and used in accordance with the following criteria:

Neutral electrode of electrically conductive silicone	1.5 W/cm^2 ms or 10 mA/cm2rms
Metal neutral electrode without conductive gel	3.0 W/cm^2 ms or 15 mA/cm2rms
Disposable neutral electrode	5.0 W/cm^2 ms or 20 mA/cm2rms

5.4 Accidental burns due to the use of unsuitable and/or defective accessories

It must be ensured that only faultless accessories are used for high-frequency surgery. Only accessories tested by the manufacturer within the framework of type tests or compatible accessories may be used.

The insulation on electrodes, electrode holders, cables, connectors, etc. must be in absolutely perfect condition.

Neutral electrodes must guarantee perfect electrical contact with the patient's skin.

5.5 Accidental burns due to inattentiveness

Like a scalpel, high-frequency surgery is a source of potential danger if applied without due caution.

The cutting or coagulation electrodes must always be handled with extreme care and put aside so that neither the patient nor other people can come in contact with the electrodes when they are not in use.

It is dangerous to leave unused electrode handles or coagulation forceps on or beside the patient or in the artificial folds in the sheets! Patients have been known to suffer burns because their skin was inadvertently pierced by coagulation forceps put down in the folded sheets.

5.6 Accidental burns due to output errors

The risk of accidental burns is directly proportional to the intensity and the duty cycle set on the unit for cutting and/or coagulation.

The intensity selected for cutting and/or coagulation should be no more than is actually required for the momentary purpose and should not be switched on for longer than necessary (refer also to chapter 6.4.3 "Output Error Monitor").

ATTENTION: If normal settings produce an inadequate effect, this may be due to poor contact between skin and neutral electrode, poor contact in the plug connectors, broken wires inside the insulation or encrusted electrodes. These possibilities must be checked before selecting a higher intensity.

5.7 Accidental burns due to unintentional activation of the HF-Generator

ATTENTION: Unintentional activation of a HF surgical unit can lead to patient burns when the active electrode touches the patient directly or indirectly through electrically conductive objects or wet cloths.

Unintentional activation of a HF surgical unit can be caused for example by:

- Unintended depressing of a footswitch pedal
- Unintended depressing of a button on an electrode handle

- Short circuit within a cable to the elelctrode handle with push buttons or to the footswitch.

- Penetration of electrical conductive fluids into a fingerswitch, into an electrode handle or into a footswitch. Electrically conductive fluids are for example blood, urine, physiological saline, irrigation fluids and amniotic fluid. Special care is called for in cesarean section.

- Defects within the electrosurgical unit

In order to avoid patient burns due to unintended activation of an electrosurgical unit, the following rules of application must be observed:

- Never place active electrodes on or beside the patient in such a way, that the electrodes can touch the patient directly or via electrically conductive objects or wet cloths.

- The acoustic signal which indicates the activation of the electrosurgical unit must always be adjusted so that it can be heard.

- In operations in which the cutting or coagulation electrode unvoidably remains in contact with the patient even in the unactivated state, e.g. in endoscopic operations, special care is called for. An electrode activated unintentionally owing to a mistake should not be removed without due precautions from the body. In removal of the activated electrode from the body of the patient, burns may arise at all areas within the body which come into contact with the activated electrode. For this reason, the mains switch of the unit must be turned off immediately before an attempt is made to remove the active electrode from the body.

5.8 Unintended burns caused by hot electrodes

CAUTION: Cutting and/or coagulation electrodes become hot indirectly from the heated tissue and from the electric arcs during cutting and/or coagulation processes. Tissue may be unintentionally burned after cutting and/or coagulation when electrodes which are still hot have contact with the tissue. This is to be noted especially in endoscopic operations, for example in pelviscopic coagulation of the fallopian tube or in endoscopic polypectomy.

5.9 Accidental burns due to the ignition of flammable liquids, gases and/or vapors

Sparks are always produced at the active electrode when HF surgical units are in operation. For this reason, particular care must be taken during HF surgery to ensure that anaesthetics, skin cleansers, degreasing agents and disinfectants are neither flammable nor explosive. At the very least , they must be allowed to evaporate completely and taken out of vicinity of the sparks before switching on the HF surgical equipment.

HF surgery should not be performed in the gastro-intestinal tract since endogenous gases present a potential explosion hazard; this does not apply if the explosive gases are eliminated from these organs, for instance by flushing with inert gases, before and during the high-frequency surgery.

ATTENTION: H_2O molecules may dissociate to form H_2 and O_2 in the electric arc between resection loop and flushing liquid during transurethral resection . These gases may accumulate at the top of the urinary bladder to form a highly explosive mixture. Potentially dangerous explosions may be produced by cutting in such a mixture of gases.

5.10 Stimulation of muscles and nerves

Inadvertent stimulation of the patient's muscles and nerves is a familiar risk in high-frequency surgery. Such stimulation may be caused by low-frequency currents originating either in low-frequency current sources or in electric arcs between the active electrode and the patient's tissue.

Note: An alternating current with a frequency of more than 300 kHz cannot stimulate nerves and muscles.

However, the electric arcs inevitably produced when cutting and during forced or spray coagulation cause parts of the high-frequency alternating current to be rectified, thus producing more or less strongly modulated low-frequency current components stimulating those structures capable of electrical stimulation, such as nerves and muscles. This may in turn lead to more or less pronounced twitching and/or muscular contractions.

IMPORTANT: Muscular contractions must be expected during high-frequency surgery on structures capable of electrical stimulation. Such contractions may occur, for example, during endoscopic surgery in the urinary bladder, near the obturator nerve.

5.11 Cardiac pacemakers

The use of electrosurgery on patients with implanted cardiac pacemakers or pacemaker electrodes may cause irreparable damage to pacemakers and interfere with pacemaker functions leading to ventricular defibrillation. This must be taken into consideration.

5.12 Interference with other electronic equipment

By their very nature, HF surgical units generate high-frequency voltages and currents which can cause interference in other electronic equipment.

This problem should be taken into account when installing or arranging sensitive electronic equipment in the operating theatre. Sensitive electronic equipment should always be positioned as far away as possible from the HF surgical unit and away from all cables conducting HF currents. Moreover, these cables should be kept as short as possible and must never be routed near and parallel to the cables of sensitive equipment, for no matter how carefully they are shielded, the HF cables have the same effect as a transmission antenna.

On account to the interference in sensitive electronic equipment, this HF surgical unit is equipped with a special generator which outputs relatively low interference levels in comparison with conventional HF equipment.

6.1 GENERAL DESCRIPTION OF THE MCC 100

The MCC 100 is a high frequency electrosurgical unit with the following characteristic features:

Cutting Mode

* The HF output voltage of the MCC 100 unit remains constant within the output power range from zero to the respective adjusted maximum wattage. If the output voltage deviates from the nominal voltage, the output error signal does warn the surgeon.

* The respective adjusted maximum output power is not affected by blend mode setting.

* The respective adjusted maximum output power is calibrated directly in watts with a large lighted, digital display.

* Precise and reproducible output power setting from 1 to 100 watts makes this unit useful for microsurgery as well as for general surgery.

* Five different blend modes from minimum to maximum hemostasis.

Monopolar Coagulation Modes

The MCC 100 unit offers two different monopolar coagulation modes:

SOFT COAGULATION. This coagulation mode is characterized by the fact that no electric sparks ignite between the coagulation electrode and the tissue during the coagulation process. This not only prevents the coagulation electrode from sticking to the coagulated tissue, but also prevents the tissue from becoming carbonized.
The output voltage of Soft Coag. mode is automatically kept constant within the power range from zero to the respective adjusted maximum output power.

FORCED COAGULATION. This coagulation mode is characterized by the fact that electric arcs are deliberately generated between the coagulation electrode and the tissue, yielding a considerable coagulation depth in relation to the effective contact area of the coagulation electrode.

This coagulation mode should be used when relatively large coagulation depths must be obtained using fine or thin coagulation electrodes, i.e.typical cutting electrodes.

SAFETY FEATURES

The MCC 100 unit includes the following safety features reducing the risks entailed in HF surgery for both the patient and the surgeon due to:

* Output error (refer to chapter 6.3.1)

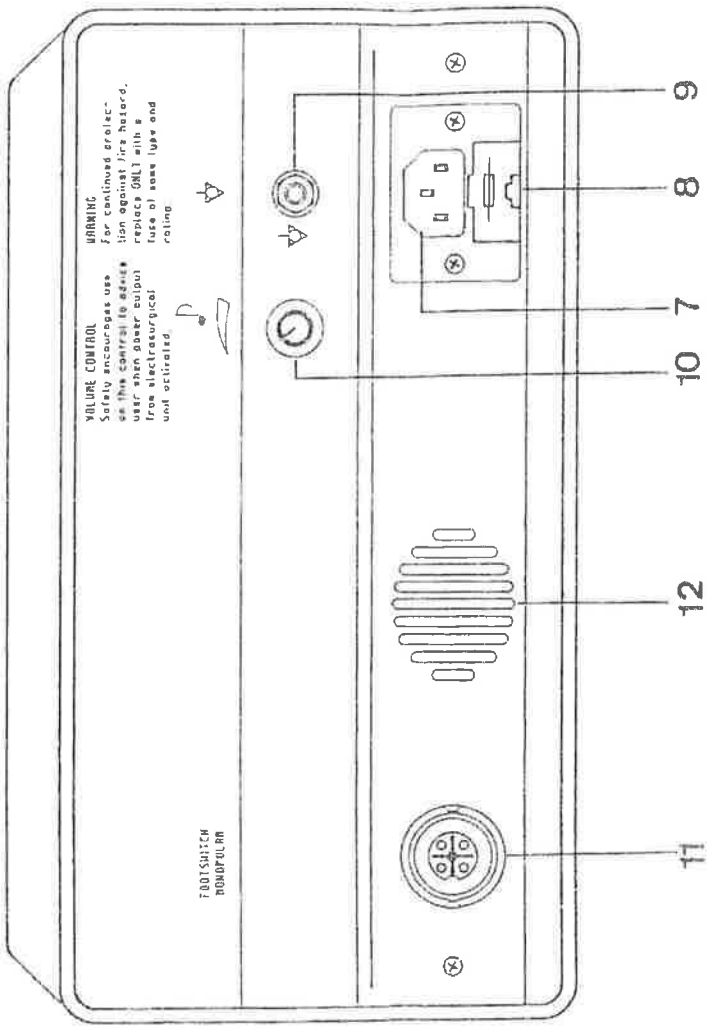
* Excessively long unintentional activation of the HF current (refer to Chapter 6.3.2)

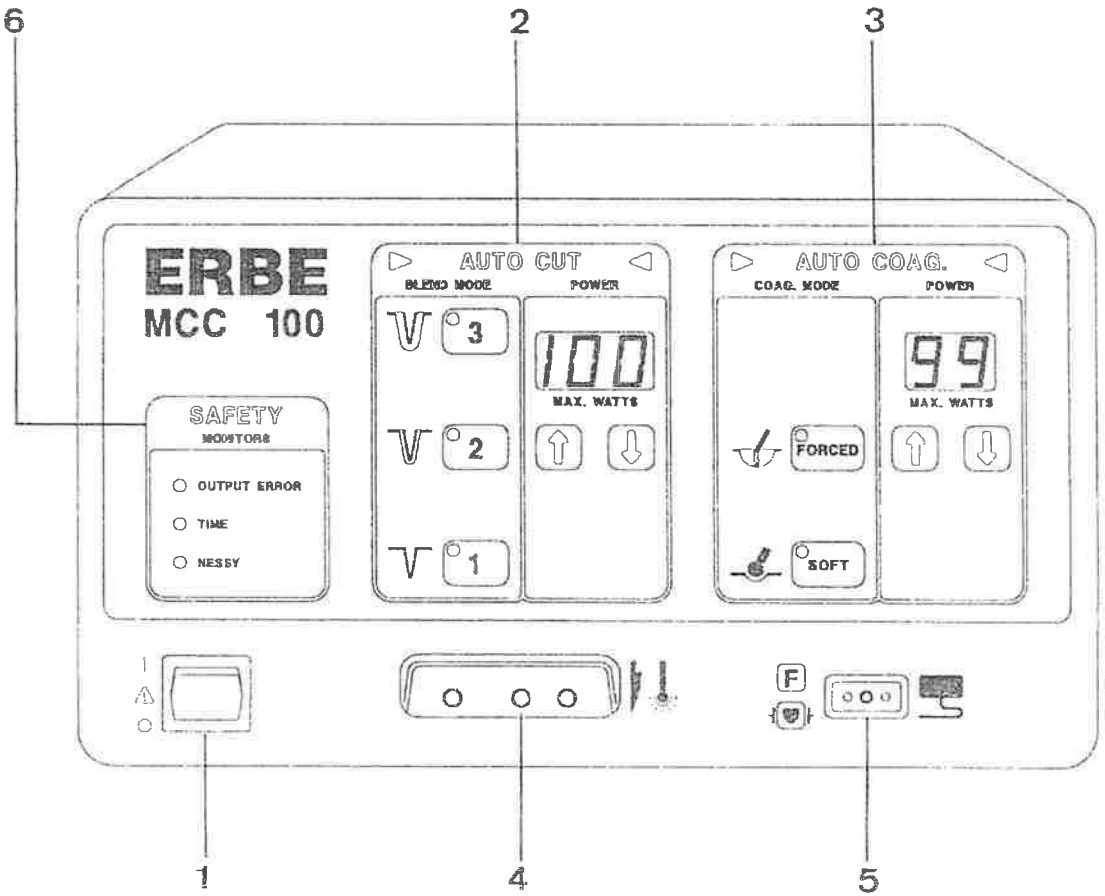
* Burns due to incorrect application of the neutral electrode (refer to Chapter 6.3.3)

Self check

When the power switch of the unit is switched on, the unit automatically performs a number of function tests. If these reveal a fault this is indicated acoustically and the revealed fault becomes indicated by an related error number on the power display within the Auto Coag. field.

ERROR 22	CUT Mode Pedal Fault
ERROR 23	CUT Mode Finger Switch Fault
ERROR 25	COAG. Mode Pedal Fault
ERROR 26	COAG. Mode Finger Switch Fault
ERROR 50	BLEND Mode 1 Key Fault
ERROR 51	BLEND Mode 2 Key Fault
ERROR 52	BLEND Mode 3 Key Fault
ERROR 55	AUTO CUT Power Down Key Fault
ERROR 56	CUTO CUT Power Up Key Fault
ERROR 57	SOFT COAG. Key Fault
ERROR 58	FORCED COAG. Key Fault
ERROR 62	AUTO COAG Power Down Key Fault
ERROR 63	AUTO COAG. Power Up Key Fault


VOLUME CONTROL
Safety encourages use
of the control to advise
user when power output
from electrosurgical
unit activated
WARNING
For continued protec-
tion against fire hazard,
replace ONLY with a
fuse of same type and
rating
FOOTSWITCH
MONOPOLAR
9
8
7
10
12
11


6
2
3
ERBE
MCC 100
SAFETY
MONITORS
OUTPUT ERROR
TIME
NESSY
AUTO CUT
BLEND MODE
POWER
3
2
1
100
MAX. WATTS
AUTO COAG.
COAG. MODE
POWER
FORCED
SOFT
99
MAX. WATTS
F
1
4
5

6.2 DESCRIPTION OF THE CONTROL ELEMENTS

1 Power Switch

When the power switch is ON, the unit automatically performs a number of function tests. If these reveal a fault this is indicated acoustically and the revealed fault is indicated by an related error number on the power display within the Auto Coag. field. During the selfcheck all LED's are illuminated to indicate that the LED's are ok.

ERROR 22	CUT Mode	Pedal Fault
ERROR 23	CUT Mode	Finger Switch Fault
ERROR 25	COAG. Mode	Pedal Fault
ERROR 26	COAG. Mode	Finger Switch Fault
ERROR 50	BLEND Mode 1	Key Fault
ERROR 51	BLEND Mode 2	Key Fault
ERROR 52	BLEND Mode 3	Key Fault
ERROR 55	AUTO CUT Power	Down Key Fault
ERROR 56	AUTO CUT Power	Up Key Fault
ERROR 57	SOFT COAG.	Key Fault
ERROR 58	FORCED COAG	Key Fault
ERROR 62	AUTO COAG Power	Down Key Fault
ERROR 63	AUTO COAG. Power	Up Key Fault

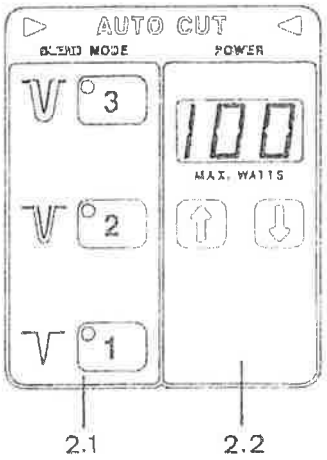
NOTE

The equipment can only be activated via fingerswitch or footswitch when the function fields have been set completely, i.e. when all indicators in the function field concerned have stopped flashing.

NOTE

If the equipment was only briefly switched off for up to approx. 15 seconds, the settings previously selected are saved and the equipment is immediately operational again.

2 AUTO CUT Function Field



2.1 BLEND MODE setting

The three push buttons select the degree of hemostasis while cutting. BLEND 1 corresponds to the minimum hemostasis degree, BLEND 3 being the maximum degree.

2.2 MAX. POWER setting

When the equipment is initially switched on, the power output display indicates 80 watts.

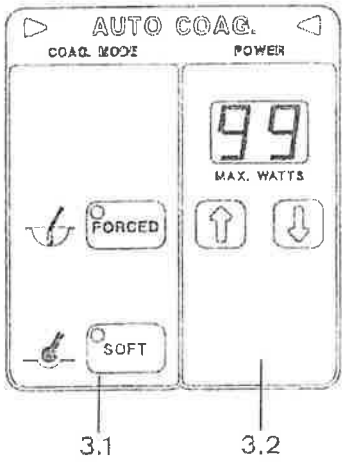
Depressing the power output UP arrow will allow the user to increase the amount of wattage that will be supplied to the cutting electrode. A single push of the button will increase the value displayed by one watt . Holding the arrow button down will cause the numerical value to scroll first slowly than rapidly. When the desired power level is displayed simply release the button and the value shown in the power output display will be the maximum amount of

power (in watts) that will be delivered to the cutting electrode. The range is from 1 watt to 100 watts in increments of one watt.

Once an initial power output value has been selected the user may lower this value by depressing the power output DOWN arrow. Depressing this button once will lower the output value displayed by 1 watt. Holding the arrow button down will cause the numerical value to scroll first slowly than rapidly. When the desired power level is displayed simply release the button and the value shown in the power output display will be the maximum amount of power (in watts) that will be delivered to the monopolar cutting electrode. The minimum power setting is 1 watt.

If the equipment was only briefly switched off for up to approx. 15 seconds, the settings previously selected are saved and the equipment is immediataly operational again.

3 AUTO COAG. Function Field



3.1 COAG. MODE Setting

The MCC 100 unit offers 2 different coagulation modes:

SOFT Coag. Mode
FORCED Coag. Mode

3.2 POWER setting

When the equipment is initially switched on, the power output display indicates 60 Watts.

Depressing the power output UP arrow will allow the user to increase the amount of energy that will be supplied to the monopolar coagulation electrode. A single push of the button will increase the value displayed by one watt . Holding the arrow button down will cause the numerical value to scroll rapidly. When the desired power level is displayed simply release the button and the value shown in the power output display will be the maximum amount of power (in watts) that will be delivered to the monopolar coagulation electrode. The range is from 0 to 120 watts in increments of one watt.

Once an initial power output value has been selected the user may lower this value by depressing the power output DOWN arrow. Depressing this button once will lower the output value displayed by 1 watt. Holding the arrow button down will cause the numerical value to scroll rapidly. When the desired power level is displayed simply release the button and the value shown in the power output display will be the maximum amount of power (in watts) that will be delivered to the monopolar coagulation electrode.

If the equipment was only briefly switched off for up to approx. 15 seconds, the settings previously selected are saved and the equipment is immediataly operational again.

4 **Monopolar Active Receptacle / Handswitch**
This monopolar active receptacle will accept handswitching active accessories.

5 **Neutral Electrode Receptacle**
A suitable neutral electrode must be applied to the patient and connected to the equipment for monopolar coagulation techniques. The unit is equipped with a Neutral Electrode Safety System (NESSY) which monitors the electrical connection between the neutral electrode and the equipment, as well as the electrical resistance between the neutral electrode and the patient. However, the latter is only possible if suitable neutral electrodes with two contact surfaces are used.

This symbol indicates that the neutral electrode is floating against ground potential according to IEC 601-2-2.

This symbol indicates that the applied part of the equipment fulfils type CF according to IEC 601-1 and is safe against defibrillation according to IEC 601-2-2 and the neutral electrode may thus remain applied to the patient during defibrillation.

6 **Safety Monitors**
The equipment is provided with three different safety monitors, OUTPUT ERROR, TIME and NESSY, which are described in chapter 6.3.

7 **Power Socket**
The equipment may only be connected to correctly installed sockets with grounded earth conductor using the mains lead supplied by the equipment's manufacturer or a lead according to IEC 601-1 §57.3. Adapters or extension leads should not be used, for safety reasons. If their use is unavoidable, they must also be fitted with a faultless protective earth conductor.

8 **Mains Fuse**
The unit is protected with one mains fuse. If this fuse blows, a technician authorized to test the unit should make a check for possible faults before the unit is operated again.
CAUTION: For continued fire protection replace only with a fuse of specified type and rating. Disconnect power input before replacing fuse.

9 **Connection for potential equalization**

10 **Volume control**
The volume of the acoustic signal can be individually set with this control.

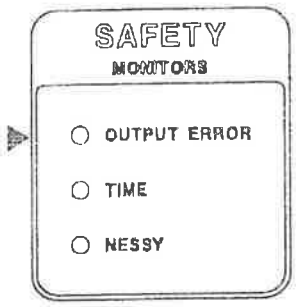
Attention: One of the main purposes of this acoustic signal is to protect both the patient and staff against burns due to accidental activation of the RF generator.

11 **Socket for Footswitch**

12 **Loudspeaker**

6.3 DESCRIPTION OF THE SAFETY MONITORS

6.3.1 OUTPUT ERROR MONITOR



An output error in this particular instance refers to every deviation of the actual value of the HF output voltage from the required value set on that unit.

If the actual value of the output voltage is lower than the required value set on the unit, the desired effect will only be achieved to an unsatisfactory extent or not at all.

If the actual value of the HF output voltage is greater than the required value set on the unit, more tissue will be damaged than is necessary to achieve the desired effect, undesired effects may also result.

The MCC 100 includes automatic monitoring of the HF output voltage which monitors any deviations of the actual value from the required value set for the HF output voltage and which generates an alarm and switches off the HF generator when the deviation becomes so great as to jeopardize the desired quality of the effect (cutting or coagulation).

For the operator, the advantage of indicating an output error due to the equipment is that he can immediately verify whether or not discrepancies or even the absence of a desired effect are due to a defect in the equipment.

Discrepancies between the actual and the required HF output voltages can only occur in the MCC 100 if the connected loads have an extremely low impedance (e.g. coagulation electrodes too large, short circuit between active and neutral electrode, fault in the unit).

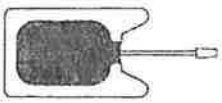
6.3.2 TIME LIMIT

The HF generator may be switched on unintentionally as a result of a fault in the equipment or accessories or as a result of an operator error. In order to prevent major damage due to such accidental activation of the HF generator, the MCC 100 unit is fitted with a monitor which automatically monitors the duty cycles of the HF generator. When a preset time is exceeded, the monitor generates an optical alarm. If the HF generator is not then switched off, it is automatically deactivated by the monitor and an acoustic alarm sounds upon expiry of a further preset time. Duty cycle in this case refers to the time during which the HF generator of a electrosurgical unit is continuously switched on.

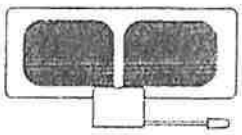
The HF generator can be restarted at any time and the duty cycle is again monitored automatically. This prevents major damage due to unintentional activation of the HF generator for indefinite periods of time.

6.3.3 NESSY (Neutral Electrode Safety System)

The MCC 100 unit is equipped with a Neutral Electrode Safety System (NESSY) that monitors the connection between the neutral electrode and patient and/or neutral electrode and the equipment.



When neutral electrodes having a single contact surface are in use, electrical contact between the equipment and the neutral electrode will be automatically monitored. The green NESSY indicator will light and all operating modes can be used. The green NESSY indicator will be extinguished and monopolar modes will be disabled if this contact should be interrupted. Any attempt to activate one of the equipment's monopolar modes under this condition will cause the red NESSY indicator to blink and an audible warning signal to sound.

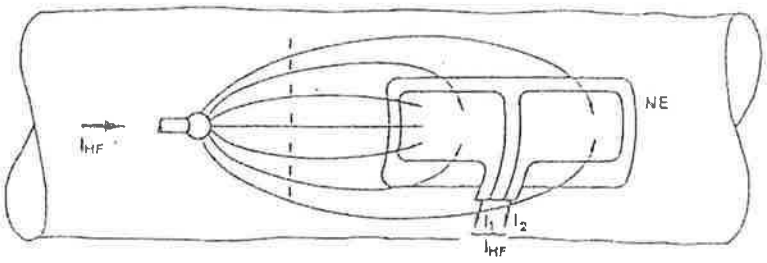


When neutral electrodes having two contact surfaces are in use, both the electrical connection between the equipment, the neutral electrode and the patient will be automatically monitored.

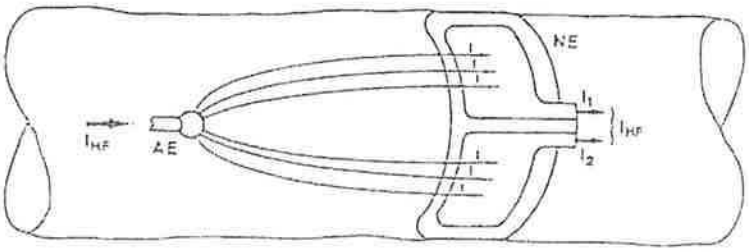
In addition to monitoring the electrical connection between neutral electrode and equipment as well as the patient, NESSY also measures the electrical impedance between neutral electrode and patient when neutral electrodes having two contact surfaces are in use. An alarm will be generated, if the high-frequency current rises above the maximum limit permitted for the electrical impedance prevailing between the neutral electrode and patient. This prevents triggering erroneous alarm signals which might lead to unnecessary interruptions during operating procedures.

This feature allows using various types of two contact surface neutral electrodes, especially of benefit in case of the relatively small contact area neutral electrodes commonly used on small children.

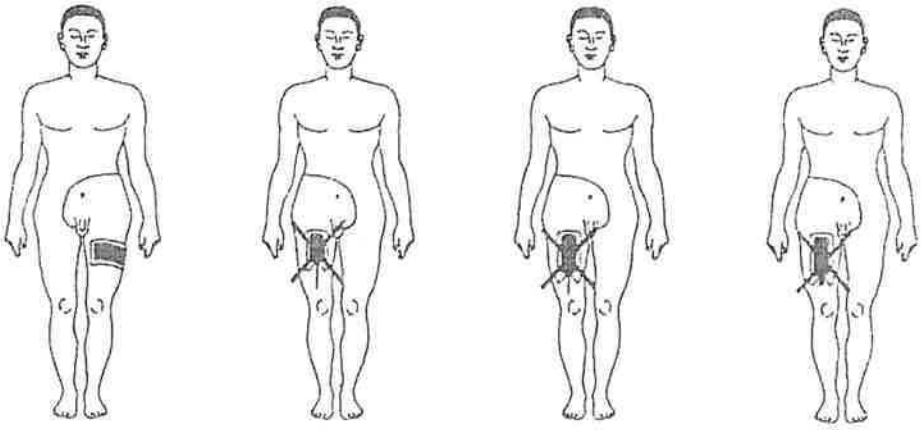
NESSY can also recognize and monitor the orientation of the neutral electrode relative to the direction of current flow when two-surface neutral electrodes are used. Since high-frequency current usually is not homogeniously distributed over the contact surfaces of neutral electrodes, but can be greater at the corners or along the edges facing the direction from which current comes, care should be taken that the longer edge of neutral electrodes faces the direction from which current flows when positioning neutral electrodes.



Incorrect orientation of neutral electrode (NE) suitable for use with NESSY



Correct orientation of neutral electrode (NE) suitable for use with NESSY



This rule should also be observed in the case of neutral electrodes having only a single contact surface.

TECHNICAL DATA OF THE ERBOTOM MCC 100	
INPUT CHARACTERISTICS	
Nominal Line Voltage	120V rms
Line Voltage Range	from 90V to 140V rms
Line Frequency Range	from 48Hz to 62Hz
Maximum Power Consumption	150W (200)VA
Idle	40VA
Line Fuse	2A, slow-blow
Duty Cycle (IEC 601 2-2, 42.4)	operating time 10s/resting time 30 s for one hour

OUTPUT CHARACTERISTICS	
1. CUT MODE	
Waveform of the HF-Voltage	unmodulated sinusoid
Constancy of the HF-Voltage	automatically controlled
Frequency	350 kHz
Hemostasis	Choice of 3 blend modes via front panel keys 1 = from 150 through 250 Veff 2 = from 250 through 350 Veff 3 = from 350 through 450 Veff
Rated HF-Output Power	100 Watts at R_L = 500 Ohms
Pulse Power System (PPS)	200 Watts at R_L = 500 Ohms
Maximum Output Power	from 1 up to 100 Watts in increments of 1 Watt
Output Power Setting	via up/down keys
Output Power Indication	3 digits display
Tolerance of the Output Power Indication	+/- 1 digit resp. +/- 10%
Pulse Power System (PPS)	yes
Activation of Cut Modes	via fingerswitch or pedal
HF Output Sockets	1 for fingerswitch or pedal activation, for 3-pin plugs

2. SOFT COAGULATION	
Waveform of the HF-Voltage	unmodulated sinusoid
Constancy of the HF-Voltage	automatically controlled
Frequency	350 kHz
HF-Voltage	from 20 V_p through 190 V_p
Rated HF-Output Power	99 Watts at 200 Ohms
Maximum Output Power	from 1 Watt up to 99 Watts in increments of 1 Watt
Output Power Setting	via up/down keys
Output Power Indication	2 digits display
Tolerance of the Output Power Indication	+/- 1 digit resp. +/- 10%
Activation of the Soft Coag. Modes	via fingerswitch or pedal
HF Output Sockets	refer to 1.13

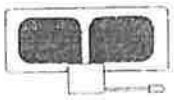
3. FORCED COAGULATION	
Waveform of the HF-Voltage	pulse-modulated
Output Power versus Load Resistance	refer to diagram Forc.-Coag.-Power versus Load
Frequency	1 MHz
HF -Voltage	max.2.5 kVp
Rated HF -Output Power	99 Watts at 500 Ohms
Maximum Output Power	from 1 Watt up to 99 Watts in increments of 1 W
Output Power Setting	via up/down keys
Output Power Indication	2 digits display
Tolerance of the Output Power Indication	+/- 1 digit resp. +/- 10 %
Activation of the Forced Coag. Modes	via fingerswitch or pedal
HF Output Sockets	refer to 1.13

SAFETY FEATURES	
6. SAFETY FEATURES	
6.1 Neutral Electrode	floating (IEC 601 part 1)
6.2 Type according to IEC 601-1	CF (IEC 601 part 1)
6.3 Neutral Electrode Monitor	NESSY
6.3.1 Max. resistance between the 2 contact areas of a splitted electrode	120 Ohm
6.3.2 Alarms depending on I_{HF} and R_e	refer to diagram $W = f(I_{HF}, R_0)$
6.3.3 Symmetry Monitor	yes
6.4 HF-Output Error Monitor	HF voltage, HF current, HF power
6.5 Limitation of maximum Duty Duration	yes
6.6 Automatic Function Tests	yes
6.7 Error Indication after Self Check	refer to listing of ERROR MESSAGES

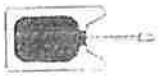
SIZE	W x H x D = 280 x152 x 368mm
Weight	9kg

OPTICAL and ACOUSTIC SIGNALS STATUS of the HF-GENERATORS			
EVENT	optical	acoustic	HF off
Power ON	*		
HF generator activated	**	**	
Output error	**	**	**
Maximum duty duration (TIME) reached	**		
Maximum duty duration (TIME) alarm ignored	**	**	**
Splitted or non-splitted neutral electrode not connected to the unit	** red	**	**
Non-splitted neutral electrode correctly connected to the unit	* green	*	*
Splitted neutral electrode correctly connected to the unit but not contacting the patient	** red	**	**
Splitted neutral electrode correctly connected to the unit and perfectly contacting the patient	* green	*	*
Resistance between splitted neutral electrode and patient exceeding 120 ohms either by faulty application or high impedance of patient's tissue	** red	**	**
Intensity of the HF current flowing through neutral electrode in relation to resistance between splitted neutral electrode and patient wrong	** red	** 3 times	**
Intensities of the current flowing through the 2 contact areas of a splitted neutral electrode are different	** red		
Intensities of the HF current flowing through the 2 contact areas of a splitted neutral electrode differ too much	** red	**	**
Faulty front panel setting	**	**	**
Trouble indication after self check	*	*	*

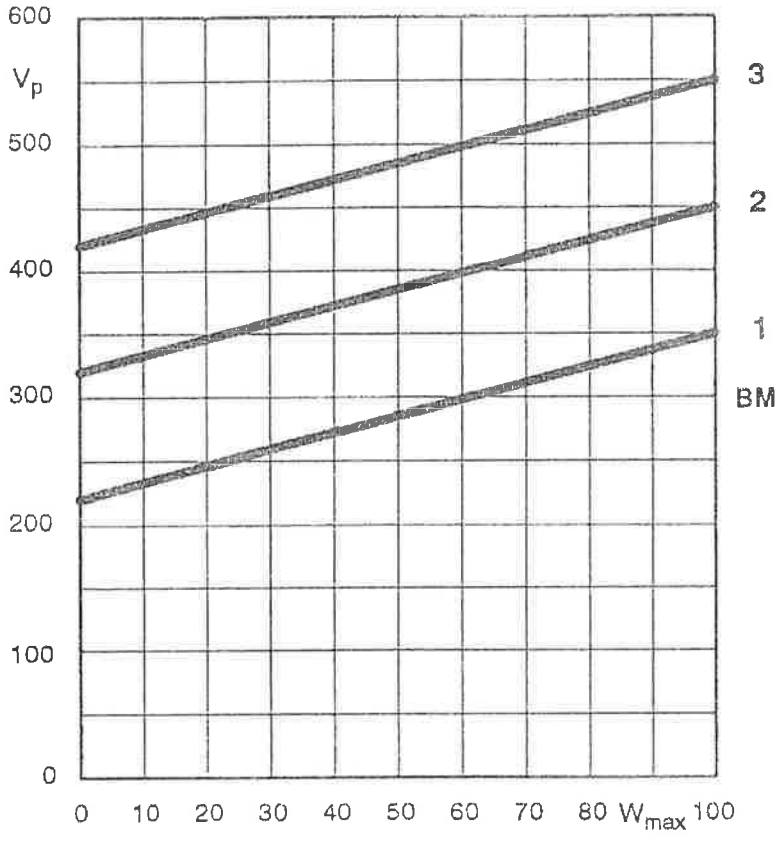
* In standby mode
** After activation



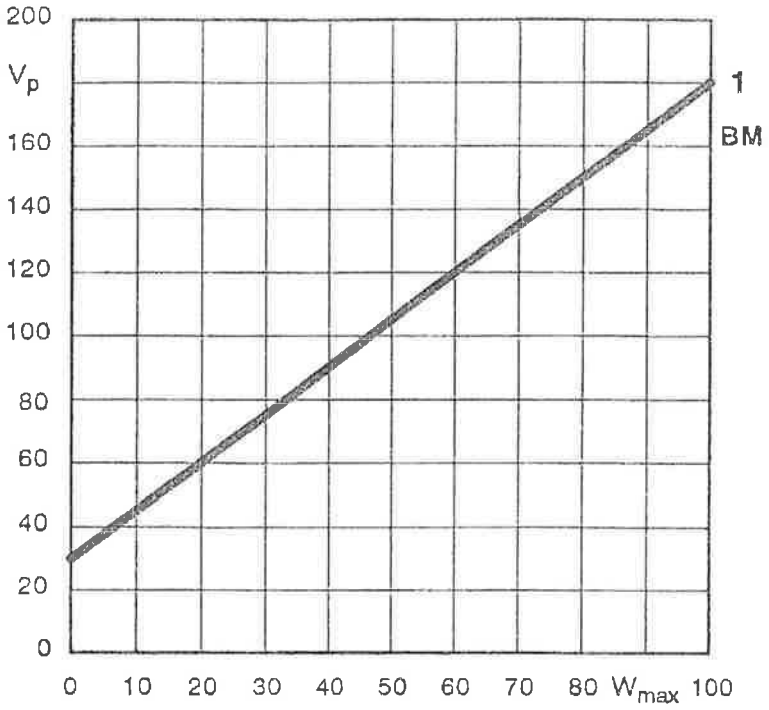
Splitted neutral electrode



Non-splitted neutral electrode



Auto Cut
Output peak voltage (V_p) versus max. power setting in Watts (W_{max}).
Blend Mode (BM) 1, 2 and 3.



Auto Coag.
Output peak votage (V_p) versus max. power setting in Watts (W_{max}).

8 INSTALLATION

8.1 Spatial requirements

HF surgical equipment may only be operated in rooms used for medical purposes if these rooms fulfil the national safety requirements. With regard to the electrical installations, these requirements concern , for example, the protective earth system , potential equalization and low frequency leakage current protection.

8.2 Possibilities for installation in operating rooms

HF surgical equipment can basically be set up on tables, brackets suspended from the ceiling or wall-mounted brackets, as well as on special-purpose equipment trolleys.

8.3 Line connection

WARNING: These units may only be connected to correctly installed earthed sockets using power cords supplied by the equipment manufacturer or power cords of the same quality. Adapters or extension leads should not be used, for safety reasons. If their use is unavoidable, they must also be fitted with a faultless protective earth conductor.

CAUTION: To avoid electric shock, the power cord protective grounding conductor must be connected to ground.

8.4 Potential equalization

Safety standards require that all equipment used for intracardiac operations must be connected to the potential equalization of the room. The purpose of this requirement is to prevent any danger to the patient due to low-frequency currents, such as the low-frequency leakage currents in a defective protective earth conductor.

In order to satisfy this requirement, the unit has a potential equalization connector on the rear panel. The units can be connected to the potential equalization system in the room by means of an equipotential cable plugged into this socket.

8.5 Protection against explosion hazards

High-frequency surgical equipment naturally produces electric arcs between the active electrode and the tissue. Electric arcs may also be produced inside the equipment. HF surgical equipment must therefore not be used in explosion-hazard areas.

The entire area up to 20 cm above the floor , as well as the area around and below the operating table are potentially explosive areas if flammable or explosive cleansers, disinfectants, anaesthetics, etc. are used.

High-frequency surgical equipment is normally installed outside the explosion-hazard zone.

ATTENTION: Footswitches used in explosion-hazard areas must be explosion-proof.

8.6 Protection against moisture

This HF surgical equipment is protected against the ingress of moisture and splash-water as required by DIN/IEC 601 Part 2-2.

Nevertheless, the equipment should not be installed near hoses or vessels containing liquids. Do not place any liquids above or on the equipment itself.

Only use waterproof pedal switches in accordance with DIN/IEC 601 Part 2-2, Section 44.6 aa, draft edition.

Only use waterproof electrode handles with push-button switches in accordance with DIN/IEC 601 Part 2-2, Section 44.6 bb, draft edition. If electrode handles are used which are not waterproof, care must be taken to ensure that no moisture enters the electrode handle in order to prevent unintended activation of the equipment.

8.7 Cooling

This unit must be set up such as to ensure an unobstructed flow of air around the housing. It must not be installed in small niches, shelves, etc.!

8.8 HF interference

HF surgical units naturally generate high-frequency voltages and currents. The fact that they may cause interference in other electromedical equipment must be taken into account when they are installed and during operation.

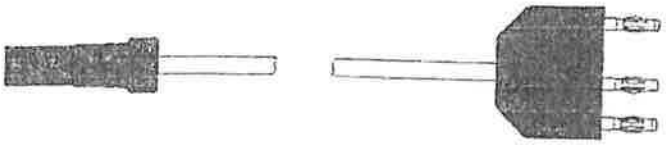
NOTE: Because they are equipped with a harmonics-free HF generator and automatic voltage regulator, these units generate considerably less HF interference than conventional units of this type. This is particularly advantageous when they are used in combination with video monitors.

Electrode handles

Electrode handles

- The electrode handles are used for the fitting of monopolar active electrodes, which can be fitted in various positions in the appropriate handle, secure against rotation.
- ERBE electrode handles consist of glass-fibre reinforced, electrically-insulated plastic material, and can be sterilized using all steam sterilization procedures up to 134° C, including connecting cables and plugs.
- The electrode handles are watertight according to DIN IEC 601, part 2–2, 44 6.bb. This prevents the handles from being accidentally switched on through penetration by liquid.

Electrode handle with 2 buttons
The electrode handle with 2 buttons allows direct actuation of the monopolar generator. The yellow button switches on the HF current for cutting and the blue button switches on the HF current for coagulation.
No. 20190-045



Connecting cable for electrode handle MCC
in compliance with IEC 601, part 2–2, 101.5

Cable 5 m long No. 20192-042

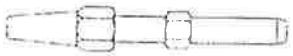
NOTE:

This electrode handle is proper for electrodes with 4 mm shaft diameter. Electrodes with 2.4 mm or 1/10 inch shaft diameter are adaptable with an ERBE adapter.

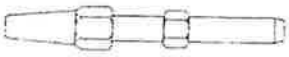
Disposable electrode handle
No. 20190-057

Chucks

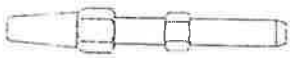
Shaft extension, 4.0 mm diameter with insulated shaft, 10 cm
No. 20191-119



Chuck, 1.6 mm diameter for microelectrodes
No. 20191-113

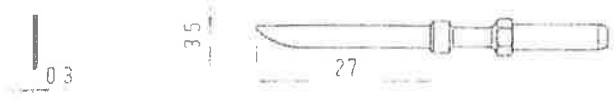


Chuck, 1.0 mm diameter for insulated epilation needles
No. 20191-013



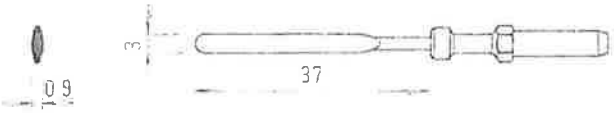
Chuck, 0.3 mm diameter for uninsulated epilation needles
No. 20191-012

Monopolar Electrodes
Cutting electrodes



Knife electrode, straight,
after Kirschner
No. 20191-007

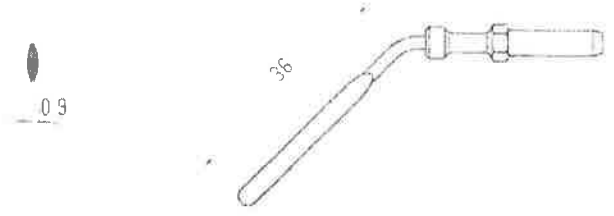
Knife electrode, straight,
lancet-shaped
No. 20191-009



Spatular electrode, straight
No. 20191-126

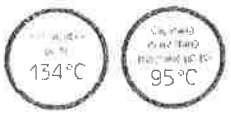
Needle electrode, straight
No. 20191-011

Knife electrode, curved
after Magenau
No. 20191-008



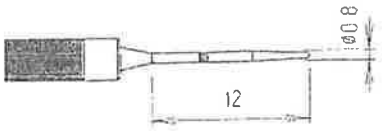
Spatular electrode, curved
No. 20191-125

Needle electrode, curved
No. 20191-124

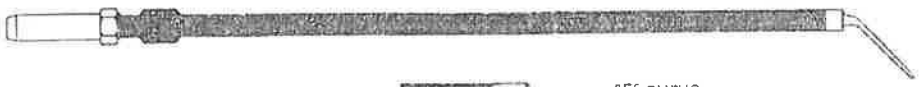


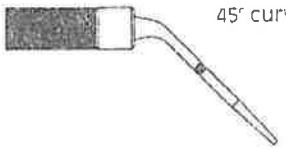
Cutting electrodes with insulated shaft for body cavities

In compliance with IEC 601, part 2–2, 101.3.2

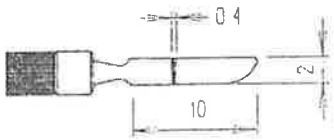


Needle electrode, straight
0.8 × 12 mm, with insulated shaft,
10 cm long
No. 20191-027

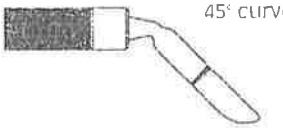




Needle electrode, curved,
0.8 × 12 mm, with insulated shaft,
10 cm long
No. 20191-122

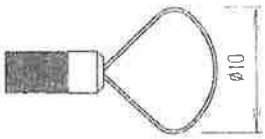


Knife electrode, straight,
0.4 × 10 mm, with insulated shaft,
10 cm long
No. 20191-028



Knife electrode, curved,
0.4 × 10 mm, with insulated shaft,
10 cm long
No. 20191-123

Wire loop electrode, straight
5 mm, with insulated shaft,
10 cm long
No. 20191-031



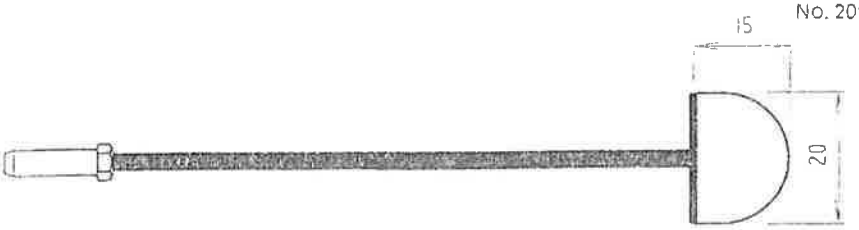
Wire loop electrode, straight
10 mm, with insulated shaft,
10 cm long
No. 20191-032

134°C

95°C

Cutting electrodes for conization of the cervical portio

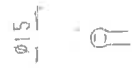
Loop-electrode, 20×20 mm, shaft 90 mm long, insulated
No. 20191-132



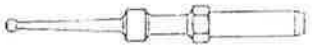
Loop-electrode, 20×15 mm, shaft 90 mm long, insulated
No. 20191-133

Loop-electrode, 10×10 mm, shaft 90 mm long, insulated
No. 20191-134

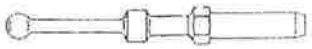
Coagulation electrodes



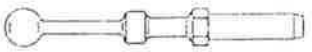
Ball electrode, straight,
diameter 1.5 mm
No. 20191-019



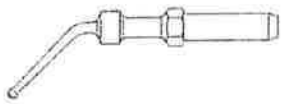
Ball electrode, straight,
diameter 2 mm
No. 20191-020



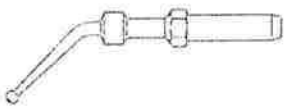
Ball electrode, straight,
diameter 4 mm
No. 20191-021



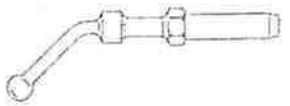
Ball electrode, straight,
diameter 6 mm
No. 20191-022



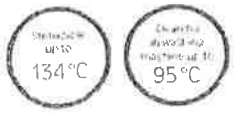
Ball electrode, curved,
diameter 1.5 mm
No. 20191-129



Ball electrode, curved,
diameter 2 mm
No. 20191-130

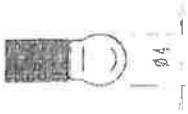


Ball electrode, curved,
diameter 4 mm
No. 20191-131



Coagulation electrodes with insulated shaft for body cavities

in compliance with IEC 601, part 2-2, 101 3 2

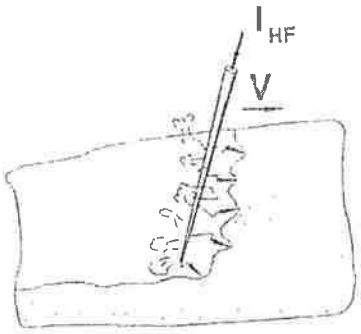


Ball electrode, straight, diameter 4 mm, with insulated shaft, 10 cm long
No. 20191-029

Coagulation needle, 1 × 3 mm, after Mittenmaier, for incision coagulation of the concha nasalis, with insulated shaft, curved, 10 cm long
No. 20191-039

Ball electrode, diameter 1.8 mm, with insulated shaft, curved, 10 cm long
No. 20191-114

Electrode handle for microsurgery



Microsurgery
It is only through the development of voltage or arc regulated high-frequency surgical equipment, that it is possible to regulate the intensity of the electric arc to a minimum between the electrode and tissue. The degree of coagulation or coagulation depth when making incisions is therefore no longer dependent on the depth and speed of incision. Regulation of the arc prevents erosion of the active cutting electrode.

Electrode handle
without button, with 3 m long cable, in compliance with IEC 601 part 2-2, 101.3 No. 20197-033

- Activation via the footswitch.
- The active electrodes are simply inserted in the handle.
- The electrodes are held securely and prevented from rotating by the elastic and coneshaped connector.

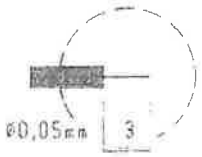
Rack for microelectrodes, long
stainless steel for 8 electrodes, diameter 1.6
190 × 96 × 25 mm
No. 20197-030

Rack for microelectrodes, short
stainless steel for 8 electrodes diameter 1.6
96 × 96 × 25 mm
No. 20197-029 not illustrated

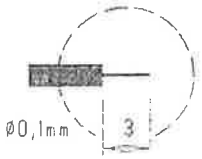
Cutting electrodes

134 °C

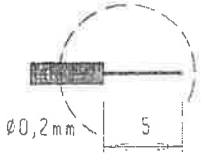
95 °C



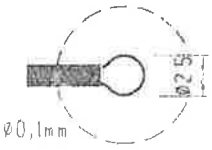
Needle, extremely fine,
diameter 0.05 mm,
with insulated shaft, straight,
40 mm long, colour: red
No. 20197-007



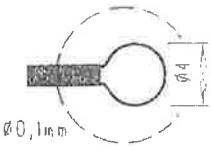
Needle, fine, diameter 0.1 mm,
with insulated shaft, straight,
40 mm long, colour: green
No. 20197-008



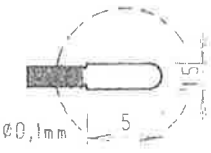
Needle, diameter 0.2 mm,
with insulated shaft, straight,
40 mm long, colour: brown
No. 20197-009



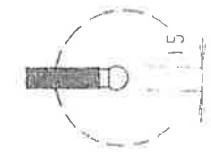
Wire loop, fine,
diameter 2.5 mm,
with insulated shaft, straight,
40 mm long, colour: yellow
Nr. 20197-010



Wire loop, fine, diameter 4 mm,
with insulated shaft, straight,
40 mm long, colour: orange
No. 20197-019



Wire loop, fine, 1.5 × 5 mm,
with insulated shaft, straight,
40 mm long, colour: violet
No. 20197-020



Ball, fine, diameter 1.5 mm,
with insulated shaft, straight,
40 mm long, colour: blue
No. 20197-011

134°C

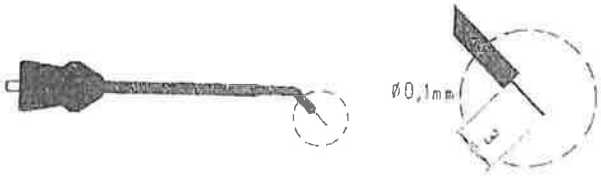
95°C

Monopolar electrodes for microsurgery

Cutting electrodes

with insulated shaft in compliance with IEC 601, part 2-2, 101.3.2

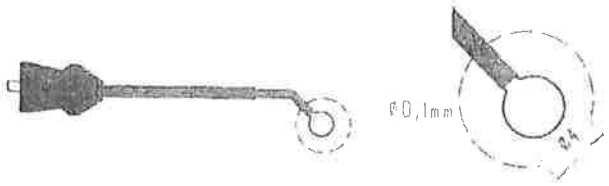
Needle, extremely fine, diameter 0.05 mm, with insulated shaft, angled, 40 mm long, colour: red
No. 20197-021



Needle, fine, diameter 0.1 mm, with insulated shaft, angled, 40 mm long, colour: green
No. 20197-022

Needle, diameter 0.2 mm with insulated shaft, angled, 40 mm long, colour: brown
No. 20197-023

Wire loop, fine, diameter 2.5 mm, with insulated shaft, angled, 40 mm long, colour: yellow
No. 20197-024



Wire loop, fine, diameter 4 mm with insulated shaft, angled, 40 mm long, colour: orange
No. 20197-025

Wire loop, fine, 1.5 × 5 mm, with insulated shaft, angled, 40 mm long, colour: violet
No. 20197-026

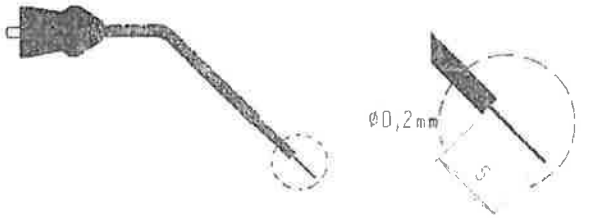
cutting electrodes

134 °C

95 °C

Needle, extremely fine,
diameter 0,05 mm,
with insulated shaft, curved,
colour: red
No. 20197-001

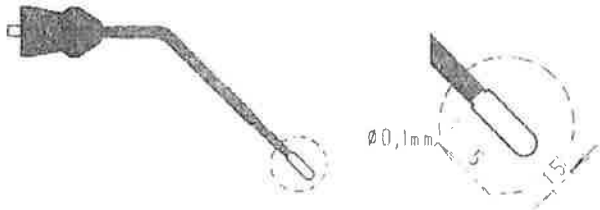
Needle, fine, diameter 0,1 mm,
with insulated shaft, curved,
colour: green
No. 20197-003



Needle, diameter 0.2 mm,
with insulated shaft, curved,
colour: brown
No. 20197-002

Wire loop, fine, diameter 2.5 mm
with insulated shaft, curved,
colour: yellow
No. 20197-004

Wire loop, fine, diameter 4 mm,
with insulated shaft, curved,
colour: orange
No. 20197-027



Wire loop, fine, 1.5 × 5 mm,
with insulated shaft, curved,
colour: violet
No. 20197-028

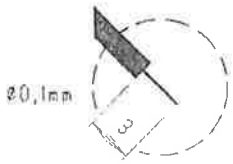
Ball, fine, diameter 1.5 mm,
with insulated shaft, curved,
colour: blue
No. 20197-005

134 °C

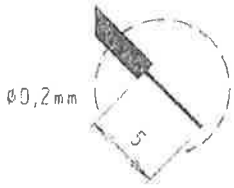
95 °C

Cutting electrodes, long, for body cavities

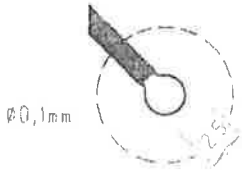
Needle, extremely fine,
diameter 0,05 mm,
with insulated shaft, 110 mm long,
colour: red
No. 20197-012



Needle, fine, diameter 0.1 mm,
with insulated shaft, 110 mm long,
colour: green
No. 20197-013



Needle, diameter 0,2 mm,
with insulated shaft, 110 mm long
colour: brown
No. 20197-014



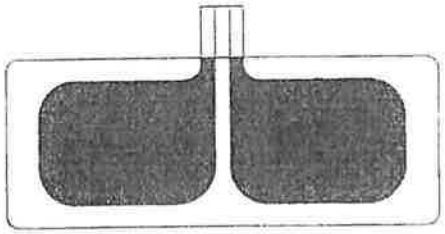
Wire loop, fine, diameter 2,5 mm,
with insulated shaft, 110 mm long,
colour: yellow
No. 20197-015

Ball, fine, diameter 1,5 mm,
with insulated shaft, 110 mm long,
colour: blue
No. 20197-016

Patient plate
disposable, double-surface

Disposable patient plate, double-surface

- The correct and safe application of the patient plate is checked and guaranteed by using patient plates with two separate contact surfaces and by a suitable »Neutral Electrode Safety System« type NESSY.



Disposable patient plate
Version: two separate contact surfaces, A = 125 cm², without cable, adhesive: electrically conductive
No. 20193-022

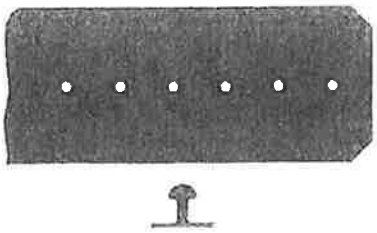
Disposable patient plate, without cable,
non-sterilizable

5 m No. 20194-050

Patient plate of conductive silicone
with short connecting cable, 40 cm long, ECG connection 4 mm diameter, with 1 rubber fastening strap, contact area 187 cm², for children
No. 20193-016

Connecting cable for patient plates
reusable, for Erbotom series T, ACC, sterilizable up to 134 °C

Cable 5 m long No. 20194-047



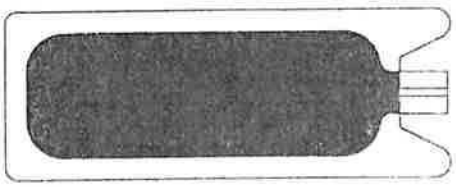
Rubber strap, elastic
with fastening stud, 6 cm wide, perforated strap,
non-sterilizable.
0.55 m long No. 20592-009
1.25 m long No. 20592-011

Fastening stud
No. 40592-003

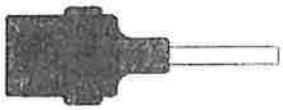
Patient plate
disposable, single-surface

Disposable patient plate

- The supporting material of the patient plate from ERBE consists of flexible and elastic plastic, which adapts well to the anatomical form of the patient in the area of application.
- The contact surface carries an electrically conductive coating of adhesive (Polyhesive).
- Simple and safe handling by applying the patient plate like a plaster.



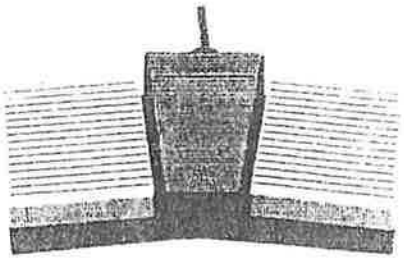
Disposable patient plate
Version: single contact surface,
A = 125 cm², without cable,
adhesive: electrically conductive
No. 20193-020



Disposable patient plate, without cable,
non-sterilizable

5 m No. 20194-050

Footswitch



Two-pedal footswitch, non explosion-protected

No. 20187-003

CLEANING, DISINFECTION AND STERILISATION OF THE UNIT AND ACCESSORIES 10

10 CLEANING, DISINFECTION AND STERILIZATION OF THE UNIT AND ACCESSORIES

10.1 Cleaning and disinfection of the unit

Cleaning and disinfection of the unit should only be done with nonflammable and nonexplosive agents. Make sure, that no moisture or detergents enter the unit.

If cleaning or disinfection of the unit with flammable or explosive agents is unavoidable, these must be completely evaporated from the HF surgical unit before it is switched on.

ATTENTION:
Alcohol must never be used to clean and disinfect the front panel. We recommend that the panel be disinfected by spraying or wiping. However, it is essential to follow the manufacturer's directions regarding concentration of the disinfectant used and the time it is allowed to act.

10.2 Cleaning, disinfection and sterilization of the accessories

Monopolar and bipolar electrodes.

Cleaning:
Tissue residue can be removed from the active electrodes with a sterile, moist cloth, steel or copper wool. No scalpel, scissors or similar pointed objects must be used for cleaning the electrodes, since they will damage the electrode surface. Such damage increases adhesion of tissue to the surfaces of the electrodes during use.

Disinfection:
Always clean and disinfect the electrodes in a disinfecting solution prior to sterilizing them. All commercially available disinfectants may be used.

Sterilization:
All ERBE active electrodes are autoclavable.

Electrode handles with cables and plugs.

These accessories may be cleaned and disinfected by spraying or wiping over with disinfectant. It is also possible to dip them into a disinfectant solution. Always ensure that the disinfectant is thoroughly rinsed off of the accessories. It is also possible to sterilize them in an autoclave up to 134°C, if necessary or to clean them in the washing machine at up to 95°C.

NOTE: Because of their better material compatibility, aldehyde preparations are more suitable for disinfection of the accessories than phenolic preparations, since they have less corrosive effect on the plastics used.

To prevent premature wear to cable and plug, be sure to comply with the manufacturer's instructions concerning concentration of the disinfectant used and the time it is allowed to act on the objects being disinfected.

Patient plates with cables, plugs and rubber straps.

Patient plates along with their cables, plugs and rubber straps should be cleaned and disinfected before and after use.

Footswitches and footswitch boards.

Non explosion-proof footswitches must not be cleaned or disinfected with flammable or explosive agents because of the existing fire and explosion hazards.

Any disinfectant can be used for surface disinfection of explosion-proof footswitches.

11 FUNCTION CHECKS

The unit includes a number of automatic function checks which are run through very quickly whenever the power is switched on.

The functions required for each application should additionally be checked before the equipment and its accessories are used.

11.1 Automatic function checks

Whenever the power is switched on, the equipment immediately runs through an internal automatic test routine which detects and signals the following faults in the equipment controls and in the accessories connected to the equipment:

1. If one of the front panel keys has been shorted due to a fault or if it is pressed when the power is switched on, this fault is indicated acoustically after switching on the power; the digit or word alongside the defective or pressed key flashes to identify the key concerned.

2. If one of the push-buttons on an electrode handle has been shorted due to a fault or has been bridged with low impedance (e.g. due to moisture in the electrode handle) or was pressed when the power is switched on, this fault is indicated acoustically after switching on the power; the triangles in the frame of the corresponding section flash to identify which key is defective or pressed.

3. If one of the contacts in the foot pedal has been shorted due to a fault , if a pedal has jammed or is pressed when the power is switched on, this fault will be indicated acoustically and the triangles in the frame of the corresponding section flash to identify which pedal is involved.

11.2 Manual function checks

11.2.1 Checking the acoustic signal

The relevant acoustic signal must always sound whenever a function field is activated.

11.2.2. Checking the HF output voltage

The equipment will generate visual and acoustic alarms if the set HF output voltage differs from that prevailing when a particular operating mode, such as CUTTING or COAGULATION, is activated (refer to the Section "OUTPUT ERRORS").

12 SAFETY CHECK

ATTENTION:
Safety checks should be performed exclusively by personnel whose knowledge, training and practical experience qualifies them to perform such checks. Refer to chapter 1 "INTRODUCTION" of this manual.

13 CARE OF THE UNIT AND ACCESSORIES

13.1 Preventing damage to the unit

Apart from proper operation and maintenance, effective protection of the unit against damage is achieved by secure positioning of the unit. This involves not only securely mounting the HF surgical unit on its base but also protecting it against damp, contamination and contact with flammable and explosive substances. In order to ensure good dissipation of the heat generated during operation, it must be ensured that cooling slots and heat sinks are open to good air circulation (for details refer to Chapter 8 INSTALLATION).

13.2 Preventing damage to the accessories

In order to protect accessories from premature wear and tear, the following instructions should be observed:

- Active electrodes must always be handled and stored so that they are not damaged.
- Monopolar and bipolar coagulation forceps must always be handled and stored so that the forceps tips are not damaged. These forceps should be kept and transported in special cases. Forceps with insulated legs must not be cleaned and kept with other hard or pointed instruments which could damage the insulation.

The legs of the forceps must not be forced apart, since this can chip the insulating layer.

- Electrode handles. Do not wrap the cable of the electrode handles around the handles, since this will deform the cable.
- Patient plates of metal must not be bent excessively and not kinked.
- Do not carry the footswitch by the cable. Do not wind the cable tightly around the footswitch.
- Do not coil the cable too tightly, kink it or bend it.
- Unplug the plugs from the unit sockets and accessories by gradually pulling on the plug shaft and not by vigorously tugging on the cable.

Recommendations on Cleaning, Desinfection and Sterilization

of Accessories for the ERBE HF surgical unit

ERBE

		Cleaning				Desinfection		Drying	Sterilisation			
										Steam		
		mechanical cleaning	chemical cleaning	ultrasonic cleaning	Washing machine up to 95°C	Spray-Desinfection	Solution	Hot air up to 120° C	Germicidal Gases	120° C 1,1 bar	134° C 2,1 bar	Hot air 180° C
Active electrodes	non-insulated	●	●	●	●	●	●	●	●	●	●	●
	insulated	●	●	●	●	●	●	●	–	●	●	–
Electrode handles		●	●	●	●	●	●	●	–	●	●	–
Forceps		●	●	●	●	●	●	●	–	●	●	–
Patient plates	flexible metal plate	●	●	●	–	●	●	–	–	–	–	–
	Silicone plate	●	●	●		●	●	●	–	●	●	–
Foot-switches	explosion-proof	●	●	●	–	●	●	–	–	–	–	–
	non-explosion proof	●	●	–	–	●	–	–	–	–	–	–
Cables with plugs		●	●	●	●	●	●	●	–	●	●	–

E-SOFT-001929

14 WARRANTY

14.1 Transport damage

The unit and accessories must be inspected immediately on receipt for deficiencies and transport damage. In this respect, claims for compensation can only be enforced when the seller or carrier are notified without delay. A damage report must be compiled.

14.2 Equipment warranty

The warranty period for the unit is 1 year from the date of delivery.

Claims under warranty are valid only when the warranty certificate has been properly completed. The warranty covers free repair of the unit provided that the deficiency has been caused by material or manufacturing faults. Other claims, particularly claims for compensation are excluded.

Repairs may only be carried out by us, our representatives or by authorized service agents. Claims under warranty are invalidated if improper modifications or repairs have been undertaken.

Work carried out under warranty neither extends nor renews the warranty.

ERBE ELEKTROMEDIZIN GmbH

Waldhörnlestr. 17
D-7400 Tübingen
P.O.Box 1420

Phone ..... (7071) 7001-0
Telex..... 7 262 839 d
FAX ..... (7071) 70 01 79

ERBE U.S.A. Inc.

3800 Camp Creek Parkway
Bldg. 2600, Suite 120
Atlanta, GA 30331

Phone:..... 404-349-0900
FAX: 404-691-2843

erbe
power your performance.

An Innovative Leader in GI Endoscopy

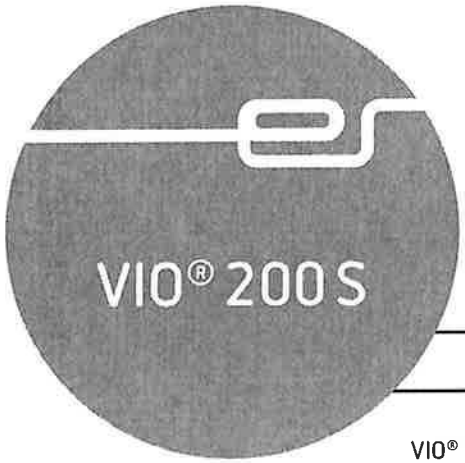
The VIO® 200 S unit offers proprietary voltage control:

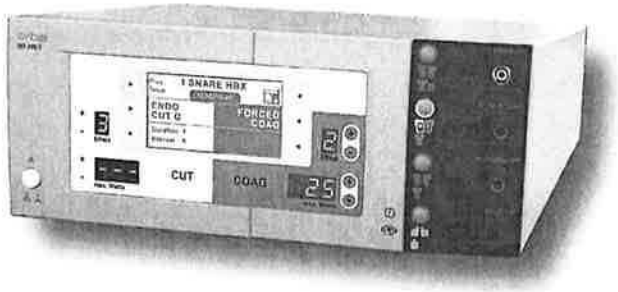
☑ **Constant Voltage Regulation with Power Dosing automatically delivers lowest effective adjusted power output in all modes, including both CUT and COAG**

- Power Peak System™, PPS, offers optimal support during the initial cutting stage, especially low contact impedance situations, allowing the electrode to start in contact with target tissue without cutting delay

☑ **Spark Recognition automatically detects the formation of micro-electric arcs (sparks) for controlled and reproducible cuts, e.g. length and quality**

- Spark Regulation (micro-electric arcs) for reproducible, efficient cuts in tissue with high or extremely low impedance





FEATURES, BENEFITS AND MODES

VIO® technology – Logical, simple, and easy to use

ENDO CUT® I and Q for use with snare wires and sphincterotomes

User-Friendly Interface
FocusView – reduces the visual information to the essentials, simplifying the operation of the unit

Up to 9 storable programs

Audio and Visual Error Recognition System

Compatible with APC™ module utilizing FORCED APC™*

Effect settings for each Mode

CUT Modes
Cutting results are largely independent of the cutting speed, the shape of the electrode and the tissue type
ENDO CUT® I, ENDO CUT® Q, AUTO CUT®

COAG Modes
Power adjustment as a result of voltage control for reproducible coagulation with optimally adjusted output
FORCED COAG®, SOFT COAG®, BIPOLAR SOFT COAG™

*Not compatible with PULSED APC® and PRECISE APC®

Erbe USA Incorporated 2225 Northwest Parkway Marietta GA 30067 USA

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Fax 770 955-2577 erbe-usa.com

Customer Service 800 778 3723

MKT/5053/01 (2017-01)

E-SOFT-005127

VIO® 200S

Product Data

Part Numbers	
10140-400	VIO® 200 S Electrosurgical Unit, 120V/60Hz UL
20189-304	VIO Two Pedal Footswitch with Bracket, AP and IP X8 Equipment
20183-053	Adapter for BICAP or Gold Probe™

Optional	
20193-084	NESSY® Omega Monitoring Pad with Cable (50 per case)
7910-1006	ESU Cart
20180-000	VIO Cart with Footswitch Holder, Cable Wrap and 1 Tank Fixation Kit
20180-010	VIO Cart Wire Basket
20180-131	VIO/APC™ 2 to VIO Cart Fastening Set (with Grounding Cable)

General Technical Data

Power Output	
Maximum Cut output	200 Watts for 500 Ohms
Maximum Coag output	Up to 120 Watts
Safety system	NESSY
Frequency	350 kHz

Power Connection	
Supply voltage	100 V–120 V / 220 V–240 V ±10 %
Frequency	50/60 Hz
Main current	Max. 8 A/4 A
Power input during stand-by	40 Watts
Power input during max. electrosurgical output	500 Watts/920 VA
Potential equalization connection	Yes
Fuse	T 8 A/T 4 A

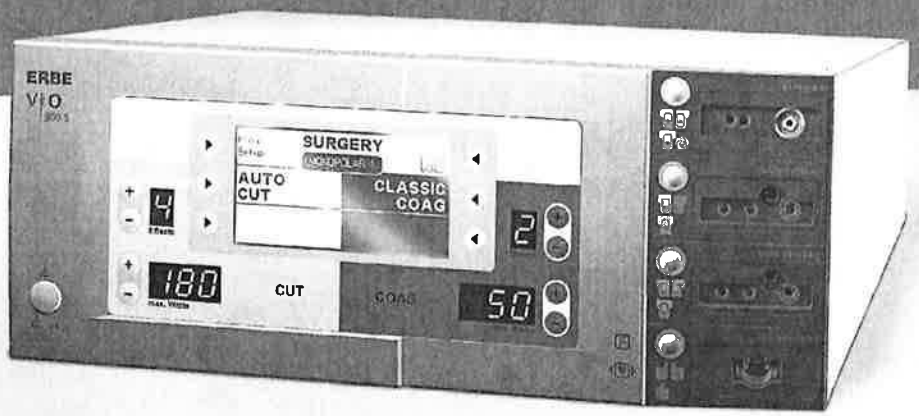
Dimensions and Weight	
Width x Height x Depth	410 x 165 x 380 mm/ 16.1" x 6.5" x 15.0"
Weight	19 lbs., 14 oz.

Ambient conditions for operation of unit	
Temperature	+10° C to +40° C/ 50° F to 104° F
Relative humidity	15 % – 80 %

VIO® 300 S

Electrosurgical Workstation for the O.R.

VIO 300 S



- Automatic Power Dosing – As much as needed and as little as possible
- New and improved CUT and COAG modes
- User Friendly

- AUTO CUT® – Electrosurgical (ES) cutting with minimal to medium hemostasis.
- DRY CUT – ES cutting with moderate to intense hemostasis.
- CLASSIC COAG® – Hemostatic dissection mode proprietary to ERBE.
- FORCED COAG – Effective, fast coagulation.
- BIPOLAR SOFT COAG – Non-sparking, gentle bipolar contact coagulation with minimal sticking and carbonization. (AUTO STOP Option)
- SWIFT COAG® – Fast coagulation for dissection with high hemostasis, but limited tissue-cutting properties. Uses power dosing.
- SPRAY COAG – Contact-free surface coagulation, low penetration depths. No power dosing.
- FORCED APC – Ability to add Argon Plasma Coagulation (APC™).

- BIPOLAR COAGULATION
- MONOPOLAR CUTTING
- MONOPOLAR COAGULATION

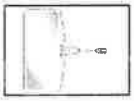
ERBE
USA INCORPORATED
Surgical Systems

2225 Northwest Parkway, Marietta, GA 30067 USA | www.erbe-usa.com | EMAIL sales@erbe-usa.com | CUSTOMER SERVICE 800.778.3723

E-SOFT-005139

ERBE VIO® 300 S

Product Data

DESCRIPTION	PART NUMBER	
ERBE VIO® 300 S Electrosurgical Unit, 120 V/60 Hz, UL Version	10140-300	
VIO Double Pedal Foot Switch with Bracket	20189-304	
ESU Cart II with Shelf	7910-1006	
Optional: NESSY® Monitoring Split Pad, 168 cm with Cable 10' (Box of 50)	20193-074	

General Technical Data

POWER CONNECTION

Rated supply voltage	100 V - 120 V (± 10%) / 220 V - 240 V (± 10%)
Rated supply frequency	50 / 60 Hz
Line current	8 A / 4 A
Power input in standby mode	40 watts
Power input with max. HF output	500 watts / 920 VA
Terminal for grounding (potential equalization)	Yes
Power fuses	T 8 A / T 4 A

OPERATING MODE

Intermittent operation	ON time 25% (e.g. activated for 10 sec. / deactivated for 30 sec.)

DIMENSIONS AND WEIGHT

Width x Height x Depth	410 x 165 x 380 mm / 16.1" x 6.5" x 15.0"
Weight	8.8 kg / 19 lbs. 14 oz.

AMBIENT CONDITIONS
FOR TRANSPORT AND STORAGE OF UNIT

Temperature	-40 °C to +70 °C / -40 °F to +158 °F
Relative humidity	10% - 95%

AMBIENT CONDITIONS
FOR OPERATION OF UNIT

Temperature	+10 °C to +40 °C / +50 °F to +104 °F
Relative humidity	15% - 80%, noncondensing

ACCLIMATIZING

If the unit has been stored or transported at temperatures below +10 °C (+50 °F) or above +40 °C (+104 °F), the unit will require approx. 3 hours to acclimatize at room temperature.

STANDARDS

Protective class according to UL 2601-1	I
Classification according to EC Directive 93/42/EEC	II b
Protection class as per EN 60 601-1	I
Type as per EN 60 601-1	CF

ERBE
USA Incorporated
Surgical Systems

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www.erbe-usa.com

MKT/5060/00 (12/11)

Day Exhibit 4 – Highly Confidential

Day Exhibit 5

ELECTROSURGERY

E-SOFT_000128

Our promise when it comes to technology:

High-tech and safety are our passion.

We have been a pioneer in the development of electrosurgery for over 90 years, gathering experience you can count on.

Power electronics

Regulated power supply adapter[1] improves power output especially with high and varying impedance loads, e.g. during bipolar resection

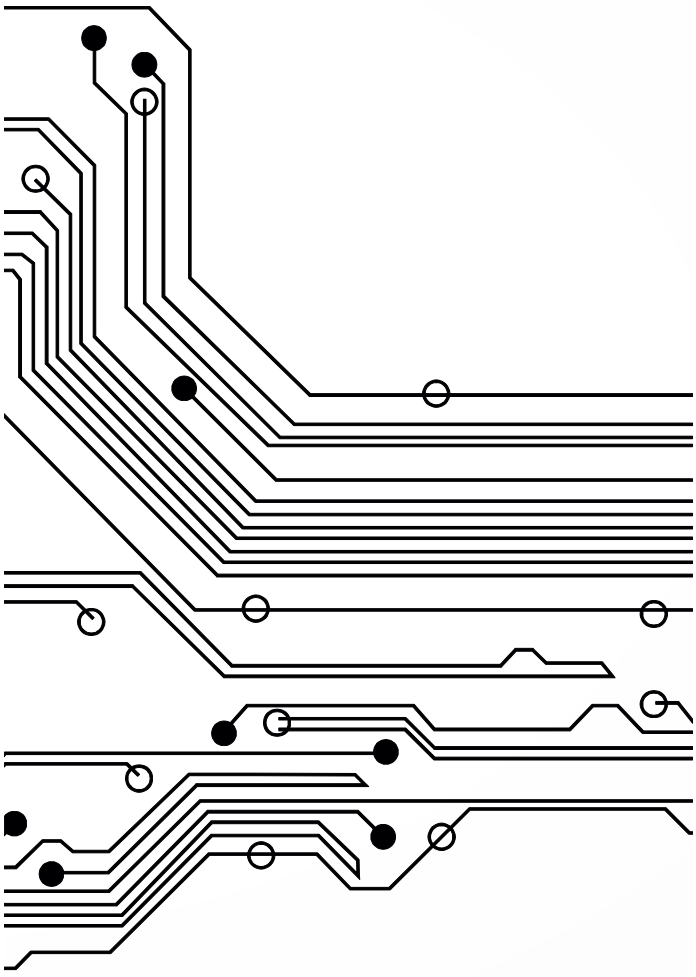
Multiprocessor technology

15 processors facilitates superior system peformance

Latest digital signal processors

25 million measurements/sec improves reproducibility of the tissue effect[2]

We have shaped electro-surgery, developing it into today's leading-edge operating room technology. This has made us an essential and reliable partner for many users. VIO 3 is yet another of our milestones in technology, following the ICC unit series and VIO 300/200. Utilize the innovative advantages the VIO 3 has to offer.



The WiFi communication interface

The basis for wireless communication, e.g. for future OR integration

WHY ERBE?

- ☑ Experts in electrosurgery for over 90 years
- ☑ Highest priority of our products: safety
- ☑ We set benchmarks and drive innovative developments
- ☑ Global sharing of experience and knowledge transfer
- ☑ Presence and support worldwide
- ☑ Internationally trusted partner

VIO® 3

With its logical and intuitive interface, the VIO 3 is designed to ensure optimal user-friendliness[3]. The size of the touchscreen display alone speaks for itself: from the operating field, the surgeon always has a clear view of all control elements. As your stepGUIDE, VIO 3 provides guidance by suggesting experienced starting settings used in various clinical applications. This results in less setting adjustment or modifications.

Plug and operate.
It couldn't be easier.

90 % *of all users feel VIO 3 is easier to use*[4]

E-SOFT_000131

plug and operate

E-SOFT_000132

Multi-modality modes for various clinical specialities

VIO 3 has the right mode for your application, supporting monopolar and bipolar techniques and our proprietary hybrid technology – a combination of different technology.

It has never been easier to achieve the desired mode-specific tissue effect using just one setting – the effect setting.

The effects can be selected in extremely fine increments using just one adjustment control. The change in effect is shown on the display.

19
OPTIMIZED MODES

The right modes
for your application adapted to your
instrument selection

PRECISE
EFFECT SETTINGS

Adjusting the selected mode
has never been easier via
the effect setting

HIGH
REPRODUCIBILITY

Advanced measurement technology

Consistent cutting
and coagulation effects

HOMOGENOUS
TISSUE EFFECTS

VIO 3 responds to parameter changes
in the tissue immediately

Regardless of the electrode shape
or incision technique

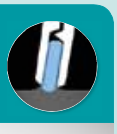
The new VIO 3 modes

preciseSECT
Low-smoke exposure

Dynamic adjustment of the modulation frequency makes this new mode ideally suited for exposing structures. preciseSECT facilitates rapid and effective coagulation with limited tissue-separating properties, in combination with less development of smoke and carbonization[4].

Disciplines: general / visceral surgery, gynecology, urology

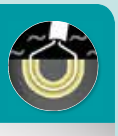
thermoSEAL®
Rapid vessel sealing



With the new AUTOSTART, thermoSEAL is twice as fast as the BiClamp mode[5]. And this mode permanently measures the tissue parameters while sparing lateral tissue. This makes thermoSEAL ideal for sealing tissue bundles and vessels as well as for coagulating bleedings extremely efficiently.

Disciplines: general / visceral surgery, gynecology, urology

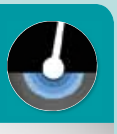
highCUT bipolar
Bipolar resection



This new mode has been optimized for bipolar resection in a saline solution. The power peak system (PPS) enables rapid incision. The stable plasma facilitates rapid cutting[1].

Instruments: bipolar resectoscopes

softCOAG®
Accelerated coagulation



Now with QuickStart[1]: in the case of bipolar and monopolar softCOAG, a short pulse of energy on contact with tissue results in accelerated coagulation.

Application: coagulation for laparoscopic procedures

92 % of all users feel preciseSECT is better[4]

Overview of modes

Our modes are regulated to a constant voltage level continually adapting output power to changing parameters to achieve reproducible tissue effects. Fine adjustment has never been easier, simply by selecting an effect. You can choose from 19 finely-adjustable CUT and COAG modes:

autoCUT

Smooth incisions,
minimum to moderate hemostasis

highCUT

Smooth incisions, minimum to moderate hemostasis. For tissue with poor conductive properties and monopolar resection using non-conductive irrigation liquids

dryCUT®

Controlled incision
with significant hemostasis

autoCUT bipolar

Smooth incisions,
minimum to moderate hemostasis,
e.g. for BiSect laparoscopic scissors

highCUT bipolar

Smooth incisions,
minimum to moderate hemostasis.
For bipolar resection in a saline solution

endoCUT® Q

Fractionated cutting mode
with cutting and coagulation intervals,
e.g. for polypectomy snare

endoCUT® I

Fractionated cutting mode
with cutting and coagulation intervals,
e.g. for sphincterotome

CUT

preciseSECT

Optimized exposure as a result of dynamically adapting modulation. Medium coagulation

swiftCOAG®

Intensive coagulation, enhanced with slight tissue-separating properties

softCOAG®

Slow, deep coagulation with no tissue carbonization[6], e.g. for use with ball electrode for tissue devitalization or with monopolar scissors

forcedCOAG®

Effective and fast "standard" coagulation with moderate to intense hemostasis

sprayCOAG®

Non-contact, efficient surface coagulation with low penetration[6]

twinCOAG®

Consistent tissue effects, even when two monopolar instruments are activated at the same time with just one unit

softCOAG® bipolar

Slow, deep coagulation with no tissue carbonization[6], e.g. for use with bipolar coagulation instruments and bipolar resectoscopes

forcedCOAG® bipolar

Fast bipolar coagulation with moderate to intense hemostasis

thermoSEAL®

Special COAG mode for sealing highly-vascularized tissue bundles and blood vessels with a diameter of up to 7 mm using appropriate Erbe instruments[5]

forcedAPC

Fast "standard" argon plasma coagulation, e.g. for hemostasis of diffuse bleeding, ablation and tissue reduction

pulsedAPC®

Argon plasma coagulation with reduced application of energy as a result of pulses, e.g. flexible APC probes

preciseAPC®

Fine argon plasma coagulation, largely independent of the distance to the target tissue. e.g. for flexible APC probes, where tissue thickness is a concern

COAG

Expanded choice in instrument selection

You can plug standard instruments into any universal socket reducing risk of confusion.
Use up to 6 instruments of your choice (including APC) in accordance with your procedure.
The connection options offered by VIO 3 support a larger number instrument combination.
Each socket supports the AUTO START function for bipolar instruments.

EXPANDED INSTRUMENT SELECTION

4 monopolar, 4 bipolar, 4 plug & play instruments
(e.g. BiClamp) or any combination thereof.

RECOMMENDED CONNECTION

Based on pre-programmed settings
the stepGUIDE supports you in selecting a socket for your
chosen instrument.

UNIVERSAL SOCKET [1]

Standard instruments can be inserted
into any universal socket.

SLOT ASSIGNMENT

The active slot and the instrument in use are shown
on the display and through the illuminated socket frame.

CONNECTION OPTIONS

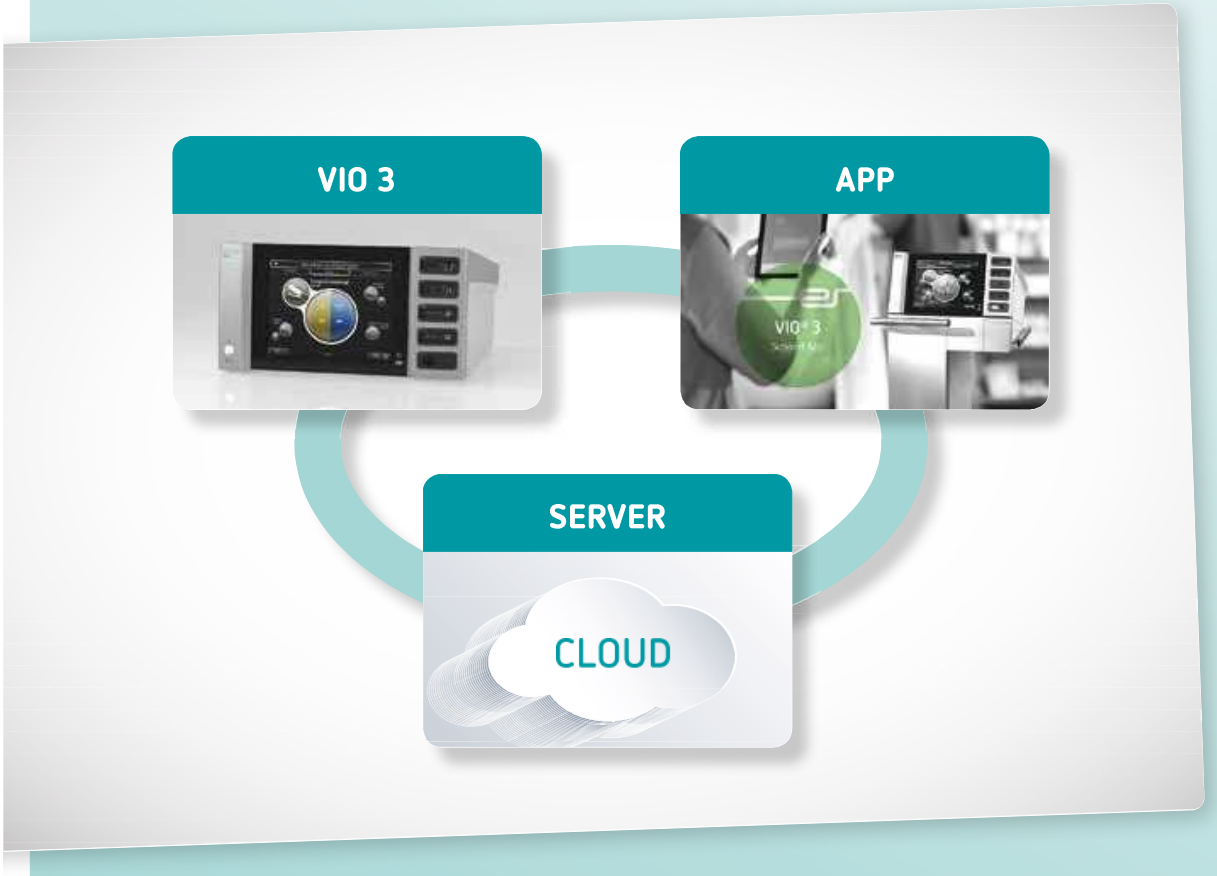
When using APC 3, you can extend your options and insert up to 6 instruments of your choice.

EASY SOCKET EXCHANGE[1]

Sockets can easily be replaced without opening the casing.

Your direct link – the Erbe support app

With the support app, you can generate and update user programs using templates and archive these on our server. Our staff and distributers can update and upgrade your VIO 3 on site using VIO WiFi (PC or tablet).



Using our support app, you can expand the performance spectrum of the VIO 3. You can procure it from the app Store. It will be cleared for use after successful registration on our website.

With our support app you can also use your personal programs on other in-house VIO 3 systems or externally, for example for live surgeries and workshops. This gives you access to your own personal setting configurations anywhere, anytime.

96 % *of all users would recommend VIO 3* [4]

BENEFITS FOR YOU:

WHY VIO 3?

- ☑ Reliably reproducible tissue effects thanks to state-of-the-art processor technology
- ☑ Fine-tuning of tissue effects using our improved effect setting is easy and more precise
- ☑ Multi-modality modes for various applications
- ☑ Multi-disciplinary ESU
- ☑ User-friendly with logical, convenient and visual user navigation (stepGUIDE)
- ☑ Selection of up to 6 different settings for your procedure from the operating field
- ☑ Use of up to 6 instruments of your choice
- ☑ Supports proprietary Erbe hybrid technology
- ☑ Upgrade compatibility with software, hardware and workstation modules

Technical data

Power connection	
Rated supply voltage	100–120 VAC (± 10%) 220–240 VAC (± 10%)
Rated supply frequency	50 / 60 Hz
Line current (averaged)	Max. 6.3 A
Power consumption in standby mode	< 30 watts
Power consumption at max. HF power	550 watts
Max. pulse power consumption	1,600 watts
Potential equalization connection	Yes
Power fuse	T 6.3 A H / 250 VAC
Type of operation	
Intermittent operation	25 % duty cycle
Dimensions and weight	
Width x height x depth	415 x 215 x 375 mm
Weight	12 kg
Display size	10.4 inches
Ambient conditions for transport and storage of the unit	
Temperature	-30 °C to +70°C
Relative humidity	10 % - 90 %
Ambient conditions for operating the unit	
Temperature	+ 10°C to +40 °C
Relative humidity	15 %–80 %, non-condensing
Standards	
Classification in accordance with EU directive 93/42/EEC	II b
Protection class in accordance with EN 60 601-1	I
Type in accordance with EN 60 601-1	CF
Programs	
Program groups	20; program storage capacity per group: 15
Programs / applications	Up to 300
ReMode levels / settings	Up to 1800

References/publications/documents:

1 Patent pending (Power supply module, Universal socket, Socket insert, Contact coagulation)
2 Technical specification of Measurement and Control module
3 Design patent pending
4 Based on a protocol of a user aceptance test (12/2014, 06/2016)
5 B. Nold et al.: thermoSEAL bench test VIO3 Y4
6 Various publications (e. g. Arima 2009, Sakuragi, T. 2008 und 2009, Repici 2012, Neugebauer, A. 2012)

E-SOFT_000142

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72072 Tuebingen
Germany

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Fax +49 7071 755-179
info@erbe-med.com
erbe-med.com

 11.16 85160-100

power your performance.

An Innovative Leader in GI Endoscopy

The VIO® 200 S unit offers proprietary voltage control:

- **Constant Voltage Regulation with Power Dosing automatically delivers lowest effective adjusted power output in all modes, including both CUT and COAG**
  - Power Peak System™, PPS, offers optimal support during the initial cutting stage, especially low contact impedance situations, allowing the electrode to start in contact with target tissue without cutting delay
- **Spark Recognition automatically detects the formation of micro-electric arcs (sparks) for controlled and reproducible cuts, e.g. length and quality**
  - Spark Regulation (micro-electric arcs) for reproducible, efficient cuts in tissue with high or extremely low impedance

VIO® 200 S

FEATURES, BENEFITS AND MODES

- **VIO® technology** – Logical, simple, and easy to use
- **ENDO CUT® I and Q** for use with snare wires and sphincterotomes
- User-Friendly Interface **FocusView** – reduces the visual information to the essentials, simplifying the operation of the unit
- Up to 9 storable programs
- Audio and Visual Error Recognition System
- Compatible with APC™ module utilizing FORCED APC™*
- Effect settings for each Mode
- **CUT Modes**
  Cutting results are largely independent of the cutting speed, the shape of the electrode and the tissue type
  ENDO CUT® I, ENDO CUT® Q, AUTO CUT®
- **COAG Modes**
  Power adjustment as a result of voltage control for reproducible coagulation with optimally adjusted output
  FORCED COAG®, SOFT COAG®, BIPOLAR SOFT COAG™

*Not compatible with PULSED APC® and PRECISE APC®

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erbe-usa.com

Customer Service 800 778 3723

MKT/5053/01 (2017-01)

E-SOFT-005127

VIO® 200S

Product Data

Part Numbers	
10140-400	VIO® 200 S Electrosurgical Unit, 120V/60Hz UL
20189-304	VIO Two Pedal Footswitch with Bracket, AP and IP X8 Equipment
20183-053	Adapter for BICAP or Gold Probe™

Optional	
20193-084	NESSY® Omega Monitoring Pad with Cable (50 per case)
7910-1006	ESU Cart
20180-000	VIO Cart with Footswitch Holder, Cable Wrap and 1 Tank Fixation Kit
20180-010	VIO Cart Wire Basket
20180-131	VIO/APC™ 2 to VIO Cart Fastening Set (with Grounding Cable)

General Technical Data

Power Output	
Maximum Cut output	200 Watts for 500 Ohms
Maximum Coag output	Up to 120 Watts
Safety system	NESSY
Frequency	350 kHz

Power Connection	
Supply voltage	100 V–120 V / 220 V–240 V ±10 %
Frequency	50/60 Hz
Main current	Max. 8 A/4 A
Power input during stand-by	40 Watts
Power input during max. electrosurgical output	500 Watts/920 VA
Potential equalization connection	Yes
Fuse	T 8 A/T 4 A

Dimensions and Weight	
Width x Height x Depth	410 x 165 x 380 mm/ 16.1" x 6.5" x 15.0"
Weight	19 lbs., 14 oz.

Ambient conditions for operation of unit	
Temperature	+10° C to +40° C/ 50° F to 104° F
Relative humidity	15 % – 80 %

Day Exhibit 6

A novel method using the VIO soft-coagulation system for liver resection

Fumitoshi Hirokawa, MD, Michihiro Hayashi, MD, Yoshiharu Miyamoto, MD, Mitsuhiko Iwamoto, MD, Ichiro Tsunematsu, MD, Mitsuhiro Asakuma, MD, Tetsunosuke Shimizu, MD, Koji Komeda, MD, Yoshihiro Inoue, MD, *and* **Nobuhiko Tanigawa, MD,** *Osaka, Japan*

Background. *The VIO soft-coagulation system (SCS) is a new device for tissue coagulation. The current study evaluated the efficacy of the SCS when used for liver resection.*
Methods. *The 252 patients were divided into 2 groups; in 155 patients (conventional group), liver transection was performed using an ultrasonic dissector and saline-coupled bipolar electrocautery for hemostasis. In 97 patients (SCS group), the SCS was used instead of bipolar electrocautery.*
Results. *The median blood loss and surgical time were less in the SCS group than in the conventional group (350 vs 640 mL, P = .0028; 280 vs 398 min, P < .0001). No significant differences were found in postoperative complications between the SCS group (32.0%) and the conventional group (40.6%). The risk factors for bleeding were nonuse of the SCS (P = .0039), macroscopic vascular invasion of the hepatic tumors (P = .0088), and collagen type IV value in the sera >200 (P = .0250) on multivariate analysis. In a subgroup analysis, in the collagen type IV value >200 subgroup, the tumor diameter >5 cm subgroup, and the inflow nonocclusion subgroup, use of the SCS decreased surgical bleeding (P = .0120, P = .0126, and P = .0032, respectively) and surgical time (P = .0001, P < .0001, and P = .0036, respectively) compared with the conventional group. Furthermore, even in the major hepatectomy group, the SCS use decreased surgical time (P < .0001).*
Conclusion. *The SCS is an effective and safe device for decreasing surgical time and surgical bleeding without increasing the rate of bile leakage and causing other complications. (Surgery 2011;149:438-44.)*

From the Department of General and Gastroenterological Surgery, Osaka Medical College, Osaka, Japan

In the last few years, the surgical techniques for liver resection have improved, and mortality rates for patients undergoing operations in high-volume centers have decreased from 0% to 4%.[1-3] It has been reported that the postoperative morbidity and mortality rates for patients who underwent liver resection are closely related to the degree of intraoperative bleeding.[4-6] Several techniques, including the intermittent Pringle maneuver,[7] and devices such as the Cavitron ultrasonic aspirator (CUSA),[8] microwave coagulation,[9] and bipolar scissors,[10] have been used to reduce bleeding during liver transection, but few reports have established the superiority of individual procedures.

In recent years, an electrosurgical device (VIO 300 D soft-coagulation system; ERBE Elektromedizin, Tübingen, Germany) containing a soft-coagulation mode has been developed. Conventional electrosurgical coagulation systems produce sparks and can cause carbonization and adhesions to the electrode during coagulation, which result in incomplete hemostasis. In this soft-coagulation mode, however, only Joule heat is emitted, and the voltage is limited to 200 V, which prevents the development of sparks, carbonization, and adhesion to the electrode, and results in a greater degree of coagulation compared with that obtained with conventional electrosurgical coagulation systems. In a preliminary report, use of the VIO soft-coagulation system (SCS) was effective for hemostasis in the transected pulmonary artery model[11] and for the prevention of pancreatic fistulae after pancreatectomy.[12]

Accepted for publication November 24, 2009.

Reprint requests: Fumitoshi Hirokawa, MD, Department of General and Gastroenterological Surgery, Osaka Medical College, 2-7 Daigaku-machi, Takatsuki City, Osaka 569-8686, Japan. E-mail: sur122@poh.osaka-med.ac.jp.

0039-6060/$ - see front matter

doi:10.1016/j.surg.2009.11.015

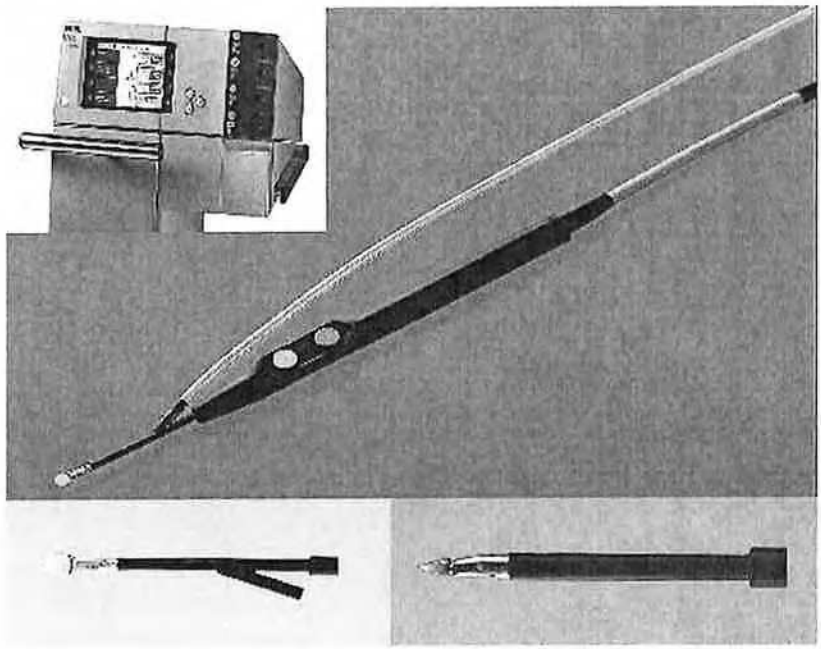

Figure. The tip of the paddle-type electric scalpel. The tip attaches to the paddle-type electrode with a small tube for dropping saline solution during coagulation, because saline irrigation reduces the contact resistance between the electrode and the tissue. (Color version of figure is available online.)

The aim of this study was to evaluate the efficacy of the SCS for liver resection.

PATIENTS AND DESIGN

From May 2001 to November 2008 at Osaka Medical College Hospital, 252 patients underwent primary hepatectomy without concomitant operations on another organ or the bile ducts and had no digestive tract anastomosis. We started to use the SCS device for transection and hemostasis during liver resection in January 2007. The 252 patients were divided into 2 groups to assess the value of the SCS: In 155 patients (conventional group), liver transection was conducted using an ultrasonic dissector and saline-coupled bipolar electrocautery for hemostasis, whereas in 97 patients (SCS group), the SCS was used instead of bipolar electrocautery for hemostasis and in addition to the ultrasonic dissector. Except for the abovementioned change of devices, other surgical techniques were carefully conserved throughout this study to minimize possible bias. All metastatic liver tumor patients underwent asynchronous liver resection.

All patients received the same perioperative care by the same team. Serum collagen type IV and hyaluronic acid were adopted at preoperative examination to predict liver fibrosis.[13] The degree of liver fibrosis was finally diagnosed histopathologically after surgery. Minor hepatectomy was defined as the limited resection of ≤2 Couinaud segments, and major hepatectomy was defined as the resection of ≥3 Couinaud segments. The surgical time was defined as starting from the skin incision until the end of the wound closure. Postoperative bile leakage was defined as the presence of bile in drainage fluid for >7 days, or the bile duct was clearly visible in a contrast study. Intra-abdominal abscess was defined as an intra-abdominal fluid collection on ultrasonography or computed tomography associated with persistent fever and positive cultures.

The SCS. The VIO 300 D system was set to the soft-coagulation mode. The effect level was set at effect 7, and the maximum output was set at 100 W. The tip attaches to the paddle-type electrode with a small tube for dropping saline solution during coagulation, because saline irrigation reduces the contact resistance between the electrode and the tissue (Figure).

Surgical procedure and technique. A single senior surgeon (M.H.) supervised all operations in this study. Three surgeons performed all operations, and 2 junior surgeons (J.I. and F.H.) performed >60% of liver resections. Liver inflow was controlled during liver transection for major hepatectomy (selective hemihepatic individual vascular processing or none), but the methods of control varied (Pringle maneuver, selective

Table I. Patients' characteristics

	Conventional (n = *155*)	*SCS* (n = *97*)	P *value*
Male:female	114:41	64:33	NS
Age (years)*	65.6 ± 9.6 (25–82)	64.6 ± 13.6 (0–87)	NS
Disease			
HCC & CCC	115 (74.2%)	58 (59.8%)	NS
Metastatic liver tumor	33 (21.3%)	29 (29.9%)	NS
Others	7 (4.5%)	10 (10.3%)	NS
Liver cirrhosis			
Yes	73 (47.1%)	37 (38.1%)	NS
No	82 (52.9%)	60 (61.9%)	NS
Pre-operative data			
Hepatitis B or C	89 (57.4%)	47 (48.5%)	NS
ICG R15*	16.0 ± 8.7	17.1 ± 8.9	NS
HA* (ng/mL)	133 ± 124	165 ± 224	NS
Collagen type IV*(ng/mL)	195 ± 73	218 ± 116	NS
Tumor characteristics			
Size			
≤5 cm	115 (74.2%)	72 (74.2%)	NS
>5 cm	40 (25.8%)	25 (25.8%)	NS
Number			
Single	107 (69.0%)	58 (66.0%)	NS
Multiple	48 (31.0%)	33 (34.0%)	NS
PV/HV thrombus†	15 (9.7%)	7 (7.2%)	NS
Type of hepatectomy			
Major hepatectomy	44 (28.4%)	33 (34.0%)	NS
Minor hepatectomy	101 (71.6%)	64 (65.9%)	NS

*Data are means ± SD.

†Data indicate number of patients with HV and PV.

Major hepatectomy indicates the resection of ≥3 Couinaud segments. Minor hepatectomy indicates the resection of ≤2 Couinaud segments. Data are the number (%) of patients.

CCC, Cholangiocarcinoma; *HA*, hyaluronic acid; *HCC*, hepatocellular carcinoma; *HV*, hepatic vein; *ICG*, indocyanine green clearance; *NS*, not significant; *PIIIP*, procollagen III N-terminal propeptide; *PV*, portal vein.

hemihepatic vascular occlusion, or none) for minor hepatectomy. Liver transection was performed following the standard technique; an ultrasonic dissector (SonoSurg system; Olympus Inc., Tokyo, Japan) was used for parenchymal transection, and small vessels (<1 mm) were coagulated using saline-coupled bipolar electrocautery. Vascular channels were ligated using a synthetic absorption string or clips. Starting in January 2007, the SCS was used for hemostasis for bleeding from liver parenchyma during liver transection instead of saline-coupled bipolar electrocautery. The SCS can coagulate blood vessels ≤3 mm easily, but bigger vessels (>4 mm) need ligation. The hepatic vein was separated at the final stage of the liver transaction in most cases of major resections. During the study period, no major change in technical aspects were undertaken except for the use of SCS. Topical hemostatic agents were applied to the raw cut surface of the liver, when usual hemostasis with the suture and/or the electric coagulation was difficult. Finally, a bile leakage test (injection of 5–7 mL of indigocarmine into the bile duct through a cystic duct cannula) was performed occasionally. The abdominal cavity was irrigated by 4 L warm saline, and a closed-suction silicone drain was inserted before abdominal wound closure into the subphrenic or subhepatic space close to the transection surface at the end of the operation. Regarding anesthetic management during hepatic resection, central venous pressure was generally maintained under 8 cm H_2O. Blood transfusion was carried out by the anesthesiologist under the criteria when surgical bleeding exceeded 1,000 mL and hemoglobin level decreased to less than 8.0 g/dL.

Statistical analysis. Statistical analysis was performed using the JMP ver 7.0.2 software package (SAS Institute, Cary, NC) using a Mac OS X computer. All data values are expressed as means ± standard deviation (SD) or medians. Statistical comparisons between the 2 groups were made using

Table II. Surgical outcomes

	Conventional (n = *155*)	*SCS* (n = *97*)	P *value*
Intra-operative outcomes			
Blood loss (mL)*	640 (10–14,440)	350 (20–5,200)	.0028
Surgical time (min)*	398 (80–1,080)	280 (90–805)	<.0001
Blood transfusion†	47 (30.3%)	16 (16.5%)	.0165
Control of liver inflow†	71 (45.8%)	51 (52.6%)	NS
Thoracotomy†	31 (20.0%)	16 (16.5%)	NS
Use of coating agent†	119 (76.8%)	28 (28.9%)	<.0001
Postoperative complications	63 (40.6%)	31 (32.0%)	NS
Septic complications	33 (21.3%)	16 (16.5%)	NS
Wound complications	33 (21.3%)	12 (12.4%)	NS
Infection	18 (11.6%)	10 (10.3%)	NS
Abdominal complications	37 (23.9%)	22 (22.7%)	NS
Liver failure	3 (1.9%)	4 (4.1%)	NS
Bile leakage or abscess	9 (5.8%)	4 (4.1%)	NS
Bleeding	3 (1.9%)	0 (0%)	NS
Pulmonary complications	22 (14.2%)	7 (7.2%)	NS
Postoperative hospital stay (days)*	17 (5–300)	12 (3–366)	<.0001

*Data are in medians (range).
†Data indicate patients who underwent these procedures.
Data are the number (%) of patients.
HV, Hepatic vein; *NS*, not significant; *PV*, portal vein.

Table III. Risk factors for surgical bleeding

Univariate analysis risk factor	P *value*
Nonuse of the SCS	.0007
Major hepatectomy	<.0001
Diameter >5 cm	<.0001
Collagen IV ≥200	.0055
Macroscopic vascular invasion	.0012
Inflow occlusion	<.0001
Thoracotomy added	.0045
Pathologic liver fibrosis	.0161
Multivariate analysis risk factor	P *value*
Nonuse of the SCS	.0039
Macroscopic vascular invasion	.0088
Collagen type IV ≥200	.0250

Major hepatectomy indicates the resection of ≥3 Couinaud segments. Macroscopic vascular invasion is ≥Vp2 or Vv2. Pathologic liver fibrosis is ≥F3.

the χ^2 test, the Fisher exact test, or the Mann-Whitney *U* test for nonparametric data. A multivariable analysis was performed using a multiple linear regression model to identify independent factors that were associated with blood loss. Statistical significance was defined as a *P* value <.05.

RESULTS

The 252 patients who underwent liver resection were divided into 2 groups: 155 patients in the conventional group and 97 patients in the SCS group. The clinical features and characteristics of the patients and their hepatic tumors were surgical outcomes are listed in Table II. No significant differences were observed between the 2 groups in control of liver inflow and thoracotomy. The median blood loss and surgical time were less in the SCS group than in the conventional group (350 vs 640 mL, $P = .0028$; 280 vs 398 min, $P < .0001$). Naturally, fewer blood transfusions were performed in the SCS group ($P = .0165$). In addition, a marked reduction was found in the number of ligatures (in lobectomy, the number of ligatures was 1.7 ± 0.9) (data not shown), as well as a significant reduction in the frequency of use of hemostatic products such as the TachoComb (Nycomed, Zurich, Switzerland). No significant differences in were observed in postoperative complications and in the incidence of serious complications, such as liver failure, bile leakage, and postoperative bleeding, between the SCS group (32.0%) and the conventional group (40.6%). Additionally, the postoperative hospitalization period was shorter in the SCS group (12 days) than in the conventional group (17 days).

Postoperative serum aspartate aminotransferase and alanine aminotransferase levels on POD1 were significantly higher in the SCS group than in the conventional group, but the levels then fell by POD7, when there were no differences between the groups (data not shown). No significant differences were found between the 2 groups in total

Table IV. Influence of the SCS on blood loss and surgical time by subgroup

	Conventional group	*SCS group*	P *value*
Collagen type IV ≥200 (49 cases)	*n* = 29	*n* = 20	
Blood loss (mL)*	1,000	355	.012
Surgical time (min)*	440	303	.001
Diameter >5 cm (65 cases)	*n* = 40	*n* = 25	
Blood loss (mL)*	1,445	590	.0126
Surgical time (min)*	502	325	<.0001
Inflow occlusion (-) (130 cases)	*n* = 84	*n* = 46	
Blood loss (mL)*	513	265	.0032
Surgical time (min)*	295	260	<.0036
Major hepatectomy (77 cases)	*n* = 34	*n* = 33	
Blood loss (mL)*	1,215	830	.0596
Surgical time (min)*	480	345	<.0001

*Data are in medians.

Major hepatectomy is the resection of ≥3 Couinaud segments.

bilirubin (TB) levels and the prothrombin time-international normal ratio (PT-INR). The risk factors for surgical bleeding are shown in Table III. Nonuse of the SCS ($P = .0007$), major hepatectomy ($P < .0001$), tumor diameter >5 cm ($P < .0001$), collagen type IV value in the sera >200 ($P = .0055$), macroscopic vascular invasion ($P = .0012$), inflow occlusion ($P < .0001$), additional thoracotomy ($P = .0045$), and pathologic liver fibrosis ($P = .0161$) were identified on univariate analysis. On multivariate logistic regression analysis, nonuse of the SCS ($P = .0039$), macroscopic vascular invasion ($P = .0088$), and collagen type IV value >200 ($P = .0250$) were independent risk factors. The effects of the SCS on surgical bleeding and time by subgroup are listed in Table IV. In the subgroup with a collagen type IV value >200, in the subgroup with a tumor diameter >5 cm, and in the inflow nonocclusion subgroup, use of the SCS clearly decreased surgical bleeding ($P = .0120$, $P = .0126$, and $P = .0032$, respectively) and duration of surgery ($P = .0001$, $P < .0001$, and $P = .0036$, respectively). Furthermore, even in the major hepatectomy group, use of the SCS decreased surgical time ($P < .0001$).

DISCUSSION

The importance of controlling bleeding in hepatic resection is well known,[4-6,14] and methods used to date include vascular occlusion by means of the Pringle maneuver,[15] Glisson's pedicle transection of 1 lobe,[16] or inferior vena cava clamping to reduce bleeding from the hepatic venous system.[17] During hepatectomy, the Pean hemostat or CUSA is generally used for hepatic transection. In recent years, the usefulness of novel devices such as a dissecting sealer[18] and the Monopolar Floating Ball (Tissuelink Medical Inc., Dover, NH)[19] has also been reported, but none of these has yet had sufficient impact to bring about changes in existing methods. Because their adjuvant use involves additional costs, they have yet to be adopted widely.

Because the soft-coagulation mode of the VIO system that was used in the present study uses a computer-controlled low voltage (<200 V) without electric discharge, heat is transferred to the deeper areas without surface carbonization. The absence of electric discharge means that no sparks are generated. This means that not only can it be used in areas such as the vicinity of major blood vessels where electric scalpels could not formerly be used, but also in the case of pinhole bleeding, it can be applied directly to achieve hemostasis. In addition, because the tip can drip saline to prevent the attachment of blood clots and is paddle shaped, it can be inserted into narrow gaps, and it is effective both for pinpoint hemostasis with the tip and for hemostasis over a somewhat wider area using the surface.

In the current study, using the SCS instead of saline-coupled bipolar electrocautery decreased bleeding and surgical time. One reason for this was the fact that ligatures were no longer needed because blood vessels ≤3 mm in diameter that remained after CUSA hepatic transection, which had previously required ligatures, could be coagulated easily. Another reason was that by pressing down with the flat side of the paddle, deep bleeding could be stopped across a fairly wide area in cases where hemostasis had previously been difficult to achieve with suturing hemostasis or the application of a TachoComb, such as deep bleeding from damage from veins being pulled out, as well as diffuse bleeding from the parenchyma associated with advanced hepatic steatosis and hepatic cirrhosis. Thus, less time is spent on

hemostasis. Another point that should be emphasized is that the SCS can be used safely in the vicinity of the hepatic vein or inferior vena cava without damaging the venous wall. Until now, when approaching tumors near the hepatic vein or inferior vena cava, hemostasis of bleeding from the fine branches of the venous wall or the parenchyma around the vein had been problematic, because of the poor field of vision and the difficulty of finding space. However, using the SCS makes it possible to take direct action to stop bleeding, even from the parenchyma surrounding deep, thick veins with a poor field of view without having to worry about damaging the blood vessels. In addition, fine branches can be sealed easily without the need for ligatures, and bleeding from any holes can be stopped by applying the SCS directly to the venous wall, which leads to reduced bleeding and surgical time.

When the risk factors for bleeding were investigated, nonuse of the SCS was shown to constitute a new risk factor, in addition to tumor size, vascular invasion, liver fibrosis, and inflow nonocclusion. It is particularly noteworthy that in cases in which preoperative testing indicated a high risk of bleeding (collagen type IV values ≥200 ng/mL [indicating liver fibrosis] or tumor diameter ≥5 cm), use of the SCS reduced bleeding and surgical time, even in the major hepatectomy group and the inflow nonocclusion subgroup.

A point of caution concerning the SCS is that because it is basically an electric scalpel, the greater its hemostatic effect the hotter it becomes, and in its early stages, problems such as hyperthermia during surgery, widespread burn injury to the liver stump, and increased postoperative transaminase levels were evident. Cooling the surface of the liver during incision by irrigating it with cold saline, swiftly aspirating the heated saline, and not performing more coagulation than necessary, however, avoids the occurrence of hyperthermia. Postoperative changes in transaminase values are also considered to be greatly affected by intraoperative release from the side of the resected liver, and although significantly higher values were found on POD1, these values swiftly declined, with no difference found in TB or PT-INR and no major problems. Another point of concern was delayed-onset postoperative bleeding and bile duct damage possibly caused by burn injury to vascular vessels and biliary tract, but to date no increase in such complications has been observed, and these would not be regarded as a major problem.

In conclusion, SCS is useful for the hemostasis of bleeding from the parenchyma or hepatic vein during liver transection. Because it is based on the familiar electric scalpel, it is user friendly, and it offers a method that should reach widespread acceptance.

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CASE REPORT

Active gastrointestinal bleeding: Use of hemostatic forceps beyond endoscopic submucosal dissection

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Abstract

To the best of our knowledge, this is the first report of the application of hemostatic forceps in active gastrointestinal (GI) bleeding that is not related to endoscopic submucosal dissection. An 86-year-old woman with chronic intake of low-dose aspirin had a Dieulafoy's lesion of the third duodenal portion. Bleeding control with epinephrine injection was unsuccessful. A 60-year-old man presented with a bleeding ulcer in the duodenal bulb. Ten days after combined endotherapy, he had recurrent bleeding from two minimal lesions in the same location. A 66-year-old woman under combined antithrombotic treatment was referred to us for chronic GI bleeding of unexplained origin. Endoscopy revealed active diverticular bleeding in the second duodenal portion. A 61-year-old woman underwent endoscopic mucosal resection of superficial gastric adenocarcinoma, which was complicated with immediate bleeding. In all cases, the blood was washed out using a water-jet-equipped, single-channel gastroscope with a large working channel. The bleeding points were pinched and retracted with hemostatic forceps. Monopolar electrocoagulation was performed using an electrosurgical current generator. Hemostasis was achieved. No complications occurred. In conclusion, hemostatic forceps may be an effective as well as safe alternative approach for active GI bleeding of various origins.

INTRODUCTION

Therapeutic endoscopy has greatly reduced the indications for urgent surgery in cases of gastrointestinal (GI) bleeding. Despite several advances in endoscopic technology, hemostasis can be technically challenging. In addition, the risk of rebleeding, which is associated with high mortality, cannot be eliminated[1].

Hemostatic forceps is commonly included in the essential accessories for performing endoscopic submucosal dissection (ESD)[2]. Therefore, we assumed that it could be also applicable in the treatment of active GI bleeding that is not related to ESD.

CASE REPORT

Case 1

An 86-year-old woman was admitted for melena. She had a medical history of ischemic heart disease and chronic intake of low-dose aspirin. She was intravenously administered omeprazole (8 mg/h). Her endoscopic findings were suggestive of a Dieulafoy's lesion that was located in the third duodenal portion at the level of the genu inferius. An initial attempt at bleeding control with injection of epinephrine solution at a dose of 25 mL proved

to be unsuccessful. At that point, the decision was made to use a hemostatic forceps (Coagrasper, FD-410LR; Olympus, Tokyo, Japan). The blood was washed out using a water-jet-equipped, single-channel gastroscope (GIF1T 140; Olympus), with a large working channel (diameter: 3.8 mm), and the hemostatic forceps was advanced through it. The bleeding point was gently grasped and retracted with the hemostatic forceps (Figure 1A). At that point, monopolar electrocoagulation was delivered using an electrosurgical current generator (ICC 200; ERBE, Tubingen, Germany) with forced mode at a setting of 60 W (Figure 1B). The coagulation effect was evaluated by washing out the blood again. The whole hemostatic procedure was carried out with success within 5 min. The bleeding point had to be grasped twice. The total duration of complete coagulation with this setting was about 1 min. The patient tolerated the procedure well. She had no perforation or rebleeding.

Case 2

A 60-year-old man presented with ulcer bleeding in the duodenal bulb. He was managed with injections of epinephrine solution in combination with the placement of two hemoclips (QuickClip Ⅱ, standard size; Olympus) and intravenous administration of omeprazole (8 mg/h). However, during the next 10 d, he developed recurrent bleeding. A repeat endoscopy demonstrated two simultaneously oozing, bleeding, minimal lesions in the ulcer area. The endoclips remained attached to the site of application. Although high doses of epinephrine solution (60 mL) were injected again, they failed to achieve hemostasis. After that, a VIO 200 ERBE generator was set to soft coagulation mode (Effect 5, 80 W) to coagulate the bleeding lesions with hemostatic forceps. The same endoscope and technique were used (Figure 2). As it was difficult to keep the endoscope stable in the retropyloric bulb, coagulation was also delivered by applying the tip of the unopened hemostatic forceps to the bleeding points. Prompt and effective hemostasis was achieved without any further episodes of bleeding. Following an uneventful recovery, the patient was discharged home a few days later.

Case 3

A 66-year-old woman was referred to our Endoscopy Unit for chronic GI bleeding of unexplained origin. She was receiving combined antithrombotic treatment with low-dose aspirin and clopidogrel for advanced cardiovascular disease. She was also receiving omeprazole for ulcer prevention. On upper endoscopy, she had signs of active diverticular bleeding of the second duodenal portion. She underwent endoscopic hemostasis by using an ERBE VIO 200 generator with either soft coagulation mode (Effect 5, 80 W) or forced mode (60 W), as well as hemostatic forceps, which grasped and retracted the bleeding point. The procedure was well tolerated and resulted in bleeding control. No late-onset complications were observed.

Case 4

A 61-year-old woman was diagnosed with depressed-type Ⅱc superficial adenocarcinoma in the stomach, with a diameter of approximately 1.5 cm. Cap-assisted endoscopic mucosal resection (EMR) of her neoplastic lesion was complicated with immediate bleeding. Coagulation of the spurting bleeding vessels using an ERBE VIO 200 generator (soft mode, Effect 5, 50 W) and hemostatic forceps allowed us to complete successfully the EMR procedure (Figure 3). The patient was treated with omeprazole 20 mg *bid*. She did not experience any further complications. She was discharged home within 48 h.

DISCUSSION

Several techniques or devices have been used for the endoscopic control of active GI bleeding. The widely available endoscopic hemostatic options include injection techniques such as epinephrine or sclerosant, ablative ones such as heater probe or argon plasma coagulation (APC), and mechanical methods such as endoclips or endoscopic banding[1]. In several ulcer bleeding cases, combination endoscopic treatment with epinephrine injection and thermal coagulation or endoclipping has been recommended to achieve better outcomes[3]. Bleeding control of a Dieulafoy's lesion may require hemostasis with multiple endoscopic treatment methods, whereas clinical experience with endotherapy of duodenal intradiverticular bleeding is limited to a small number of cases[4,5].

GI bleeding is a major complication of endoscopic surgery. Minor bleeding during ESD can be managed with coagulation using an electrosurgical knife. When that fails, conventional endoscopic means such as hemoclips or APC can be applied[6]. However, endoclipping may pose several difficulties in the completion of the dissection procedure[7].

A hemostatic forceps is a valuable tool for performing safely ESD procedures, which are usually demanding[8]. Its intraoperative use is extended from the coagulation of actively bleeding or oozing vessels to the pre-coagulation of visible, exposed vessels on the artificial ulcer. It does not only aim at facilitating an ESD procedure, so as to continue the endoscopic intervention safely, but also to prevent delayed bleeding as a late-onset complication[9].

In our small study, a hemostatic forceps was used in the endoscopic management of GI bleeding that was unrelated to ESD. To the best of our knowledge, this is the first report of its application beyond ESD in the English-language literature. Our initial experience demonstrated that monopolar coagulation using a hemostatic forceps as: (1) a second-line therapeutic approach during the same hemostatic procedure; (2) second-line retreatment of two simultaneously bleeding sources after recent combined endotherapy with other modalities; and (3) first-line treatment of a non-iatrogenic bleeding lesion or an EMR-induced lesion, was effective as well as devoid of any post-procedural complications.

Although omeprazole was introduced prior to endotherapy in all our cases, the clinical efficacy of proton pump inhibitors (PPIs) in acute bleeding is a matter of debate. They can reduce the severity of endoscopic signs

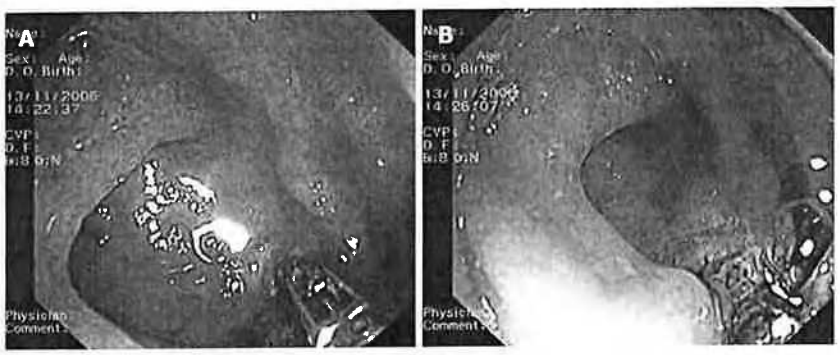

Figure 1 Endoscopic images. A: The bleeding point is pinched with a hemostatic forceps; B: Coagulation delivery at the retracted bleeding point.

Figure 2 An opened hemostatic forceps while washing out the blood after coagulation.

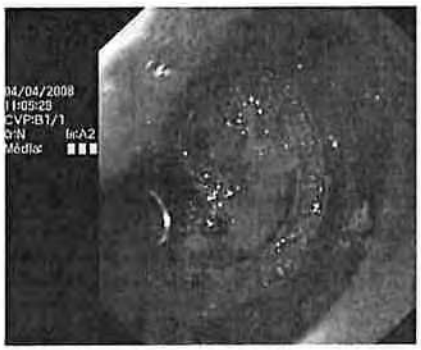

Figure 3 Coagulating the bleeding vessels during cap-assisted endoscopic mucosal resection (EMR).

of recent bleeding and the need for endotherapy, but they have not provided a clear benefit in terms of rebleeding, mortality or the need for surgery[10]. In addition, the administration of PPIs prior to ESD does not seem necessary for the prevention of postoperative bleeding[11]. However, they can prevent delayed bleeding more effectively than H_2-receptor antagonists[12]. Moreover, epinephrine was initially injected in two cases. Epinephrine alone can provide initial hemostasis of 80%-100% in bleeding ulcers, but recurrent bleeding rates range from 6% to 36%. Similar to ulcers, it may only provide temporary hemostasis of bleeding of Dieulafoy's lesions[13].

Although that hemostatic tools appears to be a reasonable alternative option for the endoscopic treatment of various bleeding lesions, a few practical and technical issues should be taken into consideration before encouraging endoscopists to use it for non-variceal, actively bleeding cases, to achieve definitive hemostasis. To date, the clinical experience of its hemostatic applications has not extended further than those interventionists that perform ESD procedures. However, it is conceivable that excessive coagulation with it might result in delayed perforation. Therefore, one should be aware of the mode of use of a hemostatic forceps, to avoid any complications. The bleeding point should be precisely pinched, retracted and coagulated with a minimal contact area for a minimum time[7]. In difficult cases, it is also possible to achieve prompt tissue coagulation with the simple contact of an unopened hemostatic forceps, as shown in our second case. However, by pinching an artery, its use seems more advantageous than other endoscopic techniques, such as APC, for avoiding unnecessary maneuvers and providing accurate hemostasis. To facilitate capture, a hemostatic forceps can be also rotated.

Several experts in ESD procedures usually coagulate the blood vessels using a hemostatic forceps in soft mode[7,9,14-20]. Others use the coagulation mode of the knife for hemostasis[21,22]. In our endoscopy unit, we generally use an ERBE VIO 200 generator in soft mode (Effect 5, 50, 80 or 100 W) for a hemostatic forceps. However, an ICC 200 generator, which can be set to soft or forced mode, is the only available option for emergency cases. This is the reason why that was used for the coagulation of the Dieulafoy's lesion and the duodenal intradiverticular bleeding. In the case of the Dieulafoy's lesion, the field was blood-filled and large amounts of water were required to clear it. It took us a long time to grasp the spurting lesion twice and coagulate it with the forced mode to complete the hemostatic procedure. Despite the prolonged duration of coagulation, the bleeding was controlled with no early or delayed-onset complications. It seems doubtful if the use of soft coagulation would be effective in achieving hemostasis. In the case of the large bleeding diverticulum in the second duodenal portion, which was not easily accessible, we continued the coagulation using the forced mode (60 W), because the hemostatic effect of the soft mode with 80 W current was not rapid enough. Although there might be a higher risk of excess tissue injury from thermocoagulation

in thin-walled duodenal diverticula, an endoclip-induced perforation has been reported as the only complication of endotherapy of diverticular bleeding in a recent case series[5]. Possible explanations include the sharp tip of the hemoclip and excessive air inflation during therapeutic endoscopy[1,23].

In conclusion, our case series supports the potential value of the application of a hemostatic forceps in active GI bleeding of various origins. It suggests that it seems to be a reliable and safe therapeutic tool even for those cases of bleeding that are unrelated to ESD, which are difficult to treat with other endoscopic means, although more cases need to be studied before any firm conclusions can be made. Proper techniques and settings should be followed to avoid any procedure-related complications.

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The VIO soft-coagulation system can prevent pancreatic fistula following pancreatectomy

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Abstract

Background/Purpose. The VIO soft-coagulation system (SC) is a new device for tissue coagulation. We hypothesized that this device would be an effective tool for sealing small pancreatic ducts, thus reducing pancreatic fistula following pancreatectomy.

Methods. To confirm whether the SC could be used to seal small pancreatic ducts, we measured the burst pressure in sealed ducts in mongrel dogs. Eight dogs underwent distal pancreatectomy, with the remnant stump coagulated by using the SC. The animals were necropsied on postoperative day 10. In a clinical trial, 11 patients who underwent pancreatoduodenectomy with SC treatment (SC group), and 24 patients who underwent pancreatoduodenectomy without SC treatment (non-SC group) were compared.

Results. In the experimental study, the burst-pressure test revealed that the SC had efficiently sealed the small pancreatic ducts. Histological examination revealed completely obstructed pancreatic ductal structures, ranging from large pancreatic ducts (diameter, 500 μm) to microscopic ducts. No pancreatic leakage was observed following distal pancreatectomy without main pancreatic duct (MPD) suturing in dogs that had an MPD diameter of less than 500 μm. In the clinical trial, pancreatic fistula developed in only one patient (9.1%) in the SC group, but a pancreatic fistula developed in five patients (20.8%) in the non-SC group.

Conclusions. This novel technique using the SC is an effective procedure for preventing the development of pancreatic fistula following pancreatectomy.

Key words VIO soft coagulation · Pancreatic fistula · Pancreatic leakage · Distal pancreatectomy · Pancreatoduodenectomy

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Introduction

The development of a pancreatic fistula is a serious postoperative complication of pancreatectomy.[1,2] The use of several surgical techniques and devices for the prevention of pancreatic fistula has been reported. However, the incidence of pancreatic fistula following resection remains high.[3] Several studies have demonstrated that pancreatic fistula occurs frequently even when there is no leakage from the main pancreatic duct (MPD), and they have considered the leakage that occurs to be due to leakage from branches of the pancreatic duct (BPDs) that communicate with the MPD on the cut surface.[4,5] Therefore, to reduce the incidence of pancreatic fistula, it is necessary to develop a novel technique for the management of BPDs on the cut surface.

In recent years, an electrosurgical device (VIO 300 D; ERBE Elektromedizin, Tübingen, Germany) containing the VIO soft-coagulation system (SC) has been developed. Conventional electrosurgical coagulation systems produce sparks and can cause carbonization and adhesions to the electrode during coagulation, resulting in incomplete hemostasis. However, this new device uses only Joule heat, and the voltage is limited to 200 Vp, thus preventing the development of sparks, carbonization, and adhesion to the electrode, and resulting in a greater degree of coagulation as compared with that obtained with conventional electrosurgical coagulation systems.

We hypothesized that treatment of the whole cut surface using the SC would completely seal the BPDs on the stump without the need for suturing and with little damage to the pancreatic tissue, thus decreasing the incidence of pancreatic fistula. Based on this hypothesis, we have been using this device to treat the pancreatic stump in the performance of pancreatoduodenectomy in clinical trials during recent years. Furthermore, we consider that this device may also be effective in patients

with distal pancreatectomy, partial resection, and pancreatic enucleation, because it can be used to seal the BPDs without the need for oversewing or suturing the stump.

To confirm the above hypothesis, we first examined whether the SC could be used to seal small pancreatic ducts; we did this by performing a burst-pressure test, which is frequently used in evaluating surgical devices used for sealing vessels.[6] Further, we performed pilot animal studies in mongrel dogs to evaluate whether the use of the SC would be an appropriate procedure for the prevention of pancreatic fistula following distal pancreatectomy. Finally, we evaluated whether the SC was an effective tool in the performance of pancreatoduodenectomy by undertaking a clinical trial.

Here, we report a novel surgical technique using the SC for the prevention of pancreatic leakage following pancreatectomy.

Methods

VIO soft-coagulation system

The VIO 300 D system was set to SC mode. The effect level was set at effect 6 and the maximum output at 80 W. A paddle-type electrode was employed. Further, we installed a small tube at the tip of the electrode for dropping saline solution during coagulation (Fig. 1), because saline irrigation reduces the contact resistance between the electrode and the tissue.

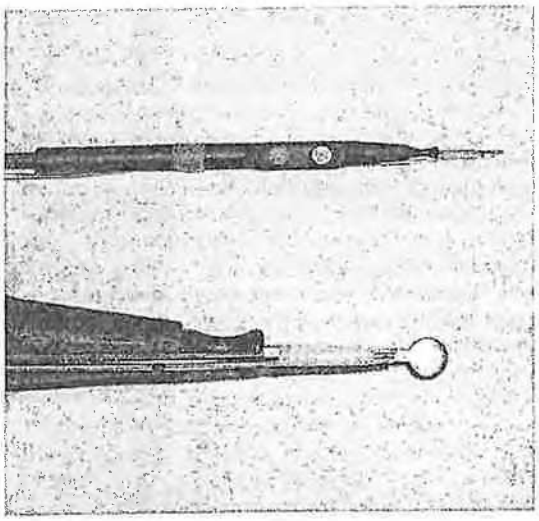

Fig. 1. A paddle-type electrode was employed. A small tube was installed at the tip of the electrode for dropping saline solution during coagulation, because saline irrigation reduces the contact resistance between the electrode and the tissue

Experimental study in mongrel dogs

The experimental study involved ten mongrel dogs (weight, 10–23 kg), and it was conducted according to a protocol that had been approved by the Animal Care Facility Research Committee of Tokyo Medical University. Anesthesia was induced with pentobarbital sodium and atropine and was maintained by administering isoflurane. Prior to surgery, 200 mg flomoxef was intravenously administered to each animal.

Burst-pressure tests and histological examination of the sealed MPD

In a preliminary study, we observed that the internal diameter of the MPD in mongrel dogs was approximately 500 μm, which is similar to the diameter of large BPDs in humans. Therefore, in a pilot study to investigate whether the SC would be useful for sealing human BPDs, we used MPDs in mongrel dogs. After sealing the MPDs, we measured the burst pressure and compared the sealing efficiency of the SC (SOFT group) with that of conventional electrosurgical coagulation (CONV group).

Approximately 6 cm of the distal pancreas was resected and used for the burst-pressure test. A 24-G catheter was inserted into the MPD at the cut surface; it was secured to the pancreatic parenchyma with a stay suture (Fig. 2c). A digital pressure manometer (FUSO-8230; Fuso, Tokyo, Japan) was attached to the catheter via a tube. The distal 3 cm of the previous cut surface was then divided using a steel scalpel. The MPD on the cut surface was coagulated by SC or conventional electrosurgical coagulation. A solution (saline containing indigo carmine) was infused into the duct by using an inflation device (Medtronic Japan, Tokyo, Japan). The pressure was steadily increased until failure of the MPD seal was noted. The burst pressure (maximum tolerable pressure), in mmHg, was automatically recorded on the FUSO-8230 system. Following the burst-pressure test, the internal diameter of each MPD on the cut surface was measured under a microscope, and the pancreata were divided into two groups (small-MPD group: diameter, less than 500 μm; large-MPD group: diameter, 500–1000 μm). Each coagulated cut surface was histologically examined.

Distal pancreatectomy performed on mongrel dogs

The distal pancreas was dissected away from the splenic vessels. The distal 4 cm of the pancreas was then divided using a steel scalpel, and hemostasis was achieved by using 4-0 polydioxanone suture ligatures. The stump of the remnant pancreas was coagulated by SC until the cut surface turned white (Fig. 2a, b). The MPD was not

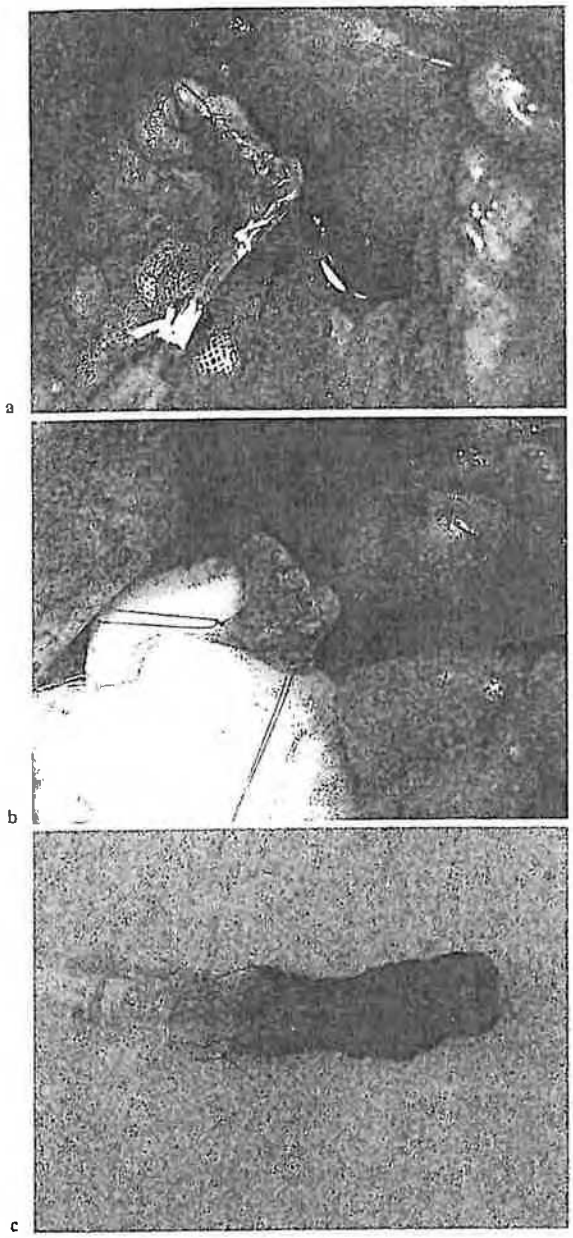

Fig. 2. a, b After distal pancreatectomy in a mongrel dog, the stump of the remnant pancreas was coagulated, using the VIO soft-coagulation system (SC), until the cut surface turned white. c The resected distal pancreas was used for a burst-pressure test. A 24-G catheter was inserted into the cut surface of the main pancreatic duct (MPD)

ligated with the suture, and the pancreatic stump was not oversewn. Cefdinir 200 mg was administered daily for 5 days after the surgery. The abdomen was re-explored after 10 days, and the operative results were evaluated. Pancreatic tissue was collected from the stump 3, 5, and 10 days after the surgery to assess the early histological effects of the treatment, and the tissues were stained with hematoxylin and eosin (see Fig. 3 for results of the histological examination).

Clinical trial of SC in patients with pancreatoduodenectomy

In the clinical trial, 35 patients who underwent pancreatoduodenectomy between January 2006 and November 2007 at Tokyo Medical University Hospital were retrospectively investigated. The new technique using SC was employed for 11 of these 35 patients (SC group; 6 patients with cancer of the pancreatic head, 1 with cancer of the papilla of Vater, 1 with cancer of the bile duct, 1 with intraductal papillary mucinous neoplasm (IPMN), and 2 with other forms of neoplasm). SC was not used in the remaining 24 patients (non-SC group; 11 patients with cancer of the pancreatic head, 5 with cancer of the papilla of Vater, 5 with cancer of the bile duct, 1 with IPMN, and 2 with other forms of neoplasm).

In the pancreatoduodenectomy, the pancreatic neck was dissected from the superior mesenteric and portal veins. In the SC group, the pancreatic stump was coagulated by SC. The remnant pancreas was clamped with tape to reduce bleeding and it was then transected with a steel scalpel. The whole pancreatic stump was coagulated by gently rubbing an electrode back and forth on the surface until the entire cut surface turned white (Fig. 4). Heavy arterial bleeding was arrested by ligation with a 4-0 or 5-0 polydioxanone suture. During coagulation, appropriate suctioning was performed to minimize the accumulation of blood and saline that leads to incomplete coagulation. In addition, coagulation around the MPD was restricted in order to prevent damage to it. In the non-SC group, arterial bleeding points on the pancreatic stump, if any, were ligated with a 4-0 or 5-0 polydioxanone suture, and oozing points, if any, were coagulated with a conventional electrosurgical device. Following this treatment, pancreatojejunostomy was performed via anastomosis of the duct to all layers of jejunal wall and anastomosis of the pancreatic parenchyma to the jejunal seromuscular layer.

Statistical analyses

All data values were expressed as means ± SD of the mean and were compared by using Student's *t*-test. Significance was assumed at a level of $P < 0.05$. The

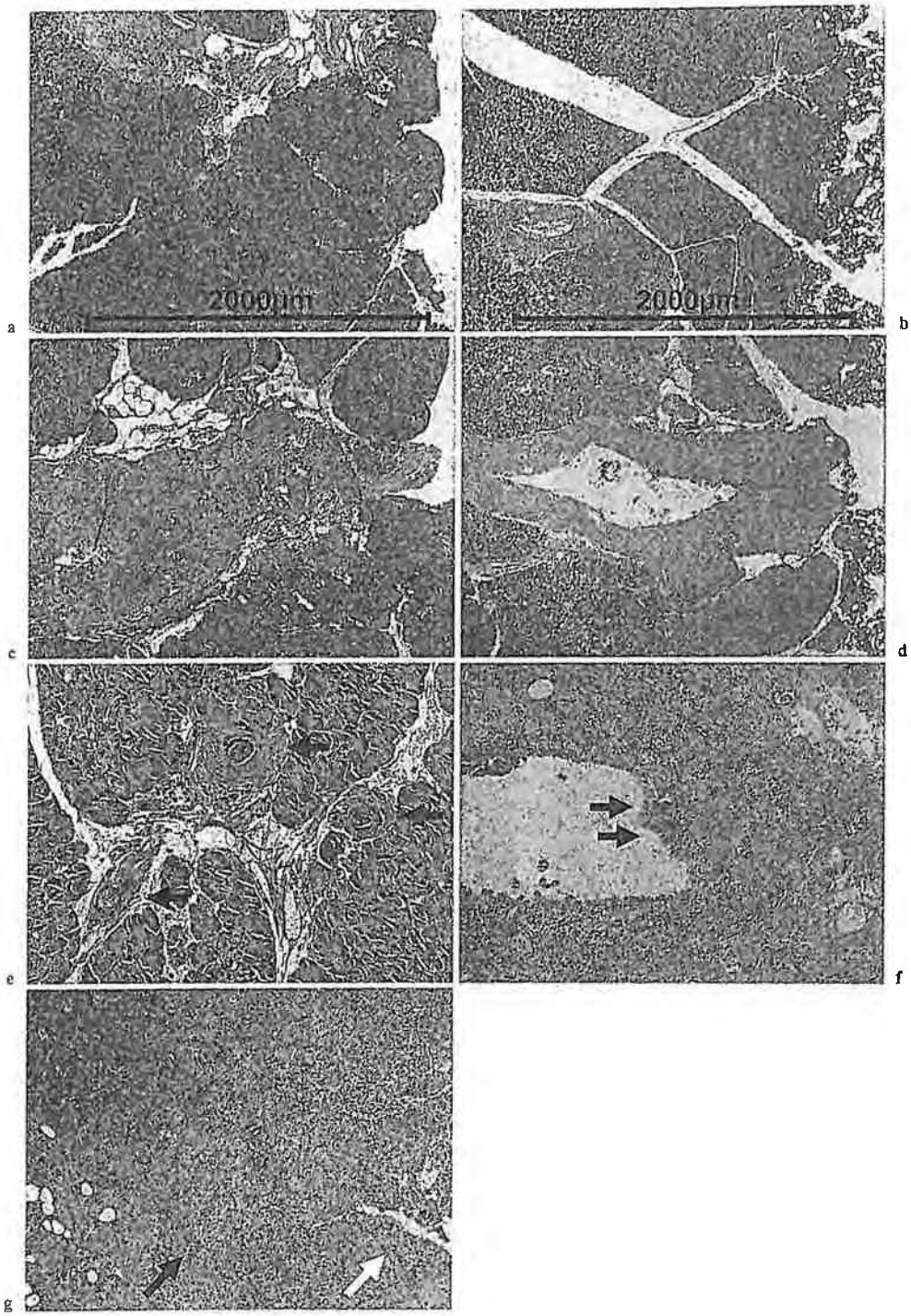

Fig. 3a–g. Histological examinations in the experimental study. **a** The SC achieved uniform coagulation at a depth of approximately 2000 μm. **b** Conventional electrosurgical coagulation achieved nonuniform coagulation at a depth of 0–2000 μm. **c** The specimens treated by SC exhibited complete obstruction of the pancreatic ductal structures in the coagulated pancreatic parenchyma. **d** The specimens treated by conventional electrosurgical coagulation revealed that the MPD was only partially obstructed, and most of the ductal structures in the coagulated pancreatic parenchyma remained intact. **e** Microscopic pancreatic ducts (*arrows*) were also obstructed by SC. **f** Regenerative epithelium (*arrows*) appeared on the sealed surface of the MPD on postoperative day 3. **g** On postoperative day 5, the specimens exhibited proliferation of granulation tissue (*black arrow*) in the remnant pancreatic parenchyma, and coagulation necrosis (*white arrow*)

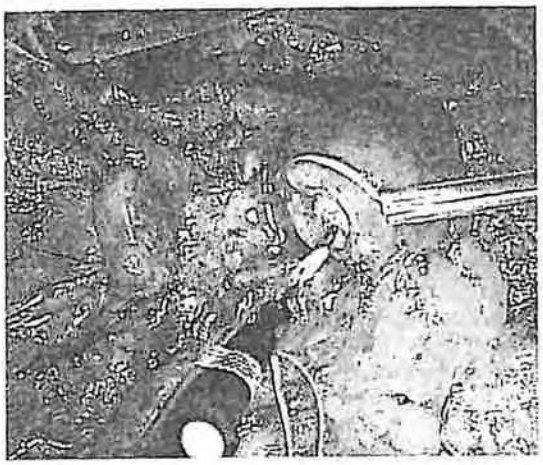

Fig. 4. In the patients with pancreatoduodenectomy, the pancreatic stump was treated by SC. The whole pancreatic stump was coagulated by gently rubbing an electrode on it until the cut surface turned white

analyses were performed using StatView 4.5 statistical software (Abacus Concepts, Berkeley, CA, USA).

Results

Experimental study

Histological examinations of sealed MPDs, and burst-pressure tests

We histopathologically compared pancreatic stumps that had been coagulated by SC and stumps that had been treated by conventional electrosurgical coagulation. With conventional electrosurgical coagulation, nonuniform coagulation was achieved at a depth of 0–2000 μm (Fig. 3b) and the degree of tissue damage varied depending on the depth. In contrast, uniform coagulation at a depth of approximately 2000 μm was achieved with SC (Fig. 3a). Specimens that were treated by SC exhibited complete obstruction of the pancreatic ductal structures in the coagulated pancreatic parenchyma (Fig. 3c). The microscopic pancreatic ducts were also obstructed by SC (Fig. 3e). However, the specimens treated by conventional electrosurgical coagulation exhibited only partial obstruction of the MPD, and most ductal structures in the coagulated pancreatic parenchyma remained intact (Fig. 3d).

The burst-pressure tests revealed a statistically significant difference in the burst pressure between the SOFT group and the CONV group for each MPD diameter (small-MPD group: SOFT group, 349.0 ± 79.1 mmHg; CONV group, 106.0 ± 62.0 mmHg; $n = 5$ per group; $P < 0.01$; large-MPD group: SOFT group, 259.0 ± 47.8 mmHg; CONV group, 67.0 ± 30.4 mmHg; $n = 5$ per group; $P < 0.01$; Fig. 5). Furthermore, in the SOFT group, the burst pressure in the small-MPD group was lower than that in the large-MPD group, although this difference was not statistically significant (Fig. 5).

Operative results of distal pancreatectomy

Eight dogs were selected for the outcome analysis. Among the dogs with an MPD diameter of 500 μm or more, one exhibited pancreatic leakage and abscess formation around the cut stump. However, none of the dogs with an MPD diameter of less than 500 μm exhibited pancreatic leakage or abscess formation (Table 1). Histological examination revealed the appearance of regenerative epithelium on the sealed surface of the MPD on postoperative day 3 (Fig. 3f). On postoperative day 5, the specimens exhibited proliferation of granulation tissue in the remnant pancreatic parenchyma, and coagulation necrosis (Fig. 3g). On postoperative day 10, the coagulation necrosis had almost completely disappeared, and thick granulation tissue covered the cut surface of the remnant pancreas.

Clinical trial

Operative results of pancreatoduodenectomy

The hemostatic effect of SC was excellent, and suture ligation was not required for pancreatic stump bleeding in most patients, except in a patient with heavy arterial bleeding. Pancreatic fistula developed in only one patient (9.1%) in the SC group, but a pancreatic fistula developed in five patients (20.8%) in the non-SC group.

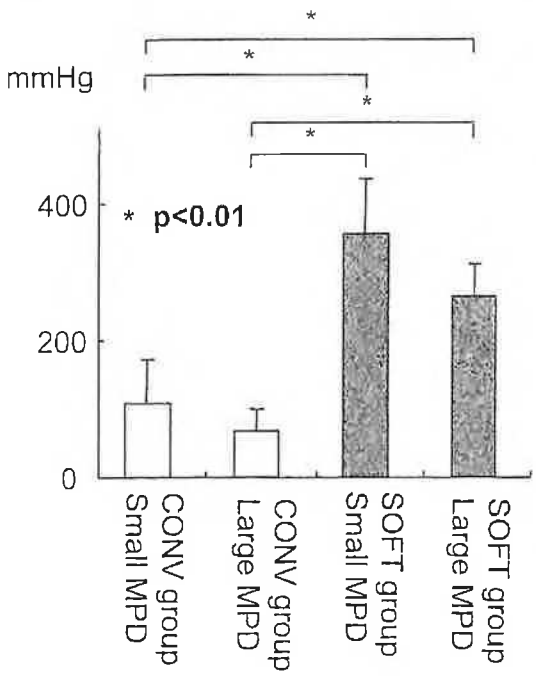

Fig. 5. Burst-pressure tests revealed a statistically significant difference in the burst pressure between the SC (*SOFT*) group and the conventional electrosurgical coagulation (*CONV*) group for each MPD diameter (small-MPD group: SOFT group, 349.0 ± 79.1 mmHg; CONV group, 106.0 ± 62.0 mmHg; $n = 5$ per group; $P < 0.01$; large-MPD group: SOFT group, 259.0 ± 47.8 mmHg; CONV group, 67.0 ± 30.4 mmHg; $n = 5$ per group; $P < 0.01$)

Table 1. Experimental study: diameter of the main pancreatic duct sealed by VIO soft-coagulation system, and postoperative complication

		Diameter of the main pancreatic duct (mm)	
	Total	<500 μm	≥500 μm to <1000 μm
Pancreatic leakage and postoperative complication	1/8 (12.5%)	0/5 (0%)	1/3 (33.3%)

Discussion

To our knowledge, this is the first report of experimental and clinical studies of the use of SC for preventing the development of pancreatic fistula following pancreatectomy. In the present study, we focused on whether the use of SC could seal BPDs at the cut surface. There are various methods for the management of the pancreatic stump in pancreatectomy, such as division with an ultrasonic dissector[7] or an ultrasonically activated scalpel;[5] these methods have been developed to reduce pancreatic leakage from the BPDs on the cut surface. However, there have been few reports confirming that these methods can ensure complete occlusion of the BPDs.

In the present experimental study, to confirm whether SC could be used to seal small pancreatic ducts such as branch ducts, we performed a burst-pressure test; this test is frequently used to evaluate surgical devices used for vessel sealing.[6] This is the first report on the use of the burst-pressure test for evaluating the sealing of small pancreatic ducts. Our results revealed that stronger pancreatic duct sealing was achieved with SC than with conventional electrosurgical coagulation. Furthermore, no pancreatic leakage was observed following distal pancreatectomy in dogs that had an MPD diameter of less than 500 μm, although the MPD was not sutured. Interestingly, histological examination revealed that regenerative epithelium appeared on the sealed surface of the MPD on postoperative day 3 and that granulation tissue covered the cut surface of the remnant pancreas on postoperative day 5. These results strongly support our hypothesis that SC could be effective for sealing human BPDs.

BPDs can be securely ligated by performing pancreatic transection using an ultrasonic dissector.[7] However, it is difficult to identify and ligate microscopic ducts that may be covered by the pancreatic juice that may accumulate near the cut surface after surgery. In our experimental study, histological examination revealed that SC produced uniform coagulation at a depth of approximately 2000 μm and completely obstructed most pancreatic ductal structures within the coagulated pancreatic tissue, ranging from large ducts with a diameter of 500 μm to microscopic pancreatic ducts. This result indicates that SC can efficiently seal most branch ducts on the cut surface.

Complete hemostasis is important in pancreatic transection. Parenchymal suturing is frequently performed to achieve hemostasis following pancreatic transection. However, this may cause ischemic damage to the pancreatic parenchyma, leading to the development of pancreatic fistula. In our clinical trial, SC exhibited an excellent hemostatic effect with little tissue damage. Suturing was not required for pancreatic stump bleeding in most patients, except in one patient with heavy arterial bleeding. Therefore, this method can reduce the need for suturing and, consequently, the ischemic damage that follows.

MPD ligation with subsequent suturing of the pancreatic stump has been the standard method used for

management of the cut surface following distal pancreatectomy. However, Truty et al.[8] reported that the sutures themselves may cause tears within the pancreatic parenchyma, increase pancreatic leakage, and provide a nidus of inflammation, leading to the development of infection and abscess formation.

A stapler is also frequently used to close the pancreatic stump.[9] However, Suzuki et al.[10] have reported that a stapler does not occlude small BPDs with absolute certainty; this may lead to pancreatic leakage and, ultimately, to major anastomotic leakage. Of note, we observed that SC effectively sealed most BPDs, including microscopic pancreatic ducts, without the need for oversewing or suturing the stump. Therefore, we consider our SC method to be an appropriate procedure for use in distal pancreatectomy.

In conclusion, our studies indicated that our novel surgical technique using SC completely sealed BPDs with little tissue damage, thus reducing pancreatic leakage. In addition, the use of this technique without parenchymal suturing may reduce the degree of damage to the remnant pancreas. This novel technique is considered to be a useful procedure for preventing the development of pancreatic fistula following pancreatic surgery, including pancreatoduodenectomy and distal pancreatectomy.

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Endoscopic submucosal dissection with insulated-tip knife for large mucosal early gastric cancer: a feasibility study (with videos)

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Background: According to clinicopathologic studies, differentiated-type mucosal early gastric cancers without ulcer or ulcer scar have little risk of lymph-node metastasis, irrespective of tumor size. However, patients with large mucosal early gastric cancer have been subjected to surgery because conventional EMR methods could not resect large tumors en bloc.

Objective: To evaluate the feasibility and the efficacy of endoscopic submucosal dissection for treatment of early gastric cancers larger than 3 cm in diameter.

Design: Case series study.

Setting: Referral cancer center.

Patients: A total of 30 consecutive patients were enrolled with the following characteristics: diagnosis of differentiated-type early gastric cancer larger than 3 cm, lack of ulcerative change, no endoscopic evidence for submucosal invasion, and no evidence of lymph-node or distant metastasis (22 men and 8 women; median age, 69 years; median tumor size, 40 mm).

Interventions: Tumors were resected by endoscopic submucosal dissection with an insulated-tip knife.

Main Outcome Measurements: Complete resection, complication rate, and operation time.

Results: Complete resection was obtained in 23 of 30 cases (77%). Complications included hemorrhage (n = 4), perforation (n = 1), and pyloric stenosis (n = 1), but no severe complications occurred that required surgery or that led to major morbidity. Complete resection and complication rates improved in the last 10 cases (90% and 0%, respectively), though operation time was not shortened.

Limitations: Small sample size and lack of controls.

Conclusions: Endoscopic submucosal dissection when using the insulated-tip knife is feasible and efficacious for selected patients with mucosal early gastric cancer larger than 3 cm.

In Japan, EMR is regarded as a standard treatment for patients with differentiated-type mucosal early gastric cancers (EGC) less than 2-cm diameter,[1] and its effectiveness has been confirmed by favorable long-term outcomes.[2] According to clinicopathologic studies, differentiated-type intramucosal EGCs have little risk of lymph-node involvement or hematogenous dissemination, irrespective of tumor size, unless it has evidence of ulcer or an ulcer scar.[3] Therefore, patients with large intramucosal EGC without ulcer or ulcer scar would be good candidates for local therapy such as EMR. Unfortunately, a significant limitation of conventional EMR techniques, such as strip biopsy[4] or cap methods,[5] is the size of a resected specimen.

Recently, the insulated-tip (IT) knife was developed to improve the rate of en bloc resection (entire tumor removal in a single piece) for EGC.[6] We used the IT knife in a previous study, where it enabled us to resect larger areas of mucosa en bloc by using the endoscopic submucosal dissection (ESD) technique. The advantage of ESD over EMR was indicated.[7] However, a previous case series

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study of ESD included patients with small lesions who could be treated by conventional EMR; therefore, absolute benefit of this technique was equivocal. Although several case reports dramatically showed the results of ESD for large tumors,[8,9] the actual information, whether it could be used as standard treatment, was not disclosed. We suspect that the limitation of attempting to perform ESD on larger lesions is largely technical, likely attributable to a lack of information or a lack of experience. Therefore, in this study, we proposed to elucidate technical feasibility, efficacy, and safety of en bloc resection of a large EGC (>3 cm) confined to the mucosal layer by using ESD with an IT knife.

PATIENTS AND METHODS

This was a prospective case series study performed at an endoscopy unit at the Osaka Medical Center for Cancer and Cardiovascular Disease. An endoscopist (N.U.) who has experienced 7800 EGDs and 180 conventional EMRs performed all procedures.

Patients

Eligibility of patients was as follows: EGC larger than 3 cm in diameter, without ulcer or ulcer scar; no evidence of submucosal or deeper invasion; a diagnosis of differentiated-type tumor after biopsy; and no signs of lymph-node or distant metastasis. Patients who had severe organ failure were excluded.

Written informed consent was obtained from all patients after an explanation of the possible risks and complications of the procedures, anticipated results, and alternative treatments, including surgery and nontreatment. The study protocol was approved by the institutional review board in our center.

Pretreatment evaluation

The extent and depth of the tumor were carefully assessed by chromoendoscopy with 0.2% indigo carmine. The types of tumor were classified according to the Japanese classification of gastric carcinoma[10]: type 0I (protruded), type 0IIa (elevated), type 0IIb (flat), or type 0IIc (depressed). The tumor extent was determined by the differences in color, height, and area patterns between cancer and noncancer mucosa. The depth of the tumor was assessed mainly with morphologic features, under chromoendoscopic observation. Tumors that showed evidence for regions of hardness, irregular nodules, ulceration, or submucosal tumorlike marginal elevation were regarded as submucosal or deeper. After inflation of the stomach with air, tumors that extended flatly were regarded as intramucosal cancer and tumors that protruded into the lumen were considered submucosal invasive cancer. In the case of inconclusive findings, we used EUS with a standard echoendoscope with 7.5 and 20 MHz, (GIF-UMQ200; Olympus Medical Systems, Co, Ltd, Tokyo, Japan). Contrast-enhanced helical CT (5-mm slices) of the thorax and the abdomen, and US of the abdomen were performed for staging of lymph-node and distant metastasis.

Premedication

After overnight fasting, patients took dimethicone (Gascon; Kissei Pharmaceutical Co, Ltd, Nagano, Japan) as an antifoaming agent and pronase (Pronase MS; Kaken Pharmaceutical Co, Ltd, Tokyo, Japan) as a proteolytic agent to remove mucus.[11] Then, an intravenous catheter was inserted into a peripheral vein in the forearm, and fluids were administered via drip infusion to maintain access for sedatives on demand. Also, 15 mg pentazocine (Pentazin; Sankyo Pharmaceuticals, Tokyo, Japan) and 2.5 mg midazolam (Dormicum; Astellas Pharma Inc, Tokyo, Japan) were injected through the intravenous route just before the procedure, and 1.25 mg midazolam was given as needed throughout the procedure.

ESD technique with IT knife

All procedures were performed with videoendoscopy (EVIS 2T240, EVIS Q240; Olympus). The disposable distal attachment (D-201 series; Olympus) was fitted on the tip of the endoscope for pushing and lifting mucosa or submucosa, and to keep an adequate distance in the endoscopic view. A power source (ICC-200; ERBE, Tübingen, Germany) was for electrical cutting and coagulation.

Marking for removal area. With the patient under sedation, we inserted the endoscope to the stomach, estimated the extent of the tumor under chromoendoscopic observation, and decided the resection area (Fig. 1A, Video 1, available online at www.giejournal.org). The needle knife (KD-1L-1; Olympus) was used to place marking dots circumferentially 3 mm from the tumor margin. These dots were placed 5 mm apart so that the area to be resected was well visualized (Fig. 1B). A forced coagulation current of 30 W was used for marking.

Circumferential mucosal cut. A solution of 2% epinephrine (Bosmin; Daiichi Pharmatheutics Co, Ltd, Tokyo, Japan) with 20% concentrated glycerin-fructose (Glyceol; Chugai Pharmatheutics Co, Ltd, Tokyo, Japan) was injected into the submucosal layer just outside the marking dots to elevate the lesion. A hole to insert the tip of the IT knife (KD-610L; Olympus) was made outside of the region to be resected with the needle knife (Fig. 1C, Video 2, available online at www.giejournal.org). The hole was made at the distal side of the lesion in the endoscopic view, and additional holes were made during mucosal cutting if needed. The hole needed to be deep enough to reach the submucosa. The tip of the IT knife was fully inserted into the submucosa through the pre-cut hole, and the proximal mucosa was cut continuously outside the marking dots by using an endo-cut mode with 80 W currency. During mucosal incision, the ceramic tip was pressed to the gastric wall and was pulled with some tension (Fig. 1D, Video 3, available online at www.giejournal.org).

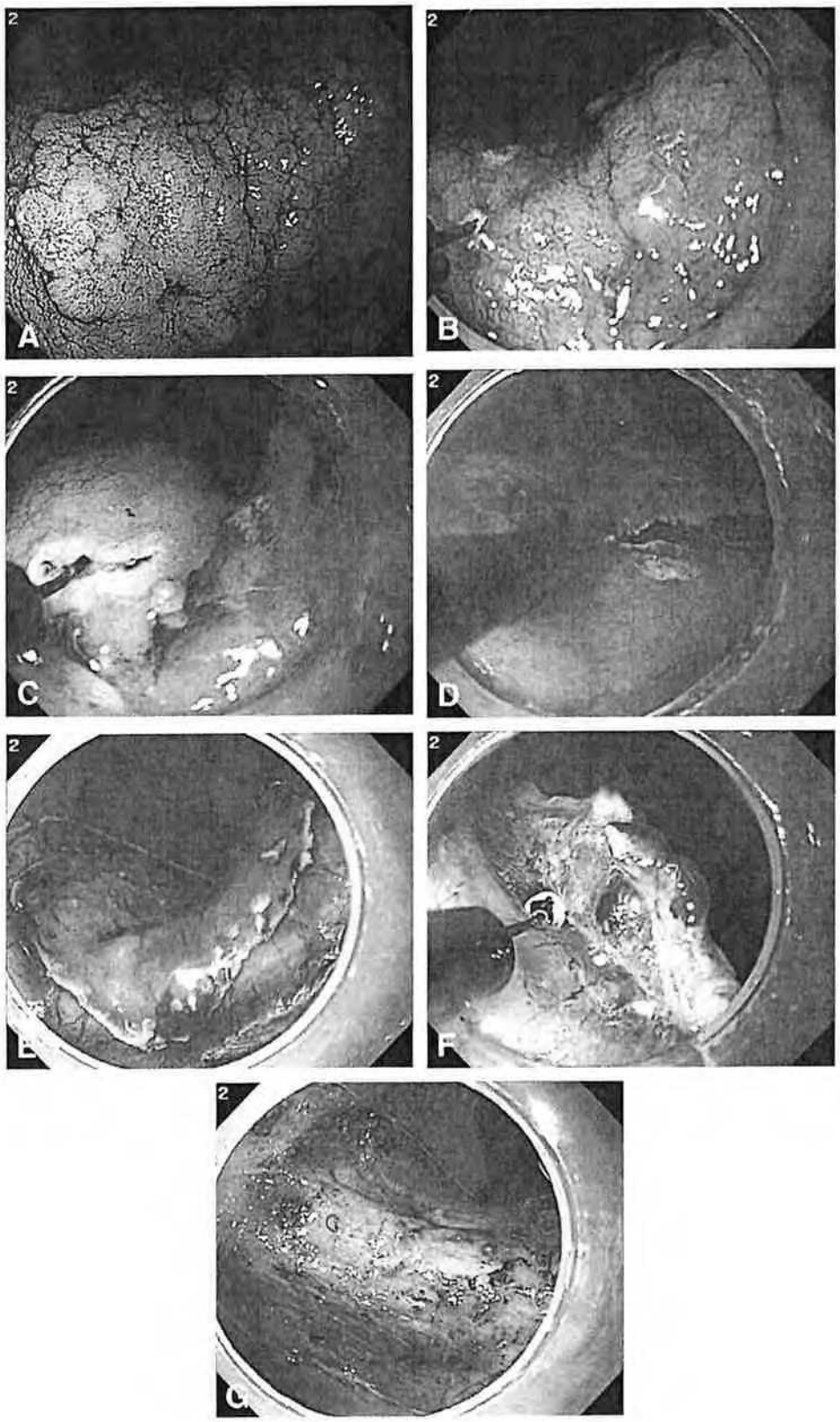

Figure 1. A, Chromoendoscopic observation: the elevated lesion (about 40-mm diameter) in the lesser curvature of stomach was carefully assessed around the perimeter, and chromoendoscopy with indigo carmine was used to assess tumor extent and depth. **B,** Marking: we made marking dots about 3 mm outside of the tumor and placed 5 mm apart with the needle knife by using a forced coagulation mode with 30 W currency. **C,** Making the initial hole: a hole was made outside of the marking dots with the needle knife; the hole needed to be deep enough to cut muscularis mucosae. **D,** Circumferential cutting: the tip of the IT knife was fully inserted into the submucosa through the hole, and we cut the mucosa continuously around the outside of the marking dots by using an endo-cut mode with 80 W currency. **E,** After circumferential cutting. **F,** Submucosal dissection: submucosal dissection was performed with the IT knife by using an endo-cut mode with 80 W currency or a forced coagulation mode with 50 W currency. **G,** Large ulcer after the resection: the ulcer base was washed out repeatedly and any adherent clots or suspicious protrusions were coagulated with coagulation forceps by using the soft coagulation mode with 80 W currency to avoid delayed hemorrhage.

Then the mucosa was cut circumferentially around the marking dots (Fig. 1E).

Submucosal dissection. Submucosal dissection was started after completing the circumferential mucosal cut. We injected glycerol solution into the submucosa to obtain sufficient mucosal elevation. We moved the IT knife laterally with the tip continuously touching against the gastric wall (Fig. 1F, Video 4, available online at www.giejournal.org). Lateral movement was acquired by torquing the scope rather than by using scope angle. Submucosal dissection was performed with the IT knife by using an endo-cut mode with 80 W currency or forced coagulation mode with 50 W currency (Fig. 1G).

Hemostasis. Immediate hemostasis was attempted to obtain a clear endoscopic view, ie, good position without bleeding. When oozing was noted from a small vessel, the bleeding point was coagulated with the blade of the IT knife by using a forced coagulation mode with 50 W currency (Video 5, available online www.giejournal.org). When hemorrhage from larger vessels was observed, the bleeding point was coagulated with the coagulation forceps (FD-410LR; Olympus) by using the soft coagulation mode with 80 W currency. When large vessels were visible in the submucosa during dissection, they were precoagulated with a coagulation forceps by using the soft coagulation mode with 80 W currency (Video 6, available online at www.giejournal.org).

Retrieval of the specimen and coagulation preserving delayed hemorrhage. After removal of the area, the resected specimen was retrieved with the grasping forceps (FG-47L-1; Olympus). The ulcer base was washed out repeatedly and any adherent clots or suspicious protrusions were coagulated with a coagulation forceps by using the soft coagulation mode with 80 W currency to avoid delayed hemorrhage.

Histologic assessment

The specimen was pinned onto a hard Styrofoam plate (Dekopane, Koyo Sangyo Co Ltd, Tokyo, Japan) and immersed upside down in 20% formalin. Piecemeal resected specimens were reconstituted as possible, with an orientation of marking on the peripheral of the resected mucosa. The fixed specimen was serially sectioned at 2-mm intervals and was subjected to histologic examination. According to the Japanese classification of gastric carcinoma,[10] histologic type, the depth of invasion, the presence of ulcerative change, lymphatic and venous involvement, and the tumor involvement to the lateral (mucosal) margin and vertical (submucosal) margin were estimated.

Treatment protocol

The patients were admitted the day before ESD, had a 2-day fasting period after the procedure, and were discharged from the hospital on the 8th hospital day. In all eligible patients, en bloc resection by the ESD technique by using an IT knife was attempted. When the procedure could not be continued, the lesion was resected by the strip biopsy method in a piecemeal fashion.

The final tumor staging and prognosis for curability were determined by histologic examination of the resected specimens. We considered it to be curable when the completely resected specimen satisfied the following criteria and when the patients did not require additional therapy in the future: (1) differentiated-type histology, (2) intramucosal cancer, (3) no ulcer or ulcer scar, and (4) neither lymphatic nor venous involvement. In the case of possible lymph-node metastasis, submucosal invasion, lymphatic or venous involvement, or ulcerative changes, the patients were subjected to gastrectomy with lymph-node dissection.

End points

We evaluated the rate of complete resection as a primary end point. We defined complete resection as an en bloc resection without cancer involvement to the lateral and vertical margin of the specimen. Operation time, complication rate, and clinical outcomes were evaluated as secondary end points. Operation time was measured from the start of the marking until the end of removal of the tumor; it was divided into time for "mucosal incision" and that for "submucosal dissection" by completion of the circumferential mucosal cut. Complications included hemorrhage, perforation, and stenosis that were greater than grade 3 according to the National Cancer Institute's *Common Terminology Criteria for Adverse Events*, version 3.0.[12]

Follow-up examination on cancer recurrence and distant metastasis

Follow-up endoscopies were scheduled for the complete resection cases at 3 months, 12 months, and yearly thereafter. During the follow-up period, biopsy samples were taken from the ESD ulcer, scar, or other suspicious abnormalities. Local recurrence was defined as the presence of cancer cells in any of the biopsy specimens. We performed contrast-enhanced helical CT, US of the abdomen, chest radiography, and blood studies, including tumor markers yearly after EMR or when the patient complained of sickness.

Statistical analysis

For descriptive statistics, data were shown as median (interquartile range). We compared categorical variables with the χ^2 test and continuous variables with the Mann-Whitney U test. A P value less than .05 was considered to be significant in 2-sided tests.

OBSERVATIONS

Between July 2002 and December 2004, 95 patients with EGC larger than 3 cm presented to our center. Of

TABLE 1. Characteristics of the study subjects

Case	1st 10 cases (Jul 2 to Mar 3)	2nd 10 cases (Mar 3 to Feb 4)	3rd 10 cases (Feb 4 to Dec 4)	Total
Median age (IQR), y	74 (67-78)	67 (54-75)	67 (63-74)	69 (65-76)
Male/female	9/1	9/1	4/6	22(73%)/8(27%)
Location of EGC, U/M/L	2/5/3	0/2/8	6/2/2	8(27%)/9(30%)/13(43%)
Type of EGC, 0-I/0-IIa/0-IIc	1/6/3	1/6/3	2/6/2	4(13%)/18(60%)/8(27%)
Median tumor size (IQR), mm	41 (35.5-45)	35 (35-43)	43.5 (40-50)	40 (35-49)
Median length of stay after ESD (IQR), d	7 (4-15)	6 (4-8)	6 (6-7)	6 (5-7)

IQR, Interquartile range; *L*, lower third; *M*, middle third; *U*, upper third.

them, 32 patients who were diagnosed as having submucosal EGC, 23 patients with intramucosal EGC with ulcer or scar, and 10 patients with undifferentiated-type mucosal EGC underwent gastrectomy. Thus, a total of 30 consecutive patients were enrolled (Fig. 2). Characteristics of the subjects are shown in Table 1. We divided the 30 patients into 3 groups of 10 (1st, 2nd, and 3rd) to assess the learning curve. Age, sex, location, endoscopic type, and median tumor size were not statistically different among the groups.

Complete resection rate

Complete resection was obtained in 23 of 30 patients (77%). Complete resection rate was 50% in the 1st 10 cases and increased to 90% in the 2nd and 3rd 10 cases (Table 2), though this was not statistically significant. The 7 incomplete resection cases included 6 piecemeal resection cases and 1 case that had a positive vertical margin. In the 6 piecemeal resection cases, procedures were discontinued for technical difficulty (n = 4), bleeding (n = 1), or perforation (n = 1) during the submucosal dissection.

Operation time

Median operation time was 104 minutes (19-280 minutes). There was no significant difference among the 3 groups (Table 2). The submucosal dissection occupied about 75% of the operation time.

Complications

Six of 30 patients (20%) experienced complications. Blood transfusion was required in the first patient 5 days after the procedure secondary to bleeding. Hemorrhage arose in 3 patients on the night of the procedure, and 1 and 8 days after the procedure. This was treated by endoscopic reintervention with a coagulation forceps by using a soft coagulation current of 80 W. A perforation occurred in 1 patient during the procedure, and it was closed by endoscopic clipping. Stenosis was found in 1 patient with a tumor in the prepylorus and was treated by endoscopic balloon dilation. There were no severe complications that required surgery or resulted in major morbidity.

Treatment outcomes

Eighteen of the 23 complete resection patients were regarded as curable and were followed. Five of the complete resection patients were found to have submucosal invasion, and 3 of them were accompanied by lymphatic invasion. In 4 of 7 patients who had a incomplete resection and who underwent piecemeal resection, retrieved specimens were well reconstituted and fulfilled curable criteria by histologic assessment. The other 3 patients with a incomplete resection were found to have evidence of submucosal invasion. A total of 8 patients with submucosal invasion were referred for surgery, and 5 of them underwent gastrectomy with lymph-node dissection; the remainder refused surgery as a matter of personal preference. In patients who underwent surgery, no lymph-node metastasis was found. Thus, a total of 25 patients were followed without gastrectomy, for a median observation time of 25 months. No local recurrence, lymph-node involvement, or distant metastasis has been found to date (Fig. 2).

DISCUSSION

In this case series study, we demonstrated the technical feasibility of ESD for large intramucosal EGC with the IT knife. The possibility for cure from large intramucosal EGC by endoscopic resection could be demonstrated by complete removal of the tumor and assurance of a lack of lymph-node metastasis by histologic examination. En bloc resection is not absolutely necessary for complete removal of the tumor but is strongly preferred to piecemeal resection for elimination of local recurrence and improvement of histologic assessment.

In this study, we achieved a complete resection rate of 77% for EGC that exceeded 3 cm. Complete resection rates of EMR with an IT knife vary among the reports from 25% to more than 90%.[6,9,13,14] The wide variations might be partly caused by a learning curve. Choi et al[15] indicated that the complete resection rate significantly increased after 40 patients. Our operator demonstrated improvement

TABLE 2. CR rate, resection time and complication rate of ESD

Case	First 10 cases (Jul 2 to Mar 3)	Second 10 cases (Mar 3 to Feb 4)	Third 10 cases (Feb 4 to Dec 4)	Total
CR (%)	5 (50)	9 (90)	9 (90)	23 (77)
Median operation time (IQR), min	131 (68-280)	72 (19-164)	121 (79-280)	104 (19-280)
Mucosal incision time	40 (32-44)	15 (9-17)	37 (23-43)	26 (16-40)
Submucosal dissection time	109 (73-132)	62 (43-82)	89 (67-101)	79 (61-105)
No. of complications	5 (50%)	1 (10%)	0	4
Bleeding	3	1	0	4
Perforation	1	0	0	1
Stenosis	1	0	0	1

CR, Complete resection; *IQR*, interquartile range.

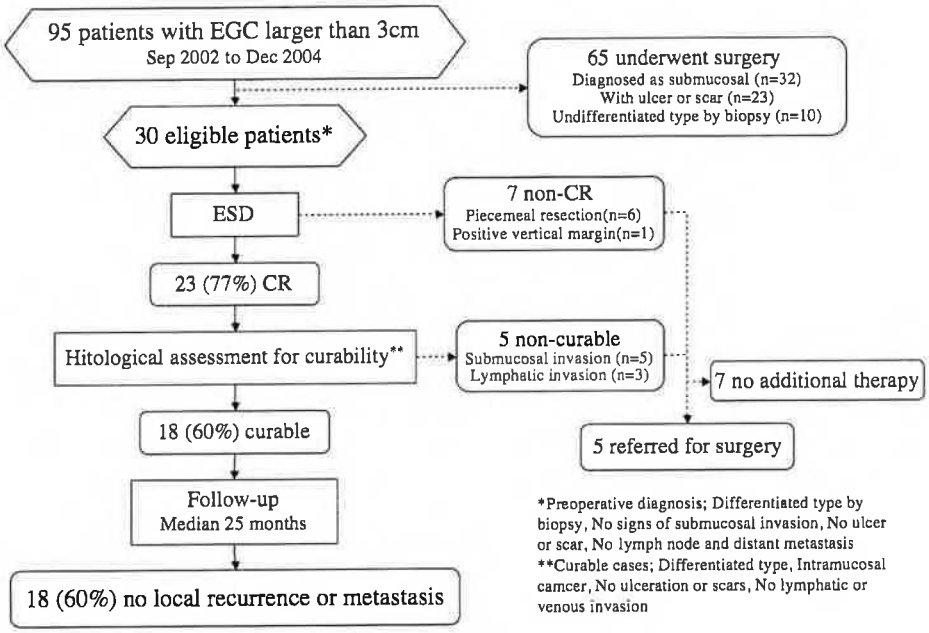

Figure 2. Clinical courses of the patients with large EGC during the study period in our center.

after only 10 cases; this accelerated learning curve was likely attributable to his experience with 180 conventional EMRs and his expertise with emergency hemostasis. Choi, however, stated that he performed only 10 standard EMRs and observed 15 procedures before performing the study.[15] It is highly likely that the establishment of required expertise or a training system such as a model or a simulator would be expected to decrease the amount to time to achieve proficiency.

In this study, pretreatment assessment of tumor depth was made by conventional endoscopy (29 cases) or EUS (1 case), and it was correct in 73.3% of cases (22/30). The invasion depth was underestimated by conventional endoscopy, because some of the tumors invaded in a small area without morphologic change. Yanai et al[16] reported in a prospective study that the overall accuracy rate of assessing EGC invasion depth was 63% for conventional endoscopy and 71% for EUS, which was largely consistent with our experience. Although diagnostic accuracies for tumor depth of EGC by images depend on volumes of hospitals or experience of examiners, EUS provides generally better accuracy and higher reproducibility in combination with conventional endoscopy.[17] Despite the apparent advantage of EUS, we do not perform it on all patients, because it has a tendency to overestimate tumor depth and lead to unnecessary surgery in some cases. In the same period of our study, 14 patients with EGC received EUS before surgery in our center because of difficulty in

determining the tumor depth by conventional endoscopy. The depth was predicted to be submucosal for 11 patients, but 7 of them were later shown to have intramucosal cancer by histologic assessment of the surgically resected specimen. Yanai et al[18] suggest that patients can make a better informed decision regarding treatment when an accurate diagnosis is made by strip biopsy rather than one based upon inaccurate pretherapeutic information. Although diagnostic modality should not have a higher rate of complication associated with the procedure, accuracies for staging by images were ultimately limited. Therefore, we believe that, for a patient who has the possibility of a cure by mucosal resection, ESD offers the advantage of not only representing a therapeutic procedure but also serving as a diagnostic modality to decide whether or not the patient necessitates lymph-node dissection with gastrectomy. However, this concept cannot be overemphasized unless full attempts were made at preoperative diagnosis and careful explanation about the possibility for additional surgery was discussed with the patients before ESD.

Operation time did not improve in this study. Imagawa et al[19] indicated that complete resection rate was lower, and the longer procedure time was required for the tumor in the gastric body. In our study, most of the tumors were located in the antrum in the 2nd group of 10 cases, whereas, most of them existed in the gastric body in the 3rd group of 10 cases; therefore, the bias in the tumor location might affect the operation time.

We think the major limiting factor for the operation time was the process of submucosal dissection. The submucosal dissection was technically challenging and occupied most of the operation time. In the early period, we used a snare to shorten the process, but it rendered piecemeal resection unless at least 80% to 90% of the areas were dissected. Thus, it was absolutely necessary to achieve complete resection for the large lesions, even if we finally used the snare cutting. During submucosal dissection in the gastric body, spurting hemorrhage from large vessels occurred more frequently and the submucosa was more fibrous and required more technique for dissection, thus causing oozing hemorrhage, which interrupted the procedure. We think a key to improve the long operation time will be to better control hemorrhage during the submucosal dissection.

We chose the IT knife for this study because it was the first endoknife that was used for ESD in the stomach, and its usage had been most established when we conducted the study. Now, many devices have been developed for ESD in the various organs. The Hook knife (KD-620LR; Olympus) is a kind of needle knife that has an angulated L-shaped tip.[20] Although the amount of dissectable submucosa is restricted, a Hook knife is relatively safe because it cuts the submucosa by hooking and pulling and allows the user to directly view the area being cut. The Flex knife (KD-630L; Olympus) was modified from a thin snare (SD-7P-1; Olympus); actually, the developers originally used a very short (1-2 mm) projected thin snare.[21] Its flexibility offers good maneuverability and relative safety, although there is technical difficulty in keeping the projection length of the knife during the procedure. One of the newest devices, the Flush Knife (DK2618JN10-30; Fujinon Toshiba ES Systems Co, Ltd, Tokyo, Japan) is equipped with a unique water jet function from the tip of the short needle knife.[22] It allows one to wash out blood shed or coagula instantly for finding bleeding points and obtaining a clear view. In addition, the water jet permits one to add saline solution into the submucosa without needle injection. We are expecting that those functions will help to shorten the operation time.

In conclusion, we found that ESD was effective for local treatment in selected patients with a large intramucosal EGC, although it has the limitation of a long operation time. A larger number of patients will need to be followed prospectively to better assess long-term outcomes.

DISCLOSURE

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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De novo stent-stone complex after long-term biliary stent placement: pathogenesis, diagnosis, and endotherapy

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Background: Long-term and permanent biliary stenting have been reported in many studies and are infrequently practiced in selected patients with irretrievable common bile duct stones and biliary strictures.

Patients: Here we report 3 new cases and review 7 other cases of de novo stent-stone complex formation after long-term biliary stent placement.

Interventions: De novo stent-stone complexes developed in 3 young patients after unintended long-term biliary stent placement of 4.5 to 11 years' duration. The stent-stone complexes were successfully removed during ERCP with electrohydrolic lithotripsy (EHL) in combination with choledochoscopy or extracorporeal shock wave lithotripsy (ESWL) with mechanical lithotripsy (ML).

Results: The de novo radiolucent stones formed around and above the stent in the proximal and end part of the stent. The stones were generally large with a diameter >2 to 3 cm. The stent-stone complex usually assumed a 1-sided dumbbell configuration inside the bile duct. The mean duration to clinical presentation after initial biliary stenting is 5.64 years (range 2-11 years).

Conclusions: It is important to keep in mind that a biliary stent can act as a nidus for new biliary stone formation around the stent after long-term placement. We recommend that the optimal endotherapy in this situation is ML for the free-floating complexes with short stents, and choledochoscopy with EHL or laser lithotripsy and ESWL for impacted complexes with longer stents.

Long-term and permanent biliary stenting have been reported in many studies and are infrequently practiced in selected patients with irretrievable common bile duct (CBD) stones and biliary strictures who are too high risk for surgical procedures or aggressive endoscopic management.[1-15] Occasionally, long-term biliary stenting occurs when patients are lost to follow-up for various reasons. The well-known complications related to long-term biliary stent placement include stent occlusion, biliary colic, cholangitis, stent migration, stent-induced ulceration, fistula formation,

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Endoscopic submucosal dissection in patients with early esophageal squamous cell carcinoma: results from a prospective Western series

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Background: Although endoscopic submucosal dissection (ESD) is becoming accepted as an established treatment for superficial esophageal squamous cell neoplasia, the majority of data on this endoscopic modality has been provided by Japanese series.

Objective: To assess the efficacy and safety of ESD for esophageal squamous cell neoplasia in a consecutive series of patients treated in a Western setting.

Design and Setting: Single-center, prospective observational study.

Patients and Intervention: From January 2005 to July 2008, 20 patients with superficial esophageal squamous cell neoplasia were treated by ESD.

Main Outcome Measurements: Rates of en bloc resection, complete resection, and complications were evaluated as short-term outcomes. Overall survival, local or distant recurrence, and postoperative stricture rates were evaluated as long-term outcomes.

Results: ESD was performed in 20 patients (mean age 64 years, range 46-81 years; 16 men). The mean size of the lesion was 32 mm (range 15-60 mm); it was 30 mm or larger in 14 patients (70%). The mean time of ESD was 89 minutes (range 58-180 minutes). En bloc resection with resection-free margins was achieved in 18 patients (90%), whereas 2 patients presented with incomplete or indeterminate resection. Two cases (10%) of mediastinal emphysema without overt perforation and 1 case (5%) of post-ESD symptomatic stricture were reported. No local or distant post-ESD recurrence occurred in those with resection-free margins at a median follow-up of 18 months.

Limitations: Small number of patients and limited follow-up.

Conclusion: This Western series study confirms that ESD is a potentially curative treatment for superficial esophageal squamous cell neoplasia. Early and late complication rates were comparable to those of Japanese series. ESD should be probably considered as the treatment of choice in all large lesions amenable to endoscopic treatment. (Gastrointest Endosc 2010;71:715-21.)

The incidence of squamous cell cancer of the esophagus has been estimated to range between 4 and 16 cases per 100,000 in Western populations, representing nearly half of all the diagnosed esophageal carcinomas.[1] Surgical treatment has been associated with high morbidity and mortality rates, especially in patients at high risk of surgery.[2,3] For this reason, when the disease is limited to the esophageal mucosa, EMR has been shown to be a safer alternative, with long-term survival outcomes similar to those achieved with surgery.[4-7] However, EMR is hampered by some technical limitations. Less than half of the patients treated with EMR have been reported to have an en bloc resection, and, in particular, en bloc resection of lesions larger than 20 mm is extremely difficult.[4-9] More-

Abbreviation: ESD, endoscopic submucosal dissection.

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over, post-EMR recurrence or metachronous carcinoma was reported to occur in as many as 26% of the cases.[4-12] To overcome these limitations, endoscopic mucosal dissection (ESD) was developed.[13] ESD enables the operator to achieve an en bloc resection regardless of the tumor size. Despite the technical difficulties, ESD was shown to be an effective and relatively safe treatment for the squamous cell cancer of the esophagus.[8,14,15] However, all of these preliminary applications of ESD have been exclusively performed in Asian countries, presumably because of the higher numbers of patients diagnosed with early esophageal cancer during screening endoscopy for asymptomatic subjects.[16] On the other hand, no Western series on ESD for squamous cell cancer of the esophagus has been reported.

We therefore conducted this study to investigate the safety and efficacy of ESD in a Western setting.

Capsule Summary

What is already known on this topic

- Endoscopic mucosal dissection (ESD) facilitates en bloc resection, regardless of tumor size.

What this study adds to our knowledge

- In a single-center, observational study, ESD achieved en bloc resection with resection-free margins in 18 of 20 patients with superficial esophageal squamous cell neoplasia.
- No local or distant recurrence occurred at a median follow-up of 18 months.

PATIENTS AND METHODS

From 2005 to 2008, 28 patients with squamous cell esophageal cancer that was presumed to be confined to the superficial layers were referred to our center to undergo an ESD. According to a center protocol, all patients underwent (1) CT of the neck, chest, and abdomen; (2) EUS; and (3) chromoendoscopy after direct instillation of 1.5% iodine solution. Only patients in whom the cancer appeared to be confined to the esophageal mucosa were selected for ESD treatment. Informed consent was obtained in all patients before ESD was performed. The data for the patients and lesions were stored consecutively in a database that included the location and size of the tumors, the histologic findings of the resected specimens, the details of the procedure, and the follow-up examinations. Retrospective analysis was approved by the Institutional Review Board of the Humanitas Hospital.

ESD

ESD was usually performed with the patient under deep sedation by periodic intravenous administration of diazepam and propofol. If deep sedation was considered inappropriate because of patient's condition or expected long duration of the procedure (>90 minutes), general anesthesia was used. ESD was performed by using a hook-knife (Olympus, Milan, Italy) as previously described.[8,13-15] Briefly, a forward-viewing, single-channel endoscope (GIF-Q165/160T; Olympus) with a distal attachment (D-201-11804; Olympus, Milan, Italy) on its tip was introduced. The transparent attachment was fitted on the tip of the endoscope mainly to obtain a constant endoscopic view and to create tension on the connective tissue for the submucosal dissection. Lugol chromoendoscopy was necessary before marking the lateral margin of the lesion, which could be visualized as the border between the stained and unstained areas. Marking dots were made with the hook-knife 2 to 3 mm outside the margins of the lesion. A mixed solution of saline and hydroxylpropyl methyl cellulose that contained 0.005 mg/mL epinephrine and few drops of a blue dye was injected into the submucosa, and the mucosa was incised outside the marking dots with the hook-knife by using the Endocut mode of an electrosurgical generator (ICC 200; Erbe, Tubingen, Germany). The diseased mucosa was then separated from the muscularis propria by injection of the same solution into the submucosa with an injection needle. The submucosal connective tissue just beneath the lesion was dissected from the muscle layer by using the hook-knife and the IT-knife with a forced coagulation current (40 W). Injections were repeated as needed, and a further resection was progressively carried out until total removal of the lesion was achieved. To control bleeding, hemostatic forceps (FD-410LR; Olympus) was used in soft coagulation mode (40-W output).

After resection, all patients were treated with a full dose of an intravenously administered proton pump inhibitor (omeprazole 80 mg). The day after the procedure, if the patients' symptoms, laboratory findings, and chest radiograph were unremarkable, a light meal was permitted, and the patients were discharged within few days. If complications occurred, the schedules were changed according to the individual patient's condition. All of the procedures were performed by a single operator (A.R.) who had completed a training program with live pigs and isolated stomach under tutoring of Japanese experts.

Complications

Bleeding related to the procedure was defined as bleeding that required hemostatic treatment, such as thermocoagulation and endoscopic clipping. Perforation was diagnosed when mediastinal connective tissue was observed during the procedure. Mediastinal emphysema was diagnosed by the presence of air in the mediastinal space on plain radiography. A postoperative stricture was defined as a stricture that required endoscopic treatment.

Histologic assessment

The resected specimens were fixed on a piece of cork and immersed in 4% formalin. The specimens were embedded in 10% paraffin, cut into 2-mm slices, and stained with hematoxylin and eosin. The tumor size, depth of invasion, lymphovascular invasion, grade of differentiation, and resection margins were examined histopathologically. The depth of invasion was subclassified as intraepithelial cancer (m1), cancer invading the lamina propria mucosae (m2), and cancer invading the muscularis mucosae (m3).[7] In patients in whom the cancer was invading the superficial portion of the submucosa, the invasion depth was defined as sm1. The resection was expressed as complete (R0), incomplete (R1), or not possible to establish (Rx), depending on the basal and lateral border involvement by the pathological process.

Follow-up

Post-ESD surgery was considered for all patients with submucosal involvement or those with a lymphovascular invasion at histology. When surgery was performed, a postsurgical TNM staging was always obtained. In those patients in whom ESD was considered the definitive treatment, an upper GI endoscopy with iodine staining was performed at 1, 3, 6, and 12 months, and a chest-abdominal CT scan was performed at 6 and 12 months. Local recurrence was considered positive when cancer cells were histologically verified at the site of the ESD.

RESULTS

Characteristics of the study population

Eight (28.5%) of the 28 patients initially considered for ESD were excluded after accurate staging. The main reason for exclusion was submucosal invasion in 6 (21.4%) patients and the presence of lymph node or distant metastasis in 2 (7.1%) patients.

ESD was performed in 20 patients (mean age 64 years, range 46-81 years; 16 men) during the study period. The clinicopathological characteristics of the 20 squamous cell carcinomas are reported in Table 1. Overall, 4 (20%) carcinomas were located in the upper esophagus, 11 (65%) in the middle third, and 3 (15%) in the lower third. The mean size of the lesion was 32 mm (range 15-60 mm), being 30 mm or larger in 14 (70%) patients. The macroscopic type was IIa in 9 (45%) patients, IIb in 6 (30%), IIc in 2 (10%), and IIa + IIc in the remaining 3 (15%) patients.

TABLE 1. Clinicopathological characteristics of the patients with squamous cell esophageal cancer treated with endoscopic submucosal dissection

Patients	Age (y)/sex	Esophageal site	Size (mm)
1	57/M	Medium	40
2	81/M	Medium	34
3	68/F	Lower	40
4	63/M	Medium	60
5	70/M	Medium	25
6	64/M	Medium	30
7	72/M	Upper	28
8	70/F	Lower	30
9	56/M	Medium	36
10	55/M	Medium	15
11	49/M	Upper	20
12	64/M	Upper	34
13	66/M	Medium	40
14	58/M	Medium	45
15	46/M	Medium	30
16	69/M	Medium	25
17	69/M	Medium	40
18	73/F	Upper	30
19	60/F	Lower	25
20	62/M	Medium	30

ESD

The mean time of the procedure was 89 minutes (range 58-180 minutes), being more than 80 minutes in 8 (40%) patients (Table 2). At endoscopy, en bloc resection of the lesion was successful in all 20 (100%) patients (Fig. 1). Minor bleeding occurred in all of the dissections, but prompt hemostasis was achieved with thermocoagulation. Two (10%) cases of mediastinal emphysema occurred, even though both the procedures were apparently completed without an endoscopically recognizable perforation of the esophageal wall. Both patients recovered well with conservative management and were hospitalized for 5 and 7 days, respectively. Eventually, 1 of these patients was operated on for other reasons. One (5%) case of post-ESD symptomatic stricture occurred in a patient in whom the resected area involved half of the esophageal circumference. The stricture was diagnosed 30 days after the procedure because the patient reported dysphagia for solid and semisolid foods (Fig. 2). At endoscopy, it was impossible to pass the fibrotic stricture located at the middle part of the esophagus. Multiple biopsies were performed to rule out the presence of neoplastic tissue at the site of the stricture. The patient was successfully treated with 3 sessions of Savary dilation and was symptom free at 10-month follow-up.

Histopathological analysis and follow-up

Resection-free margins were achieved in 18 (90%) patients. Only 2 patients with 20-mm and 36-mm lesions

TABLE 2. Technical features of the endoscopic submucosal dissections and histopathological characteristics of the resected specimens

Pt	ESD time (min)	En bloc resection	Complications	Resection margins	Depth of invasion	Grade of differentiation	Post-ESD surgery	Post-ESD FU (mo)	Post-ESD cancer
1	80	Yes	No	R0	m2	Well	No	30	No
2	68	Yes	No	R0	m3	Well	No	28	No
3	84	Yes	No	R0	m2	Well	No	26	No
4	180	Yes	Emphysema	R0	m1	Moderate	No	20	No
5	100	Yes	No	R0	m2	Poor	No	18	No
6	66	Yes	No	R0	m2	Moderate	No	22	No
7	58	Yes	No	R0	m2	Moderate	No	16	No
8	80	Yes	No	R0	m2	Moderate	No	18	No
9	60	Yes	Emphysema	Rx	sm1	Well	Yes	11	No (surgery)
10	80	Yes	No	R0	m2	Moderate	No	22	No
11	78	Yes	No	R1	sm1	Moderate	Yes	24	No (surgery)
12	80	Yes	No	R0	m2	Well	No	20	No
13	66	Yes	No	R0	m2	Moderate	No	14	No
14	120	Yes	Stricture	R0	m2	Well	No	10	No
15	70	Yes	No	R0	m1	Well	No	12	No
16	150	Yes	No	R0	m1	Moderate	No	12	No
17	88	Yes	No	R0	m2	Poor	No	18	No
18	100	Yes	No	R0	m2	Well	No	22	No
19	66	Yes	No	R0	m2	Moderate	No	16	No
20	110	Yes	No	R0	m3	Well	No	20	No

Pt, patient; *ESD*, endoscopic submucosal dissection; *FU*, follow-up.

presented with incomplete (R1) or indeterminate (Rx) resection, respectively. Regarding depth of invasion, intraepithelial cancer (m1) was diagnosed in 3 (15%) patients, cancer invading the lamina propria mucosae (m2) in 13 (65%), and cancer invading the muscularis mucosae (m3) in 2 (10%), whereas submucosal invasion (sm1) was reported in the remaining 2 (10%) patients. Of note, the 2 patients with sm1 cancer were the only patients in whom a R0 resection was not achieved.

Based on the endoscopic and histopathological data, post-ESD surgery was required only for 2 (10%) patients (Fig. 3), whereas 18 (90%) were scheduled for periodic follow-up. In the 2 patients with m3 staging, the potential indications for surgery were discussed with pathologists, surgeons, and oncologists at our institution, and the decision was made not to refer them to surgical resection because of the high-grade of differentiation of the disease, the absence of lymphovascular involvement, the tumor-free margins, and the absence of regional lymph node at EUS examination. Postsurgical TNM staging was T1N1M0 and T1N0M0 in the 2 patients operated on, respectively. In the patients not operated on, median follow-up was 18 months (range 11-30 months). No local or distant recurrence was reported.

DISCUSSION

Our study shows that ESD is a greatly effective, technically feasible, and relatively safe treatment for selected squamous cell esophageal carcinomas in a Western setting. The 90% rate of en bloc R0 resections is in line with the rates of 78% to 93% reported by 3 previous Japanese series.[8,14,15] Similarly, the 15% major complication rate is within the 13% to 22% range extrapolated from the Asian studies.[8,14,15]

When dealing with a potentially metastasizing cancer, the risk of lymph node or distant metastasis could outweigh the apparent safety of endoscopic cancer treatments, so that the use of these techniques as a valid alternative to esophagectomy has been questioned.[17] In

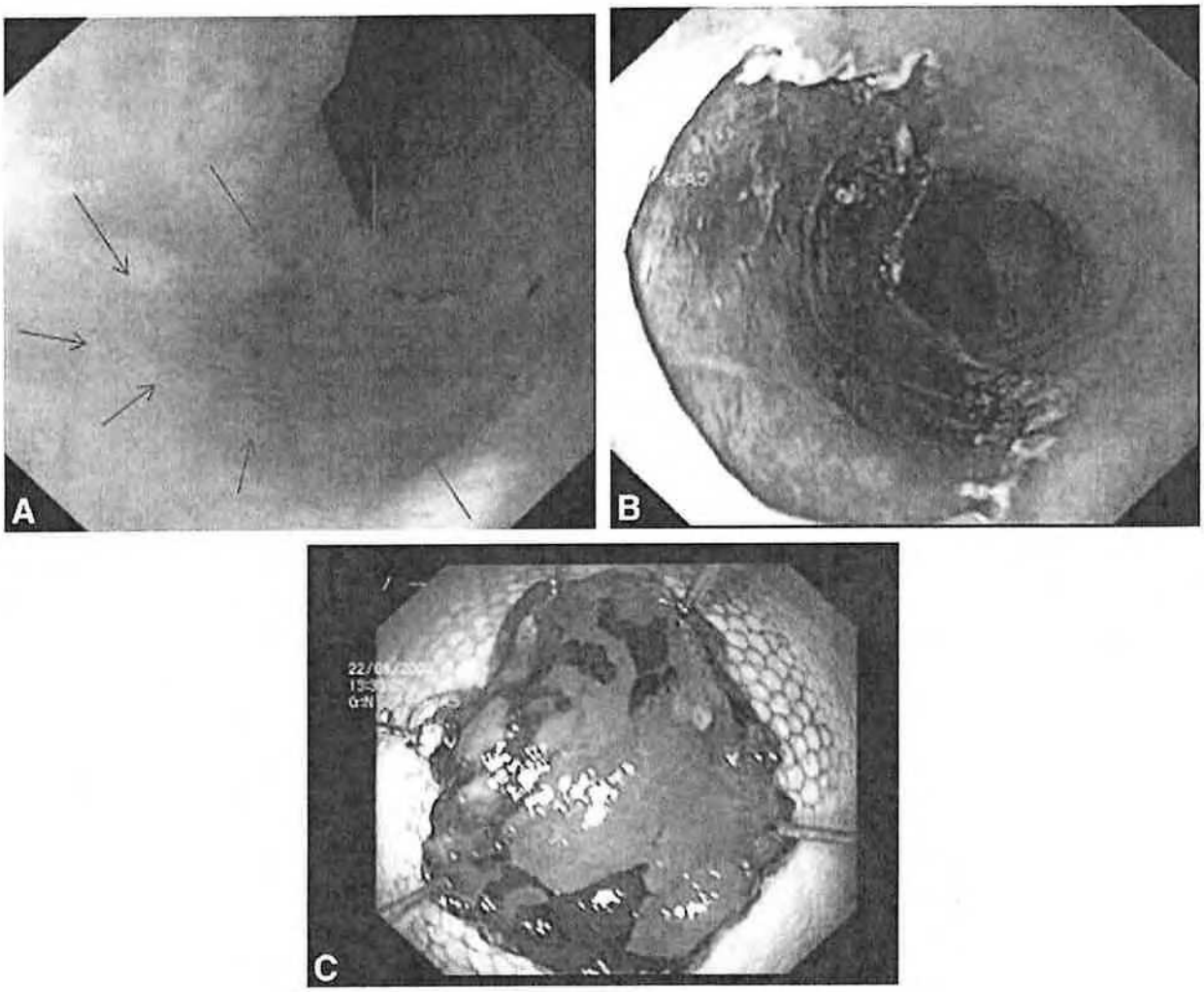

Figure 1. A, 3-cm superficial squamous cell carcinoma presenting as irregular area of the thoracic esophagus under conventional white light. **B,** The artificial ulcer after resection has been completed and **C,** the resected specimen with the lesion in en bloc fashion is shown.

our study, none of the patients in whom ESD was performed as definitive treatment presented with local or lymph node metastasis at 19 months of follow-up, confirming the previous reports.[8,14,15] There may be at least 2 main explanations for such a very high success rate. When dealing with large lesions, ESD allows en bloc resection in the majority of the patients. This represents a substantial improvement compared with EMR, in which en bloc resection of carcinomas 20 mm or larger was feasible only in 4% to 43% of the cases because of the intrinsic limits of the technique.[4-12] The higher efficacy of ESD compared with that of EMR is also confirmed by the net difference of local recurrence rates. In our study, no local recurrence was observed, similar to previous Japanese studies, in which 0% to 3% rates were reported in those with a R0 ESD.[8,14,15] On the other hand, post-EMR local recurrence rate has been consistently shown to be as high as 26%.[4-12] Interestingly, a large size, an extensive circumferential spread, and a multifocal pattern have been shown to be independent predictors of post-EMR local recurrence, suggesting that ESD would be a valuable alternative in these selected cases.[11] Second, post-ESD histopathological staging allows a clinically meaningful stratification of patients according to the risk of lymph node metastasis. In particular, revision of large series has unequivocally demonstrated a virtually 0% risk of lymph node involvement when the depth of invasion is limited to m1 or m2 layers, increasing the risk to 9% and 19% for m3 and sm1 involvement, respectively.[18] Lymphovascular invasion and a poor differentiation grade were also shown to predict the spread of the disease to the lymph nodes.[7] When comparing the extremely low risk, if any, of metastasis in patients with favorable post-ESD staging with 55% and 3% rates of surgery-related morbidity and mortality, respectively,[2,3] ESD seems to be a more acceptable option than surgery.[16] The efficacy of surgery is also greatly reduced in patients with esophageal

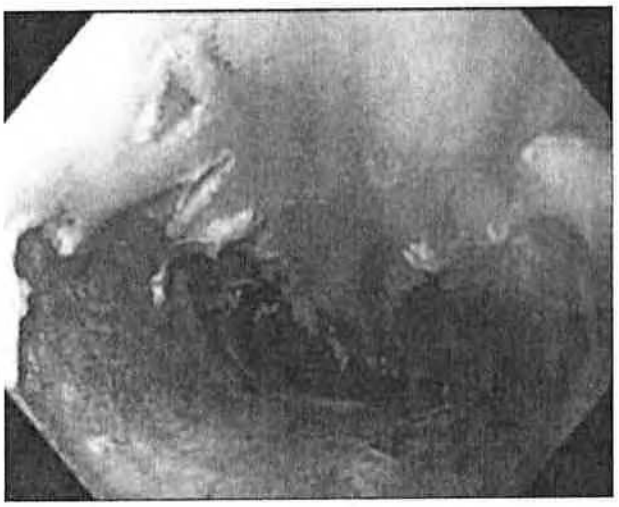

Figure 2. Semicircumferential artificial ulcer after en bloc resection for a large superficial squamous cell carcinoma. An esophageal stricture developed in the patient a few weeks after resection.

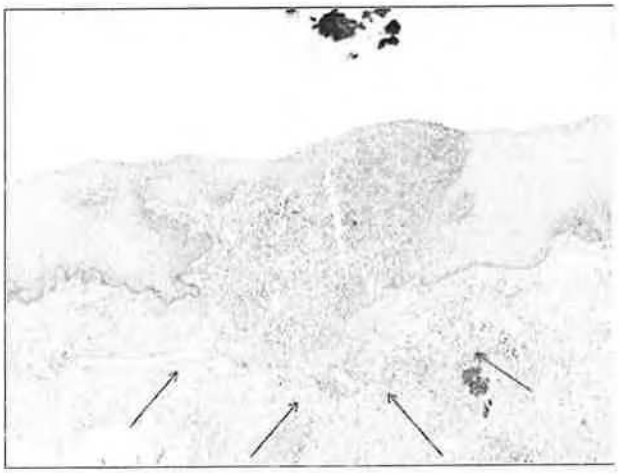

Figure 3. Histopathological view of a small superficial squamous cell carcinoma invading the submucosa.

cancer with already-developed lymph node or distant metastasis, with disappointing 5-year survival rates of 18% and 3%, respectively.[19] Therefore, ESD should not be considered an irreversible alternative to surgery, but, on the contrary, as an efficient means to select those patients in whom surgery may be substantially more effective than endoscopic treatment. In our series, 10% of the patients were referred to surgery because of unfavorable post-ESD staging, which is consistent with a previous report.[8,14,15]

From a technical point of view, ESD seems to be a demanding procedure even for ESD-dedicated endoscopists. This is because the esophageal wall is thinner than that of the stomach, and moves with respiration and heart beat. Moreover, the esophageal lumen is narrow, precluding knife maneuverability and endoscope retroflexion, at least with standard instruments. For these reasons, ESD seemed to be a very time-consuming procedure in our experience, in agreement with the previous reports.[8,14,15] This represents a clear disadvantage compared with EMR, which has been shown to be a simple and user-friendly technique requiring a relatively short period of time.[4-12] Moreover, ESD seems to be associated with a relatively high risk of major complications, such as emphysema and strictures, occurring in 15% of cases in our experience. Such complication rates seemed to be substantially higher than those reported for EMR, ranging between 2% and 6%.[8,14,15] Therefore, when addressing technical feasibility and safety issues, EMR would represent an apparently attractive alternative to ESD. However, such technical appeal needs to be balanced with the much higher possibility of achieving an en bloc resection with ESD compared with EMR. When considering that the therapeutic target is cancer, minimizing the chance of local recurrence should be regarded as an absolute priority.[16] For this reason, the risk/benefit profile of ESD seems favorable, especially for large lesions, in which EMR performs poorly. It should also be emphasized that none of the complications required a surgical intervention, being conservatively treated in a few days, in agreement with previous reports.[8,14,15] Of note, after collection of nearly 300 cases in the literature, the death rate of ESD for esophageal cancer is still 0%.[8,14,15]

There are limitations to this study. We did not include an EMR arm as a control. However, a previous retrospective comparison of EMR and ESD showed such a large discrepancy regarding en bloc resection for large lesions that it is unlikely that future studies may contradict this evidence.[8] Overall, we included 20 patients, so that a small sample size error may not be excluded. However, when dealing with a 90% efficacy rate, such a possibility is minimized. Our selection protocol was very rigid, including a combination among chromoendoscopy, EUS, and CT. It cannot be excluded that less rigid inclusion criteria could increase the rate of submucosal cancers, apparently reducing ESD efficacy.

In conclusion, our study showed that ESD is a successful and relatively safe treatment for squamous cell cancer of the esophagus, fulfilling the criteria of lymph node–negative tumors. When combining our Western experience with that of the previous Asian series, ESD should probably be considered the treatment of choice in all large lesions amenable to endoscopic treatment.

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ORIGINAL ARTICLE: Experimental Endoscopy

Prospective, randomized study of conventional versus HybridKnife endoscopic submucosal dissection methods for the esophagus: an animal study

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Background: Endoscopic submucosal dissection (ESD) increases en bloc and histologically complete resection rate of neoplastic mucosal tumors but is technically more demanding than EMR. Limited data are available comparing the efficacy and safety of a new ESD designed to overcome these limitations and conventional ESD (C-ESD) techniques.

Objective: To compare the safety, efficacy, and operation time of the new HybridKnife ESD (HK-ESD) with C-ESD in the esophagus.

Design: Prospective, randomized, controlled study.

Setting: Animal research laboratory.

Subjects: Seventeen anesthetized Yorkshire pigs.

Interventions: Removal of a 4-cm length of half-circumference esophageal mucosa by C-ESD with Hook knife or Flexknife versus HK-ESD.

Main Outcome Measurements: Procedure time, en bloc and complete resection rate, and complications (bleeding and perforation).

Results: All resections were completed en bloc. Procedure time was shorter in C-ESD. However, it was similar after 12 procedures. Significantly more bleeding occurred during C-ESD (28 vs 12, $P = .0007$). Histological muscularis propria injuries occurred with equal frequency (16 vs 17) and were mostly seen during the first 11 procedures. There were 3 perforations (2 endoscopic, 1 histological), all with C-ESD.

Limitations: Nonsurvival study, use of 2 conventional knives, no training period for a new procedure.

Conclusions: The HK-ESD technique was equally effective as the C-ESD technique for successful en bloc resection and was safer with less bleeding and perforation. Although procedure time was longer in HK-ESD, the difference became nonsignificant after 12 procedures. (Gastrointest Endosc 2011;73:1246-53.)

EMR is now widely accepted as the standard treatment strategy for early gastric cancer because it is less invasive than surgical resection.[1,2] Endoscopic submucosal dissection (ESD) was introduced in Japan to overcome the main shortcoming of EMR, ie, a relatively high recurrence rate. ESD increases the en bloc and histologically complete resection rate and may reduce local recurrence.[3,4] EMR is an accepted method for the removal of nodular dysplasia

Abbreviations: C-ESD, conventional endoscopic submucosal dissection; ESD, endoscopic submucosal dissection; HK-ESD, endoscopic submucosal dissection with HybridKnife; MP, muscularis propria.

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in Barrett's esophagus.[5] Similar results of high residual and recurrence rates of dysplasia or cancer by piecemeal resection EMR have been reported in Barrett's esophagus,[6,7] and ESD may be more appropriate for selected patients with extensive or a large area of nodularity to reduce residual disease and local recurrence. With refinement in the methodology and equipment, ESD is increasingly gaining acceptance worldwide.[8,9] However, ESD has some limitations. Compared with EMR, ESD requires a longer procedure time, is technically more demanding, and is associated with a higher complication rate, especially perforation.[10] To overcome these limitations and decrease procedure complications, improvements in the equipment and the techniques are essential. Standardization of this procedure would further improve its acceptance worldwide.[11]

A new system, the HybridKnife, combines electrosurgical technology with a novel water-jet system (ERBEJET 2; ERBE, Tübingen, Germany) that allows rapid needle-free infusion of saline solution in the submucosa to lift a target mucosal lesion.[12,13] Marking, injection, mucosal incision, submucosal dissection, and quite often hemostasis can be performed with this one instrument. This new ESD device may increase the safety of ESD and shorten the procedure time compared with conventional ESD (C-ESD).[14,15] The aim of this study was to compare the efficacy, operation time, and safety of C-ESD techniques and of the new HybridKnife ESD (HK-ESD) for esophageal ESD in the porcine model.

MATERIAL AND METHODS

This was a prospective, randomized trial comparing 2 different modalities (C-ESD knives and HybridKnife with ERBEJET 2 water-jet system) for the removal of target esophageal mucosa. This study was approved by the Institutional Animal Care and Use Committee.

Animals

Seventeen Yorkshire pigs weighing 44.5 to 60 kg were used.

Study design

Each pig was to undergo 3 removals of esophageal mucosa of half circumference, each 4 cm in length and 2 cm apart. The devices to be used for each resection site were assigned randomly by using a computer-generated randomization sheet. Completion time of each resection was documented, and the resected specimen was retrieved and evaluated for completeness. To assess procedure complications, an independent assessor documented events during the procedure. Intra- and postprocedure perforation assessment was performed with endoscopic video images, leak test, gross tissue examination, and microscopic tissue examination.

Take-home Message

- The new endoscopic submucosal dissection (ESD) knife (HybridKnife), designed to improve the safety and ease of esophageal ESD, was shown to be equivalently effective as conventional ESD and was safer with fewer complications in the porcine model. This new technology may facilitate the use of ESD of esophageal disease in humans.

Pigs were euthanized after the completion of the procedures, and the esophagus of each was harvested. Gross specimen inspection and histopathological examination were performed by 2 pathologists blinded to the type of ESD performed.

Procedures

Devices and settings. An 8.6-mm gastroscope (GIF 160; Olympus Medical Systems, Center Valley, Pa) was used for all the procedures with a distal attachment cap (D-201; Olympus Medical Systems). Three different knives were used for ESD. C-ESD was performed with either a Hook knife or FlexKnife (KD-620LR and KD-630L; Olympus Medical Systems). HK-ESD was performed with the HybridKnife with the ERBEJET 2 water-jet system (ERBE). The HybridKnife is a 5 mm long and 0.7 mm in diameter electroconductive retractable needle with a micronozzle; the catheter is 220 cm long and 1.7 mm in diameter (Fig. 1.) In combination with ERBEJET 2 water-jet system, this needle produces a 120-μm stream of water at high pressure that can penetrate the mucosa without incision or puncture. In addition, this needle serves as a cutting and coagulation electrode.

The VIO generator (VIO 300D; ERBE) was used for all ESD procedures as an electrosurgical generator. The settings for each knife were as follows: conventional knives used Endocut Q 2-2-1 for marginal incision and Swift coagulation E2 40 W or forced coagulation E1 20 to 40 W for submucosal dissection. The HybridKnife used Endocut Q 2-4-1 for marginal incision and Endocut D 1-3-3 for submucosal dissection. SOFT coagulation E 5-7 80 W was used for all knives to mark the target area.

Injection solution was prepared as follows: C-ESD used 0.5% carboxymethylcellulose mixed with methylene blue, whereas the ERBEJET 2 water-jet system for HK-ESD used 0.9% saline solution with methylene blue. A 23-gauge sclerotherapy needle was used to inject the solution for C-ESD.

C-ESD and HK-ESD techniques. Two experienced endoscopists (C.B.R., N.F.) performed all procedures; both had performed hundreds of EMRs and C-ESDs in the clinical setting.

The pigs were anesthetized with tracheal intubation. First, each target area or pseudo-lesion was marked with

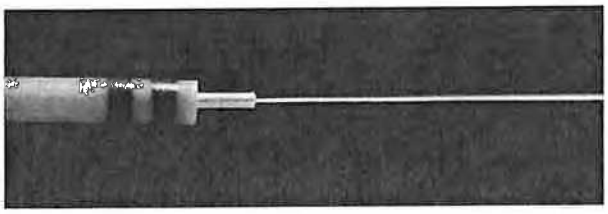

Figure 1. Needle-less HybridKnife with water-jet nozzle.

the assigned knife using the SOFT coagulation mode starting 5 cm proximal to the gastroesophageal junction within the esophagus. The markings encircled half circumference of the esophageal lumen measuring 4 cm in length, representing the area to be removed. Once the targeted area was removed by using the assigned ESD technique, the next half circumference of 4-cm target area was marked 2 cm proximal to the previous resection margin. The ESD procedure was then repeated by using the next randomly assigned ESD technique. A total of 3 sites aligned longitudinally were removed in each pig. For both techniques, the knives were directed away from the muscular layer. Injection of the solution was repeated as necessary at the discretion of the operator. When intraprocedure bleeding occurred, the knife was used initially to achieve hemostasis with coagulation current. The knife was exchanged for hemostasis forceps (Radial Jaw hot biopsy forceps; Boston Scientific, Natick, Mass) if initial attempts failed.

C-ESD. Injection of solution was initiated at the distal side of the pseudo-lesion to achieve an adequate submucosal injection outside of the markings. Mucosal incision was then started and extended around the markings to complete the mucosal incision. Injection of solution was added as needed to produce an adequate cushion before incision. Once the circumferential incision was made, additional fluid was injected in submucosal space before submucosal dissection. Submucosal dissection was initiated at the proximal end, proceeding distally by using the settings described previously.

HK-ESD. An initial elevation was made distally with the HybridKnife with the ERBEJET 2 water-jet system, and the same HybridKnife was used to cut the mucosa at the injected site. Alternating water-jet and electrosurgical cutting maneuvers were repeated to complete the circumferential mucosal incision. Submucosal dissection was continued with the same alternating maneuver from the proximal end. The water-jet was used to create adequate water-filled submucosal space for submucosal dissection followed immediately by cutting with the HybridKnife.

Endpoint evaluation

The study assessed the procedure time, completeness of the resection, and procedure complications (bleeding and perforation) of ESD procedures.

Procedural measures. Procedure time was measured from the first injection of solution to the complete removal

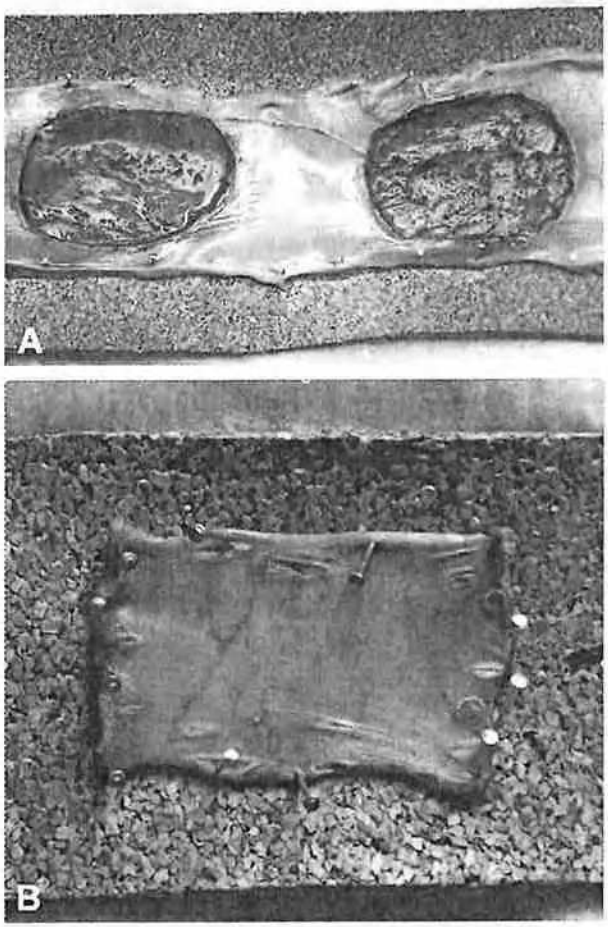

Figure 2. A, Pinned tissue of harvested esophagus showing the resection beds. **B,** Removed tissue flaps pinned on a cork board.

of the target area. Completeness of the resection was assessed by endoscopic and macroscopic inspection of resection site for remaining coagulation markings. If no markings were identified within the postprocedure esophagus and the markings were seen on the removed tissue, it was considered complete. Any use of hemostasis forceps in exchange for the ESD needle was considered as significant bleeding. A diagnosis of perforation was made when deep muscular injury was seen intraprocedurally (endoscopic perforation). Procedure time and endpoint events were measured and recorded by a study assistant not involved in performing the procedure.

Gross inspection. A leak test was performed by using blue-dyed water after the esophagus was harvested. The adventitial side was examined for gross abnormalities. Then the distal end was clamped and the ex vivo lumen was filled with water from the proximal opening of the esophagus. The esophagus was suspended for 1 minute while inspecting for any leak of blue water at the resection sites. If a leak was seen, the leak test result was considered positive. The resected pseudo-lesions were retrieved,

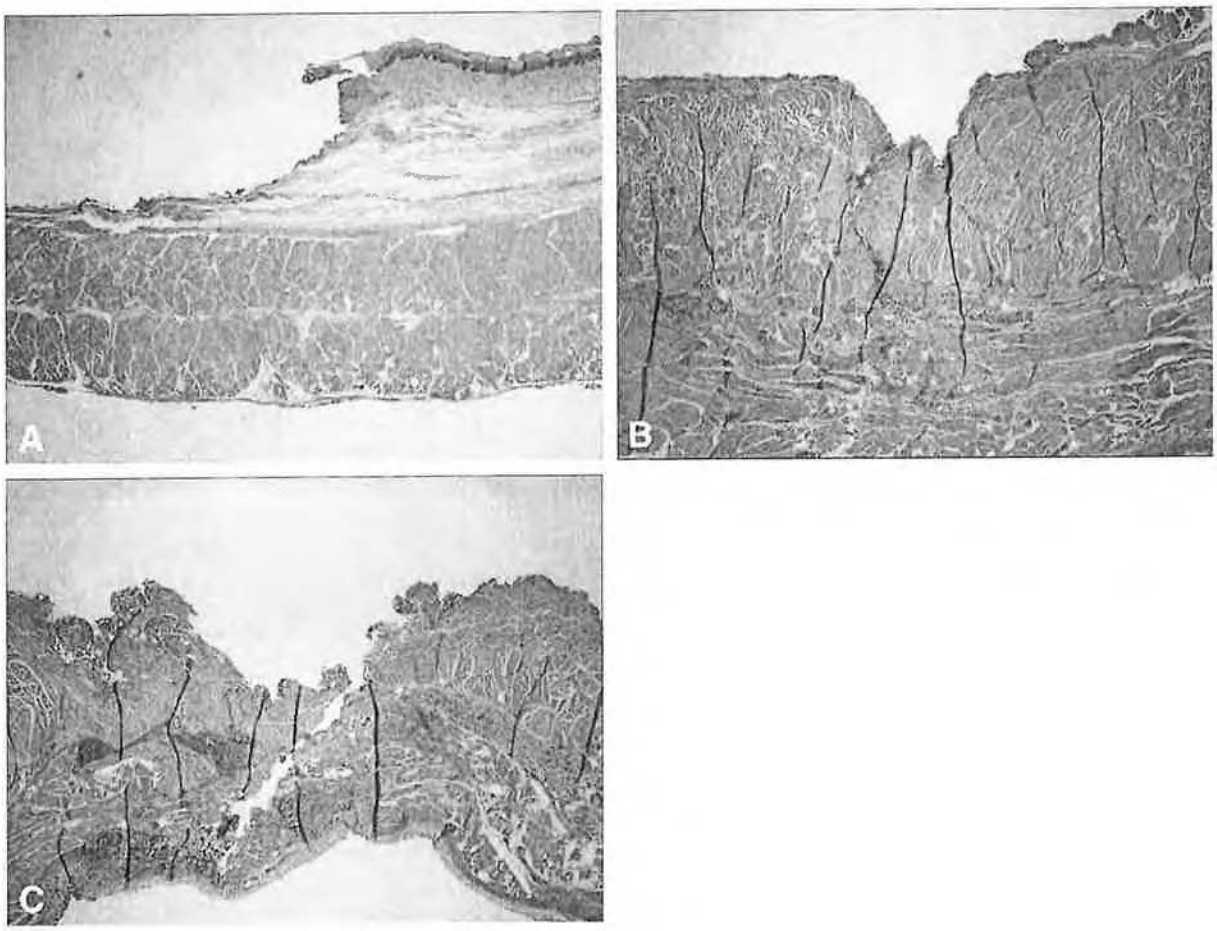

Figure 3. A, Histological image showing the intact MP layer covered by the residual submucosal tissue. **B,** Injury to less than 50% of inner MP. **C,** Transmural injury to the MP layer; histological perforation.

pinned on a cork board, and measured. The harvested esophagus was opened and pinned on a cork board (Fig. 2). The tissues were then placed in 10% formalin.

Histological evaluation. After fixing the tissue in formalin, both the mucosa flap and the surgical bed were processed. Each flap and each surgical bed was sequentially sectioned and submitted in total for paraffin block embedding and sectioning after staining with hematoxylin and eosin. When sectioning the surgical bed, all the margins of the surgical bed were submitted first, after which the surgical bed itself was submitted.

The microscopic observations were made based on the following guidelines. The depth and number of injuries into the different muscle layers were recorded per surgical bed. To record the level of injury, each component of the muscularis propria (MP) layer (inner circular and outer longitudinal) was divided into inner (<50%) and outer (>50%). For example, a surgical bed may incur the following injuries: the first is superficial, involving only less than 50% of the inner circular layer; the second may involve a deeper injury involving either the more than 50% inner circular layer or the less than 50% outer longitudinal layer; and the third may involve the more than 50% outer longitudinal layer (Fig. 3). Histological perforation was considered to be present if there was injury involving more than 50% of the outer MP layer.

Statistical analysis

Estimation of the number of cases to be performed per group was calculated by using the primary objective criterion (operating time) by the standard procedure for quantitative criteria. For the power analysis, it was assumed that the HK-ESD operating time is approximately 25% faster compared with C-ESD. This decrease in the operating time should be detected at a level of significance of .05 and a power of 0.8 (â = .2). Thus, the number of cases was estimated to be at least 46. The verification of the hypothesis was done by using a Student *t* test if variances were equal and the data were normally distributed between groups.

Data were collected and analyzed by means of descriptive statistics (mean [standard deviation]) and by the Student *t* test as well as the Fisher exact test. Between-group comparisons were performed by using a χ^2 test for cate-

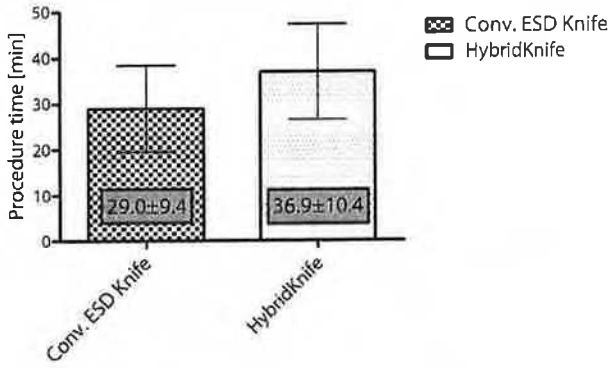

Figure 4. Overall procedure time of C-ESD and HK-ESD ($P = .08$).

gorical variables (bleeding rate, perforation rate, injuries of the MP). Independent-samples Student *t* tests were used to compare normally distributed variables (operation time, specimen area) between groups. All *P* values ($P < .05$ was considered statistically significant) were 2 sided and were not adjusted for the number of parameters evaluated. All calculations were performed by using GraphPad Prism 5.01 software (GraphPad Software Inc, La Jolla, Calif).

RESULTS

A total of 51 ESD procedures were performed in 17 pigs; 27 C-ESD procedures and 24 HK-ESD procedures. All resections were completed as en bloc resections. The measured surface areas of removed specimens were similar between the 2 groups; C-ESD specimens were 7.20 ± 1.97 cm^2 and HK-ESD specimens were 7.20 ± 1.78 cm^2 (P = not significant).

Procedure time

C-ESD procedure time was significantly shorter than for HK-ESD (29.0 ± 9.4 minutes vs 36.9 ± 10.4 minutes, respectively; $P = .0063$) (Fig. 4). For both methods, procedure time shortened gradually as the study progressed. However, after 12 procedures, both methods were performed in a similar amount of time (C-ESD, 24.7 ± 9.8 minutes vs HK-ESD, 30.3 ± 7.6 minutes; $P = .14$) (Fig. 5).

Complications

Bleeding and perforations. There were 40 bleeding episodes requiring intervention. Bleeding occurred more frequently with C-ESD (28 bleeding episodes in C-ESD vs 12 in HK-ESD, $P = .0007$). Significant bleeding occurred during 7 C-ESD resections (26%) compared with 1 HK-ESD resection (4%) ($P = .05$). There was no uncontrollable bleeding. There were 3 perforations caused by C-ESD. Two were endoscopic perforations observed in 1 resection during C-ESD; the third was a histological perforation observed in another pig in C-ESD. The leak test results were negative in all specimens. No perforations were observed with HK-ESD (Table 1).

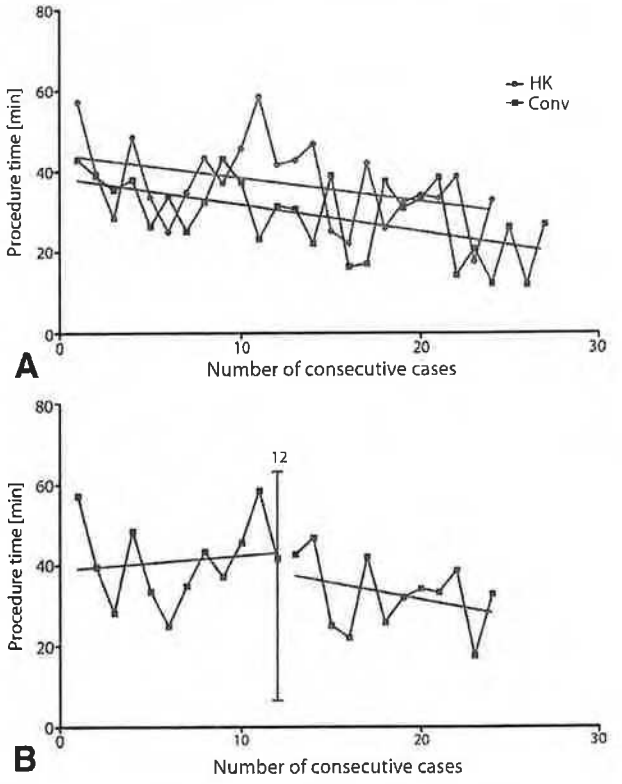

Figure 5. A, Decreasing procedure time with consecutive C-ESD and HK-ESD procedures. **B,** Decreased procedure time after 12 consecutive HK-ESD procedures.

Histological evaluation of MP injuries. A total of 33 injuries to the MP were documented; 16 were observed in C-ESD and 17 in HK-ESD (Table 1). Injuries to the inner MP layer were observed in 14 C-ESD and 16 HK-ESD procedures. Injuries to the outer MP layer were observed in 2 C-ESD and 1 HK-ESD procedures. There was only 1 injury involving more than 50% of the outer MP layer (histological perforation), which was observed in C-ESD. Thirty-one of the 33 of injuries (94%) occurred within the first 11 procedures, suggesting a significant learning curve (Fig. 6).

DISCUSSION

ESD was developed to perform large mucosal resections and thereby increase the rate of complete en bloc resection.[1,16] A variety of equipment and techniques is available to facilitate a safer procedure and in a less time-consuming manner; however, ESD techniques and settings have not been standardized, and studies directly comparing various ESD techniques are not available. Case series comparing ESD with EMR have proven its efficacy with higher complete resection rate and lower recurrence rate in the region of the esophagus, stomach, and colon.[16-19] Despite its efficacy in complete removal of

TABLE 1. Frequency of esophageal muscular injury and perforation after C-ESD and HK-ESD observed by endoscopy, leak test, gross pathological inspection, and histological evaluation‡

	Endoscopic perforation	Positive leak test results	Gross specimen perforation	Histological perforation	Histological injury to MP*		
C-ESD	2‡	0	2‡	1†	Inner	<50%	11
					MP	>50%	3
					Outer	<50%	1
					MP	>50%	1†
HK-ESD	0	0	0	0	Inner	<50%	11
					MP	>50%	5
					Outer	<50%	1
					MP	>50%	0

C-ESD, Conventional endoscopic submucosal dissection; *HK-ESD*, HybridKnife endoscopic submucosal dissection; *MP*, muscularis propria.
*91% of injuries (30/33) occurred within 10 procedures, 94% of injuries (31/33) occurred within 11 procedures (Fig. 6).
†Histological perforation was considered present if injury was deeper than 50% of outer MP layer.
‡Within 1 resection bed.

tumor, there are known limitations of ESD; the procedure is more time-consuming and technically challenging compared with EMR, with higher rates of bleeding and perforation complications.[10,11,20]

The newly developed HybridKnife combines a needle electrode with integrated water-jet system that allows rapid injection without mechanical penetration of the mucosa. The benefits of this knife are minimizing the exchange of tools and maintaining the safe cutting plane within the submucosal layer by on-demand injection. The feasibility of this new device and technology has been tested in the porcine model. Lingenfelder et al[13] reported that the use of HybridKnife with water-jet function shortened the procedure time and injury to the MP. Subsequent studies on the colon and esophagus in porcine models were reported.[14,15] Yahagi et al[14] found in their comparison study of standard colon ESD and colon ESD using the HybridKnife that the use of the HybridKnife resulted in fewer perforations (25% vs 5.5%, $P = .035$) with a similar bleeding rate. Neuhaus et al[15] reported that compared with EMR, HK-ESD had a higher complete resection rate, a similar bleeding rate, and a longer procedure time in the esophagus.

Our study is the first to compare C-ESD and HK-ESD in the removal of esophageal tissue. Complete resection of target mucosa was achieved by both ESD methods in all resections (100% complete resection rate), thus showing equal efficacy of tissue removal when using the HK-ESD. Removed surface area was also similar in both groups. Procedure time was significantly longer for HK-ESD, and procedure time with either technique became shorter as the study progressed, showing a significant learning curve (Fig. 5A). Both operators had experience with C-ESD in the clinical setting but were new to HK-ESD. The learning curve of HK-ESD may be responsible for the observed difference in procedure times. After 12 HK-ESD procedures, a significant decrease in procedure time was realized (Fig. 5B), and both methods were performed in similar time. On the other hand, C-ESD time steadily and gradually decreased, suggesting that there was no initial learning period. Yahagi et al[14] practiced before their HK-ESD study, and our results might have been different if we had planned practice ESD for the new technique. The best approach for training in ESD has been an issue of debate. In Japan, physicians learn ESD by observation and self-study first and then progress to supervised procedures. This has been successful, and approximately 30 to 40 procedures are required to achieve adequate proficiency.[21,22] Training in animal models appears feasible and roughly simulates the human anatomy.[23,24] The optimal number of training procedures has not been determined and depends on the skill level of the endoscopist. Our study was limited by the small number of resections with each method to draw any conclusions on the number of procedures needed for proficiency.

Significantly more bleeding was observed with C-ESD compared with HK-ESD (28 vs 12, $P = .0007$) and also significant bleeding per procedure was more with C-ESD (7 vs 1, $P = .05$) in contrast to the study by Yahagi et al ($P =$ not significant) using the same electrocautery mode in colon ESD, Endocut-D. The Endocut-D mode may be optimal for esophageal ESD with effective coagulation producing a decrease in the number of bleeding episodes.

There were 3 perforations (2 endoscopic perforations, 1 histological perforation) with the C-ESD technique. No perforation was seen with HK-ESD. Histological assessment by a blinded histopathologist showed an equal number of tissue injuries to the MP. Interestingly, the majority

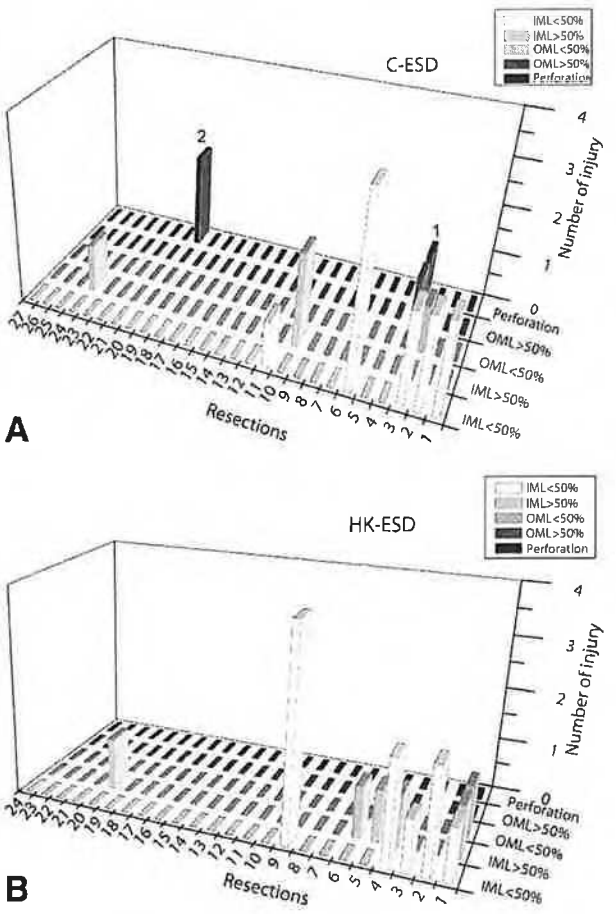

Figure 6. A, Number and depth of injuries by the procedure count: C-ESD. Blue bar indicates perforation including 2 endoscopic perforations (20) and 1 histological perforation (4). **B,** Number and depth of injuries by the procedure count; HK-ESD. IML, inner muscular layer; OML, outer muscular layer.

of injuries (94%) occurred during the first 11 procedures for both C-ESD and HK-ESD, suggesting a significant learning curve (Table 1, Fig. 6). Deep MP injury (injury to >50% of outer MP layer) was seen in C-ESD in the fourth procedure, and this was considered a histological perforation. HK-ESD did not cause any deep MP injury. The HybridKnife allows on-demand saline solution injection for timely optimal mucosal lifting, and this may have prevented inadvertent injury to the MP. This may translate into fewer perforations during ESD procedures, which is the most important goal for the widespread use of ESD. The use of universally available saline solution is an additional advantage over using special solutions for ESD procedures.

Our study has a several limitations. This was a nonsurvival study, and the clinical significance of the endoscopic perforation and histological perforation was not addressed. The use of 2 different C-ESD knives was allowed, and C-ESD used a different solution that expands the submucosal space for a prolonged time. Our intent was to compare the 2 methods in similar clinical settings, and thus comparison of HK-ESD with saline solution–assisted C-ESD was considered less meaningful. The small sample size limits the subgroup analysis and conclusive results of the learning curves.

CONCLUSIONS

The HK-ESD technique was equally effective as the C-ESD technique for successful en bloc resection and was safer with less bleeding and perforation in the removal of esophageal tissue. Although the overall procedure time was longer in HK-ESD, this difference may be attributable to the learning curve. HK-ESD may facilitate ESD for the treatment of early esophageal cancer, but further study is necessary to determine the learning curve and proper training methods for the widespread use of ESD.

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ORIGINAL ARTICLE

Giant laterally spreading tumors of the duodenum: endoscopic resection outcomes, limitations, and caveats

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Background: Giant hemicircumferential and greater nonampullary duodenal adenomas or laterally spreading tumors (LSTs) may be amenable to safe endoscopic resection, but little data exists on outcomes or risk stratification.

Design: We interrogated a prospectively maintained database of all patients who underwent endoscopic resection between January 2008 and November 2010. The resection technique was standardized. Major complications were defined as perforation, bleeding requiring readmission with hemoglobin drop of more than 20 g/L, or other substantial deviations from the usual clinical course. Outcomes were analyzed in 2 groups: giant lesions (>30 mm) and conventional duodenal polyps (<30 mm in diameter). Statistical evaluation was performed by using a χ^2 test.

Results: A total of 50 nonampullary duodenal polyps and LSTs were resected from 46 patients (23 men, mean age 59.4 years, range 35-83 years). Nineteen were giant hemicircumferential and greater LSTs (mean size 40.5 mm, range 30-80 mm), and 31 were less than 30 mm in diameter (mean size 14.5 mm, range 5-25 mm). Intraprocedural bleeding occurred more frequently in giant lesions (57.8% vs 19.3%, $P = .005$) and was treated with a combination of soft coagulation and endoscopic clips with hemostasis achieved in all cases. Major complications, mostly bleeding related, occurred in 5 patients (26.3%) with giant lesions and 1 patient (3.2%) with a smaller lesion ($P = .014$). There were no deaths.

Limitation: Retrospective observational study in a tertiary center.

Conclusions: Endoscopic resection of giant nonampullary duodenal LSTs is a successful treatment. However, it is hazardous and associated with significantly higher complication rates, primarily bleeding, when compared with conventional duodenal polypectomy. Safer and more effective hemostatic tools are required in this high-risk location. (Gastrointest Endosc 2012;xx:xxx.)

Nonampullary adenomas of the duodenum are uncommon lesions that may be sporadic or occur as part of a genetic syndrome. Our group and others have previously described the technique and outcome of endoscopic resection (ER) of these lesions based on the well-established principles of colonic EMR.[1-6]

Conventional EMR seems safe and effective for small to even moderately large lesions, however it is subjectively associated with higher risk compared with lesions of a similar size in other locations such as the colon.[6-9]

An accepted system of morphological characterization for duodenal adenomas does not currently exist. A subgroup of patients have giant, minimally elevated sessile lesions that are hemicircumferential or greater. These adenomas share morphological and possibly biological commonalities with laterally spreading tumors (LSTs) of the

Abbreviations: ALOS, average length of stay; CDP, conventional duodenal polyp; ER, endoscopic resection; FAP, familial adenomatous polyposis; LST, laterally spreading tumor.

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colon in that they grow laterally at a low vertical height along the luminal circumference achieving a large size before exhibiting vertical growth or invasive behavior, and thus present an opportunity for endoscopic intervention and potential cure despite their impressive size. At present, the optimal therapy for these lesions remains unclear. The existing premise is that at this dimension, malignancy is likely and complete ER is technically impossible and hazardous. Therefore, these lesions are primarily treated surgically by duodenectomy with attendant morbidity risks and potential mortality.[10] Wide-field ER has been shown to be safe and effective in anatomic sites such as the colon, esophagus, and stomach,[9,11,12] but whether such aggressive endoscopic treatment is feasible, effective, or safe in the duodenum is currently unknown.

The aim of this study was to determine the safety, efficacy, and outcome of ER of giant hemicircumferential and greater LSTs of the duodenum and compare this with a control population of smaller conventional duodenal polyps (CDPs) treated in the same time period.

PATIENTS AND METHODS

Between January 2008 and November 2010, a prospective observational study was conducted of all patients referred to our department for ER of a CDP or LST of any size. For the purposes of the study, giant LSTs were defined as those with predominant Paris 0-IIa morphology, 30 mm or larger in maximum dimension, and occupying approximately 50% or more of the luminal circumference. The greatest dimension of the polyp was estimated by reference to an open polypectomy snare.

Data collected included lesion location, size, morphological type, histological diagnosis, intraprocedural and delayed complications, and results of follow-up endoscopies. Patients with polyposis syndromes, predominantly familial adenomatous polyposis (FAP), were also included. Procedures were performed with the patients under sedation with a combination of midazolam, fentanyl, and propofol. Intravenous hyoscine (10-20 mg) was given at the time of EMR if required to limit duodenal peristalsis. EUS was not routinely performed.

Technical success was defined as complete resection confirmed by the endoscopic absence of adenomatous tissue after inspection with high-definition white light and narrow-band imaging.

Major complications were defined as perforation, bleeding requiring readmission with a hemoglobin drop of greater than 20 g/L, or other substantial deviations from the usual clinical course. Intraprocedural bleeding was recorded but not classified as a complication unless it led to a deviation in the anticipated clinical course. The study was approved by the Sydney West Area Health Service Human Research Ethics Committee.

Take-home Message

- Wide-field endoscopic resection, as in other sites, is technically possible, but the risks are greatly magnified compared with lesions of comparable size located elsewhere. Uncontrollable bleeding is a major risk, and, other than size, risk factors are unknown.
- Safe and effective prophylactic techniques do not currently exist.

Technique

All ERs were performed by 2 experienced interventional endoscopists (M.J.B. and S.J.W.) or by a senior endoscopy fellow under their direct supervision. Our previously described standardized EMR approach was used.[5,13] The duodenoscope (TJF-Q180V; Olympus Optical, Tokyo, Japan) was used for lesions predominantly occupying the anteromedial wall of the duodenum, with a pediatric variable-stiffness colonoscope (PCF-Q180AL/I; Olympus Optical), used for lesions on the lateral or posterior wall (Fig. 1).

Submucosal injection solution consisted of normal saline solution in combination with dilute epinephrine (1 in 10,000) and indigo carmine until March 2010 after which succinylated gelatin (Gelofusin; B. Braun, Sydney, Australia) supplanted normal saline solution when its technical superiority became known.[14]

Spiral snares were preferred (20-mm SnareMaster; Olympus). The mini oval snare (15- to 30-mm AcuSnare, Cook Medical, Brisbane, Australia) was used to remove any residual at the margin. Attempts were made to resect CDPs en bloc if possible. Larger lesions were resected in as few pieces as safely possible. Care was taken to orient the long axis of the snare parallel to the long axis of the lesion along the line of the mucosal fold (rather than across it) to facilitate maximal safe tissue capture. Before any resection, entrapment of the muscularis propria and deeper wall layers was excluded by completely closing the snare to extrude muscle, and testing the mobility of the captured tissue relative to the surrounding duodenal mucosa. After resection, the defect was carefully scrutinized with high-definition white light and narrow-band imaging to confirm complete ER and to exclude any undetected perforation or mirror target sign.[15]

Minor but persistent intraprocedural venous oozing of the resection margin was controlled with the snare tip by using soft coagulation at 80-W effect 4.[13] Areas of more significant hemorrhage arising from within the defect were treated with endoscopic clips (Resolution Clip, Boston Scientific, Natick, Mass) or coagulating forceps (Coagrasper; Olympus). An ERBE electrosurgical unit (VIO 300; ERBE, Tübingen, Germany) set to Endocut Q, effect 3, delivering a cut duration of 2 ms, and a cut interval of 1200 ms was used for all procedures.

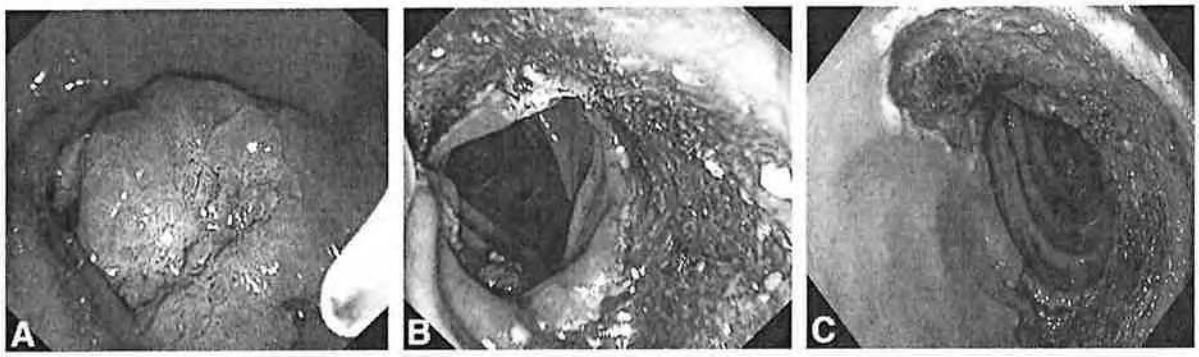

Figure 1. A, An 80% circumferential lesion at the junction of first and second parts of the duodenum. **B,** Side-viewing image of a large circumferential defect extending vertically over several mucosal folds. **C,** An end-viewing image of the final clean-based three quarters mucosal defect.

Postprocedural care and surveillance protocol

Duodenal EMR procedures were performed in the morning. After an extensive resection, patients were observed for 4 hours before discharge. A clear liquid diet was commenced, and this was continued overnight, after which a normal diet was resumed. Antiplatelet agents were resumed after 7 days. Written information on potential complications and the signs to look for and a contact number were provided to the patient. Twice-daily proton pump inhibitor therapy was taken for 2 weeks after resection. Endoscopic follow-up was scheduled at intervals of 4 and 12 months. Patients were then discharged from our service and advised to attend for annual surveillance with the referring endoscopist for the next 2 years. Residual tissue at follow-up endoscopies was resected with the mini oval or micro mini snare (Cook Medical, Bloomington, Ind). Submucosal injection was not used, thus avoiding a "valley" effect with tethered residual tissue surrounded by a submucosal cushion of fluid that had tracked laterally. In cases with only a clean scar detected, biopsy samples were taken for histological examination to confirm the macroscopic impression.

Histological assessment

All en bloc resections and the dominant portions of larger polyps were flattened and fixed with thin needles onto corkboards before pathological fixation. All specimens were reviewed by specialist GI pathologists. Lesions with high-grade dysplasia or invasive carcinoma were reviewed in conjunction with the investigators.

RESULTS

A total of 50 nonampullary CDPs and LSTs were resected from 46 patients (23 men, mean age 59.4 years, range 35-83 years). Lesions were stratified according to size. Outcomes were analyzed in 2 groups: giant LSTs (>30 mm) and CDPs (<30 mm).

Nineteen were giant LSTs (mean size 40.5 mm, range 30-80 mm), and 31 were CDPs (mean size 14.5 mm, range 5-25 mm). Giant lesions were located in the first part of the duodenum (n = 1), junction of first and second parts (n = 4), second part (n = 13), and junction of second and third parts (n = 1). CDPs were located in the first part (n = 3), second part (n = 25), junction of second and third parts (n = 2), and third part (n = 1). Paris classification morphology for giant lesions was Paris 0-IIa (n = 15), 0-IIa+c (n = 2), and 0-IIa + Is (n = 2). Seven lesions were granular, 7 were nongranular, and 5 were mixed.

EMR was performed on all lesions, with complete ER achieved in 47 of 50 cases. Complete excision was not possible in one 0-IIa + c lesion because of poor central lifting related to submucosal fibrosis from previous extended attempts at resection. This patient underwent duodenectomy with long-term postsurgical morbidity. One patient was difficult to sedate and declined further attempts. The final patient was 80 years of age with a massive, almost circumferential second part LST (Fig. 2). A small perforation was immediately recognized early in the procedure after one snare excision as a mirror target sign.[15] This was closed with clips, and the procedure continued. Despite the substantial extent of the resection, an approximate 30-mm residual remained on the anterior wall and would have required a duodenoscope to resect. With the endoscopic clips on the posterior wall and the possibility of disrupting these with the duodenoscope, we elected to proceed to a 2-stage excision. This patient had asymptomatic pneumoretroperitoneum and was discharged well after 4 days of intravenous antibiotics. A subsequent unrelated illness has delayed the second stage of therapy.

En bloc resection was possible in 23 of 31 CDPs (70.9%), but in only 2 of 19 LSTs (10.5%) ($P < .0001$), both 30 mm in size. One lesion in each group, adjacent to but not involving the papilla, required prophylactic short 5F pancreatic stents to prevent postprocedural pancreatitis (Fig. 3). Succinylated gelatin (Gelofusin, B. Braun) was used in 13 of 31 (41.9%) and 12 of 19 (63.1%) of the CDPs and giant LSTs, respectively (P = not significant).

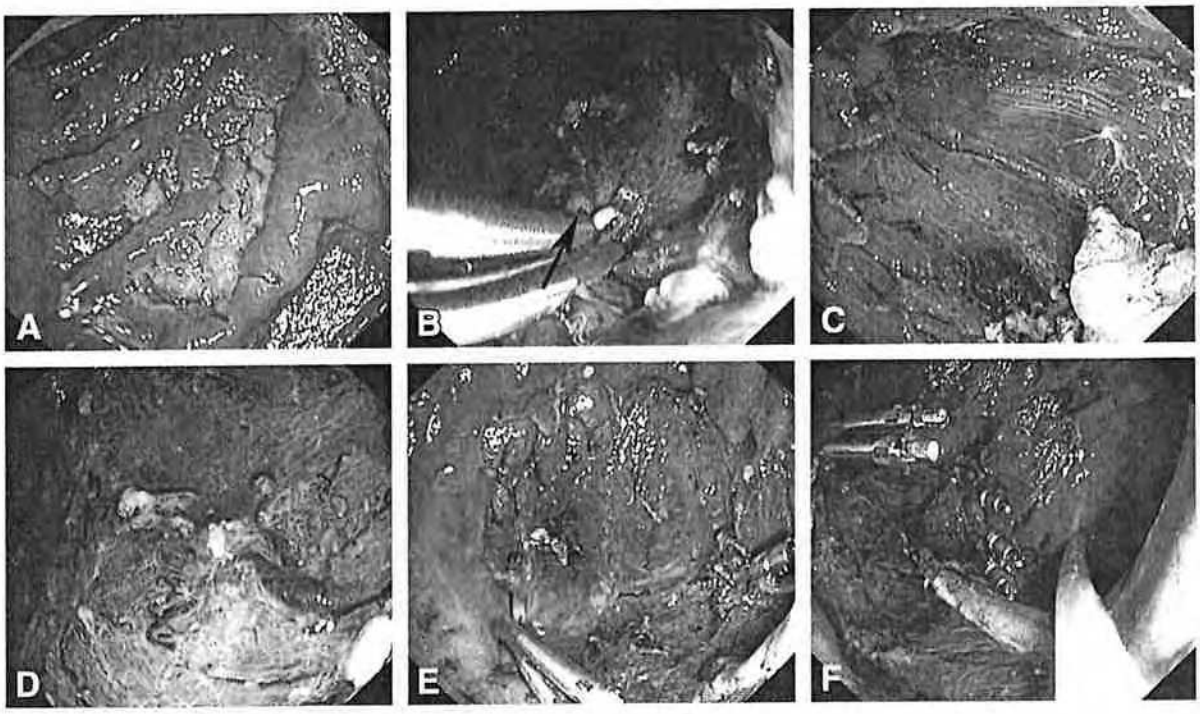

Figure 2. A, An 80% circumferential mixed granular/nongranular laterally spreading tumor occupying the posterior, lateral, and anterior walls of the second part of the duodenum. **B,** Perforation recognized and immediately clipped. The *arrow* indicates the characteristic appearance of the incised muscularis propria layers within the EMR defect. **C,** Initial extensive resection. Note some exposed muscle. **D,** A large submucosal vessel exposed and prophylactically clipped in **E**. **F,** Final result.

Intraprocedural bleeding occurred in 11 of 19 giant LSTs compared with 6 of 31 CDPs (57.8% vs 19.3%, $P = .005$). It was treated with soft coagulation alone (10/17) or in combination with endoscopic clips (7/17), with hemostasis achieved in all cases. However, prolonged efforts at hemostasis were required in some cases, one of which is thought to have resulted in a delayed perforation requiring surgical correction after the patient presented with an acute abdomen the day after ER.

Major complications occurred in 5 patients (26.3%) with giant LSTs and 1 patient (3.2%) with a CDP ($P = .014$). One intraprocedural perforation occurred as described; all others were bleeding related. The mean inpatient stay for all patients with major complications was 8 days (range 4-15 days). There were no deaths.

The first patient had a 50-mm lesion resected from D2, with intraprocedural bleeding treated with soft coagulation and endoscopic clips. Repeat endoscopy and clipping were required because of recurrent bleeding on day 1. Three units of blood were transfused, with the patient admitted for 6 days. Surgery was not required. The second patient also had a 50-mm lesion removed from D2. There was no intraprocedural bleeding; however, delayed bleeding occurred on day 1, requiring repeat endoscopy. Hemostasis was achieved with epinephrine injection and cautious soft coagulation with coagulation forceps. Surgery was not required, and the patient was discharged on day 5.

Two patients (10.5%) with giant LSTs did require surgery. The first with a 40-mm lesion presented with delayed perforation, complicating prolonged but successful thermal hemostasis with coagulating forceps for intraprocedural bleeding. The patient presented with an acute abdomen on the day after resection and proceeded to laparotomy where an area of deep thermal injury associated with a small perforation was identified within the EMR defect. This was oversewn, and the patient was discharged on day 10. The second patient had a 35-mm lesion and, after an initial uneventful recovery, developed massive uncontrolled bleeding manifest as bright hematemesis and hematochezia associated with severe abdominal pain on day 1. This patient proceeded directly to surgery, and the vessel was oversewn, resulting in a 15-day admission. There was no perforation (Fig. 4).

In the CDP group, significant delayed bleeding occurred after resection of a 10-mm lesion from D2. This was managed conservatively with a blood transfusion of 2 units, and the patient made an uneventful recovery.

Histological assessment after resection of giant LSTs revealed tubulovillous adenoma with low-grade dysplasia in 12 patients and diffuse or focal high-grade dysplasia in 5 patients, 1 pyloric gland adenoma, and 1 case of follic-

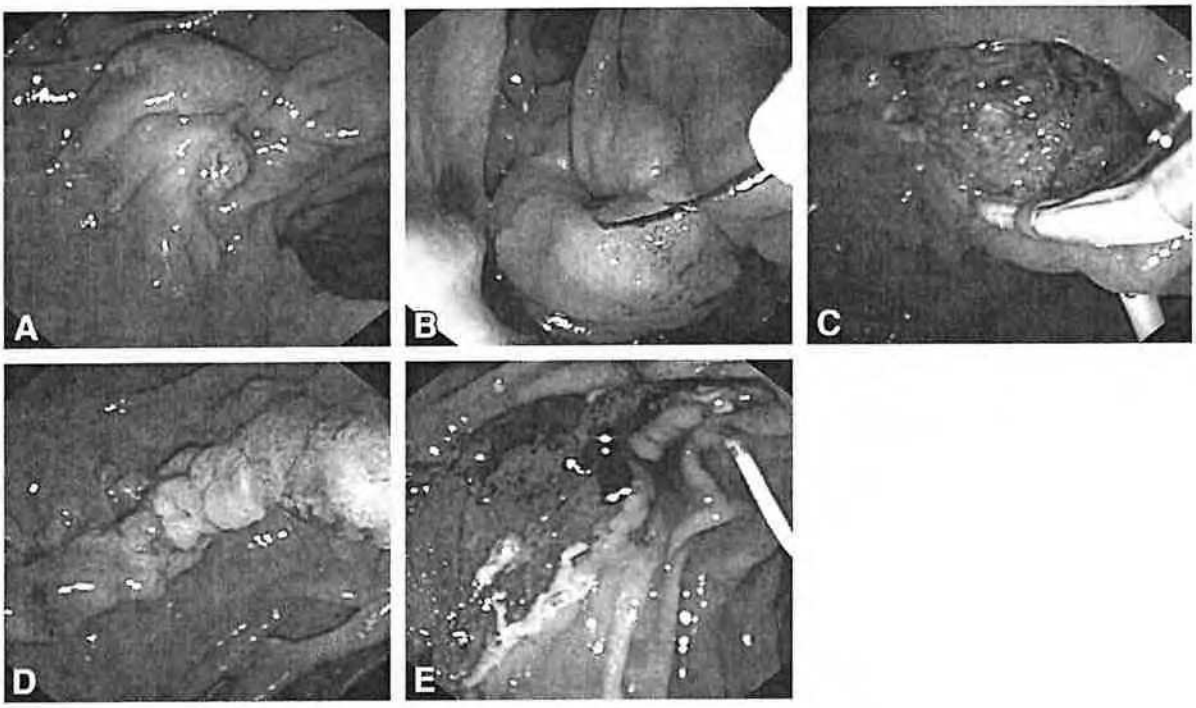

Figure 3. A-C, A 15-mm nongranular suprapapillary lesion before and after en bloc EMR. A pancreatic stent was placed to prevent pancreatitis from mucosal edema. **D, E,** A 30-mm Paris classification 0-IIa juxtapapillary laterally spreading tumor requiring prophylactic pancreatic stent placement to prevent postprocedural pancreatitis.

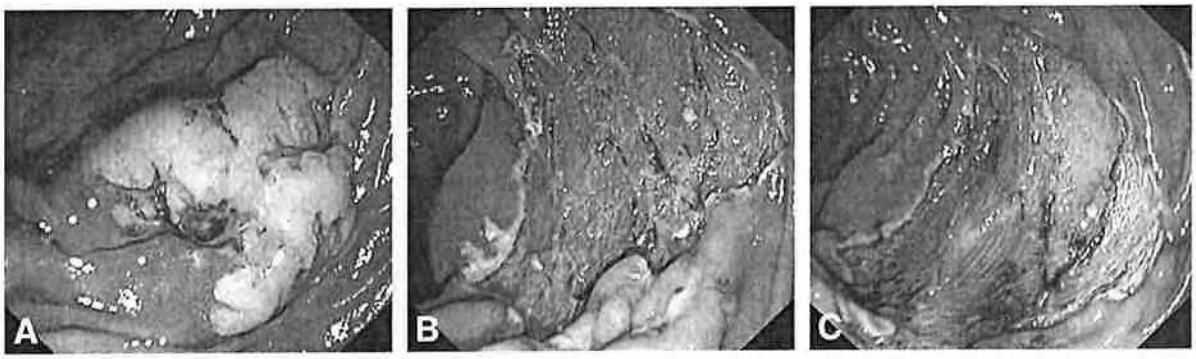

Figure 4. A, A 35-mm hemicircumferential lesion. **B,** Resection nearly complete. **C,** Final result with a clean EMR defect without conspicuous risk factors for the massive delayed bleeding that would then ensue.

ular lymphoma. The patient with lymphoma had a presentation diagnosis of adenoma, and the lesion was macroscopically consistent with this. There was no evidence of disseminated lymphoma found after staging, and subsequent surveillance procedures have failed to reveal any residual or recurrent lymphoma at 24 months. In the CDP group, there were 24 cases of tubulovillous adenoma with low-grade dysplasia and 1 each of Brunner's gland lesion, carcinoid, hyperplastic polyp, gastric heterotopia, and a hamartomatous polyp. Unfortunately, 2 smaller specimens were lost and not submitted for histological assessment. There was no residual lesion identified in either case at repeat endoscopy.

No recurrence was found at median endoscopic follow-up of 11 months (range 3-28 months) in 13 of 17 evaluable patients with giant LSTs. The ER site revealed regenerated mucosa, often with prominent villi and absent valves of Kerckring or mucosal folds (Fig. 5). A small amount of recurrent/residual adenoma was evident in 4 cases and was treated with a combination of snare excision and thermal ablation. One patient eventually required surgery for persistent unresectable adenoma caused by

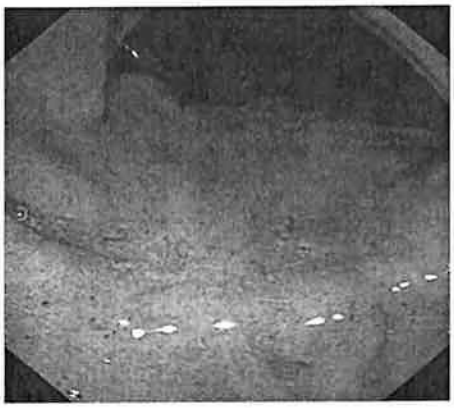

Figure 5. Well-formed scar and absent valves of Kerckring or mucosal folds in the region of a previous complete endoscopic resection.

marked submucosal fibrosis, with the other 2 patients endoscopically and histologically clear at per-protocol examinations of 4 months (1 patient) and 12 months (1 patient). All patients who were in remission at 4 months remained so at 12 months. One patient has declined surveillance, and another has not completed resection.

No recurrence was found at median follow-up of 12 months (range 3-26 months) in 23 of 27 patients with CDPs, pending in 2 patients, and declined by 2 patients. Residual tissue was removed from 4 patients, with 1 patient now clear at 12-month review. The others have FAP, and possibly sporadic adenomas close to the resection rather than residual. One patient with FAP finally proceeded to surgery because of an extensive adenoma burden.

DISCUSSION

This study describes the experience of a tertiary referral center in the endoscopic treatment of CDPs and giant hemicircumferential or greater LSTs of the duodenum. These lesions are uncommon and usually solitary[16] unless associated with a polyposis syndrome. Wide-field ER in this location has traditionally been considered technically challenging and hazardous.[17] However, duodenal adenomas are premalignant, and some form of treatment is indicated in patients with reasonable life expectancy.[18-20]

Traditional treatment options are purely surgical and involve segmental resection, duodenotomy with local excision, and Whipple resection, all with their attendant cost, morbidity, and potential mortality risk.[10,21,22]

It is likely that ER confers a significant cost benefit and reduction in average length of stay (ALOS). A complex gastroscopy is associated with a cost of AU$1487 (US$1412) and an ALOS of 1 day, and with a complication (eg, postprocedural bleeding), an average cost of AU$5623 (US$5341) and an ALOS of 3.93 days. A catastrophic or severe complication (eg, perforation) generates a cost of AU$12,595 (US$11,965) and an ALOS of 9.75 days. However, a complex gastric/esophageal/duodenal surgical procedure has been associated with a cost of AU$26,294 (US$24,979) and an ALOS of 13.65 days.[23]

In the current study, we have demonstrated that ER in the duodenum can be performed safely and successfully, even for hemicircumferential or greater lesions in a tertiary referral setting with same-day discharge in the majority of cases with the following caveats.

Lesion classification

In contrast to mucosal neoplasia of the colon, stomach, or squamous esophagus, a practical system of lesion classification has not yet been promulgated or adopted.[9,24] Ideally, such a system would inform on the risk of invasive disease, the likelihood of ER technical success, and the optimal surveillance strategy. It would also incorporate the Paris classification system.[25] Because duodenal LSTs have many histological features in common with LSTs of the colon, we applied both the Paris and the surface classification systems of granular/nongranular to aid in lesion assessment. In the colon, this has proved to be of substantial utility.[9,24]

Bleeding

Delayed bleeding after duodenal ER is a feared complication and may be catastrophic, as exemplified in this series.[6] Currently, risk-stratification algorithms to aid in clinical decisions do not exist. The extensive second-order arterial blood supply of the duodenum is an independent risk factor for immediate and delayed bleeding (Fig. 6). In addition, the thin-walled duodenum is at risk of transmural thermal injury or perforation during both the initial broad excision of the LST but also from subsequent application of hemostatic methods.

Endoscopic clips have had a pivotal role to play in hemostasis of both upper and lower GI bleeding.[26,27] However, their place in hemostasis for duodenal EMR is less clear. The application of clips may be technically challenging in the duodenum as a result of a long-scope position or use of a duodenoscope for resection. In addition, although considered safe in the colon,[15,26] stomach,[28] and esophagus,[29] their role in the duodenum is less well established. The thin duodenal wall poses a risk of transmural injury by the clip itself. This may be greater when the clip cannot be anchored by normal tissue on both sides of a resection defect, a significant issue with extensive resections.

In our experience, there is a tendency for multifocal or diffuse oozing from duodenal ER sites, presumably as a result of the extensive vascular supply. Whether such oozing should be treated is unknown. Endoscopic clips tend not to be suitable for this type of bleeding, and our preference is to cautiously use soft coagulation with co-

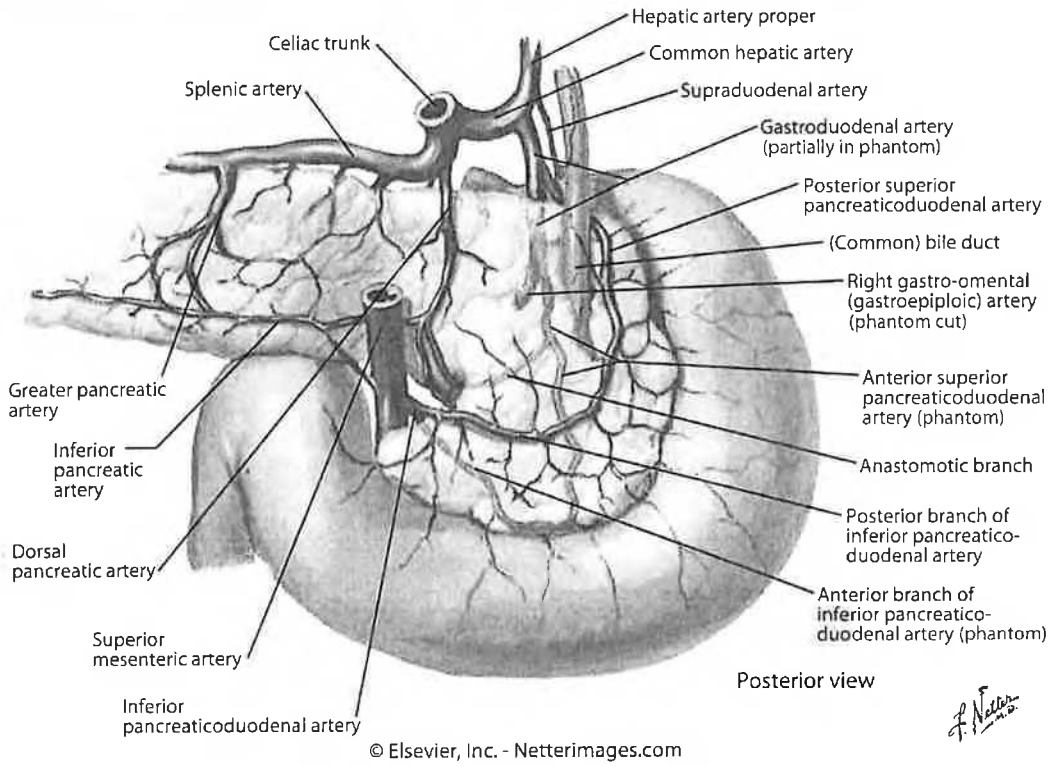

Figure 6. Posterior view of the pancreaticoduodenal arterial arcade demonstrating the extensive vascular supply of the second part of the duodenum (used with permission from the publisher).

agulating forceps. Clinically necessary but substantial use of this technique may increase the risk of perforation.

Other unanswered issues with respect to bleeding are whether to close the ER defect, and what to do regarding nonbleeding visible vessels. Although closure of defects smaller than 20 mm is usually possible, it is probably not necessary unless high-risk features are observed. By their very nature, duodenal mucosal defects larger than 20 mm cannot be safely closed by any currently available method because of an inability to appose the edges of the defect. This results in the ER defect remaining open with no additional measure to minimize the risk of delayed bleeding. Even if such a method of closure was possible, there is the theoretical risk of "burying" undetected residual adenoma, which may then escape subsequent surveillance.

In conclusion, this study demonstrates that it is possible to safely and effectively resect giant LSTs of the duodenum. However, resection of giant lesions is associated with significantly higher rates of intraprocedural bleeding and major bleeding-related complications. Substantial challenges and limitations remain regarding immediate and delayed hemorrhage. Perforation and transmural thermal injury are persistent risks with wide-field ER at any site in the GI tract. In the duodenum, these risks appear to be greatly magnified. Further technical refinement of current techniques or alternative therapies are required to achieve better outcomes for those patients with giant lesions.

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NEW TECHNOLOGY

High-pressure jet injection of viscous solutions for endoscopic submucosal dissection: a study on ex vivo pig stomachs

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Abstract
Background Long-lasting lifting is a key factor during endoscopic submucosal dissection (ESD) and can be obtained by water-jet injection of saline solution or by injection of viscous macromolecular solutions. Combination of the jet injection and the macromolecular viscous solutions has never been used yet. We assessed the ability of a new water-jet system to inject viscous solutions in direct viewing and in retroflexion. We compared jet injection of saline solution and hyaluronate 0.5 % to perform ESD on ex vivo pig stomachs in order to evaluate the benefits of macromolecular solutions when injected by a jet-injector system.
Methods This is a prospective comparative study in pig stomachs. Using the jet injector, four viscous solutions were tested: hydroxyethyl starch, glycerol mix, hyaluronate sodic (0.5 %), and poloxamer mix. Ten ESDs larger than 25 mm (five in direct viewing and five in retroflexion) and one larger than 10 cm were performed with each solution. ESD with hyaluronate jet injection was then compared with ESD with saline jet injection by performing 50 ESDs in each group. A single, minimally-experienced operator conducted all the procedures.
Results All 145 resections were complete, including all marking points with two perforations. Eleven jet ESDs per solution were conducted without any injection issue. In the second part of the study, when compared with saline, significant benefit of hyaluronate was observed on dissection speed (0.80 vs. 1.08 cm^2/min, $p < 0.001$).
Conclusion This is the first report on a jet-injector system allowing injection of macromolecular viscous solutions even with retroflexed endoscope. Jet injection of macromolecular solutions can speed up dissection in comparison with saline, and should now be tested on humans

Keywords Therapeutic/palliation · Technical · Endoscopic submucosal dissection · Endoscopy new technologies

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Endoscopic submucosal dissection (ESD) is the reference method used to treat superficial carcinomas of the digestive tract over 20 mm in diameter. Nevertheless, it is considered a high risk and time-consuming method.

Use of a water jet with a bi-functional (injection and cutting) catheter allows time reduction with a significant decrease of perforation risk [1, 2]. In addition, injection of macromolecular solutions induces long-lasting mucosal elevations. Al-Taie et al. [3] observed longer lifting times with different macromolecular solutions, including

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hydroxyethyl starch (HES). In the experience of Fujishiro et al. [4–6], a mix of glycerol induced longer mucosal cushion than saline solution, with a non-significant superiority. Different studies showed the superiority of hyaluronate solutions [4, 7], even in reducing tissue damage, but its high cost limits the widespread use of such a solution. Recently, a polymer called poloxamer was tested for endoscopic mucosal resection (EMR) versus saline and resulted in a longer-lasting mucosal cushion [8]. This solution is cheaper than hyaluronate and its viscosity increases with temperature so that the solution is liquid when temperature is under 20 °C and becomes viscous at 37 °C.

Water-jet injection of macromolecular solutions may combine advantages of both water-jet injection and macromolecules, but the available water-jet systems were not able, to date, to inject macromolecular solutions. A new water-jet system has been developed with a high-pressure generator, allowing pulsed injection of macromolecular solutions, even with the endoscope retroflexed. This system showed its safety and ability to inject saline solution for ESD in pigs [9]. We thus performed a feasibility study on ex vivo pig stomachs to confirm the ability of the system to inject viscous solutions; in a second part we performed a comparative study between jet injection of saline solution and jet injection of hyaluronate for ESD with this system This comparative study appeared necessary to measure the combined effects of both water-jet and macromolecular solution.

Material and methods

Water-jet system and bi-functional catheter

The water-jet system used in this study (Nestis Enki 2®, Lyon, France) is not a pump like other available water-jets, such as the ERBE Jet® (ERBE, Tuebingen, Germany), but comprises a high-pressure chamber (Fig. 1A) that can accommodate and compress plastic bags of saline or viscous solutions. The pressure in the chamber is obtained with medical nitrogen and can be set by the operator between 2 and 25 bars with a touch screen. A flexible tube is connected to the plastic bag in the chamber. This tube passes through an electric clamp controlled by a foot pedal before going out the pressure chamber, and is connected to the cutting knife with a standard luer lock connection (Fig. 1B). This system allows a pulsed injection that, theoretically, can improve mucosal lifting by the pulse due to a hammer effect. The Nestis knife is a bi-functional catheter (injection through the catheter and cutting with the electrode that is connected to an electrosurgical generator) with a 2.3 mm external diameter sheath covering a retractable metal electrode of 1.8 mm long, with a distal plate of 1.2 mm diameter. The injection hole is 200 μm wide and is central to the metal electrode (Fig. 1C). By contrast with the Flushknife BT (DK2618JN, Fujifilm, Saitama, Japan), the liquid is injected with higher pressure at the distal part of the catheter in the center of the plate and not around the electrode. By contrast with other water jets available, the Nestis system is able to inject macromolecular viscous solutions through a very soft catheter. Suction is preserved during the procedure with normal endoscopes and its flexibility allows smooth movements when working in the retroflexed position. The pressure used during the whole study was 12 bars since it is efficient to have a good mucosal cushion; we never experienced any perforation with this pressure in preceding works or during procedures in humans.

Electrocoagulator and settings used

We used the ERBE® VIO 200D generator (ERBE, Tubingen, Germany) with the following settings: soft coagulation, effect 4, 50 w, for marking and coagulation; mode Endocut I, effect 4 for cutting; swift coagulation, effect 3, 40 w, for dissection.

Methods

We used pig stomachs since they are a widely reported model for ESD optimizations [10, 11]. The ex vivo model was preferred to avoid animal sacrifices for this preliminary work. Furthermore, a pig's gastric mucosa is often difficult to lift, making the injection more challenging.

Prior to the study we measured the viscosity of each solution with a rheometer (RM180 Rheomat, Maple instruments, Toronto, ON, Canada) to determine poloxamer relative viscosity in comparison with hyaluronate, HES, and glycerol mix.

A single, young operator with minimal experience performed all ESDs using an upper gastrointestinal endoscope (Olympus GIF Q-140; Olympus, Tokyo, Japan) with a distal cap attached (4 mm length with a 3-mm side hole; D201-11304; Olympus, Tokyo, Japan).

Prior to the study, we scheduled one ESD to be performed, longer than 10 cm in diameter, with each of the first three solutions, to check the system's ability to inject macromolecular solutions without catheter obstruction during a long-lasting procedure. A fourth ESD (> 10 cm) was performed at the end of the study to verify this ability with poloxamer mix. In order to have a standard size, lesion marking was guided by trans-illumination. When the 'long procedure' was shorter than 1½ h, we continued to use the same catheter with the same solution for other short procedures to verify the lack of obstruction over 90 min.

The first part of the study was a feasibility study. Ten ESDs larger than 25 mm were conducted for each solution, including five in direct viewing and five in retroflexion. Retroflexion was used to control injection ability with

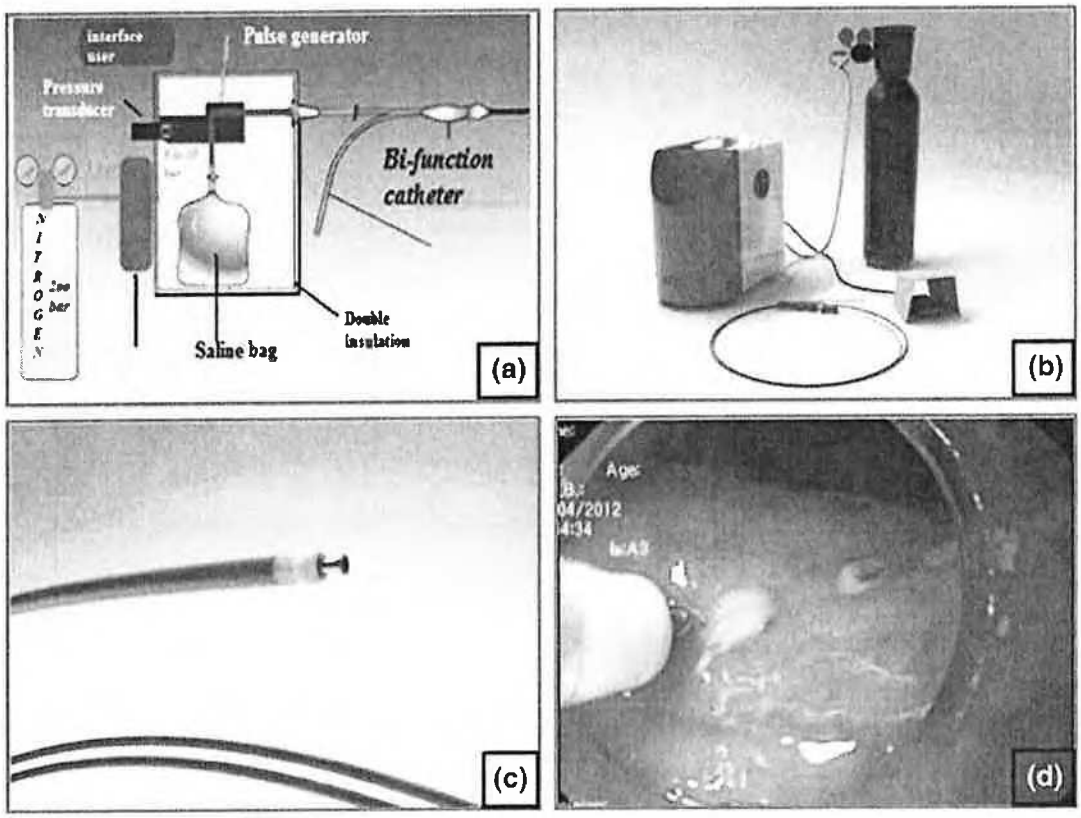

Fig. 1 Description of Nestis Enki II® system. **A** Operating principles; **B** aspect of pressure chamber with nitrogen bottle, injection pedal, and catheter; **C** aspect of the catheter; **D** endoscopic view of the catheter during an ESD procedure. *ESD* endoscopic submucosal dissection

maximal curvature of the catheter in the operating channel. The first three tested solutions were HES 130/0.4 (HES, Voluven®, Fresenius Kabi, France), a mix of glycerol (glycerol 10 %, fructose 5 %, and normal saline solution; Edouard Herriot Pharmacy, Lyon, France), and a solution of hyaluronate 0.5 % (5 g of pure hyaluronate dissolved in normal saline solution 0.9 %). This first part was also a learning time to standardize ESD procedures. Poloxamer solution (poloxamer 407 10 %, glycerol 5 %, normal saline solution 0.9 %; Edouard Herriot Pharmacy) was not available at the beginning of the study, therefore its injection by the Nestis system has been tested after the comparative part of the study. As poloxamer is viscous at body temperature, we placed the stomachs in controlled hot water (37 °C) in this group. For the other groups and for the comparative study using solutions without temperature-related viscosity changes, we left the pig stomachs without water at room temperature.

To summarize, we chose to test the injection of HES because it is currently available in all gastroenterology care units and can be injected easily. We selected glycerol mix because it is largely recommended in Japan to perform ESD and we usually use it in humans in our unit. We opted for hyaluronate 0.5 % because it is the reference solution to get an optimal mucosal cushion, and at the end of the study we tested poloxamer mix because our pharmacy suggested it as a cheaper viscous solution than hyaluronate.

In the second part of the study, we compared ESD with hyaluronate, and ESD with normal saline solution, both injected via the water-jet system. As previously reported, poloxamer was not available at this stage and hyaluronate was chosen as a macromolecular solution of reference. We performed 50 ESDs in each group. To reduce learning effect, the solution injected was changed every five procedures. Time was calculated between the first injection and the end of dissection, and included circumferential cutting and dissection up to specimen fall. Solutions were colored with indigo carmine, and prior to beginning each new ESD we checked that the area had not been already injected during a previous procedure. After ESD, we analyzed the muscular layer to find small perforations.

Specimen size was measured at the end of the procedure on the lesion stretched on a cork piece, and was defined by its two larger diameters and its surface using the ellipse formula: area (cm^2) = (small diameter (cm)/2) × (big diameter (cm)/2) × π.

Dissection speed was defined as follows: speed (cm^2/min) = area (cm^2)/duration (min).

Sample-size calculation or statistics

The hypothesis was that the ENKI 2® water jet with viscous solution decreases dissection time by 30 %. Yahagi et al. [1] have shown that the average time for the standard ESD technique to remove an artificial 25 mm diameter lesion is 32.7 ± 16.2 min. Using 'Power and Sample Size Program' software, the calculated sample size was 88 lesions, 44 lesions in each study arm ($\alpha = 0.05$, power = 0.8, $\delta = 9.81$ min, $\sigma = 16.2$ min, $m = 1$). We chose to perform 50 ESDs in each arm. A p-value of less than 0.05 was considered statistically significant. SPSS 11.0 software (SPSS, Inc., Chicago, IL, USA) was used for statistical analysis.

Results

We performed the 145 ESDs scheduled between November 2012 and February 2013 on 19 stomachs, either in the body (118) or at the junction between the antrum and the body (27). Injection has always been easy to perform. All resections were complete, including marking points. Two perforations occurred: one in the second part of the study in the saline group, and one at the end of the study using poloxamer mix.

Preliminary study

We measured mean dynamic viscosity (mPa.s) using a Searle rheometer with Rheomatic® software and using a ciseling rate of 100–1,000/s with the following results: HES 4.64 mPa.s (±0.73), glycerol mix 3.40 mPa.s (±0.97), hyaluronate (0.5 %) 45.18 mPa.s (±14.72), poloxamer mix at 37 °C 12.36 mPa.s (±3.30), and saline solution 1 mPa.s (±0.2).

We performed one long procedure to evaluate the obstruction risk of the catheter with each of the following solutions: HES, glycerol mix, hyaluronate, saline solution, and then poloxamer mix. Characteristics of these procedures are presented in Table 1. No catheter obstruction occurred and mucosal cushion was sufficient to perform ESD with all five solutions.

First part of the study: feasibility with different solutions

In this feasibility step, we performed ten ESDs, including five in direct viewing and five in retroflexion, with each of the four viscous solutions: HES, glycerol mix (glycerol 10 %, fructose 5 %, saline 0.9 %), hyaluronate sodic, and poloxamer mix. Results are presented in Table 2. No injection issue or perforation occurred with the first three solutions, and one perforation occurred that was clearly due to a lack of attention of the operator in the poloxamer group.

Time and dissection speed cannot be compared in the different groups of this feasibility study since the operator became more skilled for the last group with poloxamer at the end of the study.

A histological example of injection in the submucosal layer using poloxamer 10 % solution is given in Fig. 2.

Second part: comparative study

Results and statistics are presented in Table 3. Dissection speed was significantly higher in the hyaluronate group, with an average of 1.08 cm^2/min (SD 0.43, median 1.05) versus 0.80 cm^2/min (SD 0.26, median 0.82) with saline

Table 1 Results of the preliminary study: long-lasting ESD procedure with each solution

Solution	HES	Glycerol mix	Hyaluronate	Poloxamer mix	Saline serum
Maximum diameters (cm)	12 × 6	14 × 7	10 × 7.5	11.5 × 8	11 × 6
Duration (min)	165	210	47	51	55
Surface (ellipse area; cm^2)	56	77	59	72	52
Perforation	0	0	0	0	0

ESD endoscopic submucosal dissection, *HES* hydroxyethyl starch

Table 2 Results of procedures in each group, including ten ESD (five in direct viewing and five in retroflexion)

Solution	HES (10 ESD)	Glycerol mix (10 ESD)	Hyaluronate (10 ESD)	Poloxamer mix (10 ESD) [after comparative part]
Mean maximum diameter (cm)	4.3	3.6	3.9	3.4
Mean duration (min)	25.8	21.2	24	8.6
Speed (surface/time; cm^2/min)	0.41	0.40	0.44	1.09
Perforation	0	0	0	1
Injection issue	0	0	0	0

ESD endoscopic submucosal dissection, *HES* hydroxyethyl starch

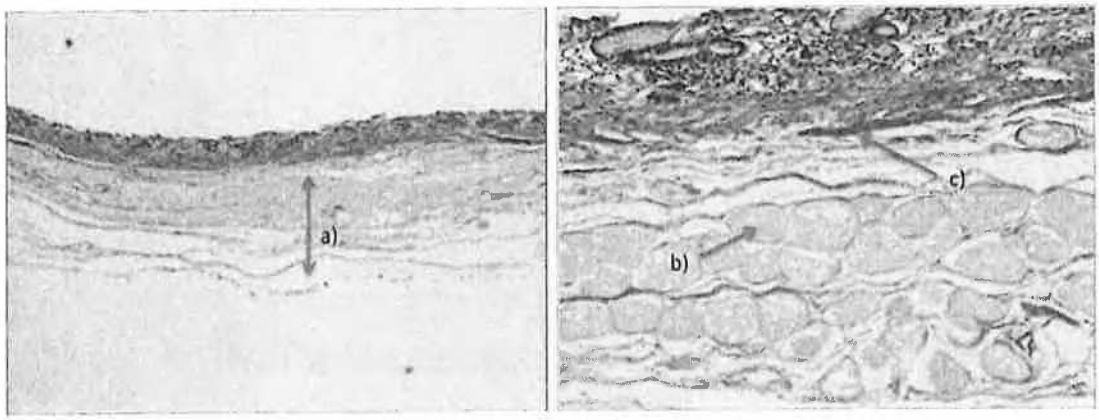

Fig. 2 Histological example of submucosal injection. **A** Depth of submucosal layer; **B** amounts of injected solution in the submucosa (Poloxamer 10 %); **C** muscularis mucosa layer

Table 3 Comparative study between saline injection and hyaluronate injection using the Nestis® water jet

Solution	Saline 0.9 %	Hyaluronate 0.5 %	*p* value
Mean maximum diameter (cm)	4.0 (±SD 0.82)	4.2 (±SD 0.74)	0.242
Mean duration (min)	12.9 (±SD 3.99)	10.7 (±SD 4.21)	0.002
Surface (ellipse area; cm^2)	9.9 (±SD 3.54)	10.8 (±SD 4.21)	0.483
Speed (surface/time; cm^2/min)	0.80	1.08	
Mean			<0.001
SD	0.26	0.43	
Median	0.82	1.04	
Perforations	1	0	NS
Injection issue	0	0	NS

NS non-significant, *SD* standard deviation

($p < 0.001$). Dissection speed increased by 35 % due to the macromolecular solution. Only one perforation occurred in the saline group in a fibrotic zone of the great curvature, close to a penetrant vessel.

Discussion

So far as we know, the new water-jet system Nestis Enki 2® is the first device that is able to inject not only saline but also macromolecular solutions through a single bi-functional catheter. Even if the inner diameter (0.2 mm) is smaller than that of usual needles (>0.6 mm), this system allowed the injection of tested viscous solutions despite their high viscosity, such as HES (4.64 mPa.s), glycerol mix (3.40 mPa.s), hyaluronate acid (45.18 mPa.s), and poloxamer mix (12.36 mPa.s), without any catheter obstruction. Injection was always made possible in direct viewing and retroflexion. Indeed, retroflexion is frequently necessary to perform ESD in the upper part of the stomach or in the rectum for human procedures.

Moreover, we report a significant difference ($p < 0.001$) in the dissection speed between isotonic saline solution (0.80 cm^2/min) and hyaluronate (1.08 cm^2/min). The results show the positive effect of combining jet injection and hyaluronate solutions to perform ESD: even if the procedure is only 35 % faster, this benefit is a significant step for such a difficult and time-consuming procedure. Since previous works comparing ESD with a water jet or classical needle reported insignificant benefit in procedure time with the water-jet system [4, 12], combined viscous solutions and jet injection could permit a significant shortening of procedures. This comparison will be tested in the colon of a living pig, as will the perforation risk.

We chose the first three solutions because of their ability to give higher and longer mucosal cushions than saline solution [5, 7, 8, 13, 14]. In addition, hyaluronate has demonstrated a significant benefit on the R0 resection rate [13, 15]. Despite the high viscosity (45.18 mPa.s) of this solution, we tested a fourth solution of poloxamer, a polymer that has been used in vascular applications [16, 17] with accepted tolerance; this solution is cheaper than hyaluronate. Although it is not so viscous as hyaluronate (12.36 mPa.s) it could be an alternative for EMR and ESD procedures. Further evaluation on digestive tissue cicatrization remained to be carried out before clinical use.

Our study has some limitations, notably because of the improvement of the operator's skills during the study. To

reduce this learning-curve effect, we introduced a first part regarding feasibility with 40 procedures. Then, for the comparative part, we changed the solution injected every five procedures so the two compared groups were performed in parallel and not successively. The second important limitation is the isolated stomach model, therefore further investigations are needed in living animals.

Conclusions

The Nestis Enki 2® system is the first jet injector able to inject viscous macromolecular solutions, even with retroflexed endoscope, through a flexible bi-functional catheter. In particular, jet injection of poloxamer mix is feasible and allows high dissection speed. The benefits of macromolecular solutions on saline shown in classical procedures are preserved using a water-jet system, and the jet injection of macromolecular solutions should then have a clinical value. Further studies in humans are scheduled.

Disclosures Mathieu Pioche has received financial support for PHD courses from Nestis. Thierry Ponchon is a co-founder of Nestis but has received no financial support. Mihai Ciocirlan, Vincent Lépilliez, Damien Salmon, Valérie Hervieu, Laetitia Mais, Olivier Guillaud, Marco Petronio, Isabelle Lienhart, Jean-Luc Adriano, and Cyril Lafon have no conflicts of interest to declare.

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Work in progress report - Thoracic non-oncologic

Efficacy of SOFT COAG for intraoperative bleeding in thoracic surgery

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Abstract

We present and examine two cases of the dramatic hemostasis with SOFT COAG in general thoracic surgery. SOFT COAG is a coagulation mode unique to VIO electrosurgical units (ERBE Elektromedizin GmbH, Germany). This system regulates the temperature rise below boiling point without generating sparks, which is high enough to denature protein. In addition to clinical applications, this coagulation system makes use of a reusable device, Slim line hand switch®, which has economically and ecologically major advantages for ecosurgery.

Keywords: Bleeding; Hemostasis; Ecosurgery; SOFT COAG

1. Introduction

We have previously reported the transected pulmonary artery model in beagle dogs to establish the validity of SOFT COAG of a modern electrosurgical unit (VIO300D, ERBE Elektromedizin GmbH, Germany) [1]. The successful results indicated the possibility for further applications. In response to such indication, this report investigates two clinical cases of the dramatic hemostasis with SOFT COAG in general thoracic surgery.

As previously described [1], SOFT COAG is a unique coagulation mode that automatically regulates output voltage below 200 V, causing the generation of Joule heat alone. The heat induces the denaturation of the protein and no tissue carbonization as a result. This method is based on the fact that the protein within the target tissue is effectively coagulated at the temperature between 70 and 80 °C due to the Joule heat generated in the tissue [2]. The bleeding point coagulated by this system showed permanent change of the protein in the microscopic finding, which was maintained even when scratched by a surgical instrument [1].

2. Materials and methods

Two patients who underwent thoracic surgical interventions were chosen. One was a 32-year-old woman who took a posterior mediastinal tumor resection and the other was a 62-year-old woman who had a squamous cell carcinoma of the lung. These patients were selected as they were to take different surgical procedures; open and thoracoscopic. Investigating two different surgical interventions indicates how clinically applicable the method is. The study was approved by the Institutional Review Board of Saga Prefectural Hospital Koseikan and the enrolled patients signed a full informed consent.

2.1. Technique of the hemostasis

After the temporary control of the bleeding by the finger or surgical instruments, a ball electrode with tip diameter of 4 mm (Slimline hand switch®) (Fig. 1), connected to VIO300D was placed against the bleeding point. SOFT COAG was set at Effect 6 and 80 W (our own upper limit setting). VIO's effect setting represents the setting of power voltage. Effect 6 is 156 V.

3. Results

3.1. Case 1

A 32-year-old woman underwent thoracoscopic posterior mediastinal tumor resection (neurogenic tumor). During the dissection of the cranial side of the tumor, an intercostal vessel was injured and caused active bleeding. After the temporary control of the bleeding, a ball electrode was placed against the bleeding point. The bleeding gradually subsided and finally was well controlled by the technique (Video 1).

3.2. Case 2

A 62-year-old woman was suffering from the squamous cell carcinoma of the lung, which completely occluded the

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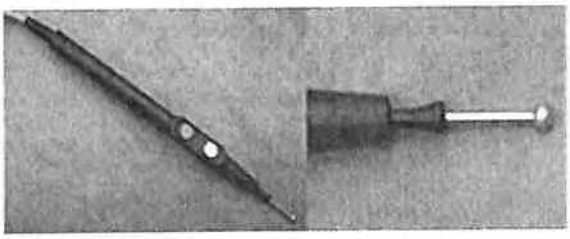

Fig. 1. Slimline hand switch® and ball electrode with 4 mm tip diameter.

Video 1. After the temporary control of the bleeding, a ball electrode was placed against the bleeding point. The bleeding gradually subsided and finally was well controlled by the technique.

right upper bronchus. She underwent a sleeve upper lobectomy of the right lung. During the dissection of the tumor along the intermedial trunk of the right bronchus, traction of the taped pulmonary artery (A6, already untapped in the video) made a small tear in the artery. After the bleeding was temporarily controlled, the electrode was placed against the carefully searched bleeding point. The bleeding was easily controlled (Video 2).

4. Discussion

The purpose of this study was to investigate the clinical efficacy of SOFT COAG, which was proven valid in a previous animal study. Once we understood the hemostatic ability of SOFT COAG in the animal experiment [1], the methods were applied to clinical cases. The demonstrated methods were to control the active bleeding from the intercostal vessel and pulmonary artery during the surgical procedures.

Bleeding during thoracoscopic procedures could necessitate conversion to thoracotomy in order to control it. In

Video 2. During the dissection of the tumor along the intermedial trunk of the right bronchus, traction of the taped pulmonary artery (A6, already untapped in this video) made a small tear in the artery. After temporary control of the bleeding, the electrode was placed against the carefully searched bleeding point. The bleeding was easily controlled.

our case 1, SOFT COAG made it possible to avoid an open procedure to stop such active bleeding. The hemostatic ability and its utility are also highlighted in case 2, which is an open procedure. If SOFT COAG was not available, we would have probably needed to suture the bleeding point, which would have taken much more time than the treating time with SOFT COAG. Easy control of bleeding contributes to avoiding time-consuming procedures in such a bleeding situation. In addition, the protein denaturation controls the bleeding permanently, which is not possible by the conventional electrosurgical units forming a carbonized eschar.

In addition to such clinical applications, the device used with a VIO unit, Slimline hand switch® (Fig. 1) has a major economical advantage for the daily clinical practice; it is reusable for ~100 times by autoclave sterilization. Now there is even a term 'Ecosurgery', which respects the economical and ecological aspects. Sitges-Serra [3] insists on refraining from the use of single-use devices. With less industrial wastes of plastic materials, reusable devices contribute to economy and ecology.

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VIO 300D Principles and Waveforms

ERBE "Platform" –every[1] ERBE waveform operates on the principle of constant voltage and automatic power dosing (SPRAY Coag does not power dose according to Ohm's Law).

Quick Facts:

- Energy Equation: Current (i) X Voltage (V) = Power (watts)
- According to Ohm's Law as circuit resistance increases current flow decreases and vice-versa (taking liberties with his "law").

$$I = \frac{V}{R}$$

- ERBE's patented Constant Voltage algorithm allows current to fluctuate (to a pre-set wattage maximum) according to Ohm's law
- ≥200Vp (Volts Peak) is needed to create micro-electric arcs required for electrosurgical cutting (vaporization)

- >600Vp leads to carbonization. Other factors (Table 1)[2] such as temperature also effect target tissue results
- Key impedance variables influence a waveform's function at target tissue:
  - Electrode surface area
  - Technique of high current density vs. low current density
  - Speed of movement of electrode
  - Electrode material
  - Tissue itself (fibrotic vs. water soluble)
  - Pad placement on patient
  - Etc.
- Considerations for electrosurgical application in GI Intervention are multifold (See Fig.1)[3]

[1] SPRAY Coag does not power dose but does maintain "high constant voltage" at target tissue without minimized effect due to capacitive coupling. Result is reproducibility/consistency of fulguration or arcing.

[2] "Principles of Electrosurgery" (Chapter 11), from Successful Training in Gastrointestinal Endoscopy, David L. Carr-Locke MB, FRCP, FASGE, John Day BBA

[3] "Principles of Electrosurgery" (Chapter 11), from Successful Training in Gastrointestinal Endoscopy, David L. Carr-Locke MB, FRCP, FASGE, John Day BBA

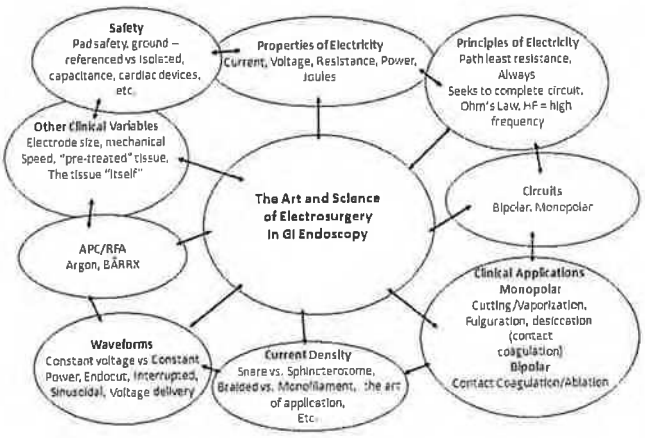


Fig 1

TABLE 1 Thermal Effects on Human Tissue [1]

TEMPERATURE	EFFECT
≤ 40 °C	None
40–50 °C	Hyperthermia: Changes in the cell membrane and internal cellular structures depending on the duration of the necrosis
~ 60 °C	Coagulation (denaturation) of the cellular proteins Devitalization
~ 80 °C	Coagulation of the extracellular collagen Destruction of cell membranes
~ 100 °C	Vaporization of tissue fluid depending on vaporization speed Desiccation and attrition or Incision due to mechanical rupture of the tissue
> 150 °C	Carbonization
> 300 °C	Vaporization

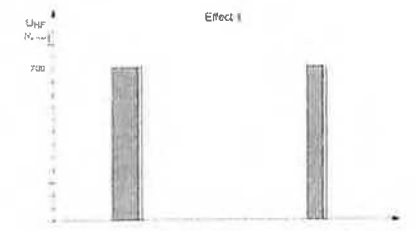
Waveforms

ENDOCUT Q – the same waveform as ENDOCUT I except approximately **700Vp** used in order to generate arcs over larger surface area i.e. snares or when used in saline rich environment (saline injection). Some data[4] shows better histologic quality with specimens resected (snare wire) with ENDOCUT. ENDOCUT Q is also used by "ESD" experts for mucosal incision phase and for submucosal dissection. It could be argued that in highly conductive saline-rich environment ENDOCUT offers more reliable cutting.

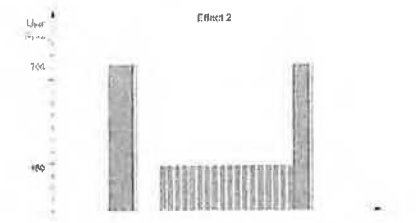
ENDOCUT employs a patented spark generation and recognition algorithm that calculates real-time when a spark is present based upon circuit variables and upon generation of the "sparks" occurs. During true electrosurgical cutting intracellular fluid rapidly boils and disrupts cellular membranes and the electrode rides through the incisional plane on a tiny steam barrier. ENDOCUT generally produces cutting arcs within 5ms of activation but can cycle up to 50ms if necessary to recognize and control arcing.

[4] Am J Gastroenterol. 2006 Sep;101(9):2123-7. Epub 2006 Jul 18, **Diagnostic quality of: polyps resected by snare polypectomy: does the type of electrosurgical current used matter?**

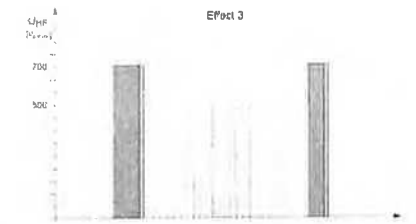
- EFFECT
  - 1-no coag between cuts



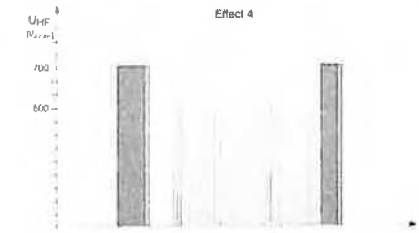
  - 2-SOFT coagulation– type waveform between cuts



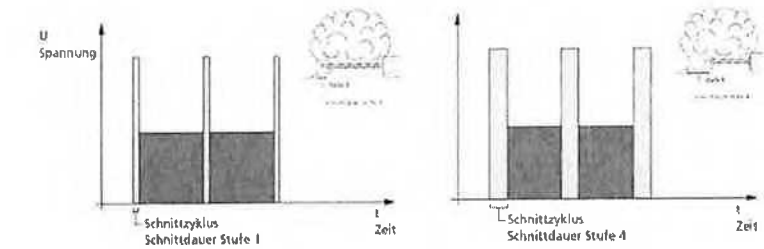
  - 3-FORCED coagulation-type constant voltage waveform between cuts



  - 4- FORCED coagulation-type constant voltage waveform between cuts – a bit more intense (due to higher duty cycle) than EFFECT 3.



- DURATION (based upon patented algorithm) determines the amount of time (in milliseconds) the arcing is present

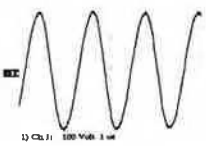


- For instance, once a spark is generated in the briefest time after activation at a duration of "2" the spark stays "on" for approximately 6 milliseconds (varies slightly between "I" and "Q")
  - D1 – 2ms
  - D2 – 6ms
  - D3 – 10ms
  - D4 – 14ms

- INTERVAL is the time between the cutting phases if the unit is allowed to cycle

Cutting Interval	Level 1	400 ms
	Level 4	880 ms
	Level 6	1200 ms
	Level 10	1840 ms

ENDOCUT uses sinusoidal waveforms for the cutting phase. The Cutting phase also uses patented spark recognition. The waveform is considered sinusoidal as follows and uses > 200Vp:



For EFFECT 2 a SOFT Coag occurs with a sinusoidal waveform (above) but <200Vp.

For EFFECT 3 and 4 a "FORCED" coag waveform (intermittent bursts of relatively higher voltage ~ 1000+Vp) occurs with less frequent duty cycle.

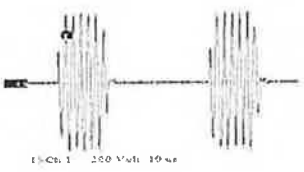
During "EMR" or saline assisted polypectomy using ENDOCUT, many experts use the theoretical rationale that ENDOCUT Q Effect 3-Duration 1- Interval 3 limits thermal insult in especially thin-walled anatomy (e.g. cecum) and they use taps (no cycling) to limit thermal insult even further. Obviously they are erring on the side of immediate bleeding. Attached is an overview from Michael Bourke MD that explains his technique during saline assisted EMR of flat lesions. He has been prolific in publishing in recent years, and I've had the pleasure of working with him each year at Norman Marcon's annual therapeutic endoscopy course in Toronto.

FORCED COAG- "pinpoint" contact coagulation/hemostasis. Uses approximately 1000+Vp. 25-40W E1 (lowest voltage for this mode) per your technique. E 2 (increase Effect in increments of 1 to increase coagulation/"hemostasis" effect). Increasing Effect increases voltage and thus increases thermal insult towards wall and lateral to electrode.

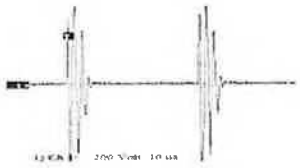
For physicians using "coag" for snare resection, the voltage is constant and the accustomed technique is employed. Generally 25W Effect 2 (or 1 for larger surface braided wires) is used and tissue effect guides the interventionalist whether to raise or lower the maximum setting.

DRY CUT / SWIFT COAG (submucosal dissection) - Use when cutting and simultaneous extra (relative to **ENDOCUT Q**) hemostasis is needed i.e. vascular submucosal dissection during (Yahagi often does this with **DRY CUT**). DRY CUT uses approximately 1000Vp depending on Effect and SWIFT Coag approximately 1200Vp. DRY CUT used primarily for mucosal incision when tissue is bleeding more, but the downside is increased thermal insult thus important to note wider margins to protect specimen read-ability. **SWIFT** Coag used primarily for submucosal dissection and is a bit more hemostatic with less cutting than DRY. It can be used like FORCED for pinpoint hemostasis of vessels during submucosal dissection. **SWIFT** is slightly less "hemostatic" than **FORCED**. Very dependent on user tissue goals and electrode and tissue –type.

Dry Cut



SWIFT COAG



SOFT COAG-primarily used with hemostatic forceps and marking. Uses less <200Vp and voltage (like above waveforms) is constant. As target tissue proteins denature (coagulate) impedance rises and current falls off. The result is virtually non-stick and very homogenous application of energy. Often you can observe the slow progression of white coagulation and stop process during visual monitoring.

50W Effect 5 for Marking

80W Effect 5 for coagulation forceps

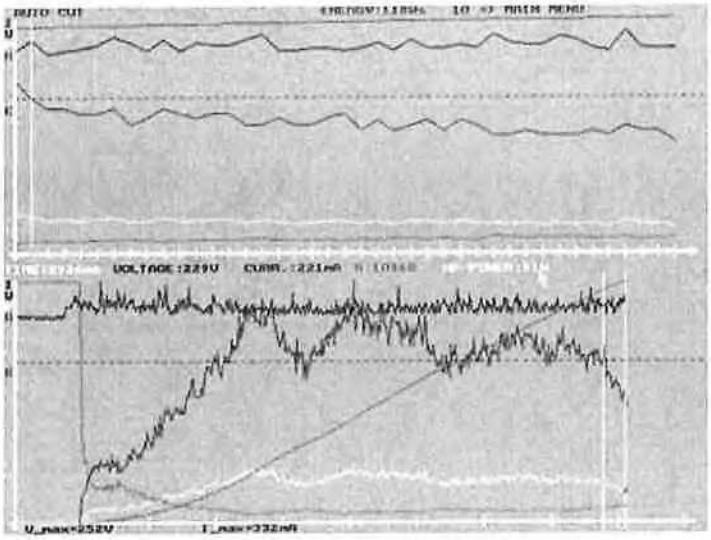
SOFT Coag Effects are counter-intuitive from a target tissue perspective in that the higher the Effect, the more superficial the thermal damage in general around the target tissue electrode and towards the path of least resistance. Contrarily, the lower the Effect causes a slower rise in impedance and a longer current flow until power drops to near zero, thus the clinical effect at lower effect settings is deeper and more intense.

SPRAY COAG (POEM Myotomy)– 4000Vp max, very low duty cycle (approximately 6%). Used for non-contact coagulation procedures primarily.

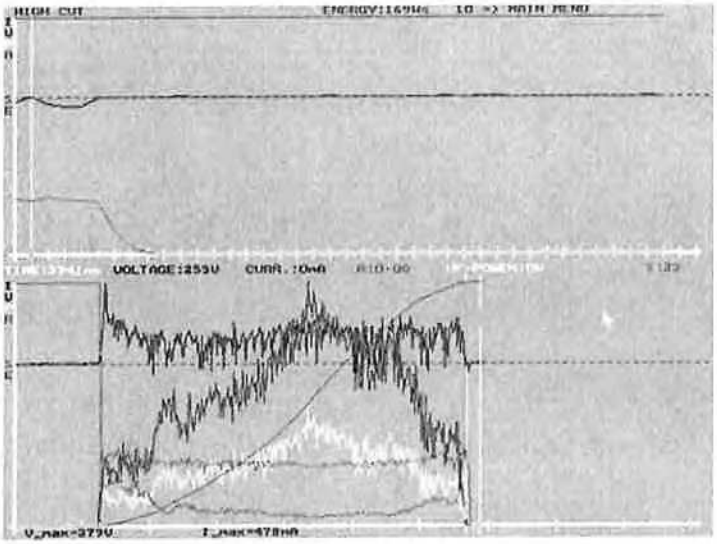
AUTOCUT – (used by few as alternative to ENDOCUT I for sphincterotomy) sinusoidal waveform operating between 200-600Vp and used for rapidly vaporizing tissue using various surgical electrodes. Prior to ENDOCUT I (VIO 300D) EFFECT 1 many biliary endoscopists used for pancreatic papillotomy to decrease thermal insult during incision. It is used primarily in very demanding surgical procedures (i.e. TURP). Very clean "cuts". Increasing Effect (i.e. Voltage) increases thermal insult.


Effect 1-4 (left to right)

Here is an electrical output of AUTOCUT from a surgical application. The darker blue line is voltage which is constant. The dashed line is the max power. Current in RED Power in yellow Impedance/resistance in Green



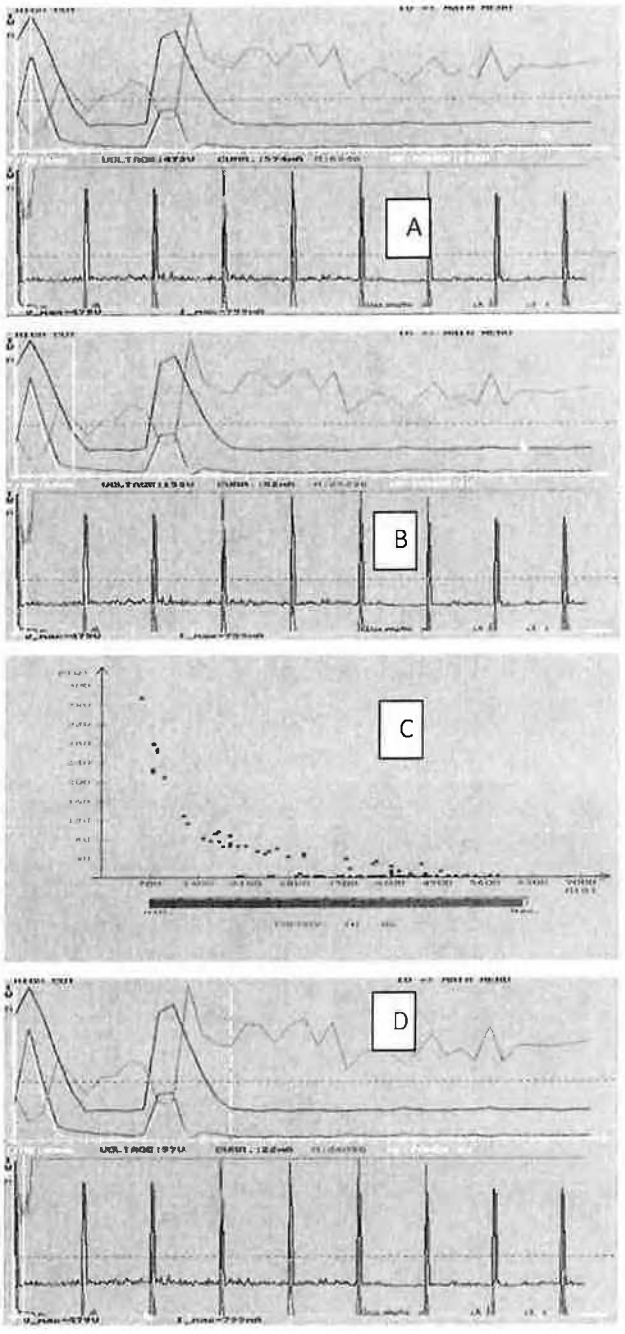
Below is HIGH CUT. SPARK is constant and voltage varies but within a very small "window" and is still fairly constant compared to a conventional ESU (i.e. Valleylab). SPARK is represented by lighter blue line.



Confidential Dr. Samarasena Eyes Only

And lastly, from in vivo patient use – ENDOCUT in Sphincterotomy with a monofilament wire Effect 2

ENDOCUT™ reads circuit resistance along the electrode (sphincterotome or pre-cut needle knife) at target tissue, measuring electrode surface area, tissue density and resistance, pad placement, etc.) and outputs appropriate power in intervals up to 50 ms in order to create a brief electrosurgical (versus mechanical) incision. Since voltage (electromotive force) is controlled and constant below 600vp, carbonization along the incision plane rarely occurs. In the in vivo electrical graphs herein recorded on 12/28/2000 at 15:47 hours, (A) shows that at 2ms in this incision 272 watts of power was used at that given millisecond in time [Also represented by one of the small corresponding "blue dots – electrons or current flow –in (C)]. In the graph labeled (B), at 10 ms into the 'cut' the power is registering 8 watts as the approximately 1 millimeter incision has occurred and is completing the initial cutting phase of this ENDOCUT ™ activation. In (D), 40 ms into this ENDOCUT™ incision the ERBE ICC electrosurgical unit is entering an approximate 750 ms SOFT COAGULATION™ phase that coagulates (denatures tissue protein) prior to the next 50ms electrosurgical incision cycle.



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ORIGINAL ARTICLE

VIO soft-coagulation system for major pulmonary resections: results in 68 patients with primary lung cancer

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Abstract
Purpose. The VIO soft-coagulation system is a new device for tissue coagulation in which the output voltage is automatically regulated. We evaluated the safety and efficacy of this system for major pulmonary resection of lung cancer.
Methods. We used bipolar VIO soft-coagulation for major pulmonary resection in 68 patients with primary lung cancer using the following three surgical procedures: (1) coagulation of the tissues around lobar vessels and bronchus; (2) fissure dissection; (3) lymph node dissection. The dissection in those steps was performed with both bipolar VIO soft-coagulation forceps and scissors. Results were analyzed with special reference to intraoperative complications, blood loss, and postoperative morbidity. The data in this study (VIO group) were compared with those of 78 lung cancer patients who underwent surgery using conventional electrocautery (CE group).
Results. The operations in this series included 60 lobectomies, 1 bilobectomy, 1 pneumonectomy, and 6 segmentectomies. With the VIO soft-coagulation system, coagulation of tissues around the lobar pulmonary vessels without injury to the pulmonary vessels or bronchus was effective. The mean blood loss in the VIO group was 90.6 g (range 5–595 g), which was significantly lower than that in the CE group (mean 141.0 g, range 5–700 g) ($P = 0.014$). Postoperative morbidity rates in the VIO and the CE group were 11.7% and 17.9%, respectively.
Conclusion. The VIO soft-coagulation system is safe and feasible for major pulmonary resections in patients with lung cancer.

Key words VIO soft coagulation · Lung cancer

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Introduction

Conventional electrocautery is widely used in general thoracic surgery. Although clearly useful, this popular surgical device has a weak point for use in clinical settings in that it generates sparks, which could cause accidental injury of adjacent organs. During lung cancer surgery, an accidental injury of major pulmonary vessels could lead to critical bleeding. Devices that would cause less damage to surrounding organs are desirable for improving the safety of major pulmonary resections in patients with lung cancer.

The VIO soft-coagulation system (ERBE Elektromedizin, Tubingen, Germany) was recently developed in Germany. The main characteristic of the VIO system is autoregulation of output voltage by a built-in computer. This system controls the temperature below the boiling point, without generating sparks, thereby causing minimal damage to surrounding tissues. Recent reports have shown the usefulness of the VIO soft-coagulation system in liver[1] and pancreatic[2] surgery. Sukuragi et al. reported achievement of dramatic hemostasis of bleeding

from the pulmonary artery by monopolar VIO soft-coagulation.[3,4]

Based on those clinical reports, we hypothesized that the VIO soft-coagulation system may be useful for major pulmonary resection in patients with lung cancer. In this study, we applied the bipolar VIO soft-coagulation system to lung cancer surgery and evaluated the efficacy of this new device in the field of general thoracic surgery.

Patients and methods

From January 2009 through June 2010, the bipolar VIO soft-coagulation system was used in 70 patients with primary lung cancer who underwent major pulmonary resection in the Department of Surgery, Kyushu Kosenenkin Hospital. Two patients with T4 pathological stage were excluded from this study. The data on the remaining 68 patients were retrospectively analyzed. Those patients were candidates for complete resection by means of lobectomy, bilobectomy, pneumonectomy, or segmentectomy. Patients who were treated with pulmonary wedge resection were excluded from the study. The study protocol was approved by the institutional review board at Kyushu Koseinenkin Hospital. Informed consent for use of this new coagulation device was obtained from all participating patients. This study was not financially supported by any organization.

In this study, bipolar-type VIO soft-coagulation was used in the following three surgical procedures: (1) coagulation of the tissues around lobar vessels and bronchus; (2) fissure dissection; (3) lymph node dissection. The dissection in those steps was carried out with both bipolar VIO soft-coagulation forceps and scissors. The output voltage was regulated up to 190 Vp, and the maximum temperature was set at <100°C. For the other surgical procedures, such as thoracotomy or mobilization of the lobe, surgeons could use either the VIO system or conventional electrocautery.

The results were analyzed with special reference to intraoperative complications, blood loss, and postoperative morbidity. The data among the 68 patients who underwent major pulmonary resections using the VIO system (VIO group) were compared with data on 78 patients with primary lung cancer who underwent major pulmonary resection in our institution between July 2007 and December 2008 using conventional electrocautery (CE group).

Student's *t*-test was used to examine intergroup differences in blood loss and operating time. The threshold of significance was set at $P < 0.05$.

Results

Patient characteristics and co-morbidities are shown in Table 1. Enrolled in the study were 31 (45.5%) men and 37 (54.5%) women with a mean age of 71 years (range 53–85 years). The type of resection was lobectomy in 60 patients (88.2%), bilobectomy in 1 (1.4%), pneumonectomy in 1 (1.4%), and segmentectomy in 6 (8.8%). All pulmonary resections were performed by thoracotomy.

Table 1 Patients' characteristics

Variable	VIO group ($n = 68$)	CE group ($n = 78$)
Male	31 (45.5%)	42 (53.8%)
Age (age), mean and range	71 (53–85)	70 (49–94)
Tumor location		
Right upper lobe	22 (32.3%)	25 (32.0%)
Right middle lobe	1 (1.4%)	8 (10.2%)
Right lower lobe	16 (20.5%)	19 (24.3%)
Left upper lobe	14 (20.5%)	15 (19.2%)
Left lower lobe	15 (22.0%)	11 (14.1%)
Pathological stage		
IA	41 (60.2%)	51 (65.3%)
IB	14 (20.5%)	17 (21.7%)
IIA	0	2 (2.5%)
IIB	3 (4.4%)	5 (6.4%)
IIIA	8 (11.7%)	6 (7.6%)
IIIB	0	0
IV	2 (2.9%)	1 (1.2%)
Histology		
Adenocarcinoma	54 (79.4%)	57 (73.0%)
Squamous cell	7 (10.2%)	15 (19.2%)
Adenosquamous	3 (4.2%)	3 (3.8%)
Large cell	2 (2.9%)	0
Pleomorphic	1 (1.4%)	1 (1.2%)
Atypical carcinoid	1 (1.4%)	2 (2.5%)
Type of resection		
Lobectomy	60 (88.2%)	69 (88.4%)
Bilobectomy	1 (1.4%)	2 (2.5%)
Pneumonectomy	1 (1.4%)	0
Segmentectomy	6 (8.8%)	7 (8.9%)
Surgeon		
Consultant	31 (45.5%)	46 (58.9%)
Trainee	37 (54.5%)	32 (41.1%)
Approach		
Posterolateral	67 (98.5%)	78 (100%)
Transsternal	1 (1.4%)	0
Co-morbidities		
Arrhythmia	4 (5.8%)	4 (5.1%)
Ischemic heart disease	3 (4.4%)	6 (7.6%)
Peripheral vascular disease	2 (2.9%)	0
COPD	3 (4.4%)	2 (2.5%)
Bronchial asthma	3 (4.4%)	3 (3.8%)
Old tuberculosis	5 (7.3%)	1 (1.2%)
Cerebrovascular disease	3 (4.4%)	4 (5.1%)
Liver disease	1 (1.4%)	0
Renal disease	1 (1.4%)	0
Diabetes	15 (22.0%)	10 (12.8%)
Malignancy	12 (17.6%)	13 (16.6%)

COPD, chronic obstructive pulmonary disease

Table 2 Perioperative outcomes

Variable	VIO group ($n = 68$)	CE group ($n = 78$)	P
Blood loss (ml)	90.6 (5–595)	141.5 (5–700)	0.014
Operating time (min)	286.7 (152–540)	312.4 (154–690)	0.181
Hospital stay (days)	14.4 (9–62)	15.0 (9–81)	0.736

67 patients underwent a posterolateral thoracotomy, and 1 had a median sternotomy (median sternotomy was selected for centrally located cancer). Thoracoscopy was used in all cases for assistance. The three surgeons participating in this study were general thoracic surgeons. The mean length of the posterolateral skin incision was 16 cm (range 11–22 cm).

Complete resection was performed in all 68 patients. The pathological stage was stage IA in 41 (60.2%), IB in 14 (20.5%), IIA in none, IIB in 3 (4.4%), IIIA in 8 (11.7%), IIIB in none, and IV in 2 (2.9%). The histological description was adenocarcinoma in 54 (79.4%), squamous cell carcinoma in 7 (10.2%), adenosquamous carcinoma in 3 (4.4%), large-cell carcinoma in 2 (2.9%), pleomorphic carcinoma in 1 (1.4%), and atypical carcinoid in 1 (1.4%).

Blood loss in all 68 patients ranged from 5 to 595 g (mean 90.6 g). Operating time ranged from 152 to 540 min (mean 286.7 min) (Table 2). Tissue coagulation by bipolar VIO soft-coagulation was successful in the dissection of lobar vessels and bronchus, fissure dissection, and lymph node dissection. The tip of the bipolar VIO soft-coagulation is blunt, so it can be safely used for tissue dissection (Fig. 1). No pulmonary vessels or bronchi were accidentally injured by VIO bipolar soft-coagulation. No intraoperative bleeding occurred that complicated the surgical procedure.

In two cases, minor bleeding from a branch of the pulmonary artery occurred during dissection of lobar vessels, but it was unrelated to the VIO system. The VIO soft-coagulation system was used in both cases. Direct hemostasis by the VIO system was immediately achieved without accidental injury of the pulmonary artery.

Postoperative complications occurred in 8 of the 68 patients (11.7%) (Table 3). One patient (1.4%) required chest tube drainage for more than 7 days for prolonged air leakage. There was no chylothorax or postoperative hemorrhage that required transfusion. The operative mortality was zero.

The perioperative outcome among the 68 patients in this study (VIO group) was compared with that of the 78 patients who underwent lung cancer surgery using conventional electrocautery (CE group). Characteristics including age, tumor location, pathological stage, and type of resection were similar in the two groups. The mean blood loss in the VIO group (90.6 g) was significantly lower than that in the CE group (141.0 g, range 5–700 g) ($P = 0.014$). Intraoperative bleeding, which complicates surgical procedures, occurred in two patients of the CE group versus none in the VIO group. There was no significant difference in operating time between the two groups. Postoperative morbidity rates in the VIO and CE groups were 11.4% and 17.9%, respectively (Table 3).

Table 3 In-hospital morbidity and mortality

Event	VIO group ($n = 68$)	CE group ($n = 78$)
Intraoperative bleeding[a]	0	2 (2.5%)
Air leak >5 days	2 (2.9%)	6 (7.6%)
Chest tube drainage >7 days	1 (1.4%)	4 (5.1%)
Chylothorax	0	1 (1.2%)
Hemorrhage with transfusion	0	0
Pyothorax	1 (1.4%)	2 (2.5%)
Respiratory	2 (2.9%)	3 (3.8%)
Arrhythmia	1 (1.4%)	2 (2.5%)
Subcutaneous hematoma	2 (2.9%)	0
Morbidity	8 (11.7%)	14 (17.9%)
Mortality	0	2 (2.5%)

[a]Bleeding complicating surgical procedure

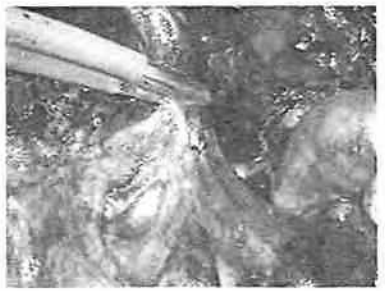

Fig. 1 Thoracoscopic photograph. Bipolar VIO soft-coagulation forceps is used to coagulate the bronchial artery

Discussion

Results of this preliminary study showed that the bipolar VIO soft-coagulation system could be safely applied to major pulmonary resection in patients with lung cancer. This unique device enables effective coagulation of tissues around lobar vessels without accidental injury to pulmonary vessels or bronchi. We found that bipolar VIO soft-coagulation had some advantages over conventional electrocautery.

The VIO soft coagulation system is an electrosurgical output device newly developed in Germany that automatically regulates output voltage to a maximum of 200 volts. Therefore, VIO soft-coagulation can avoid generating both sparks and carbonization of the attached tissues. The prevention of spark generation is the most distinctive advantage over conventional electrocautery because sparking can lead to accidental injury of adjacent organs. In this study, we frequently used bipolar VIO soft-coagulation in dissection of lobar vessels and bronchus, fissure dissection, and lymph node dissection. We found two key points in favor of the use of bipolar VIO soft-coagulation. One is that it can be safely used in the narrow space close to lobar vessels. Direct contact of the bipolar tip with lobar vessels presents no danger because no spark is generated by VIO soft coagulation during coagulation. Another key point is that bipolar soft-coagulation is effective for separating incomplete fissures. Soft coagulation followed by dissection with scissors could avoid bleeding and minimize air leakage from lung parenchyma. The rate of prolonged air leakage over 7 days after surgery was low, occurring in only 1 of 68 patients. We emphasize that the use of bipolar VIO soft-coagulation was safe and effective, particularly for dissecting incomplete fissures near lobar vessels.

Recent reports have shown that the VIO soft-coagulation system is effective for hepatic resection[1] and in preventing a pancreatic fistula following pancreatectomy.[2] In general thoracic surgery, Sakuragi et al. described dramatic hemostasis with this device in both an experimental model and in clinical situations.[3,4] In our study, minor bleeding from a branch of the pulmonary artery occurred in two cases. Immediate hemostasis was achieved with the VIO soft-coagulation system in both cases. Together with the previous reports, our experience indicates that the VIO soft-coagulation system can be considered effective for minor bleeding from pulmonary vessels in some situations.

There was significant difference in mean blood loss in the VIO group compared with that in the CE group. Most important is that we did not experience any intraoperative accident caused by bipolar VIO soft coagulation. Because the key points in major pulmonary resections are fissure dissection and management of the lobar vessels and bronchi, the use of bipolar VIO soft coagulation in those procedures could improve intraoperative safety.

Conclusion

The results of this study showed that the bipolar VIO soft-coagulation system is safe and feasible for major pulmonary resections in patients with lung cancer. This device could improve safety, especially in regard to fissure dissection and management of the lobar vessels and bronchus. Although selection of a device for tissue coagulation depends on the surgeon's preference, the bipolar VIO soft-coagulation system could be an important option among several surgical devices for major pulmonary resection in patients with lung cancer.

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Morphological changes induced by extensive endobronchial electrocautery

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Morphological changes induced by extensive endobronchial electrocautery. C. Verkindre, A. Brichet, C.A. Maurage, P. Ramon, J-P. Homasson, C.H. Marquette. ©ERS Journals Ltd 1999.

ABSTRACT: Due to recent improvements of safety conditions for therapeutic devices, electrocautery is being considered with renewed interest in the field of therapeutic bronchoscopy. The efficiency of this technique for destructing intraluminal tumours is well documented and makes it an attractive alternative to Yttrium aluminium garnet (YAG) laser photo-coagulation. Little is known, however, about the morphologic changes induced by electrocautery within the bronchial wall structures. This information is, however, important since electrocautery has been proposed as an alternative to other techniques to treat superficial tumours of the bronchial wall.

Soft coagulation, with autostop, using two different power setting (40 and 120 W), produced by a new generation of high frequency voltage regulated generators was applied circumferentially to the trachea or left main bronchus, in a series of 52 piglets. Early (48 h) and late effects (6 weeks) were assessed through gross examination (bronchoscopy and autopsy) and light microscopy.

Early effects of electrocautery included coagulation necrosis of the mucosa only and intense acute inflammation extending deep into the bronchial structure. The inflammatory phase progressively resolved while extensive transmural fibrosis and deterioration of the cartilage plates developed. The nature and extent of these lesions did not depend upon the energy delivered (40 W *versus* 120 W). Retractile scar formation and loss of cartilaginous support then produced iatrogenic secondary stenoses.

These results do not question the use of electrocautery to palliate endoluminal tumours but should make operators careful when treating extensive infiltration of the bronchial wall.

Eur Respir J 1999; 14: 796–799.

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Malignant tracheobronchial obstruction can cause major respiratory problems including dyspnoea, haemoptysis, postobstructive pneumonia and sometimes death due to terminal asphyxia.

Relief of obstruction of central airways can be achieved by several palliative techniques. External compression of the airways can be palliated with stent insertion. The intraluminal component of the tumour can be destroyed through Yttrium aluminium garnet (YAG) laser photocoagulation or electrocautery or with a delayed effect through cryotherapy, brachytherapy and photodynamic therapy.

Electrocautery almost disappeared since the old generators were very dangerous, causing burns, perforation and massive haemoptysis.

A renewed interest in the technique appeared as a result of the availability of new and safe generators of high frequency (HF) current, new probes easily usable through rigid and flexible bronchoscopes and, more recently, new insulated and electrically grounded flexible bronchoscopes [1–7].

As for Nd-YAG laser photocoagulation, electrosurgical tumour destruction is an immediate effect of thermal damage. For electrocautery the thermal effect is due to the passage of electric flows through the tissue. The depth of tissue necrosis depends on the voltage difference between the probe and the tissue and on the duration of contact. Even with the very new voltage regulated generators the depth of the necrosis which will be obtained can hardly be predicted. In addition, little is known about the morphologic changes induced by electrocautery on the normal bronchial structures. These unresolved issues clearly limit the use of the technique and could be at least partly resolved by experimental studies [2, 8, 9]. This is especially important since electrocautery has recently been proposed as an alternative to cryotherapy, brachytherapy or photodynamic therapy to treat superficial tumours of the bronchial wall [7].

The questions of this study were: does the safest mode of coagulation (*i.e.* "soft coagulation" mode with autostop) entail a risk of secondary stenosis? Does the power setting (40 *versus* 120 W) influence the risk of secondary stenosis? What is the pathological substratum for these secondary stenoses?

The authors therefore evaluated the immediate and late effects of electrocautery delivered through rigid bronchoscopy to the normal tracheobronchial tree in piglets. Of particular interest was the study of acute and late changes of the mucosa, the submucosa and the cartilage.

Materials and methods

Animals

Piglets (Largewhite-Landrace) weighing 23±6 kg were used. All animals were treated in compliance with the guidelines of the Department of Experimental Research of the Lille University and with the "Guide for the Care and Use of Laboratory Animals" [10]. In addition, the experimental protocols were reviewed and approved by the Animal Experimental Committee of the French ministry of agriculture.

Pigs of an average weight of 23 kg were chosen because their tracheal size approximates that of a human adult weighing 45–60 kg. This allows rigid bronchoscopy with the same instruments as those used in humans, and thus facilitates further extrapolation of the experience gained with therapeutic bronchoscopy in the pig models of central airway diseases [11].

Bronchoscopic procedures

All of the bronchoscopies were performed under general anaesthesia. The animals were premedicated intramuscularly with ketamine (50 mg) and atropine sulphate (0.25 mg). Anesthesia was induced with intravenous propofol (2–3 mg·kg body weight^{-1}) followed by a continuous infusion of propofol (10 mg·kg body weight^{-1}) for maintenance. Analgesia was provided by repeated intravenous bolus doses of 0.5 mg alfentanyl. Neuromuscular blockade was obtained with repeated intravenous bolus doses of suxametonium (0.1 mg·kg body weight^{-1}). An 11 mm outer diameter rigid bronchoscope (Shapsay bronchoscope ref 10317 LA; Karl Storz Gmbh, Tuttlingen, Germany) with a 5.5 mm rigid telescope (Hopkins ref 10320 A; Karl Storz GmbH) was used for bronchoscopy. Ventilation was provided by a high frequency jet ventilator through a canula adjusted to the proximal port of the rigid bronchoscope. Blood pressure, pulse oxymetry and electrocardiogram were monitored throughout the procedures.

Electrocautery

Electrocoagulation was uniformly applied circumferentially to a 2 cm long segment of the mid trachea (T) or to a 1 cm long segment of the left main stem bronchus (LB) with a semi rigid 2.5 mm diameter monopolar electrode (ref 20191-156; Erbe Elektromedizin Gmbh, Tübingen, Germany). Electric power was supplied by an HF generator (Erbotom ICC 350; Erbe Elektromedizin Gmbh) which was set on the "soft coagulation" mode with auto-stop. With these parameters there is no risk of electric arcs as with the "forced" or "spray" coagulation modes. The automatic voltage control present in the Erbotom ICC 350 (Erbe Elektromedirin) also ensures a high reproducibility of the soft coagulation depth. Finally, when setting the generator on "auto-stop", the power switches off as soon as vapour emerges from the coagulation zone, preventing adhesion of the probe to the tissues. Two levels of energy were studied 40 W and 120 W respectively. Thus, four groups of thirteen pigs were studied according to the site and the energy delivered: T 40 W, T 120 W, LB 40 W and LB 120 W.

In each group the early effects of electrocoagulation were assessed in 5 pigs, at 48 h, through bronchoscopic and histopathologic examination of the coagulated area. The late effects were assessed in the remaining 8 pigs from each group after 6 weeks.

Follow-up and evaluation

Clinical signs were monitored daily with special attention to weight loss, cough, sputum production, wheezing and dyspnoea. Video recordings and photographs were taken on each bronchoscopic examination. Additional bronchoscopies were performed as warranted by clinical signs.

The animals were sacrificed at 48 h or 6 weeks postoperatively, depending on their study group, for post-mortem examination of the tracheobronchial tree. Euthanasia was performed under general anaesthesia with intravenous potassium chloride. Animals showing severe respiratory compromise before the predetermined time of sacrifice were euthanized under general anaesthesia.

Assessment of early and late effects of electrocoagulation was based on endoscopic gross findings and pathologic examination. Endoscopically, lesions at the level of the electrocoagulated zone were classified as "intrinsic" or "extrinsic" or "mixed" according to the respective presence of lesions within the lumen (pseudo membranes, granulomas), at the level of the bronchial wall (loss of cartilaginous support with subsequent collapse of bronchial wall) or both. Lungs, mediastinium, T and oesophagus were removed in one single block through a cervicothoracic midline incision for complete histopathological examination. The T and main stem bronchi were carefully excised and transverse and longitudinal sections were cut at the level of the electrocoagulated segments. Additional sections sampled above and under the zone of interest served as controls. Specimens were fixed in formalin for 3 weeks, embedded in paraffin, cut into 4 µm slides and stained with haematoxylin-erythrosin-saffron (HES) for study with light microscopy.

Results

Immediate effects

Bronchoscopic procedures were all uneventful. Uniform whitish coagulation could easily be produced by successive circumferential applications of the electrode on ~20 adjacent sites. No fumes or unpleasant burnt flesh smell was observed. As commonly observed in clinical practice, with the preselected parameters (auto-stop and soft coagulation) the coagulation time was much shorter when delivering 120 W than when delivering 40 W.

Early effects

No premature death was observed in the animals subjected to early (48 h) evaluation. Endoscopic examination revealed a whitish coagulation ring without gross ulceration, membranes, stenosis or perforation. Microscopic examination showed ulcerated mucosa covered by fibrinopurulent membranes or shed necrotic epithelium and acute inflammation of the mucosa, the submucosa and the perichondral spaces characterized by oedema and polymorphonuclear (sometimes altered) infiltrates. Acute vasculitis of the adventitial vessels was also a common finding. No changes were seen in the extracellular matrix

of cartilage plates. The sites of coagulation (T *versus* LB) and energies delivered (40 W *versus* 120 W) could not be distinguished on the basis of early gross and microscopic findings.

Late effects

All of the 8 pigs in the T 120 W group and 7/8 pigs in the T 40 W group died prematurely, usually between the 10th and the 20th days. In fact all of the premature deaths in these groups were related to euthanasia which was performed because the animals experienced severe respiratory failure. In the animals which received LB coagulation only five premature deaths were observed, one in the LB 120 W group and four in the LB 40 W group. These deaths occurred between the 20th and the 32nd days.

Endoscopic examination revealed severe stenosis (≥ 80%) in all the animals. In the T 120 W group the stenosis was classified as extrinsic in four animals and mixed in four. All the stenoses were classified as mixed in the T 40 W group. In the LB 120 W group the stenosis was classified as intrinsic in five animals, extrinsic in two and mixed in one. In the LB 40 W group the stenosis was classified as extrinsic in six and mixed in two. Most animals in the latter two groups presented postobstructive pneumonia on gross examination of the lungs. All the bronchial or tracheal stenoses classified as extrinsic or mixed had obvious loss of structural support on palpation.

Microscopic examination revealed that normal epithelium was replaced by squamous metaplasia in half of the cases. Acute inflammation persisted only at the level of the mucosa, except in those animals that died within the first 2 weeks, in which inflammatory lesions still extended deeply into the submucosal and perichondral spaces.

Mucosal fibrosis was a constant feature. This fibrosis always extended to the submucosa and to the cartilage plates. More than 50% of the normal basophilic extracellular cartilaginous matrix was replaced by saffron stained connective tissue (collagen). In these areas, there was an obvious loss of viable-appearing chondrocytes (figs. 1 and 2). No chronic lesions of the adventitial vessels were seen. As for early lesions, microscopic examination could not differentiate electrocoagulation produced with a power set at 40 W from that produced with a power set at 120 W.

Fig. 1. – Normal bronchial section (haematoxylin-erythrosin stain), showing from right to left normal mucosa, submucosa and cartilaginous plate. Internal scale bar=500 µm.

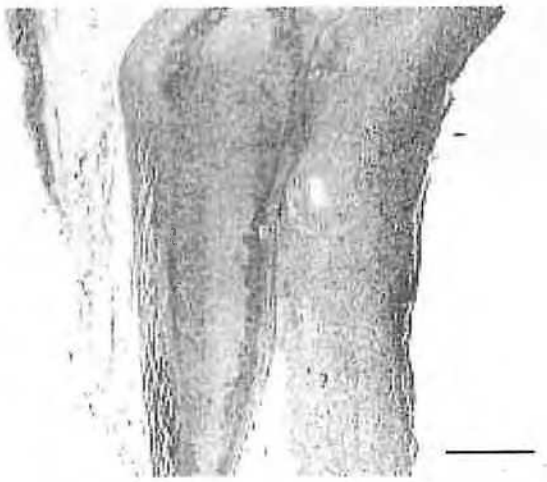

Fig. 2. – Bronchial section (haematoxylin-erythrosin-saffron stain) at the level at which electrocautery was applied 6 weeks before, showing shedding of the epithelium, intense submucosal fibrosis and degenerescence of the cartilaginous plate. Internal scale bar=500 µm.

Discussion

The present study showed that even when using optimal safety parameters, extensive electrocoagulation of the bronchial mucosa may lead to serious structural damage deep into the tracheobronchial wall independently of the power setting. Mucosal and submucosal fibrosis and destruction of the cartilaginous support may in turn result in secondary iatrogenic stenoses. These lesions which occur after an intense and acute inflammatory phase do not result from extension of the coagulation necrosis into the bronchial wall.

The safety of the new generation electrocautery equipment has improved in the recent past. The new HF generators have isolated outputs which reduce the risk of burns and electric shock to the endoscopist and patient. Insulated flexible bronchoscopes are now available. Automatic voltage control adjusts the thermal energy delivered to the effective area of contact of the tissue and thus, at least in the soft coagulation mode enhances the reproducibility of coagulation depth. Soft coagulation is now preferred [6]. Indeed forced or spray coagulation or resection may result in firing, especially in the presence of high inspired oxygen concentration. Moreover, as shown by experimental studies, the resection mode may result in bronchial wall perforation [9]. With the "auto-stop" function the generators automatically switch off as soon as the boiling point of the tissue fluids has been reached. This prevents adhesion of the probe to the tissue and the unpleasant burnt flesh smell due to excessive tissue dehydration.

Although appropriate equipment and recent safety guidelines prevent severe immediate complication of electrocautery, little is known regarding the risk of delayed complications such as secondary stenoses. In an experimental study CARPENTER *et al.* [8], comparing endoscopic cryosurgery and electrocoagulation of bronchi in a series of 20 mongrel dogs reported this iatrogenic complication. With electrocoagulation it was shown that the extent and severity of the damage to bronchial structures were unpredictable and sometimes resulted in secondary stenoses. On the contrary, cryolesions were predictable and

uniform, with constant preservation of the bronchial architecture and regeneration of normal mucosa. In this study the authors used an old generator without an automatic voltage control or the auto-stop function. Moreover the mode of coagulation was not explicated. As attested by the presence of dry, charred eschar at the site of electrocoagulation and haemorragic necrosis in the adjacent lung, it may be hypothesized that the profound structural lesions resulted from coagulation in excess. Secondary stenoses of segmental bronchi after endobronchial electrocautery were recently reported by the group of VAN BOXEM *et al.* [7]. In this study the authors used ~25–45 W of energy to treat radiographically occult lung cancers. Electrocoagulation was applied bronchoscopically with a flexible probe onto the lesions with an additional marginal area of 0.5 cm of normal mucosa. No auto-stop system was used and power was delivered until coagulation became visible to the operator.

It therefore seemed important to verify whether with the current devices and techniques, the iatrogenic lesions recently reported by VAN BOXEM *et al.* [7] could be related to the profound ultrastructural damage obtained experimentally by CARPENTER *et al.* [8] with an old generator. The HF generator used in the present study provided optimal coagulation in terms of control and reproducibility of soft coagulation depth. The lower power used here was in accordance with common practice in humans. With the auto-stop function, increasing the energy delivered shortens the duration of coagulation (the boiling point is reached more quickly). One could therefore expect that, with a higher energy level the depth of the electrically induced lesions would be reduced. The high power (120 W) was tested in order to test this hypothesis. Preoperative and early postoperative bronchoscopic examination showed only minimal superficial whitish coagulation necrosis. Light microscopy, however, revealed that, although coagulation necrosis was limited to the mucosa, acute inflammation with massive infiltration of altered polymorphonuclear cells extended throughout the bronchial structures down to the adventitia. Postoperative mortality was high. As confirmed by autopsy and microscopic examination and in contrast with the observations of CARPENTER *et al.* [8] none of the deaths were due to bronchial wall perforation. The animals which received tracheal coagulation died as a result of severe tracheal stenosis and collapse. Those in which coagulation was applied on the LB died as a result of pneumonia developing below the LB stenosis. Bronchoscopy and autopsy showed frank alterations of the cartilaginous support which could be observed 2 weeks postoperatively. In contrast with the findings of CARPENTER *et al.* [8], the present study did not show extension of the mucosal necrosis into the depth of the bronchial wall. In fact, after an acute inflammatory phase, extensive transmural fibrosis and cartilaginous deterioration developed. Latrogenic stenosis thus resulted from retractile scar formation and loss of cartilaginous support. The nature and extend of these lesions did not depend upon the energy delivered (40 W *versus* 120 W).

Electrocautery is becoming more and more popular in Europe. This is due to the low cost of the equipment and to the safety of the modern generators. In their centre the authors have electrocautery, YAG-laser, cryotherapy, brachytherapy and photodynamic-therapy at their disposal. Among the 240 patients treated for central airway malignancies last year, electrocautery was used in >60% of the cases and YAG-laser in <5%. In the opinion of the present authors, diaphragm stenoses are the only indications where YAG-laser are clearly superior to electrocautery, since YAG-laser allows very precise radial cutting of the diaphragm. These figures regarding the implemented use of electrocautery compared to YAG-laser are becoming true in many European centres which have both techniques at their disposal.

The results of the present study show that a potential risk to the bronchial wall do not question the use of electrocautery to palliate endoluminal tumours. In contrast, when treating superficial tumours of the bronchial wall, such as radiographically occult lung cancers or carcinomas *in situ* [7], the electrocautery probe can be applied to a large area of the bronchial wall circumference. From these results it can be inferred that, whatever the energy delivered, such extensive bronchial wall coagulation, even with the "safest" parameters, can produce severe ultrastructural damage with secondary stenosis formation. This risk of bronchial ultrastructure damage is also present with alternative treatments such as brachytherapy and photodynamic therapy but not with cryotherapy.

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Day Exhibit 7

-----Original Message-----
From: Colby Jones
Sent: Tuesday, June 06, 2017 3:45 PM
To: 'Seitz, Gregory'
Cc: John Day
Subject: RE: ERBE Connectors for HET

Hi Greg,

Let's chat at ASCRS. I certainly won't be at the booth for the entirety of the meeting as I'll be in labs, lectures, meetings, etc.

Either let the team know that you stopped by, or better yet, let's just stay in touch via phone and set a time to meet somewhere ad hoc.

Colby

Colby Jones
Senior Market Manager
Erbe USA, Inc.
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Marietta, GA 30067
Mobile: (404) 694-8770
Office: (800) 778-3723 x 123
Fax: (770) 955-2577
E-mail: colby.jones@erbe-usa.com
Web: www.erbe-usa.com

-----Original Message-----
From: Seitz, Gregory [mailto:gregory.m.seitz@medtronic.com]
Sent: Tuesday, June 06, 2017 10:09 AM
To: Colby Jones
Cc: John Day
Subject: RE: ERBE Connectors for HET

Thanks for the follow up Colby.

Assuming you determine a Regulatory clearance is the issue, Medtronic would be willing to cover any FDA filing fee to get the needed bipolar adapter cables cleared for sale in the US, as well as consideration for an upfront bulk order. Haven't had any luck with Wolf or Storz yet, but as a short term solution we are providing a single use "flying lead" adapter cables that ValleyLab still sells, at least for now. A one-for-one cable with each bipolar forceps. Medtronic/ValleyLab also plans to remove this item from their catalog due to the IEC regulation, but have been willing to extend the commercial availability of this product to give us some runway until a more permanent solution can be found. It's become that critical of an issue for us.

Please consider this option of Medtronic covering Erbe's regulatory costs and purchasing a bulk order. I've already pitched this to our Sr. Management and they were amenable to this. All upside to Erbe, but I fully realize it's not a huge revenue # impact in the overall picture. We could also direct customers to Erbe to purchase the cable if that's a preferred option, but by Medtronic purchasing a bulk order, it guarantees an upfront quantity thus lessening your risk since we're early into the GI Solutions involvement with HET and forecasts are less predictable at this point. It would help solve 90% of our cable issues since Erbe is so established in GI in the US, which is where 99% of the HET business currently resides. This may even help with non-Erbe units, but would defer to your guidance here (Olympus, Conmed, etc.).

Thanks in advance for your consideration, and keep me posted what you hear from your German colleagues.

Will either of you be at ASCRS this weekend?

Regards,

GS

Greg Seitz
Director, Global Market Development | Colon Program

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LET'S TAKE HEALTHCARE
FURTHER, TOGETHER

-----Original Message-----
From: Colby Jones [mailto:colby.jones@erbe-usa.com]
Sent: Monday, June 05, 2017 8:48 PM
To: Seitz, Gregory <gregory.m.seitz@medtronic.com>
Cc: John Day <john.day@erbe-usa.com>
Subject: RE: ERBE Connectors for HET

Hi Greg,

I'm still awaiting some further validation from my colleagues in Germany as it's been packed with national holidays this past few weeks "over there".

Nonetheless, things don't look overly positive due to regulatory clearance. Any luck with R. Wolf or Storz?

I'll reach out before the end of the week.

Thanks,

Colby Jones
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Web: www.erbe-usa.com

-----Original Message-----
From: Seitz, Gregory [mailto:gregory.m.seitz@medtronic.com]
Sent: Wednesday, May 31, 2017 2:11 PM
To: Colby Jones
Subject: RE: ERBE Connectors for HET

Hi Colby,

Wanted to check back in to see if you were able to find out any update on the Erbe cables that we would need to support the HET compatibility with Erbe generators in the US. I think you were going to check on the regulatory status and what it would take to get these cables sellable in the US for Medtronic to purchase.

Let me know if you have any updates.

Thanks,

Greg

Greg Seitz
Director, Global Market Development | Colon Program

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LET'S TAKE HEALTHCARE
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-----Original Message-----
From: Seitz, Gregory
Sent: Monday, May 22, 2017 3:55 PM
To: 'John Day' <john.day@erbe-usa.com>; Colby Jones <colby.jones@erbe-usa.com>
Subject: RE: ERBE Connectors for HET

Thanks, guys. Sorry to dump this on you guys as well. ValleyLab sells a disposable bipolar adapter with the 2 banana plugs (flying leads), but it's not optimal due to the economics.

Colby, look forward to your response, and if it's easier, feel free to give me a call at your convenience.

Greg Seitz
Director, Global Market Development | Colon Program

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-----Original Message-----
From: John Day [mailto:john.day@erbe-usa.com]
Sent: Monday, May 22, 2017 3:47 PM
To: Colby Jones <colby.jones@erbe-usa.com>
Cc: Seitz, Gregory <gregory.m.seitz@medtronic.com>
Subject: FW: ERBE Connectors for HET

Colby,

Sorry to dump this. The HET device is a bipolar device that Dr. Kantsevoy helped develop. You know it well. They need a bipolar cable (attached email). I'm in SoCal as you know and you're at Thoracic meeting, but wondering if you could take 10 minutes to eyeball and come up with a solution for Greg?

I thought I'd copied you last Friday - sorry!

-----Original Message-----
From: Seitz, Gregory [mailto:gregory.m.seitz@medtronic.com]
Sent: Monday, May 22, 2017 3:42 PM
To: John Day
Subject: RE: ERBE Connectors for HET

Hey John,

Sorry to bug you again, but could you connect me to Colby? He wasn't cc'd in your email back, so wasn't sure if you had sent him a separate note. Seems like we've stirred a bees nest with re-energizing accounts that have been inactive only to find out they've misplaced their bipolar adapter cables that goes from the HET device to their Erbe generator. One account actually had to cancel a case this AM.

I have to believe these cables exist, but just need to be able to direct accounts with the correct p/n. I know the ones that Erbe GmbH sells will work, just a question as to whether they can be sold in the US.

Thanks again.

-----Original Message-----
From: John Day [mailto:john.day@erbe-usa.com]
Sent: Friday, May 19, 2017 1:48 PM
To: Seitz, Gregory <gregory.m.seitz@medtronic.com>
Subject: Re: ERBE Connectors for HET

Not in the office but will look into this with cc to Colby Jones. He is our liaison with Erbe GmbH andbreports to me.

-------- Original message --------
From: "Seitz, Gregory" <gregory.m.seitz@medtronic.com>
Date: 5/19/17 1:40 PM (GMT-05:00)
To: John Day <john.day@erbe-usa.com>
Subject: FW: ERBE Connectors for HET

Hi John,

I'm hoping you can help, or direct me to the person at Erbe that can assist. With the HET Bipolar device Medtronic sells for hemorrhoid treatment, there is a Temperature Monitor that is part of the system. A cable that comes off this device bifurcates with one end going to the disposable forceps, and the other end going to a bipolar generator. Since the majority of generators in GI are Erbe, we need to find a bipolar adapter cable so we can connect into a Vio. Below is what my marketing manager found regarding Erbe adapters, but what I've found in talking to Customer Service at Erbe that Erbe USA doesn't sell any of these cables.

Do you know if we could order these cables directly from Erbe, or is there a way to direct our HET customers to order these from Erbe?

I've attached a picture of the HET cable for your reference as well. We have both the 2-pin connector as well as a flat connector that would plug into the top 2 cables below.

Thanks so much for your assistance. Our surgical colleagues kinda threw this one over the fence to us with little guidance.

GS

Greg Seitz
Director, Global Market Development | Colon Program

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LinkedIn<https://www.linkedin.com/company/medtronic?trk=biz-companies-cym> |
Twitter<https://twitter.com/Medtronic> | YouTube <https://www.youtube.com/user/MedtronicCorp>

LET'S TAKE HEALTHCARE
FURTHER, TOGETHER

From: Fox, Sherry
Sent: Thursday, May 18, 2017 4:14 PM
To: Seitz, Gregory <gregory.m.seitz@medtronic.com<mailto:gregory.m.seitz@medtronic.com>>
Subject: ERBE Connectors for HET

Hey Greg,

Please forward this to the people you know at ERBE and see if:

* These parts are available for ordering

* What is the list price

These are from the ERBE catalogue.

[cid:image001.jpg@01D2CFF5.D419E650]

Sherry Fox
Manager | Global Market Development, Colon Program

Medtronic
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medtronic.com<http://www.medtronic.com/> | Facebook<https://www.facebook.com/Medtronic> |
LinkedIn<https://www.linkedin.com/company/medtronic?trk=biz-companies-cym> |
Twitter<https://twitter.com/Medtronic> | YouTube <https://www.youtube.com/user/MedtronicCorp>

LET'S TAKE HEALTHCARE
FURTHER, TOGETHER

Day Exhibit 8 – Highly Confidential

Day Exhibit 9 – Highly Confidential

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

COVIDIEN LP, Petitioner, v. ERBE ELEKTROMEDIZIN GMBH, Registrant.	Cancellation No. 92066392 Registration Nos. 4,236,231and 4,686,396 Mark: SOFT COAG

DECLARATION OF DANIEL P. MULLARKEY

I, Daniel P. Mullarkey, do hereby declare under penalty of perjury as follows:

1. I am over 18 years of age and competent to make the following statements. I have personal knowledge of the documents attached to this Declaration and, if called to testify as a witness, I can and will testify to these facts in a court of law or in front of an administrative agency, include the Trademark Trial and Appeal Board ("TTAB").

2. I am Counsel for Registrant Erbe Elektromedizin GmbH ("Erbe") in this matter.

3. Exhibit A to my declaration are true and correct excerpts of the June 25, 2018 30(b)(6) Deposition of Erbe (by representative John Day), designated as Highly Confidential.

4. Exhibit B to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT-000001-15.

5. Exhibit C to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000110-17.

6. Exhibit D to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000118-21.

7. Exhibit E to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000122-27.

8. Exhibit F to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000144-79.

9. Exhibit G to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000180-211.

10. Exhibit H to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000212-35.

11. Exhibit I to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000349.

12. Exhibit J to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000350-51.

13. Exhibit K to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000352-53.

14. Exhibit L to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000360.

15. Exhibit M to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_000361-62.

16. Exhibit N to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_001273.

17. Exhibit O to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_001274.

18. Exhibit P to my declaration are true and correct documents produced by Erbe as Bates Nos. E-SOFT_001640-48, a portion of which are designated as Highly Confidential.

19. Exhibit Q to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_001653-54 and is designated as Highly Confidential.

20. Exhibit R to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_001686-87 and is designated as Highly Confidential.

21. Exhibit S to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT_001651-52 and is designated as Highly Confidential.

22. Exhibit T to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT-005131-34 and is designated as Highly Confidential.

23. Exhibit U to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT-005032-33.

24. Exhibit V to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT-005036-37.

25. Exhibit W to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT-005034-35.

26. Exhibit X to my declaration is a true and correct document produced by Erbe as Bates No. E-SOFT-005127-28.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: September 30, 2019

*/s/Daniel P. Mullarkey/*_____

Daniel P. Mullarkey

Mullarkey Exhibit A
Highly Confidential

Mullarkey Exhibit B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

FEB 23 1994

Erbe USA, Inc.
c/o Mr. Michael A. Clark
South East Regulatory Associates
775 Oxford Hall Drive
Lawrenceville, Georgia 30244

RECEIVED MAR 21 1994
M Clark

MAR 23 1994

Re: K933157
Erbotom ICC 200
Regulatory Class: II
Dated: November 19, 1993
Received: November22, 1993

Dear Mr. Clark:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the

labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

MICHAEL A CLARK

775 Oxford Hall Dr.
Lawrenceville, Georgia 30244
(404) 995 5720

SOUTH EAST REGULATORY ASSOCIATES

June 28, 1993

Food and Drug Administration
Center for Device and Radiological Health
Document Mail center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland, 20850

Attention: Document Control Clerk

Re: 510(k) Notification
Erbotom ICC 200
and Accessories.

This is to notify you of the intention of Erbe USA Inc. to market the following device and accessories in the USA manufactured by Erbe Electromedizin GmbH:

Classification Name: Electrical Cutting and Coagulation Device 878.4400

Common or Usual Name: Electrosurgical Generator
Electrosurgical Instrument

Proprietary Name: Erbotom ICC 200

Establishment Registration Number: 8010173

Classification: Class II

Performance Standard: We are aware of none

Labeling/Promotional Material: See enclosed table of Contents

Substantial Equivalence: This product is equivalent in design, composition, and function to the Erbotom ACC 450 also manufactured by Erbe Electromedizin GmbH. which was the subject of 510(k) notification #K896055. Copies of the labeling for this product are enclosed (see Table of Contents).

Erbe have reconfigured the Erbotom ACC 450 currently marketed outside the U.S.A. to be more consistent with accepted U.S. practices and procedures in the Electrosurgical Field. The unit designation has been changed to ICC 200 and is essentially a

scaled down version of the ACC 450. The principle changes include the fitting of jack points which are standard on U.S. electrosurgical instruments and accessories currently available from other suppliers; a feature permitting the operating surgeon to pre-set maximum power levels with digital display of setting; and the provision of an optional Endo-Cut feature for performance of this type of surgery. For a complete listing of changes, see Enclosure D.

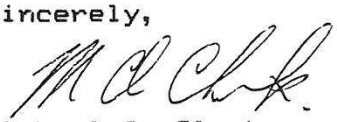
We believe the Erbotom ICC 200 is substantially equivalent to the Erbotom ACC 450 in its operating circuitry design and construction, and its functionality. The features which will be incorporated in the ICC 200 and are described in Enclosure D herein, will provide an instrument which is more consistent with the expectations of surgeons who desire state of the art technology.

Erbe have previously initiated an approval application from the Technischer Uberwachungsverein Stuttgart e.V. (TUV) for this instrument and will file for listing in the United States under UL 544. Approval under TUV is expected August/September 1993. Erbe will not market the instrument in this country without approval under UL 544. Your approval of our 510(k) notification contingent upon such UL approval would be acceptable to ourselves.

The intent to market the Erbotom ICC 200 in the United States is considered Confidential Information. The instrument has not been offered for sale or been promoted in any way in this country. We are aware that submission of false information in support of this notification is prohibited and have not knowingly done so.

Please address any correspondence in relation to this 510(k) to me by mail or telephone as shown above.

Sincerely,



Michael A. Clark

Enclosures A thru F

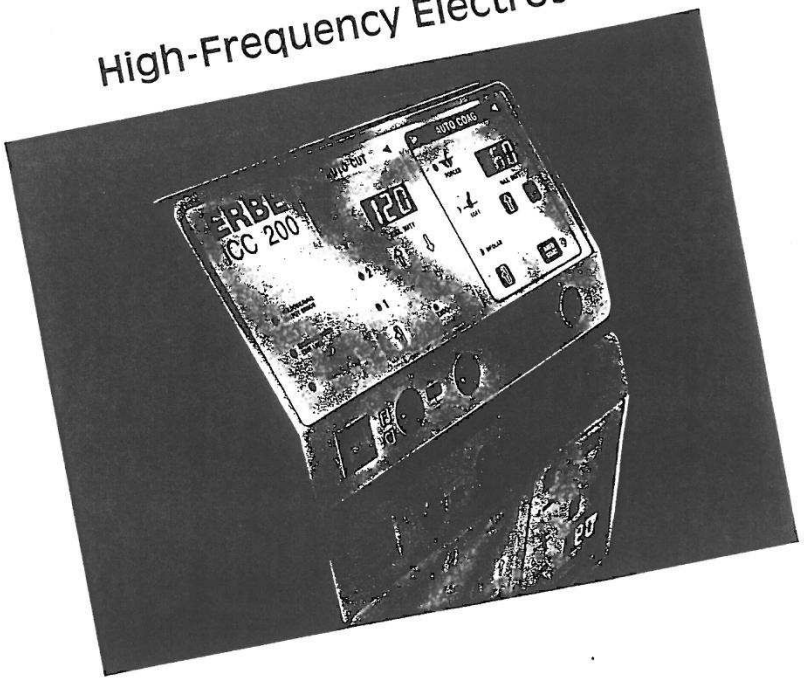
510(k)_Notification_Erbotom_ICC_200

ENCLOSURE_C

PROMOTIONAL LEAFLET FOR THE ERBOTOM ICC 200

Erbotom ICC 200

High-Frequency Electrosurgery



ERBE

ERBOTOM ICC-Series
Trail-Blazing Technology for Surgery

ERBOTOM ICC 200
The intelligent electrosurgical system

Whenever a new direction is taken in surgery, ERBE is there right from the very start. It is no surprise that this reveals itself in the high level of innovation in its products. No less can be expected of a market leader with over 60 years of experience in HF electrosurgery.
A HF electrosurgical unit today must meet more than the requirements of general surgery. Surgeons also demand appropriately safe and convenient equipment in respect of cutting and coagulation.
The target for the new generation of ERBE HF electrosurgical units was thus clearly in view: in addition to previous applications, MIS (Minimal Invasive Surgery) must also be supported by a unit easy to operate and offering the highest level of safety. This development is facilitated by the latest microprocessor technology and sensor electronics as well as the SMD production technique. The result is the ERBOTOM ICC-series, ICC standing for Intelligent Cut and Coagulation.

AUTO CUT
protects tissue

The maximum power used in the AUTO CUT mode is 200 W. Before application, the surgeon selects the power range by setting the upper maximum power limit. Within this set range, the system automatically regulates the output power according to the demand. Continuous signals from the active electrode are fed to the processor. This information is the used (in real time) as the basis for calculating the power output which is finely regulated within the selected range: as little as possible but as much as necessary. The incision quality remains reproducible and largely independent of

- size and shape of the cutting electrode,
- cutting direction and cutting speed,
- varying tissue characteristics.

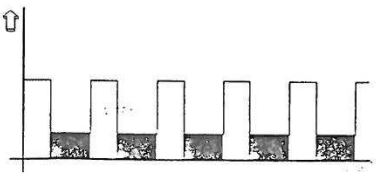
In addition, the surgeon can preselect the coagulation characteristics of the cut using four different effects. The desired effect is achieved at minimum power level. The result: minimal necrosis.

PPS – the new ERBE Power Peak System

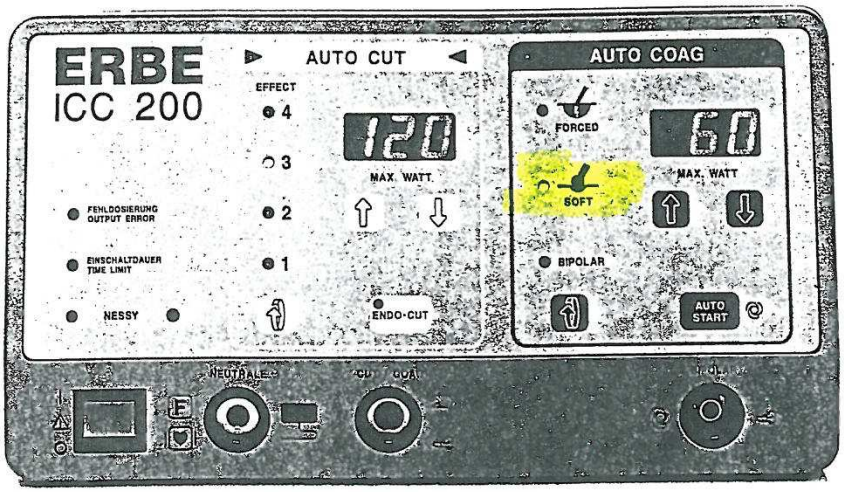
For optimum results the power must be quickly adjusted during the incision to provide the ideal cutting support for different types of tissue. PPS provides the required additional power with a wide dynamic response. Naturally PPS is also available in the HIGH CUT mode.

ENDO-CUT

allows a controlled cutting especially for polypectomy and papillotomy. The cut is fractioned into cut and pause-intervals by software control. During the pause-interval an additional soft-coagulation is activated. Furthermore ENDO-CUT is sustained by PPS.



4



The result is a maximum controlled cut with reproducible coagulation effect. This signifies a real progress for gastroenterological use of high frequency surgery.
Attention: ENDO-CUT implies a software-option. The ERBOTOM ICC 200 is available in two versions, with or without ENDO-CUT.

SOFT COAG – Coagulation instead of carbonization

The tissue is very effectively but gently treated with minimal necrosis. The electrode hardly clings to the coagulate and contaminates it only slightly. The complete absence of carbonization considerably shortens the post-operative healing phase. The tissue is protected, the operating time reduced and the life of the accessory extended.

Micro-Coagulation

By means of a lower maximum power setting and the associated lower, regulated voltage, the surgeon is able to accurately observe the coagulation process in the tissue. If necessary, he can make quick and accurate adjustments at any time. Even microscopic and extremely fine structures can be safely coagulated. This advantage is available both in soft coagulation as well as in bipolar coagulation

FORCED COAG

The FORCED COAG mode covers all requirements for standard coagulation and provides the surgeon with an effective, fast mode of operation, either directly with the coagulation electrode applied to the tissue or indirectly, for example with a surgical clamp.

Bipolar Coagulation

Bipolar coagulation also includes automatical control of HF-voltage. Therefore carbonisation of tissue as well as sticking can be extensively avoided, independent from size and figure of bipolar electrode. Bipolar coagulation is activated by footpedal or via.

AUTO START

which allows an automatic activation of the generator as soon as the bipolar electrode gets in contact with the tissue.

Accessories

Safety: The patient remains the yardstick for all technology

Safety is planned to the last detail, this distinguishes the carefully applied safety system of the ERBOTOM ICC 200 more than other manufactures. For example, the unit carries out an extensive self-check when switched on, and even includes the accessories.

- **Output error**

All output parameters are controlled by the microprocessor. A permanent set point/actual value monitoring takes place. Critical changes are immediately indicated visually and audibly.

- **Maximum activation time**

If the ERBOTOM ICC 200 has accidentally been activated for too long time, a visual warning signal switches on. If this signal has been overseen, the HF generator switches off automatically after a delay.

- **NESSY – a »delmonsterlably« safe technique**

The Neutral Electrode (patient plate) Safety System. In the customary way, the ERBOTOM ICC 200 monitors whether the patient plate is connected to the unit and applied to the patient. If the patient plate is wrongly applied, damaged, contaminated or slips during surgery, burns can occur at the site of application. NESSY gives an alarm before critical situations occur. The decisive and superior innovation of ICC technology is that NESSY continuously monitors and displays optimum application to the patient.
The unit can have either a floating output or be capacitively earthed. The existing operating condition is indicated by an LED.

Operation: fast and simple

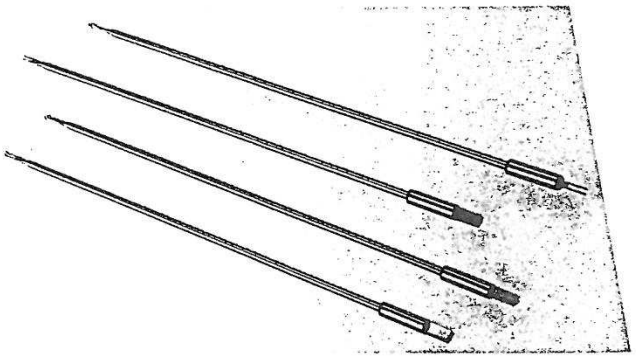
A standard setting covers the most important surgical interventions. Just one press of a button and the units is fully operational.

The control panel has a logical and clearly arranged layout. Colours separate the individual fields of application (cutting/coagulation) and explicit symbols facilitate simple working procedures.
In case of short power failures, the last setting selected is retained.

Service-friendly with diagnostic programs

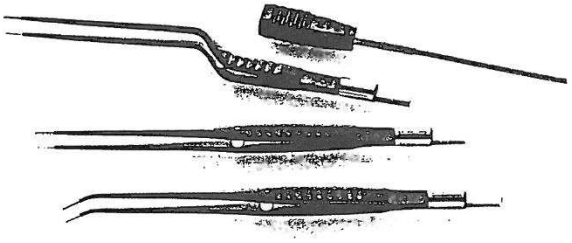
In addition to the self-check, additional test programs are installed in the ERBOTOM ICC 200. These check the functions of individual modules. Relevant faults are displayed directly by means of error messages. A digitally displayed error code immediately indicates the cause of the malfunction to the service technician without the need to open the unit.

The advantages:
- considerably reduced servicing time
- easier evaluation
- remote diagnosis

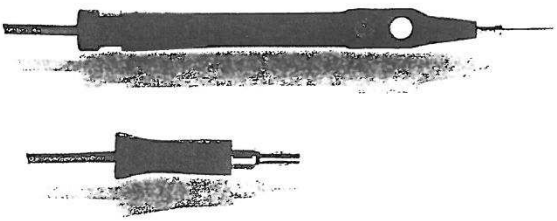


Bipolar coagulation electrodes for use in gynaecology, laparoscopic cholecystectomy etc.

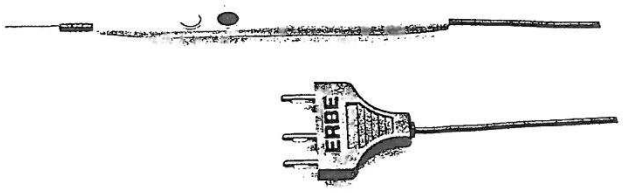
Bipolar electrode for cutting and coagulating



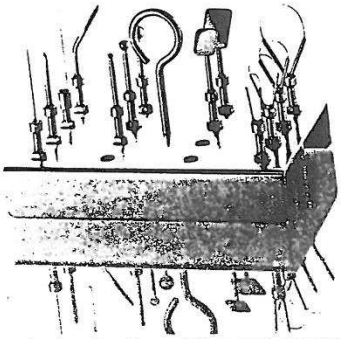
Bipolar coagulation forceps



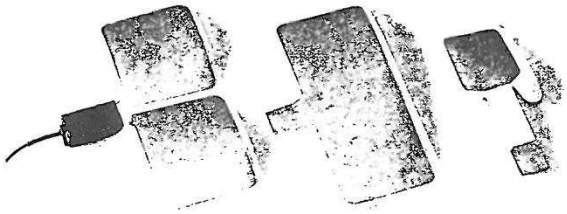
Electrode handle with 2 buttons for cutting and coagulation; water-tight complies with DIN IEC 601



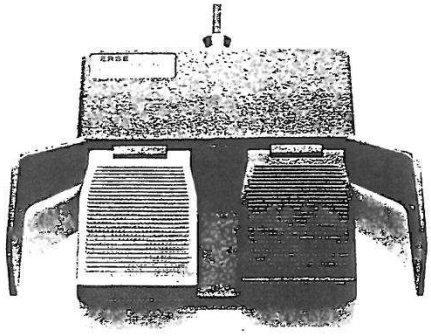
ERBE disposable electrode handle



Monopolar electrodes for cutting and coagulation



ERBE disposable patient plates



ERBE two-pedal foot switch, explosion-proof,
protected against spray water

Technical data

Erbotom ICC 200

Supply connection	
Supply voltage	230/115 V ± 20%, 50/60 Hz
Protection class	I according to DIN IEC 601-1
Type	CF according to DIN IEC 601-1
Potential equalization	connection plug according to DIN
CUTTING	
AUTO CUT monopolar	automatically controlled
output voltage	unmodulated sinusoidal
Nominal frequency	350 kHz
Cutting quality	4 coagulation effects
Constancy of the 4 coagulations effects	automatically controlled
rated HF output power	200 Watt at R_L = 500 Ω
HF peak power with PPS	200 Watt at R_L = 500 Ω
Setting the HF power limit	by up/down buttons
Constancy of the 4 coagulations effects	automatically controlled
Power Limitation	automatic
ENDO-CUT	Software-Option
COAGULATION	
SOFT COAGULATION / monopolar	
output voltage	unmodulated sinusoidal
Nominal frequency	350 kHz
rated HF output power	120 Watt at 125 Ω
Setting the HF power limit	by up/down buttons
Constancy of the 4 coagulations effects	automatically controlled
Power Limitation	automatic
FORCED COAGULATION / monopolar	
output voltage	pulse-modulated alternating voltage (ST generator)
Nominal frequency of HF voltage	1 MHz
rated HF output power	120 Watt at 350 Ω
Setting the HF power limit	by up/down buttons
Power Limitation	automatic
SAFETY MONITORS	
Dosage error monitor	according to § 3 (2) MedGV
Activation time monitor	
NESSY	Neutral Electrode (patient plate) Safety System
Type	CF, according to IEC 601-1
Circuit of patient plate	floating output
Size	W×H×D = 280×152×368 mm
Weight	8 kg
Admission no.:	01/M-225/92
Part-No.	10128-002 without ENDO-CUT-Option 10128-010 with ENDO-CUT-Option

9

510(k)_Notification_Erbotom_ICC_200

ENCLOSURE_D

CHANGES OF THE ERBOTOM ICC 200 COMPARED
WITH THE ERBOTOM ACC 450

Changes of the Erbotom ICC 200 Compared with the Erbotom ACC 450

1. The unit is equipped with digital displays indicating the maximum user selected wattage.

This feature is designed to permit the operating surgeon to pre-select the maximum setting for the specific application. The display clearly indicates the pre-set value throughout the procedure.

The ACC 450 had no such digital display feature.

---

2. When the Auto Cut mode is active, the output power is adjustable between 0 and 200 watts.

The output power selected is shown by the appropriate digital display.

The ACC 450 had no user selectable maximum output setting feature and the maximum available wattage was 400 watts.

---

3. In the Auto Cut mode there are four (4) blend settings (Effect).

This feature is to control the degree of hemostasis (ie, coagulation) effective during cutting. "1" corresponds to the minimum coagulation degree, "4" to the maximum.

The ACC 450 had five (5) blend settings.

---

4. The Coagulation mode is fully adjustable up to 120 watts and the pre-set maximum wattage is shown on the appropriate digital display.

At any time during the use of the instrument, the operating surgeon will be able to visually verify the setting level selected.

The ACC 450 had five (5) graded adjustments without the digital display.

---

5. There is no:
   - Spray Coagulation mode
   - Monopolar Autostart mode
   - Autostop mode

The ACC 450 had these modes.

---

6. The Bipolar Coagulation mode is fully adjustable up to 120 watts and

the user pre-set maximum wattage is shown on the appropriate digital display.

The ACC 450 had ten (10) graded adjustments without digital display.

---

7. The load circuit of the unit is isolated.

This feature prevents the accidental grounding by the patient from occurring during surgery (as is possible in earth reference machines).

The ACC 450 was configured in the earth reference mode.

---

8. The unit is constructed with standard U.S. electrode jack points consistent with accessories available from other U.S. manufacturers.

By providing jack points which are of a U.S. standard configuration, the operating surgeon is not limited to Erbe manufactured accessories and those of other manufacturers can be freely interchanged at the surgeons discretion.

The ACC 450 was constructed with European style jack points.

---

9. The test indicator for correct electrical connection is automated.

There is an indicator light plus audible alarm which sounds if the connection is not correctly made, or is broken at any time during surgery.

The ACC 450 had a test button requiring manual operation to activate the test feature.

---

10. An optional Endo-Cut feature has been provided specifically to accommodate the technical requirements for this type of surgical procedure.

This feature automatically fractions the cutting function in such a way that alternating short cutting intervals with defined pause intervals are produced to minimize the risk of complication during endoscopic surgical procedures.

The ACC 450 had no Endo-Cut feature.

//

Mullarkey Exhibit C

erbe

power your performance.

VIO® S

Electrosurgical system for use in clinics or specialist surgical ORs

ELECTROSURGERY

E-SOFT_000110

VIO® 300 S and VIO® 200 S:

Electrosurgery tailored to perfection.

With the VIO electrosurgical system, Erbe has set innovative standards aimed at providing optimum surgical support for almost any discipline as well as including a range of additional indications.

Erbe VIO 300 S and 200 S generator modules offer automatic power adjustment for all control technologies:

- **Voltage control for gentle, reproducible cutting and coagulation**
- **Arc control for high-energy cutting or coagulation and for cutting under water**
- **Power control to maintain constant power levels during coagulation and devitalization**

TAILORED PRECISELY TO YOUR NEEDS – BOTH IN TERMS OF HARDWARE AND SOFTWARE

- **Automatic power adjustment**
- **New and enhanced CUT and COAG functions, monopolar and bipolar**
- **Can be configured for custom setups based on the specific discipline, indication or procedure**
- **Simple, interactive and safe operation**
- **The VIO S models – the master control units for other modules in the VIO electrosurgical system, for example argon plasma coagulation, smoke plume evacuation, the endoscopy irrigation pump, and other components**

Versatile operating and safety concept that offers complete convenience.

Simple operating concept

The operational design of the VIO 300 S enables fast, direct access to the program parameters. Using the up / down buttons, power values and effects can be easily and directly adjusted.

Consistent enhancement: the NESSY patient plate safety system

With the NESSY safety concept and the Erbe patient plate NESSY Ω, VIO sets new standards with regard to the safety of monopolar electrosurgery.

Preselectable effect settings

For consistent surgical results with reproducible tissue effects.

For use in clinic ORs or specialist surgical ORs

	VIO 300 S	VIO 200 S
Gynecology	⬓	-
Urology	⬓	-
General surgery	⬓	-
Gastroenterology / Endoscopy	⬓	⬓
Pulmonology	⬓	⬓
ENT	⬓	-
Orthopedics	⬓	-
Dermatology	-	⬓
OMS	⬓	-
Ophthalmology	-	⬓

Legend:

■ *strongly recommended*
⬓ *recommended*

E-SOFT_000112

CUT

Precise cutting using these modes.

HIGH CUT 01

Suitable for cutting inside fatty structures or under water (e.g. TUR). Strong hemostasis at the incision edges. Control of arc intensity.

AUTO CUT 02

Standard mode for cutting with minimum necrosis and reproducible cutting quality.

ARGON AUTO CUT 03

Mode for argon-supported cutting. Minimum carbonization, minimum smoke plume development. Results in a good post-operative healing process.

ENDO CUT I 04

Fractionated cutting mode for papillotomy or other needle / wire applications in endoscopy.

ENDO CUT Q 05

For endoscopic polypectomy with a snare. Fractionated cutting and coagulation cycles.

DRY CUT 06

Cutting mode with pronounced hemostasis as a result of voltage control and modulated forms of current.

BIPOLAR CUT 07

Bipolar cutting with all the advantages provided by voltage regulation in 8 predetermined cutting qualities. The cutting current is only present at the distal end of the applicator. This ensures more safety and guarantees precise cuts.

COAG

Modes for exact coagulation and devitalization.

CLASSIC COAG 01

Exposure mode for visceral and cardiac surgery. Exact, layer-specific exposure and dissection. Minimum carbonization of the incision edges.

SWIFT COAG 02

Effective and fast coagulation with pronounced hemostasis that is also suitable for exposure.

TWIN COAG 03

For simultaneous activation of two instruments with only one electrosurgical unit – consistent power output.

FORCED APC 04

covers the entire spectrum of all types of non-contact APC coagulation. For hemostasis during endoscopy or open surgery or for surface coagulation and devitalization.

SPRAY COAG 05

Non-contact and efficient surface coagulation with low thermal penetration. Suitable for tissue devitalization or for stopping diffuse bleeding. Extensive carbonization effects.

FORCED COAG 06

Fast and effective standard coagulation with moderate thermal penetration. Slight carbonization effects.

SOFT COAG 07

Gentle coagulation with deep penetration, without carbonization, resulting in minimum adhesion of the electrode. Supported by the power control.

BIPOLAR SOFT COAG 08

Bipolar coagulation. The low voltages used in this mode prevent the instrument from sticking and distinctly reduce tissue carbonization. Effective – with a subtle adjustment of 8 different effects.

These modes and upgrades are available with the VIO 300 S and VIO 200 S models

CUT Modes

	VIO 300 S	VIO 200 S
AUTO CUT	■	■
HIGH CUT	○	–
DRY CUT	○	–
DRY CUT°	○	–
BIPOLAR CUT	○	–
ENDO CUT Q	□	□
ENDO CUT I	□	□
ARGON AUTO CUT	■	■
ARGON HIGH CUT	○	–
ARGON DRY CUT	○	–
ARGON DRY CUT°	○	–

COAG Modes

	VIO 300 S	VIO 200 S
SOFT COAG	○	■
SWIFT COAG	○	–
SWIFT COAG°	○	–
CLASSIC COAG	■	
FORCED COAG	○	■
SPRAY COAG	■	–
BIPOLAR SOFT COAG	■	■
TWIN COAG	□	–
FORCED APC	■	■
ARGON SOFT COAG	○	■
ARGON SWIFT COAG	○	–
ARGON SWIFT COAG°	○	–
ARGON FORCED COAG	○	■
ARGON TWIN COAG	□	–

Legend:

■ *included*
○ *depending on the version*
□ *only available ex works (must be ordered)*

FOR PERFECT CUTTING

- ☑ Newly-developed electrosurgical monopolar and bipolar CUT modes
- ☑ Power adjustment as a result of Erbe voltage control, for reproducible cutting
- ☑ Power adjustment as a result of Erbe arc control, for reproducible, efficient cutting in high-impedance tissue
- ☑ Additional area of application from microsurgery through to power-intensive vaporization
- ☑ Cutting results largely independent of cutting speed, shape of the electrode and tissue
- ☑ Bipolar cutting for more safety
- ☑ Power Peak System for optimum cutting behavior

FOR PERFECT COAGULATION

- ☑ Newly-developed electrosurgical COAG effects
- ☑ Power adjustment as a result of voltage control, for reproducible coagulation with optimally adjusted power output
- ☑ Power control for fast „non-stick" coagulation without carbonization
- ☑ Monopolar and bipolar coagulation for all your requirements
- ☑ AUTO-START and AUTO-STOP functions
- ☑ TWIN COAG: simultaneous activation of two electrodes / instruments for exposure

Technical data

VIO 300 S and VIO 200 S

Power output	
Maximum cut power (VIO 300 S)	300 watts at 500 Ohm (with PPS, briefly 400 watts)
Maximum cut power (VIO 200 S)	200 watts at 500 Ohm
Maximum COAG power	up to 200 watts
NE safety system	NESSY
Frequency	350 kHz

Power connection	
Line voltage	100 V – 120 V / 220 V – 240 V ± 10 %
Power frequency	50 / 60 Hz
Line current	max. 8 A / 4 A
Power consumption in standby mode	40 watts
Power consumption at max. HF power	500 watts / 920 VA
Potential equalization connection	Yes
Power fuse	T 8 A / T 4 A
Dimensions	Width x Height x Depth 410 x 160 x 370 mm
Weight	9.5 kg

VIO 300 S **VIO 200 S**
No. 10140-300 **No. 10140-400**

8/4 mm,
bipolar
No. 20140-610

2Pin-22 mm,
bipolar
No. 20140-612

2Pin-22-28-8/4 mm,
bipolar
No. 20140-613

9/5 mm,
monopolar
No. 20140-620

3Pin-Bovie,
monopolar
No. 20140-622

3Pin-9/5 mm,
monopolar
No. 20140-623

6 mm
patient plate
No. 20140-640

2Pin
patient plate
No. 20140-641

6 mm-2Pin
patient plate
No. 20140-642

For additional information on device configuration, see the catalog chapter on units and modules (85100-172) or the VIO product range brochure (85140-190).

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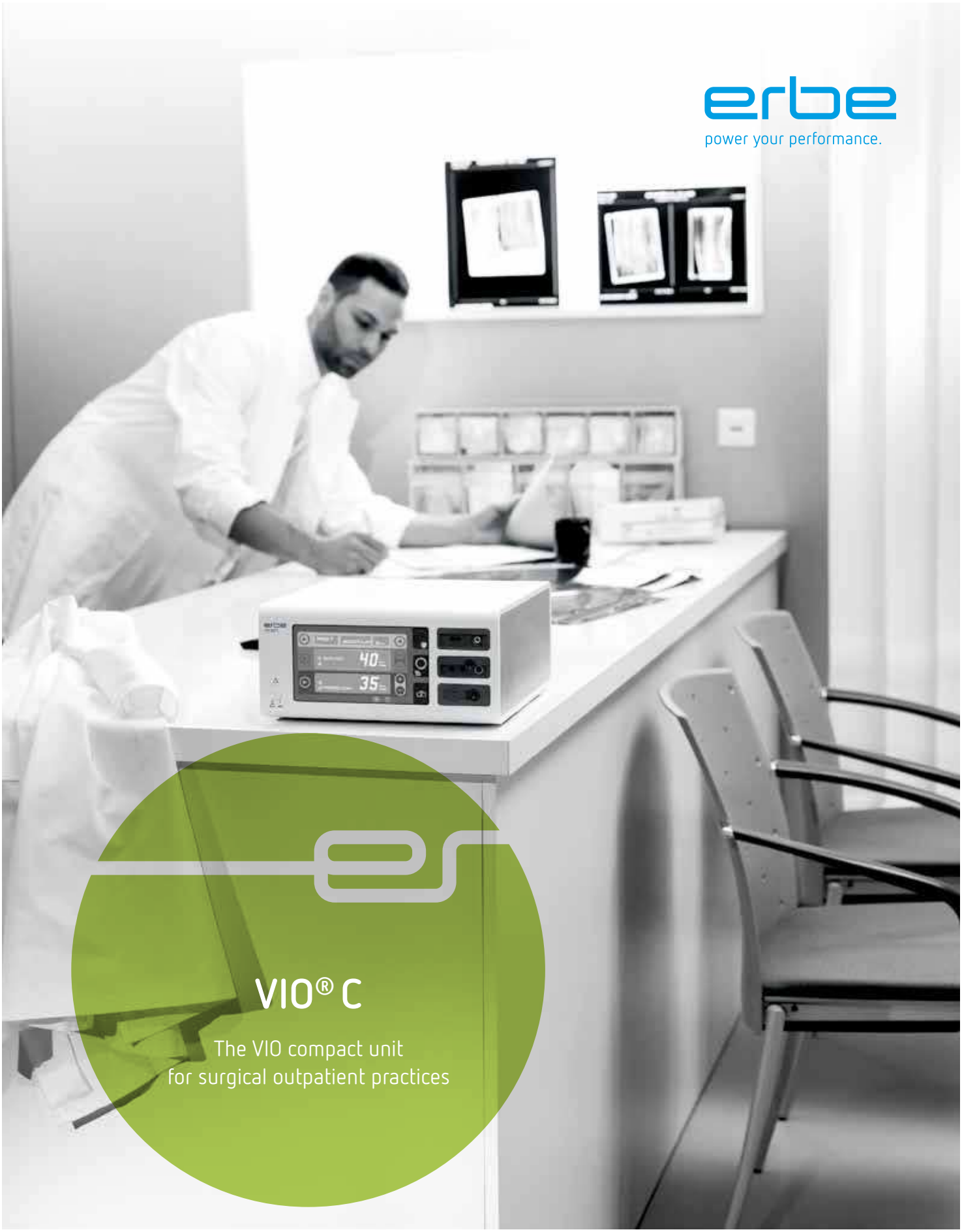
 02.16 85140-160

Mullarkey Exhibit D

erbe

power your performance.



VIO® C

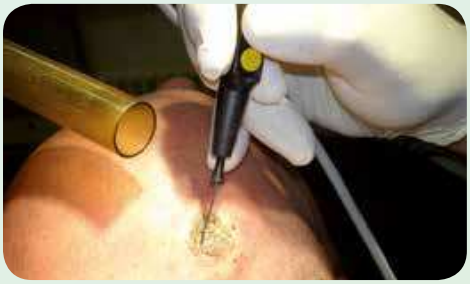
The VIO compact unit
for surgical outpatient practices

ELECTROSURGERY

E-SOFT_000118

VIO® 50 C and VIO® 100 C

Area of use



Examples of use for:
Epilation, spider veins, wet field coagulation, blepharoplasty, lipoma resection, entropion, keratoma

The VIO electrosurgical units of the C series meet all the demands of outpatient medical practices. With monopolar cutting and monopolar and bipolar coagulation. At a favorable price.

THE APPLICATION AREAS FOR THE VIO C UNITS:

- ☑ Trauma surgery
- ☑ Dermatology
- ☑ Ophthalmology
- ☑ Aesthetic plastic surgery
- ☑ ENT
- ☑ Gynecology

1

8/4 mm, bipolar
No. 20140-610

2Pin-22-28-8/4 mm, bipolar
No. 20140-613

Individual configuration according to your requirements

The user has a free hand in specifying the connection sockets. Individual programs can be stored as required. In addition, AUTO START (VIO 100 C) offers a high degree of comfort and safety-of-use.

2

3Pin-Bovie, monopolar
No. 20140-622

3Pin-9/5 mm, monopolar
No. 20140-623

3

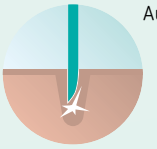
6 mm, neutral electrode
No. 20140-640

2Pin, neutral electrode
No. 20140-641

6 mm-2Pin, neutral electrode
No. 20140-642

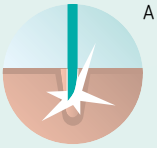
The following VIO modes are available in reproducible quality with the VIO 50 C and the VIO 100 C:

AUTO CUT



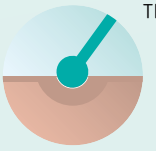
Automatically regulates the cutting quality, adjusting it according to the current flow requirement through regulation of the voltage. VIO adapts itself to the working mode of the operating physician. Minimal necrosis and reproducible cutting quality – largely independent of the electrode, the cutting process and the target tissue.

DRY CUT



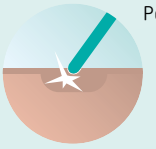
A combination of voltage regulation and modulated waveforms which produces an electrosurgical cut with a unique quality of hemostasis. Ideal for operative procedures which require a good initial hemostasis.

SOFT COAG



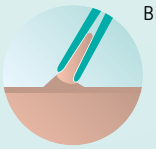
The new, rapid soft coagulation with dosage of power output. Coagulation without carbonization and almost no sticking of the electrode. Provides in-depth coagulation with minimal tissue damage.

FORCED COAG



Permits rapid and effective operation which meets all the requirements of a standard coagulation. Can be carried out either directly using the coagulation electrode or indirectly, for example, with the help of insulated surgical forceps.

BIPOLAR SOFT COAG



Bipolar coagulation.
The low voltages used in this mode prevent the instrument from sticking and distinctly reduce tissue carbonization.

Technical data

Power output		
	max. CUT output VIO 100 C	100 watts at 500 Ohm
	max. COAG output VIO 100 C	80 watts at 100 Ohm
	max. CUT output VIO 50 C	50 watts at 500 Ohm
	max. COAG output VIO 50 C	50 watts at 100 Ohm
	NE monitoring system	available
Mains connection		
	supply voltage	100 V - 240 V
	frequency	50 / 60 Hz
Dimensions and weight		
	width x height x depth	280 x 135 x 300 mm
	weight	4 kg
Standards		
	classification acc. to EC Directive 93/42/EEC	II b
	protective class acc. to EN 60 601-1	I
	type acc. to EN 60 601-1	CF
Order numbers		
	VIO 100 C	No. 10140-500
	VIO 50 C	No. 10140-550
	two-pedal footswitch	No. 20189-107
	one-pedal footswitch	No. 20188-102
	cover VIO C	No. 20140-500

ISO 9001
ISO 13485
CERTIFICATION

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Germany

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 11.15 85140-180

E-SOFT_000121

Mullarkey Exhibit E

VIO® product family

The right solution for every specialty

ELECTROSURGERY

E-SOFT_000122

Customized electrosurgery. Precisely the way you want it.

VIO stands for flexible cutting and coagulation – but also for flexibly configurable workstations for every surgical specialty.

Every surgeon can put together his own individual system, choosing from a range of modules, modes and functions. And so can gynecologists, gastroenterologists, urologists or medical specialists working in their own outpatient practice. The advantage: the system will include only those components which the physician really needs. A cost-efficient solution with no superfluous software or hardware modules. **True to the motto: less is more.**

The electrosurgical module VIO forms the basis of the workstations. Users can choose from a range of models which, in their turn, can also be configured individually and flexibly, for example, with regard to the choice of output sockets, functions, and the electrosurgical modes. This overview shows the range of VIO electrosurgery units to give you an idea of the application areas of the different models.

VIO® D

VIO® S

VIO® C

The high-end models of the D series, the VIO 300 D and the VIO 200 D, have a high-resolution TFT color display. The regulative technology of the D and S models is based on the regulation of voltage, sparking and output. Safe and easy to use, with FocusView functions. VIO 300 D is the most versatile unit for clinical applications, offering maximum functionality and a wide choice of modes and upgrades. The VIO 200 D is primarily for specific medical specialties such as gastroenterology and is equipped with modes and upgrades such as argon plasma coagulation or ENDO CUT I/Q. Submodules are linked via intelligent ECB interfaces.

The S models, the VIO 300 S and the VIO 200 S, are a cost-conscious alternative to the D series. The programmable seven segment matrix display of the S models offers direct access to all program parameters. The choice of versions allows these units to be universally used. FocusView displays essential information for all connected or activated instruments. Submodules are linked via intelligent ECB interfaces.

The VIO 50 C and VIO 100 C models fulfill all basic requirements of monopolar cutting and monopolar and bipolar coagulation. The C models are designed for outpatient clinics and practices.
Applications: interventions performed on an outpatient basis in the fields of dermatology, plastic surgery, ENT, gynecology, casualty surgery, ophthalmology.

Legend:

■ *strongly recommended*
⬓ *recommended*

E-SOFT_000123

Configuration. Modules. Areas of application.

An example of a workstation configuration:

The GI workstation with the components argon plasma coagulation APC® 2 and the waterjet surgery system ERBEJET® 2 for ESD. Additional module: endoscopic irrigation pump EIP 2.

For more detailed information on different modules, choice of sockets, modes and languages of the system's software, please refer to the individual brochures.

85140-120 (VIO D), 85140-160 (VIO S), 85140-180 (VIO C)

VIO modules for the various workstations

Argonplasma-Koagulation
APC 2

Smoke plume evacuator
IES 2

Nervtest
NT 2

Endoscopic irrigation pump
EIP 2

VIO extension module
VEM 2

Separate waterjet surgery system
ERBEJET 2

Secretion aspirator
ESM 2

For practices in hospitals and outpatient operations | Clinics / Practices

	VIO 300 D	VIO 200 D	VIO 300 S	VIO 200 S	VIO 50/100 C
Gynecology	■	-	⬓	-	⬓
Urology	■	-	⬓	-	■
General surgery	■	-	⬓	-	■
Gastroenterology / Endoscopy	⬓	■	⬓	⬓	-
Pulmonology	⬓	■	⬓	⬓	-
ENT	■	-	⬓	-	■
Orthopedics	■	-	⬓	-	■
Dermatology	■	-	-	⬓	■
OMS	■	⬓	⬓	-	■
Ophthalmology	-	-	-	⬓	■

Overview of electrosurgical modes.

CUT Modes

	VIO 300 D	VIO 200 D	VIO 300 S	VIO 200 S	VIO 50/100 C
AUTO CUT	■	■	■	■	■*
HIGH CUT	■	–	○	–	–
DRY CUT	■	⬓	○	–	■*
DRY CUT°	■	–	○	–	–
BIPOLAR CUT	■	■	○	–	–
BIPOLAR CUT +	■	–	–	–	–
BIPOLAR CUT ++	■	–	–	–	–
PRECISE CUT	⬓	⬓	–	–	–
BIPOLAR PRECISE CUT	⬓	⬓	–	–	–
ENDO CUT Q	⬓	⬓	□	□	–
ENDO CUT I	⬓	⬓	□	□	–
ARGON AUTO CUT	■	■	■	■	–
ARGON HIGH CUT	■	–	○	–	–
ARGON DRY CUT	■	⬓	○	–	–
ARGON DRY CUT°	■	–	○	–	–

COAG Modes

	VIO 300 D	VIO 200 D	VIO 300 S	VIO 200 S	VIO 50/100 C
SOFT COAG	■	■	○	■	■*
SWIFT COAG	■	■	○	–	–
SWIFT COAG°	■	–	○	–	–
CLASSIC COAG	■	–	■		–
FORCED COAG	■	■	○	■	■*
SPRAY COAG	■	–	■	–	–
BIPOLAR SOFT COAG	■	■	■	■	■*
BIPOLAR SOFT COAG +	■	–	–	–	–
BIPOLAR SOFT COAG ++	■	–	–		–
BIPOLAR FORCED COAG	■	■	–	–	–
PRECISE COAG	⬓	⬓	–	–	–
BIPOLAR PRECISE COAG	⬓	⬓	–	–	–
TWIN COAG	⬓	–	□	–	–
BICLAMP	⬓	–	–	–	–
FORCED APC	■	■	■	■	–
PRECISE APC	■	■	–	–	–
PULSED APC	■	■	–	–	–
ARGON SOFT COAG	■	■	○	■	–
ARGON SWIFT COAG	■	■	○	–	–
ARGON SWIFT COAG°	■	–	○	–	–
ARGON FORCED COAG	■	■	○	■	–
ARGON TWIN COAG	⬓	–	□	–	–

Legend:

■ *included*
○ *depending on the version*
⬓ *upgradeable*
□ *only available ex factory (must be ordered)*

** modified modes, power adjustment only*

Technical data

VIO 300 D/S and VIO 200 D/S

Power output	
Maximum Cut output (VIO 300 D / VIO 300 S)	300 Watt at 500 Ohm (with PPS momentarily 400 Watt)
Maximum Cut output (VIO 200 D / VIO 200 S)	200 Watt at 500 Ohm
Maximum Coag output	up to 200 Watt
NE monitoring system	NESSY
Frequency	350 kHz

Mains connection	
System voltage	100 V – 120 V / 220 V – 240 V ± 10 %
Power frequency	50 / 60 Hz
Max. mains current	max. 8 A / 4 A
Power input during standby	40 Watt
Power input during max. HF output	500 Watt / 920 VA
Potential equalization connection	yes
Mains fuse	T 8 A / T 4 A
Dimensions	Width x Height x Depth 410 x 160 x 370 mm
Weight	9.5 kg

VIO 50 C and VIO 100 C

Power output	
Max. CUT output VIO 100 C	100 Watt at 500 Ohm
Max. COAG output VIO 100 C	80 Watt at 100 Ohm
Max. CUT output VIO 50 C	50 Watt at 500 Ohm
Max. COAG output VIO 50 C	50 Watt at 100 Ohm
NE monitoring system	available

Mains connection	
System voltage	100 V – 240 V ± 10 %
Power frequency	50 / 60 Hz
Max. mains current	max. 2.0 A
Power input during standby	< 15 Watt
Power input during max. HF output	190 Watt / 200 VA
Potential equalization connection	yes
Mains fuse	T 4 A
Dimensions	Width x Height x Depth 280 x 135 x 300 mm
Weight	4 kg

Standards (for VIO D, VIO S, VIO C)	
Classification according to EU Directive 93/42/EEC	II b
Protection class according to EN 60 601-1	I
Type according to EN 60 601-1	CF

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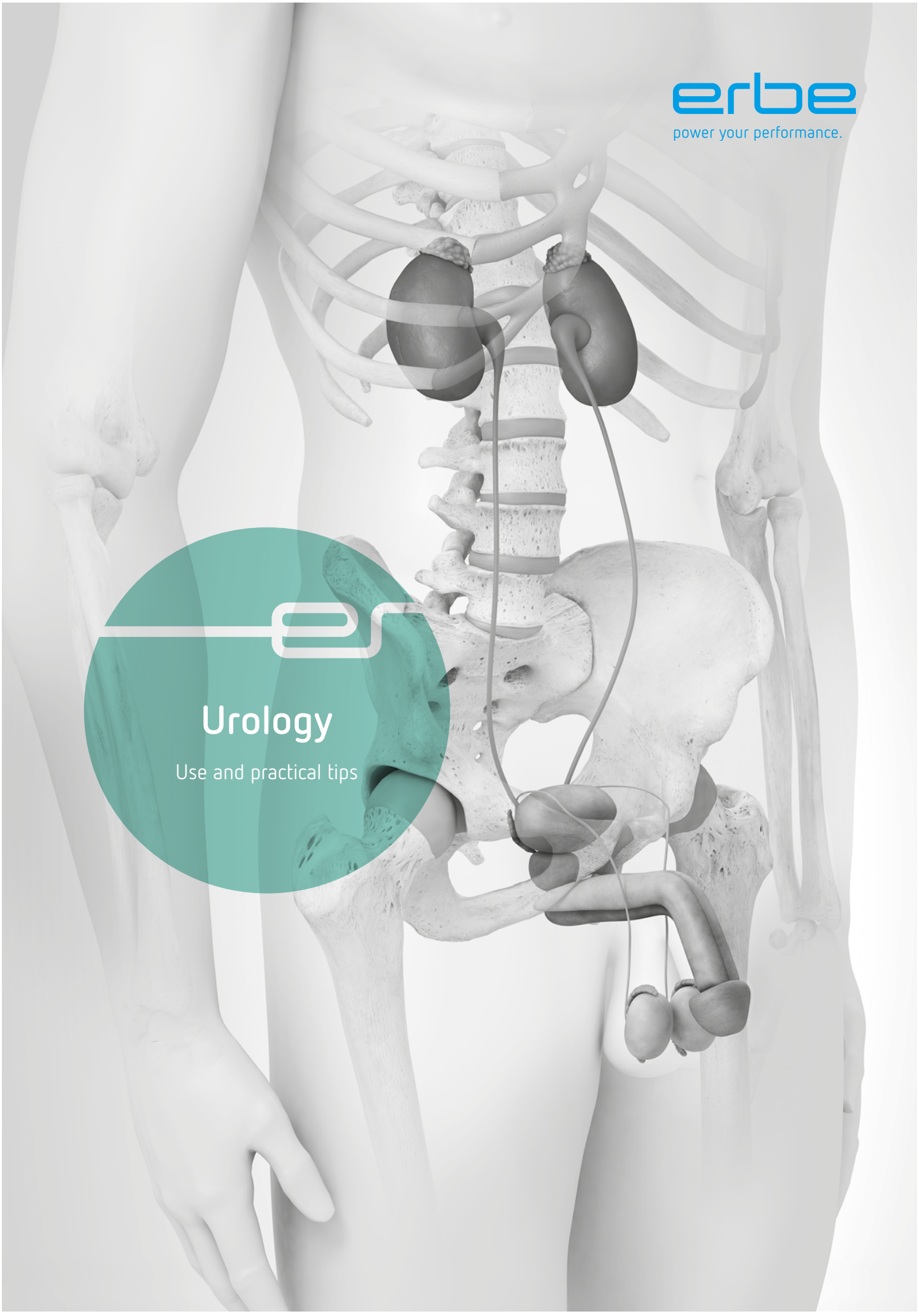
Mullarkey Exhibit F

erbe
power your performance.



Urology

Use and practical tips

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TABLE OF CONTENTS

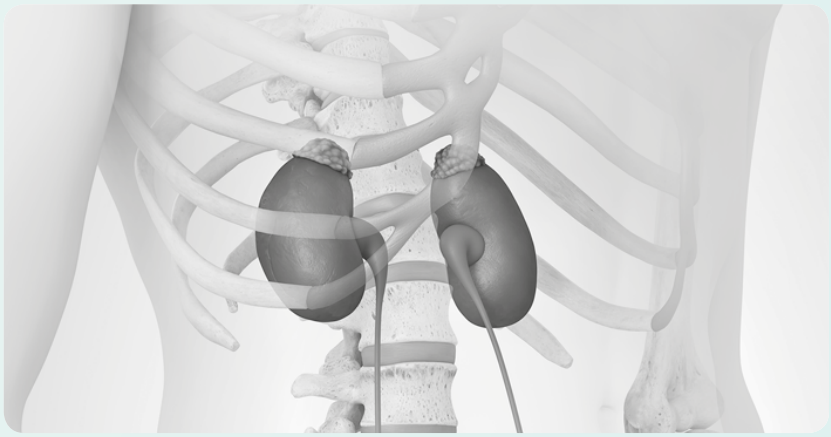
Important information

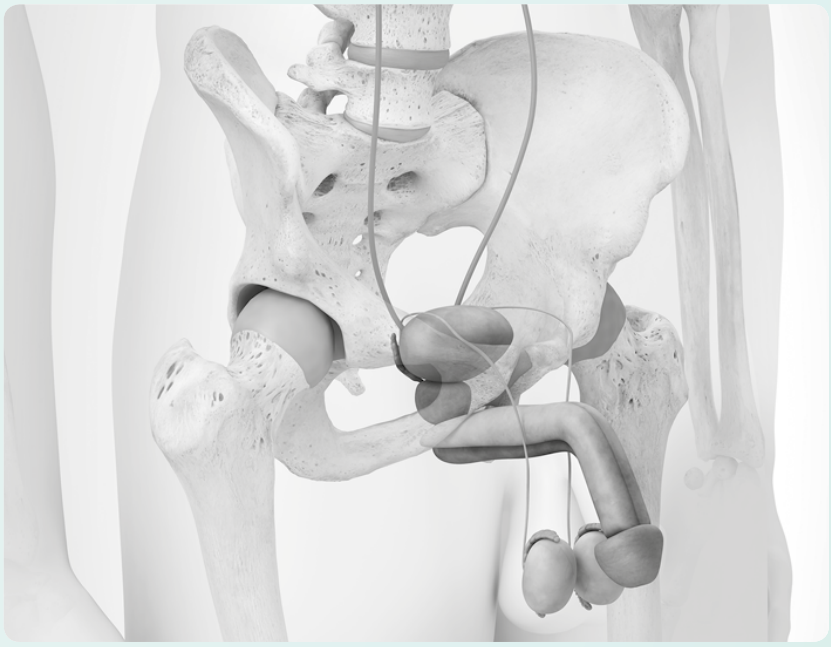
While Erbe Elektromedizin GmbH has taken the greatest possible care in preparing this brochure and compiling the proven user settings, we cannot completely rule out errors. The information and data contained in the recommended settings cannot be used to justify any claims against Erbe Elektromedizin GmbH. In the event of compelling legal justification for a claim, liability shall be limited to intent and gross negligence.

Although the information on proven user settings, application sites, duration of application and the use of instruments is based on clinical experience, individual centers and physicians also favor settings other than those recommended here. This information is intended only as a guideline and must be evaluated by the surgeon for applicability. Depending on individual circumstances, it may be necessary to deviate from the information provided in this brochure.

Medicine is constantly subject to new developments based on research and clinical experience.

This is another reason why departing from the information provided here may be appropriate.





Classification into the upper and lower urinary tract was also adopted for the applications from page 20.

Electrosurgery plays an important role in urology, making a crucial contribution to the therapeutic success of the different procedures.

The range of electrosurgical applications extends from open, laparoscopic surgery through to endoscopic procedures. It comprises all areas of the upper and lower urinary tract. The upper urinary tract includes the kidneys, adrenal glands and the ureters. The lower urinary tract is comprised of the prostate, bladder and urethra.
There are a variety of instruments available to the urologist for this range of applications. Instruments are provided with electrosurgical modes by the OR modules of the urology workstation. The tissue effects of these modes are cutting and coagulation, vessel sealing and devitalization. Hydrosurgery is used to dissect and expose tissue, and tissue layers can be elevated. The Hydrosurgery unit supports urological applications. Vessels can be selectively and gently exposed, and tissue layers separated and elevated.

Using this brochure, we would like to provide you with helpful information and recommendations which will permit you to make the most of electrosurgery and hydrosurgery in urology.

Urology workstation

The fully equipped version of the urology workstation consists of the electrosurgical unit (VIO 300 D), units for argon plasma coagulation (APC 2) and hydrosurgery (ERBEJET 2), as well as an ESM 2 unit for the suction of secretions.
It is optimized for use in urology in terms of its software, hardware and modules, as well as a large choice of instruments.
The functions of the individual modules are described in the chapters on cutting and coagulation modes (from page 12) and on applications (from page 20).

A urologist can use the electrosurgical units and instruments to perform open, laparoscopic and endoscopic surgery. Electrosurgery allows cutting without the application of force, effective coagulation and vessel sealing as well as devitalization of the target tissue throughout the urinary tract. Argon plasma coagulation, a special form of electrosurgery, staunches bleeding evenly and devitalizes tissue lesions without the instrument coming into direct contact with the tissue. Hydrosurgery is used to dissect tissue while at the same time protecting vessels and nerves. Layers can also be separated and detached from one another.

01 **VIO® 300 D**

02 **Bipolar resection adapter**

03 **APC 2**

04 **ERBEJET® 2**

05 **ESM 2**

Urology workstation with units for electrosurgery, plasmasurgery, hydrosurgery, suction module

For more information, please refer to the product brochures of the respective devices

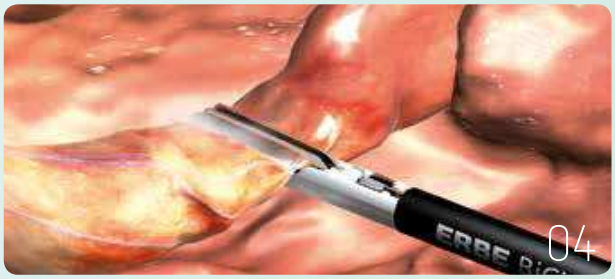
Tissue effects

Electrosurgery technique

Cutting tissue in a case of transurethral resection of the prostate TUR-P

Devitalization of a tissue layer using APC

Bipolar forceps coagulation of a tissue surface



Reliable vessel closure with BiCision

CUTTING 01

At voltages of 200 V or more, sparks are created between the active electrode and the tissue. In the cutting modes, electrical energy gives rise to temperatures of 100° C or higher. Intracellular and extracellular fluids vaporize so quickly that the cell membranes and cell layers rupture and; the result is cutting of the tissue.

COAGULATION 02

Coagulation current is used to staunch bleeding. Converting electrical energy into heat results in temperatures of 60 °C to 100 °C during coagulation. As the cytoplasm vaporizes, the tissue dries out and shrinks. Coagulation can also be used to mark a tumor with a radial safety margin.

DEVITALIZATION 03

APC or conventional electrosurgery is used to devitalize the tissue surface. At temperatures of 50–60°C or above and with a corresponding activation time, the damage to the tissue is irreversible.

VESSEL SEALING 04

Sealing reliably closes vessels and tissue bundles. The target tissue can then be dissected mechanically. Vessel sealing is increasingly replacing the use of clips and sutures.

Hydrosurgery

THERMAL EFFECTS ON BIOLOGICAL TISSUE

37-40°C

None

From ~ 40°C

Hyperthermia:
initial tissue damage, edema formation, depending on the duration of application, the tissue can recover or die (devitalization)

From ~ 60°C

Devitalization (destruction)
of the cells, shrinkage of the connective tissue through denaturation

~ 100°C

Vaporization of the tissue fluid, depending on the speed of vaporization:
- Tissue shrinkage through desiccation (drying out) or
- Cutting due to mechanical tearing of the tissue

From ~ 150°C

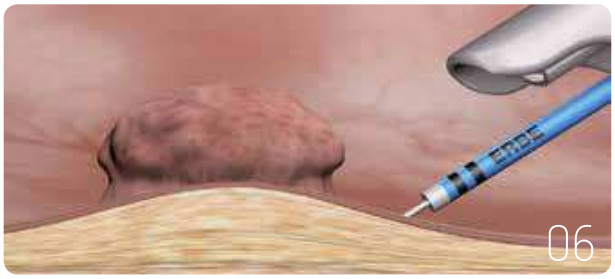
Carbonization

From ~ 300°C

Vaporization (evaporation) of the entire tissue

Source: J. Helfmann, Thermal effects. In: H.-Peter Berlien, Gerard J. Müller (Ed.); Applied Laser Medicine. Published by Springer Verlag, Berlin Heidelberg, 2003.

Selective parenchyma dissection that protects vessels



Elevation of the mucosa in the bladder

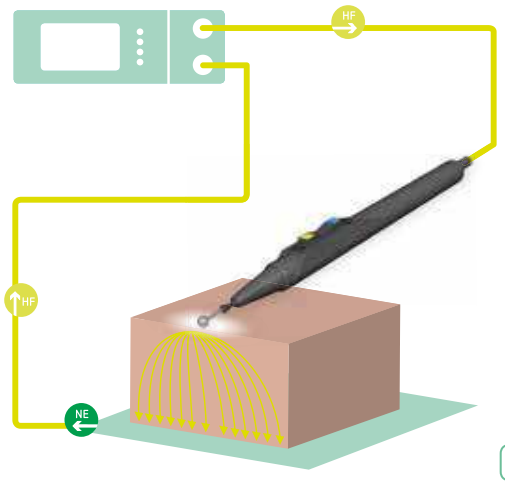
DISSECTION AND EXPOSURE USING THE WATERJET 05

Using the waterjet, tissue structures are selectively and gently dissected and exposed. Blood vessels and nerves remain intact until a certain pressure is reached. Vessels are then treated in accordance with their size.

ELEVATION AND SEPARATION USING THE WATERJET 06

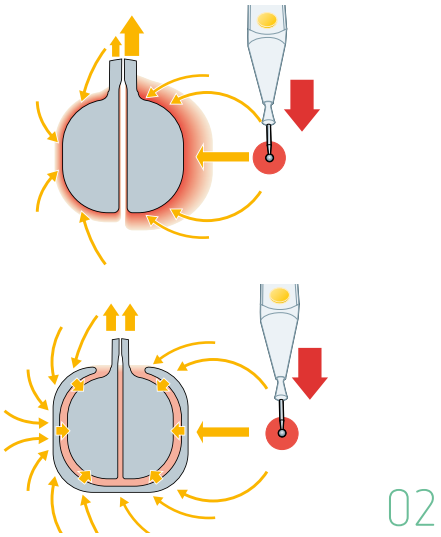
Waterjet elevation can be used to create fluid cushions in the tissue. Anatomical layers can also be separated from one another.

Electrosurgical procedures



01

Circuit for monopolar electrosurgery



02

↑High current density on the side closest to the operating field in the case of an incorrectly positioned conventional return electrode

↓Distribution of current without a localized increase in temperature with NESSY Ω, which can be positioned in any direction

MONOPOLAR TECHNIQUE 01

In monopolar electrosurgery, high-frequency current (I_{HF}) flows in a closed loop from the unit to the instrument, then through the patient's body to the return electrode, and from there back to the unit again. The surgical effect is produced at the tip of the active electrode (AE), which, due to its relatively small contact surface, is where the highest current density is reached. The second electrode, the return electrode, has a large surface area and is placed against the patient's skin at an appropriate location to allow the current to discharge.

At the points of application, the high current density and resulting thermal effect generate an incision or coagulation. By contrast, the increase in temperature on the large surface of the return electrode is not significant due to the low current density.

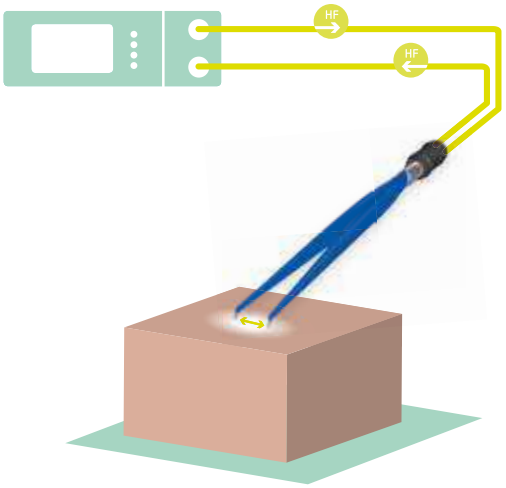
Safety in monopolar electrosurgery

Both components – the NESSY return electrode safety system of the VIO 300 D and the Erbe NESSY Ω return electrode – reduce the safety risks involved in monopolar electrosurgery in urology.
NESSY verifies whether the two-piece return electrode has been positioned correctly and whether its entire surface is in contact with the patient, and also continually compares the currents flowing through the two surfaces of the return electrode.

If there are only slight differences, activation is possible. If there are major differences, activation is interrupted a warning signal is sounded. Reactivation is not possible until the return electrode has been correctly positioned. This prevents thermal necrosis.

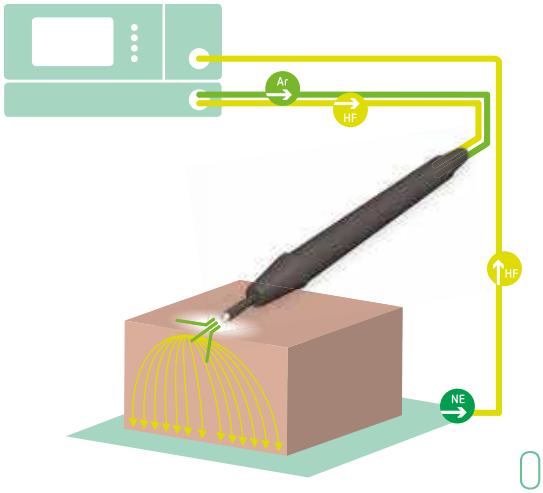
Simple and safe application with NESSY Ω

The NESSY Ω return electrode is equipped with a non-contact ring surface that surrounds the actual electrode surface. The equipotential ring distributes the current evenly across the inner contact surfaces and prevents the return electrode from heating up on one side (leading-edge effect). This means it can be positioned in any direction. Compared with conventional return electrodes, NESSY Ω **(Fig. 02 ↑ and ↓)** simplifies positioning and therefore enhances safety. As it is smaller than conventional electrodes, NESSY Ω is easier to position against the patient's body, making it universally suitable for children and adults alike.
We recommend using NESSY Ω – for maximum safety in monopolar electrosurgery.
Further information on monopolar electrosurgery is provided in the "Information on safe use" chapter.



03

Circuit for bipolar electrosurgery



04

Circuit for monopolar APC technique

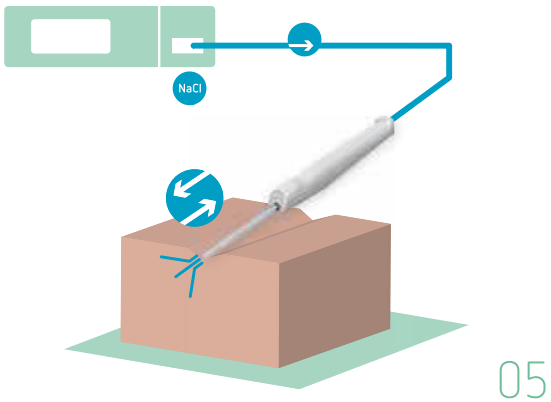
BIPOLAR TECHNIQUE 03

The advantage of the bipolar technique is that the flow of current to the target area between each pole is limited. Unlike monopolar electrosurgery, this protects sensitive structures such as nerves that are located within the flow of current between the operating field and the return electrode against inadvertent thermal damage.
Bipolar electrosurgical instruments have two integrated active electrodes. Current flows only in the area of tissue between the two poles and not through the patient's body. The bipolar technique does not require the use of a return electrode.

ARGON PLASMA COAGULATION (APC)

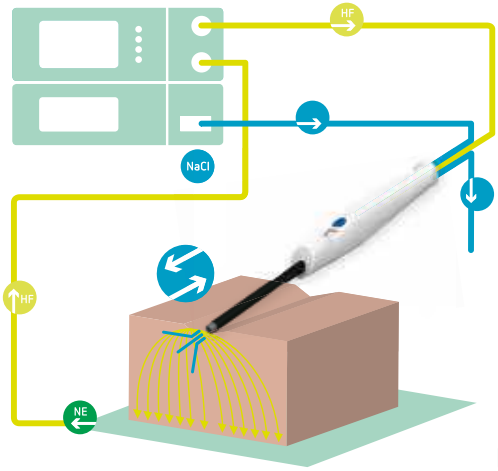
In APC, ionized argon gas conducts the current to the target tissue without contact between the instrument and the tissue.
The procedure has few complications, safely staunches bleeding, and facilitates homogeneous surface coagulation with an adjustable penetration depth. Because it is a non-contact procedure, the advantage of APC is that the distal end of the instrument cannot adhere to the coagulated tissue and tear open the scab that has just formed. The tissue effect depends on the type of probe, the power setting, the APC mode and the duration of application.
Further information on APC is provided in the "Information on safe use" chapter.

Waterjet procedures



05

Principle of hydrosurgery



06

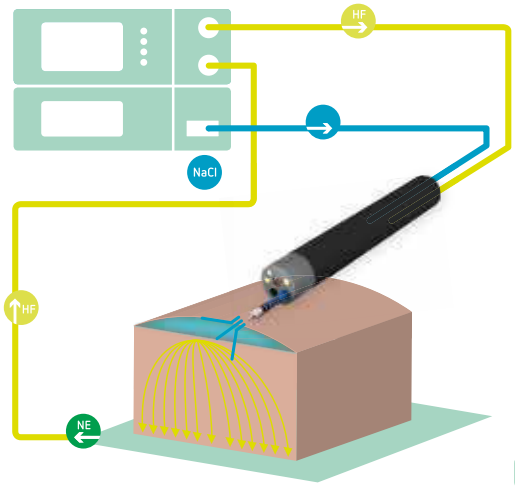
Principle of hydrosurgery with a combined monopolar circuit and monopolar applicator

WATERJET DISSECTION 05

The waterjet dissects tissue using finely adjustable pressure according to the varying firmness and elastic properties of the tissue. The parenchyma is fragmented; blood vessels and nerves are retained in this procedure and can be treated in a targeted fashion. In addition to separating the vessels, the expansion effect of the waterjet is used to detach the tissue layers.
For urology procedures users have a choice of instruments for open, laparoscopic and endoscopic surgery.
The effect levels can be set between 1 to 80. The waterjet meets the tissue; the separation medium is aspirated together with the tissue particles through the external lumen of the applicator.

WATERJET DISSECTION WITH ELECTROSURGERY 06

Using the monopolar electrosurgical applicator, both surgical techniques can be used at the same time. In partial kidney resection, the waterjet dissects the parenchyma. Blood vessels are retained and are treated simultaneously with coagulation current or alternately. Larger vessels are ligated using clips or sutures.
The diagram shows the monopolar current flowing in a closed loop from the unit to the applicator, then through the patient's body to the return electrode, and from there back to the unit. The separation medium also flows from the ERBEJET 2 pump unit through the waterjet nozzle of the applicator and meets the target tissue. The tissue is fragmented and aspirated through the external lumen of the applicator together with the separation medium.



07

Principle of electrosurgery with a combined monopolar circuit using HybridKnife

WATERJET ELEVATION WITH ELECTROSURGERY 07

With HybridKnife, the waterjet function is used for elevation: prior to resection of bladder tumors, a fluid cushion is generated in the submucosa so that the mucosa where the lesion is located is elevated. Subsequent electrosurgical cutting using HybridKnife can thus be performed at a defined resection level. Elevation reduces the risk of perforation.

Cutting and coagulation modes

Monopolar

AUTO CUT, the standard mode in urology

DRY CUT cuts with a significant level of hemostasis

HIGH CUT for cutting with a high level of hemostasis

SOFT COAG coagulates gently for deep tissue penetration without adhesion

AUTO CUT® 01

This is the standard mode for cutting with reproducible cutting quality as well as minimum necrosis, for example in subcutaneous tissue. This mode permits clean, precise cutting with hemostasis to protect tissue, as well as effective histological evaluation of the resected tissue. AUTO CUT can be used in almost any urological procedure, such as monopolar TUR-B, for example.

HIGH CUT 02

This mode is suitable for cutting in adipose structures or under water. Due to the high level of hemostasis at the margins of the incision, HIGH CUT is particularly suited to cutting vascular tissue. This mode is distinguished by a sharp incision. The arc intensity is controlled during cutting, so that hemostasis is ensured during all phases of the cut, for example in TUR-P procedures.

DRY CUT® 03

This cutting mode offers a significant level of hemostasis with voltage control and modulated forms of current, for example for cutting highly vascular tissue.
In urology, DRY CUT is suitable for TUR-P. This mode is generally suited to surgical procedures requiring a significant level of hemostasis, for example when accessing and exposing organs.

SOFT COAG® 04

SOFT COAG is a gentle, conventional mode of coagulation for deep tissue penetration. It minimizes adhesion between the electrode and the coagulated tissue.
This mode is mainly used in urology for hemostasis of parenchymal bleeding in partial kidney resection.

FORCED COAG, the standard coagulation mode in urology

FORCED APC for deep coagulation and effective devitalization

SWIFT COAG, the mode for coagulation and exposure

PRECISE APC, finely adjustable coagulation and devitalization

FORCED COAG® 05

This mode provides fast and effective standard coagulation with medium thermal penetration. Due to the slight carbonization, the instrument may adhere to the tissue. In urology, FORCED COAG is used as the standard mode in almost all cases where hemostasis is required.

FORCED APC® 07

This mode of plasmasurgery delivers high energy to the target tissue. FORCED APC provides deep coagulation and effective, even devitalization.
In the case of partial kidney resection or in other vascular tissue, parenchymal bleeding is staunched using FORCED APC and the resection bed devitalized.

SWIFT COAG® 06

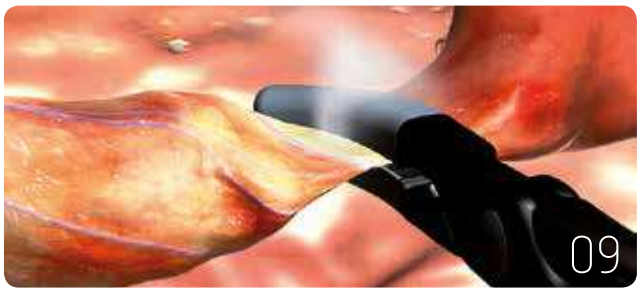
This mode offers effective and fast coagulation with a significant level of hemostasis that is also suitable for targeted, precise exposure, e.g. in cystectomies.

PRECISE APC 08

Unlike FORCED APC, PRECISE APC works at lower energy ranges. This allows uniform coagulation effects to be precisely adjusted in the target tissue, regardless of the distance between the probe and the tissue.
With PRECISE APC, precancerous conditions or other changes in tissue in the external genital area are devitalized.

Cutting and coagulation modes

Bipolar



BiClamp mode seals vessels and tissue

BIPOLAR CUT++ is the mode for bipolar TUR

BIPOLAR CUT is used for incisions

BIPOLAR SOFT COAG for forceps coagulation

BICLAMP® 09

BiClamp mode supports the BiClamp and BiCision instruments with a form of current that seals vessels of up to 7 mm diameter.* Generally, neither clips nor sutures are required.
BiClamp mode is suitable for vessel sealing in laparoscopic or open procedures. Examples: cystectomy, prostatectomy, lymphadenectomy or partial nephrectomy (to seal the distinct collateral vessels of the kidney).

BIPOLAR CUT 10

BIPOLAR CUT is suitable for cutting with reproducible cutting quality and minimum necrosis. This mode generates precise cutting with hemostasis to protect tissue. This mode can be used in urology, for example to open the renal capsule.

BIPOLAR CUT++ 11

This mode is distinguished by fast, controlled arc formation with immediate incision and low energy input. It is used in saline during bipolar TUR. The controlled arc intensity ensures safe hemostasis during resection.

BIPOLAR SOFT COAG 12

This mode is the standard mode for safe coagulation using the bipolar forceps or laparoscopic clamp.

** individual models, depending on the specification*

BIPOLAR SOFT COAG++ is the mode for surface coagulation in TUR procedures

BIPOLAR SOFT COAG++ 13

This mode creates a safe coagulation in bipolar resection. BIPOLAR SOFT COAG++ is used in saline in TUR procedures where plasma should not be formed on the snare.

Instruments

For urological procedures, we recommend the instruments listed on both double pages. In addition to these application-specific products, standard instruments are also used in urology that are not described individually or in detail here. These include monopolar electrodes of varying lengths and shapes such as ball, spatula, needle or snare electrodes, as well as PREMIUM forceps of varying lengths and shaft shapes, and forceps tips. All Erbe instruments are listed in our accessories catalog.

01

Open-surgery BiClamp 280 with anatomically-curved jaw

02

BiClamp Kelly LAP forceps with curved jaw

BICLAMP® 01

BiClamp allows vessels of up to 7 mm diameter to be sealed* so that clips and sutures are generally not required. BiClamp instruments are available in various lengths and jaw shapes. In urology, BiClamp 280 is used, for example in open prostatectomies or to seal renal tumor vessels.

All BiClamp instruments are reusable. The thermal capacity of the jaws is low, reducing the risk of thermal injury to adjacent structures. The BiClamp instrument is operated using the BiClamp mode of the VIO 300 D electrosurgical unit.

BICLAMP® LAP FORCEPS 02
BICLAMP® KELLY LAP FORCEPS

The BiClamp Kelly LAP forceps feature a specially curved jaw. As well as sealing vessels of up to 7 mm diameter*, they are also suitable for coagulation at selected locations and mechanical exposure.

They are suitable for the exposure of lymphatic tissue along the vessels and for blunt exposure or sealing of smaller vessels.

** individual models, depending on the specification*

03

BiCision, the multifunctional instrument

05

Bipolar LAP forceps with fenestrated jaws

04

Bipolar BiSect scissors

06

Bipolar Metzenbaum E-LAP scissors

BICISION® 03

Vessel sealing and dissection are the two primary functions of this instrument. In addition, the BiCision can also be used to expose, coagulate and grip tissue.

The shell-shaped jaw offers a larger sealing zone than other instruments with a 5 mm shaft that feature a comparable jaw geometry. As a result of the low thermal capacity and the minimal coagulation seam, adjacent structures (for example nerves) are protected[2]. The cutting length of 18.5 mm allows work to be carried out quickly, for example to expose organs. The BiCision is operated using the BiClamp mode of VIO 300 D.

BIPOLAR BISECT SCISSORS 04

The bipolar scissors support a variety of applications in open surgery. During mechanical cutting, the tissue is electrosurgically coagulated at the same time. The appropriate form of current with VIO 300 D is BIPOLAR SOFT COAG mode, for example for full exposure of the kidneys.

BIPOLAR LAP FORCEPS 05

Tissue is held firmly thanks to the grooved gripping surface. In addition to the precise electrosurgical coagulation of vessels and structures, the Bipolar LAP forceps are also suitable for blunt exposure. The twin mechanism opens the jaws evenly and grips the tissue with even contact pressure.

BIPOLAR METZENBAUM LAP SCISSORS 06

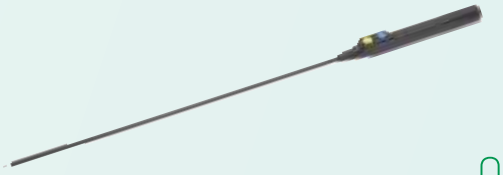
This bipolar cutting instrument with a 5 mm shaft and a shaft length of 340 mm results in superior mechanical cutting. In combination with BIPOLAR SOFT COAG, gentle coagulation is achieved and the jaws of the instrument are protected.

This instrument is also available with an ERGO handle that reduces operator fatigue during surgery.

MONOPOLAR SCISSORS

This monopolar cutting instrument is primarily used for resection in sensitive structures with low vascularity. The monopolar scissors can, for example, be used for ureteroneocystostomy.

Instruments



07

The hook electrode for blunt or electrosurgical exposure

09

APC applicator for open surgery

08

The needle electrode can be set to 4 cutting depths

10

APC applicator for laparoscopic surgery

HOOK ELECTRODE 07

The monopolar hook electrode is used in urology, for example for adhesiolysis of tissue structures as well as for general exposure.

NEEDLE ELECTRODE 08

With this instrument, the tip of the needle can be extended in 4 stages, allowing the cutting depth to be regulated. Adjustments are performed using the handle. The bipolar needle electrode is available in two shaft lengths, for standard laparoscopy with 320 mm and for bariatric surgery with a length of 480 mm.

APC APPLICATOR 09

With the open-surgery APC applicator, resection surfaces are safely and evenly coagulated, for example following partial kidney resection.

APC-APPLICATOR 10

The laparoscopic APC applicator is used in urology primarily for coagulation of large resection surfaces, for example following partial kidney resection. The advantages are comparable with open-surgery applications: even and safe coagulation, also of larger surfaces. The APC is applied contact-free, meaning there is no risk of coagulated tissue being torn open again.

11

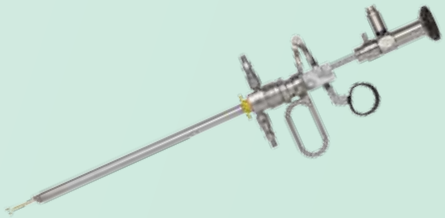
Open-surgery applicator for hydrosurgery

12

Applicator, straight, with monopolar electrosurgical function

13

HybridKnife Type I, including handle and connecting cable
(Type O, Type T, no illustration)



14

Resectoscope for TUR
(with the kind permission of: Karl Storz GmbH)

APPLICATOR, CURVED TIP 11

The curved distal end of the waterjet applicator is particularly suited for the exposure of the prostate. Laparoscopic waterjet applicators are also available for laparoscopic prostatectomy (no illustrations).

APPLICATOR, STRAIGHT WITH MONOPOLAR ELECTROSURGICAL FUNCTION 12

This applicator features an integrated electrosurgical and waterjet function. During selective dissection, for example of kidney parenchyma, the fully exposed blood vessels are coagulated and separated using COAG current. Both functions can be used simultaneously or alternately.

HYBRIDKNIFE® 13

HybridKnife is used in urology for the resection of bladder tumors.[7,8] Electrosurgery and waterjet functions are integrated in the instrument. All 4 steps, marking of the bladder carcinoma, mucosa elevation, incision / dissection as well as hemostasis are performed using just one instrument.

RESECTOSCOPE 14

Monopolar and bipolar resectoscopes are available for transurethral resection in the prostate or bladder.

Applications in the upper urinary tract

Kidney and ureter

NEPHRECTOMY

☑ In this procedure, the kidney is completely removed, where necessary together with the adrenal gland. A nephrectomy is often indicated in oncological disorders or following trauma.

NEPHROURETERECTOMY

☑ The ureter is removed at the same time as the kidney because of oncological necessity, or in a non-functional kidney with reflux.

PARTIAL NEPHRECTOMY

☑ In partial kidney resection, only part of the kidney is removed if it is possible or necessary to retain part of the kidney. This procedure is generally performed to treat oncological disorders (Fig. 01).

ADRENALECTOMY

☑ The adrenal grand is removed in primary adrenal gland disorders, depending on the size and hormonal activity. It is also removed in a nephrectomy procedures.

PYELOPLASTY

☑ In this procedure, surgical reconstruction of the renal pelvis is carried out, for example due to ureteropelvic junction obstruction or following partial kidney resection as a result of a tumor.

URETERONEOCYSTOSTOMY

☑ A ureteroneocystostomy is carried out for vesicoureteral reflux and ureteral strictures and injuries to the ureter.

Open surgical access

The skin incision can be made electrosurgically using a needle electrode and AUTO CUT mode. In order to locate the renal bed, the individual muscle layers are separated. A spatula or knife electrode and the AUTO CUT cutting mode are suitable for this with hemostasis to protect tissue. The reduction in carbonization has a positive impact on post operative wound healing.
In the case of highly vascular and less sensitive tissue, DRY CUT can also be used to achieve greater hemostasis. Any subsequent bleeding is directly coagulated using the spatula or knife electrode with FORCED COAG or SWIFT COAG – smaller bleeding vessels are treated with the bipolar forceps.
Once the renal fascia has been opened, the kidney, adrenal gland and adjacent structures can be fully exposed and mobilized using BiClamp 280 and BiSect bipolar scissors. Due to effective thermofusion, ligature and clip are not generally required.

In these procedures, the target organ is then removed:

- Nephrectomy
- Nephroureterectomy
- Adrenalectomy

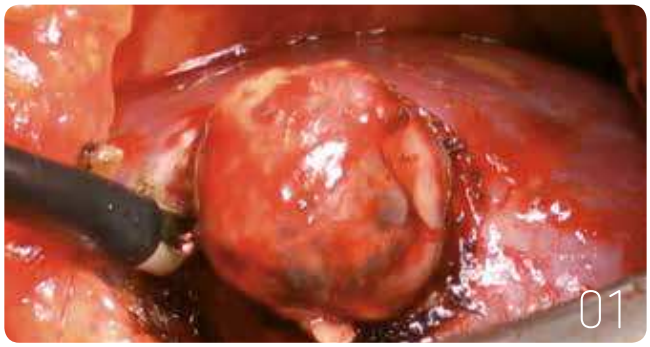
Additional steps in

PARTIAL NEPHRECTOMY	01, 02

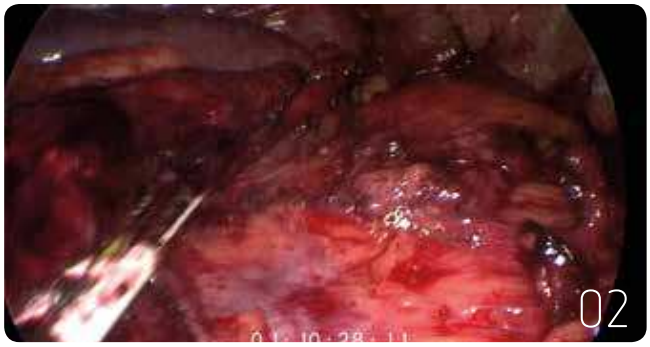
Once the organ has been exposed, the renal capsule can be opened using the bipolar needle electrode **(Fig. 01)**. The advantage is that the cutting depth can be set on the instrument and thus regulated.
The waterjet function of the straight monopolar applicator is used for selective dissection of the kidney parenchyma. Where required, the exposed vessels are coagulated and separated using the electrosurgical function of the applicator (with SWIFT COAG). Due to the low levels of blood loss, ischemia, or temporary clamping of the renal vessels, is often not required. The resulting advantages: surgery time is reduced as exposure of the renal hilum is not required. By avoiding ischemia, healthy residual kidney tissue is protected.

Contact coagulation can be performed either at individual locations of the resection bed using the ball electrode (SOFT COAG mode), or the surface can be treated using argon plasma coagulation (FORCED APC). The APC is a non-contact instrument, which is why there is no risk of previously coagulated tissue tearing open again. APC coagulation is homogenous and the procedure can be carried out without pauses.

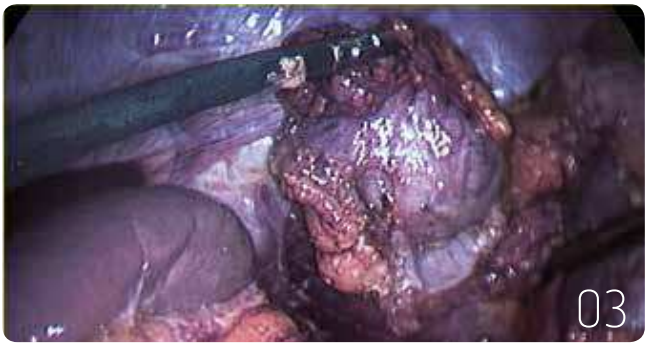
Additional instruments for these applications as well as proven user settings are provided in the overview tables from page 29



Partial nephrectomy (open surgery)



Partial nephrectomy with BiCision



Laparoscopic adrenalectomy

Laparoscopic access

Using the trocars, the organ is exposed and mobilized using BiCision, or alternatively using a BiClamp LAP forceps or a bipolar LAP forceps. The thermofusion instruments also facilitate effective mechanical exposure. BiCision offers effective vessel sealing with an integrated cutting function as well as optimum staunching of bleeding **(Fig. 02)**. Alternatively, the bipolar Metzenbaum LAP scissors can be used to perform exposure. They offer a mechanical cutting function, combined with bipolar coagulation.
The organ can then be mobilized and resected using the laparoscopic hook electrode and the SWIFT COAG or AUTO CUT modes.

In these procedures, the structures of the kidney can be fully exposed using BiCision and sealed at the same time:

NEPHRECTOMY, NEPHROURETERECTOMY, PARTIAL NEPHRECTOMY

Exposure of the central renal hilum is simplified using the curved applicator (waterjet). This allows the blood vessels that supply the resection area of the kidney to be detected and then clamped in a targeted fashion.
Thanks to this technique, known as zero ischemia, the healthy surrounding kidney tissue continues to be supplied with blood. In a partial nephrectomy, the kidney can be opened using the bipolar needle electrode. The cutting depth can be regulated and is adjusted using the handle of the instrument.

Additional steps in

ADRENALECTOMY 03

Using the mechanical function of the BiCision instrument, the adrenal gland is fully exposed. Alternatively, a bipolar LAP forceps and a monopolar scissors can be used. The enlarged blood vessels of the tumor can also be quickly and reliably sealed using BiCision.
The minimal coagulation seam of the BiCision jaw is an advantage, particularly when sealing near vulnerable structures.
In laparoscopic approaches, the VIO system supports robot-assisted surgery with DaVinci.

Additional steps in

PYELOPLASTY/URETERONEOCYSTOSTOMY

Following incision and blunt mobilization of the colon, the renal pelvis and sensitive polar vessels are exposed. As hemostasis is of primary importance, we recommend using the SWIFT COAG mode in combination with monopolar scissors.
AUTO CUT is the mode best suited for exposure of the ureter, as it reduces the risk of thermal necrosis and perforations, and as a result, of subsequent stenoses in the ureter.
The anatomically-shaped jaw of the BiClamp Kelly LAP forceps simplifies the exposure of vessels. Smaller vessels can be exposed bluntly, larger vessels sealed.

Applications in the lower urinary tract

Prostate, bladder and urethra

RADICAL PROSTATECTOMY

- ☑ The aim of prostate removal is the therapeutic treatment of a prostate carcinoma. How radical this procedure is depends on the tumor stage as well as the patient's age and prognosis. This also determines whether surgery can be carried out in such a way that nerves are protected.

CYSTECTOMY (WITH A NEOBLADDER)

- ☑ The bladder is generally removed in the case of bladder tumors that have infiltrated the muscle. There are several options for diverting urine. A neobladder can, for example, be created as a replacement from a piece of the small intestine. It takes over the reservoir function of the bladder. A prerequisite for this is that both the urethra and the sphincter are tumor-free and can be retained.

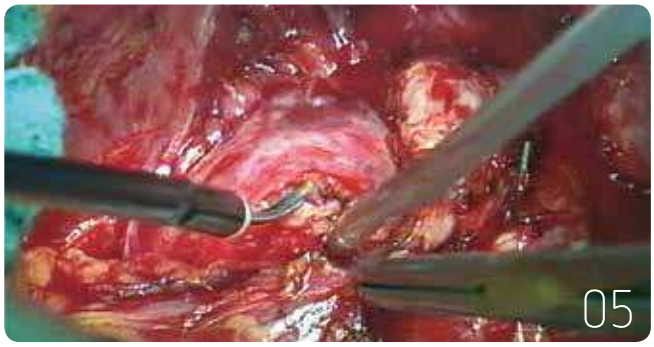
Open-surgery prostatectomy

Open approach

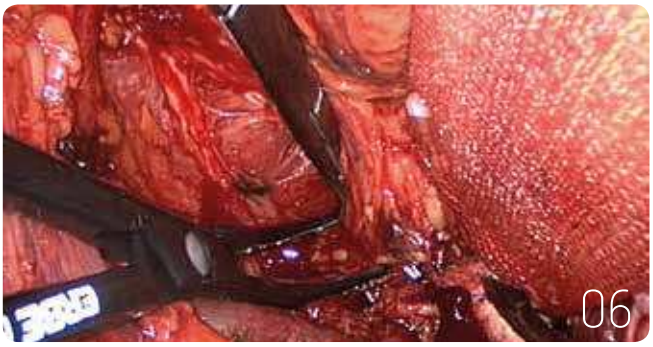
The skin incision can be made electrosurgically using a needle electrode and the AUTO CUT mode. In order to locate the operative site, the individual muscle layers are separated. A spatula or knife electrode with the AUTO CUT cutting mode are suitable for this, in particular as hemostasis is tissue-sparing. The reduced in carbonization has a positive impact on post operative wound healing.

In highly vascular and less sensitive tissue, DRY CUT can also be used to achieve greater hemostasis. Any subsequent bleeding is directly coagulated using the spatula or knife electrode with FORCED COAG or SWIFT COAG – smaller bleeding vessels can be treated with the bipolar forceps.
Following exposure, the target organ can be fully exposed and mobilized using BiClamp 280 and BiSect bipolar scissors **(Fig. 04)**. Thanks to effective vessel sealing, ligatures and clips are not generally required.

Additional instruments for these applications as well as proven user settings are provided in the overview tables from page 29



Prostatectomy using the waterjet



Cystectomy using BiClamp 280

PROSTATECTOMY 05

Using the hydrosurgery applicator, the anatomical structures can be detached from one another using gentle mechanical pressure.

Once the capsule has been opened, the glandular tissue is bluntly separated and the exposed vessels are effectively sealed using BiClamp 280. Due to the length of the instrument and the anatomically-adapted shape of the jaws, sealing can be performed close to the capsule.

CYSTECTOMY 06

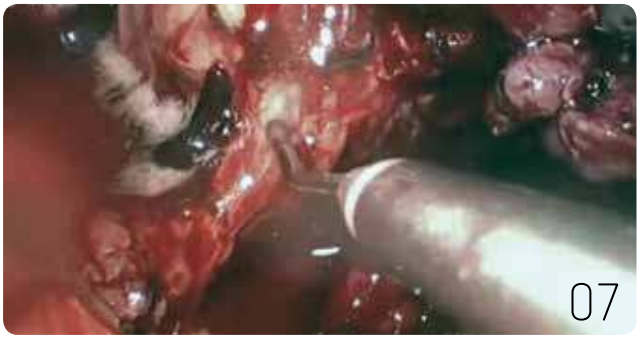
BiClamp 280 allows uterovesical ligaments to be quickly and effectively resected. Once the bladder has been removed, the section of small intestine used for the urinary diversion can be quickly exposed with minimal bleeding assisted by the anatomically-adapted jaw of the BiClamp 280.

Applications in the lower urinary tract

Prostate, bladder and urethra

LYMPHADENECTOMY

☑ The aim of this procedure is to diagnose the occurrence and extent of any lymphatic metastasis and to additionally remove pathological lymphatic tissue.



Prostatectomy using the waterjet

Laparoscopic access

Using the trocars, the target tissue is exposed and mobilized using BiCision, or alternatively using a BiClamp LAP forceps or a bipolar LAP forceps. The thermofusion instruments also facilitate effective mechanical exposure. BiCision offers reliable vessel sealing with an integrated cutting function as well as optimum staunching of bleeding. Alternatively, the bipolar Metzenbaum LAP scissors or the hook electrode can be used for exposure. They offer a mechanical cutting function, combined with bipolar coagulation.

The VIO electrosurgical system with SWIFT COAG and AUTO CUT supports all laparoscopic electrosurgical instruments when accessing, mobilizing and resecting the organ.

Additional instruments for these applications as well as proved user settings are provided in the overview tables from page 29

PROSTATECTOMY

When exposing the vasa deferentia and the seminal vesicle using the BiClamp LAP forceps, only low levels of aerosols develop.
The anatomically-shaped jaw of the BiClamp Kelly LAP forceps simplifies exposure of the vessels and enables vessels to be exposed in a blunt fashion and to be sealed.
The fasciae are mechanically separated using the monopolar scissors. In addition, SWIFT COAG can be used to perform fast and effective coagulation with a significant level of hemostasis. This mode also offers the characteristics required for electrosurgical exposure characteristics.
Once the prostate has been fully exposed, the capsule can be opened using the bipolar needle electrode. The cutting depth can be regulated and set using the handle of the instrument.

PROSTATECTOMY USING THE WATERJET 07

Using the waterjet applicator, the capsule can be detached from the prostate gland, and the fully exposed vessels sealed and separated with the BiClamp LAP forceps. Using the waterjet technique, gentle mechanical pressure is applied to the nerves, reducing the risk of post operative bladder dysfunction and sexual dysfunction.
A further advantage is the good visibility at the operative site, as the waterjet technique results in minimal bleeding and the operative site can be flushed with the saline solution.

If this procedure is carried out using a DaVinci system, the compatible VIO 300 D system offers optimal current forms for the instruments used.

Cystectomy with the BiClamp LAP forceps

Lymphadenectomy with BiCision

CYSTECTOMY WITH A NEOBLADDER 08

In laparoscopic procedures, a neobladder is created from a piece of the small intestine to act as a reservoir and replace the bladder. A prerequisite for this is that both the urethra and the sphincter (both tumor-free) are retained. When preparing the section of intestine inside the body, the ceramic insulation of the BiCision jaw reduces the risk of thermal injury to adjacent structures. The minimal coagulation seam also created by the BiClamp LAP forceps has a positive impact when incorporating the wall of the small intestine in the newly-formed neobladder.

The section of small intestine for the neobladder can be prepared outside the body using BiClamp 280, saving time and ensuring reliable hemostasis.

LYMPHADENECTOMY 09

BiCision is particularly suited to the exposure of lymphatic tissue along vessels and the sympathetic trunk. Smaller vessels are exposed bluntly, which prevents trauma, and sealed. Sealing the lymph vessels prevents the lymph from leaking. This prevents the development of seromas with the risk of tumor cell metastasis.
The instrument also speeds up the steps required as it is multifunctional and offers thermofusion and cutting.
The low thermal capacity of the jaws and the minimal coagulation seam reduces the risk of thermal injury to adjacent structures.

LYMPHADENECTOMY USING THE WATERJET

In lymphadenectomy using the waterjet, the applicator can assist in all phases of exposure.
The advantages of the waterjet technique: the high-pressure waterjet separates the various tissue structures according to their layers, enabling selective, interfascial exposure. Nerves and vessel structures are protected. The waterjet is particularly suited to separating lymphatic tissue from the aorta, vena cava and sympathetic trunk[4].
The waterjet technique can be used atraumatically, without thermal injury to adjacent structures.

Applications in the lower urinary tract

Bladder and prostate

TRANSURETHRAL RESECTION OF THE PROSTATE (TUR-P)

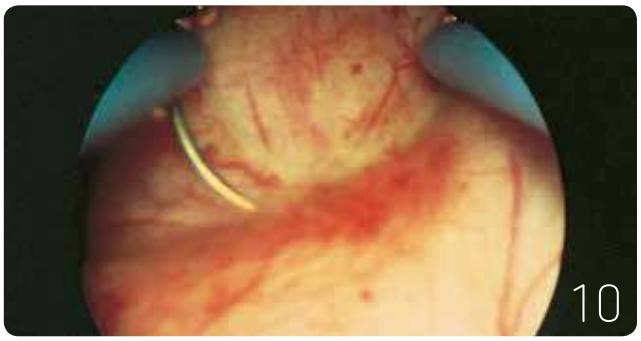
- ☑ Transurethral resection of the prostate is a therapy aimed at benign prostatic hyperplasias.

TRANSURETHRAL RESECTION OF THE BLADDER (TUR-B)

- ☑ TUR-B is used for the diagnosis and therapy of non-muscle-invasive bladder tumors.

EN BLOC RESECTION OF BLADDER TUMORS USING HYBRIDKNIFE

- ☑ This procedure is used to treat early stage bladder cancers.



Monopolar TUR-P

Endoscopic access

The resection instrument is inserted into the urethra in the direction of the target organ. The monopolar and bipolar techniques are used.

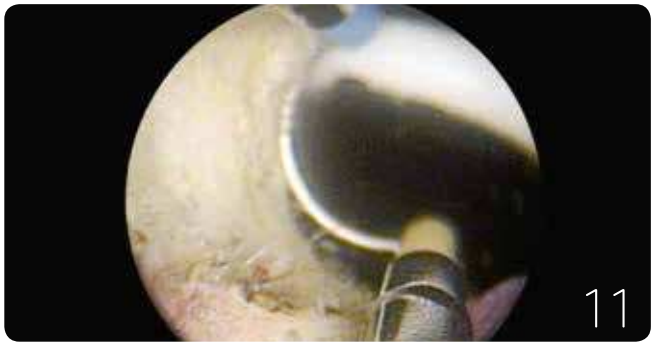
MONOPOLAR TUR-P 10

In the monopolar technique, the urinary tract is flushed with non-conductive fluid using the resectoscope. In electrosurgical cutting with a snare, DRY CUT offers a significant level of hemostasis. This mode prevents irrigation fluid from flooding into the vascular system. The irrigation fluid remains clear for an extended period; blister formation during cutting is kept to a minimum. Both are important criteria in terms of clear visibility of the target operating area. To smooth the prostatic capsule towards the end of the procedure, HIGH CUT offers optimal cutting as well as a precise incision.
The VIO 300 D electrosurgical unit enables the user to switch between both modes using the ReMode function on the footswitch. Any bleeding can be coagulated using FORCED COAG.

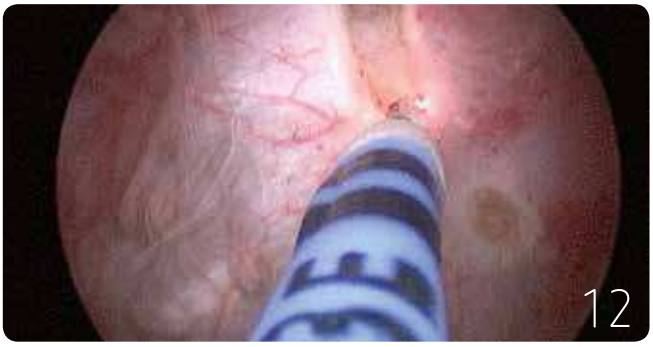
BIPOLAR TUR-P 11

With the bipolar technique, the urinary tract is flushed with an isotonic saline solution using the resectoscope.
Because of the immediate plasma ignition, BIPOLAR CUT++ mode offers a superior incision with low energy input. A prewarmed saline solution enhances this effect.
Any bleeding can be treated with BIPOLAR SOFT COAG++ using contact coagulation with deep hemostasis. The onset of the coagulation effect is slightly delayed with this mode.

Additional instruments for these applications as well as proved user settings are provided in the overview tables from page 29



Bipolar TUR-P



En-bloc resection of tumors of the bladder using HybridKnife

MONOPOLAR TUR-B

In the case of the monopolar technique, the urinary tract is flushed with non-conductive fluid via the resectoscope. In the case of snare resection, the monopolar modes AUTO CUT and HIGH CUT offer effective hemostasis properties. The irrigation fluid remains clear for an extended period; blister formation during cutting is reduced. Both are criteria in terms of clear visibility of the target operating area.
HIGH CUT mode supports optimized cutting as well as precise incision. Any bleeding can be coagulated using FORCED COAG.

BIPOLAR TUR-B

In the case of the bipolar technique, the urinary tract is flushed with an isotonic saline solution via the resectoscope. The bipolar technique reduces the risk of neuromuscular stimulation.
Thanks to immediate plasma ignition, BIPOLAR CUT++ mode offers a superior incision with low energy input – without applying mechanical pressure to the tissue. A prewarmed saline solution enhances this effect.
Any bleeding can be treated with BIPOLAR SOFT COAG++ using contact coagulation with deep hemostasis. The onset of the effect of coagulation is slightly delayed in this case.

EN BLOC RESECTION OF BLADDER TUMORS USING HYBRIDKNIFE 12

In selected cases, en bloc resection of early stage bladder cancers can be performed using the multifunctional HybridKnife instrument. For this, the urinary tract is flushed with non-conductive fluid as is the case in conventional TUR-B procedures.[7,8]

The bladder tumor is first marked using the HybridKnife mode "FORCED COAG". The mucosa where the tumor is located is then elevated using the waterjet function.
Once the mucosa has been elevated, an incision is made around the tumor, which is then resected. The fluid accumulates in the submucosa, creating a protective cushion that reduces the risk of perforation. This is particularly beneficial in the case of older patients with a thin bladder wall.
The DRY CUT mode offers cutting with optimal hemostasis. Repeated elevation results in a defined resection height (beneath the tumors), facilitating the target of R0 resection. Any bleeding can be coagulated using FORCED COAG.

Unlike conventional TUR-B, in this procedure the tumor is not fragmented but can be removed in one piece. This contributes to improving the pathological diagnosis and evaluation of vertical and horizontal resection margins to assess whether tumor tissue has been fully removed.

Applications in the lower urinary tract

More minor surgical procedures

CIRCUMCISION

- ☑ The foreskin is removed, for example in cases of phimosis.

REMOVAL OF HYDROCELES

- ☑ This procedure is carried out to treat the accumulation of fluid in the scrotum.

VARICOCELE THERAPY

- ☑ Enlarged varicose veins in the scrotum are treated with varicocele therapy.

VASECTOMY

- ☑ This procedure is performed for the purposes of sterilization.

Circumcision

CIRCUMCISION 13

In this procedure, the foreskin is completely or partially removed.
A mechanical incision is made around the foreskin using a scalpel or scissors. Bleeding is coagulated using a bipolar forceps; tissue adhesion can be minimized using PREMIUM forceps. BIPOLAR SOFT COAG mode also minimizes tissue adhesion.

VARICOCELE THERAPY

Therapy is carried out surgically, either by performing sclerotherapy on the afferent vein, or by ligating it.

In both procedures (hydrocele and varicocele therapy), bleeding can be coagulated using the bipolar PREMIUM forceps. These forceps and BIPOLAR SOFT COAG mode prevent tissue from adhering to the gripping surface.

VASECTOMY

Sterilization is achieved by severing the spermatic cords.

The skin is mechanically opened using a scalpel, and the vas deferens is then cut. Bleeding as well as the margins of the vas deferens incision can be coagulated using bipolar PREMIUM forceps.

Additional instruments for these applications as well as proved user settings are provided in the overview tables from page 29

Application overview

	CUT	COAG	JET
General skin incision			
Electrode handle with tungsten needle electrode	AUTO CUT, effect 2, 80 W	FORCED COAG, effect 2, 60 W	
Nephrectomy/Adrenalectomy, open surgery			
Electrode handle with knife or spatula electrode	AUTO CUT, effect 4–5, 180 W DRY CUT, effect 3–5, 160 W	SWIFT COAG, effect 3–4, 140 W FORCED COAG, effect 2, 80 W	
BiClamp 280		BICLAMP, effect 3	
Bipolar forceps		BIPOLAR SOFT COAG, effect 4–5, 50 W	
Bipolar BiSect scissors (open surgery)		BIPOLAR SOFT COAG, effect 3–4, 60 W	
Nephrectomy, laparoscopic with optional nephroureterectomy			
BiCision		BICLAMP, effect 2–3	
Bipolar Metzenbaum LAP scissors		BIPOLAR SOFT COAG, effect 4–5, 60 W	
BiClamp LAP forceps		BICLAMP, effect 2	
Hook electrode, (monopolar)	AUTO CUT, effect 3–4, 80 W	FORCED COAG, effect 2, 80 W SWIFT COAG, effect 3, 80 W	
Bipolar LAP forceps		BIPOLAR SOFT COAG, effect 4–5, 60 W	
Monopolar scissors, laparoscopic		SWIFT COAG, effect 2–3, 80 W FORCED COAG, effect 2, 80 W	
Applicator, curved tip (laparoscopic)			Effect 25–30
Adrenalectomy, laparoscopic			
BiCision		BICLAMP, effect 2–3	
Bipolar Metzenbaum LAP scissors		BIPOLAR SOFT COAG, effect 4–5, 60 W	
BiClamp LAP forceps		BICLAMP, effect 2	
Hook electrode, (monopolar)	AUTO CUT, effect 3–4, 80 W	FORCED COAG, effect 2, 80 W SWIFT COAG, effect 2–3, 80 W	
Bipolar LAP forceps		BIPOLAR SOFT COAG, effect 4–5, 60 W	
Monopolar scissors, laparoscopic		SWIFT COAG, effect 2–3, 80 W FORCED COAG, effect 2, 80 W	
Partial nephrectomy, open surgery			
Electrode handle with knife or spatula electrode	AUTO CUT, effect 4–5, 180 W DRY CUT, effect 3–5, 160 W	SWIFT COAG, effect 3–4, 140 W FORCED COAG, effect 2, 80 W	
Applicator, straight, with electrosurgical function, monopolar (suction)		SWIFT COAG, effect 2–4, 120 W	Effect 30, -800 mbar
BiClamp 280		BICLAMP, EFFECT 3	
APC applicator		FORCED APC, 60–80 W	
Electrode handle with ball electrode (subsequent coagulation)		SOFT COAG, effect 4, 200 W	
Bipolar forceps		BIPOLAR SOFT COAG, effect 4–5, 50 W	
Bipolar BiSect scissors (open surgery)		BIPOLAR SOFT COAG, effect 3–4, 60 W	

Application overview

	CUT	COAG	JET
Partial nephrectomy, laparoscopic			
BiCision		BiClamp, effect 2–3	
Bipolar Metzenbaum LAP scissors		BIPOLAR SOFT COAG, effect 4–5, 60 W	
BiClamp LAP forceps		BICLAMP, effect 2	
APC applicator		FORCED APC, 60–80 W	
Needle electrode, bipolar	BIPOLAR CUT, effect 4, 60 W	BIPOLAR SOFT COAG, effect 4–5, 60 W	
Hook electrode, (monopolar)	AUTO CUT, effect 3–4, 80 W	FORCED COAG, effect 2, 80 W SWIFT COAG, effect 2–3, 80 W	
Bipolar LAP forceps		BIPOLAR SOFT COAG effect 4–5, 60 W	
Monopolar scissors, laparoscopic		SWIFT COAG, effect 2–3, 80 W FORCED COAG, effect 2, 80 W	
Laparoscopic pyeloplasty with optional ureteroneocystostomy			
BiCision		BICLAMP, effect 2–3	
Bipolar Metzenbaum LAP scissors		BIPOLAR SOFT COAG, effect 4–5, 60 W	
BiClamp Kelly LAP forceps		BiClamp, effect 2	
Hook electrode, (monopolar)	AUTO CUT, effect 3–4, 80 W	FORCED COAG, effect 2, 80 W SWIFT COAG, effect 2–3, 80 W	
Bipolar LAP forceps		BIPOLAR SOFT COAG, effect 4–5, 60 W	
Monopolar scissors, laparoscopic		SWIFT COAG, effect 2–3, 80 W FORCED COAG, effect 2, 80 W	
Prostatectomy, open surgery			
Electrode handle with knife or spatula electrode	AUTO CUT, effect 4–5, 180 W DRY CUT, effect 3–5, 160 W	SWIFT COAG, effect 3–4, 140 W FORCED COAG, effect 2, 80 W	
BiClamp 280		BICLAMP, effect 3	
Bipolar forceps		BIPOLAR SOFT COAG, effect 4–5, 50 W	
Bipolar BiSect scissors (open surgery)		BIPOLAR SOFT COAG, effect 3–4, 60 W	
Applicator, curved tip (open surgery)			Effect 20–25
Prostatectomy, laparoscopic			
BiCision		BiClamp, effect 2–3	
Bipolar Metzenbaum LAP scissors		BIPOLAR SOFT COAG effect 4–5, 60 W	
BiClamp Kelly LAP forceps		BiClamp, effect 2	
Hook electrode, (monopolar)	AUTO CUT, effect 3–4, 80 W	FORCED COAG, effect 2, 80 W SWIFT COAG, effect 2–3, 80 W	
Bipolar LAP forceps		BIPOLAR SOFT COAG, effect 4–5, 60 W	
Monopolar scissors, laparoscopic		SWIFT COAG, effect 2–3, 80 W FORCED COAG, effect 2, 80 W	
Applicator, curved tip (laparoscopic)			Effect 20–25

	CUT	COAG	JET
Cystectomy with a neobladder, open surgery			
Electrode handle with knife or spatula electrode	AUTO CUT, effect 4–5, 180 W DRY CUT, effect 3–5, 160 W	SWIFT COAG, effect 3–4, 140 W FORCED COAG, effect 2, 80 W	
BiClamp 280		BICLAMP, effect 3	
Bipolar forceps		BIPOLAR SOFT COAG, effect 4–5, 50 W	
Bipolar BiSect scissors (open surgery)		BIPOLAR SOFT COAG, effect 3–4, 60 W	
Cystectomy with a neobladder, laparoscopic			
BiClamp 280		BICLAMP, effect 3	
BiCision		BICLAMP, effect 2–3	
Bipolar Metzenbaum LAP scissors		BIPOLAR SOFT COAG, effect 4–5, 60 W	
BiClamp LAP forceps		BICLAMP, effect 2	
Hook electrode, (monopolar)	AUTO CUT, effect 3–4, 80 W	FORCED COAG, effect 2, 80 W SWIFT COAG, effect 2–3, 80 W	
Bipolar LAP forceps		BIPOLAR SOFT COAG, effect 4–5, 60 W	
Monopolar scissors, laparoscopic		SWIFT COAG, effect 2–3, 80 W FORCED COAG, effect 2, 80 W	
Lymphadenectomy, open surgery			
Electrode handle with knife or spatula electrode	AUTO CUT, effect 4–5, 180 W DRY CUT, effect 3–5, 160 W	SWIFT COAG, effect 3–4, 140 W FORCED COAG, effect 2, 80 W	
BiClamp 280		BICLAMP, effect 3	
Bipolar forceps		BIPOLAR SOFT COAG, effect 4–5, 50 W	
Bipolar BiSect scissors (open surgery)		BIPOLAR SOFT COAG, effect 3–4, 60 W	
Lymphadenectomy, laparoscopic			
BiCision		BiClamp, effect 2–3	
Bipolar Metzenbaum LAP scissors		BIPOLAR SOFT COAG, effect 4–5, 60 W	
BiClamp LAP forceps		BiClamp, effect 2	
Hook electrode, (monopolar)	AUTO CUT, effect 3–4, 80 W	FORCED COAG, effect 2, 80 W SWIFT COAG, effect 2–3, 80 W	
Bipolar LAP forceps		BIPOLAR SOFT COAG, effect 4–5, 60 W	
Monopolar scissors, laparoscopic		SWIFT COAG, effect 2–3, 80 W FORCED COAG, effect 2, 80 W	
Applicator, curved tip (laparoscopic)			Effect 25–35

Application overview

	CUT	COAG	JET
Transurethral resection of the bladder (TUR-B) – monopolar			
Resection snare, monopolar	AUTO CUT, effect 3–4, 150 W HIGH CUT, effect 3–5, 150 W	FORCED COAG, effect 1–2, 60 W	
Transurethral resection of the bladder (TUR-B) – bipolar			
Resection snare, bipolar	BIPOLAR CUT++, effect 4–5	BIPOLAR SOFT COAG++, effect 4–6	
Transurethral resection of the prostate (TUR-P) – monopolar			
Resection snare, monopolar	DRY CUT, effect 6, 170 W HIGH CUT, effect 4–6, 150–250 W	FORCED COAG, effect 2–3, 80–120 W	
Transurethral resection of the prostate (TUR-P) – bipolar			
Resection snare, bipolar	BIPOLAR CUT++, effect 4–6	BIPOLAR SOFT COAG++, effect 5–8	
En-bloc resection of bladder tumors using HybridKnife			
HybridKnife Type T / I	DRY CUT, effect 3, 70 W	FORCED COAG, effect 2, 50 W	Effect 20–25
Procedures using DaVinci			
Bipolar clamp / grasping forceps		BIPOLAR SOFT COAG, effect 4–5, 60 W	
Monopolar scissors		FORCED COAG, effect 2, 80 W SWIFT COAG, effect 2–3, 80 W	
Hook electrode, monopolar	AUTO CUT, effect 3–4, 80 W	FORCED COAG, effect 2, 80 W SWIFT COAG, effect 2–3, 80 W	
Circumcision, vasectomy, spermatocele, varicocele, hydrocele			
Bipolar forceps		BIPOLAR SOFT COAG effect 3–5, 40 W	

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Lee SW, Choi JB, Lee KS, Kim TH, Son H, Jung TY, Oh SJ, Jeong HJ, Bae JH, Lee YS, Kim JC. Transurethral procedures for lower urinary tract symptoms resulting from benign prostatic enlargement: a quality and meta-analysis. Int Neurourol J. 2013 Jun;17(2):59-66. doi: 10.5213/inj.2013.17.2.59. Epub 2013 Jun 30. PubMed PMID: 23869269; PubMed Central PMCID: PMC3713243.

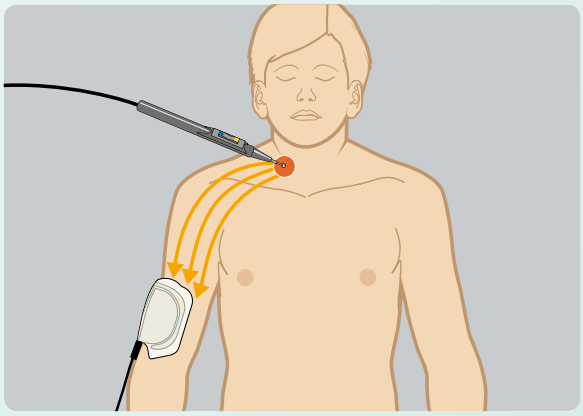
LEAFLETS AND BROCHURES

85800-103	Principles of electrosurgery
85800-127	Application brochure of electrosurgery
85800-107	NESSY Ω application brochure
85140-120	VIO D product leaflet
85134-100	APC 2 product leaflet
85150-100	ERBEJET 2 product leaflet
85100-100	Instruments and Accessories
85100-185	Vessel sealing product leaflet
85100-183	BiCision product leaflet
85810-101	Information folder for Urology

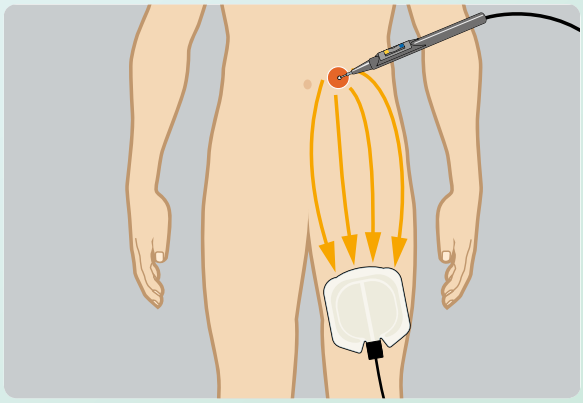
Additional information:
Up-to-date product and application information is available at www.erbe-med.com and in publications such as our accessories catalog.
Up-to-date user videos are available at www.medical-video.com

Information

on the safe use of electrosurgery and APC



The return electrode must be placed as close as possible to the operating field



General recommendations and rules for electrosurgery and APC

When used properly, electrosurgery poses virtually no risk to the patient or to surgical staff. The purpose of this checklist is to make the user aware of potential risks in order to eliminate them.

GENERAL NOTES

- Familiarize yourself with system features and learn how to operate the system properly before using it (see Germany's Medical Devices Operator Ordinance, or MPBetreibV). In addition to Instructions for Use, Erbe also offers training and accompanying literature.
- Because the electrosurgical unit, instruments and accessories are designed to work together, use either recommended accessories or equipment that has, as far as possible, been obtained from a single manufacturer. See Erbe Instructions for Use for additional information.
- Inspect the electrosurgical unit, instrument and accessories before use to ensure they are in proper working condition and free of damage.

PATIENT POSITIONING

- The patient must be dry and insulated when positioned. OR table overlays or cloth covers that are wet must be replaced during surgery.
- Place a urinary catheter if the procedure can be expected to take some time.
- The patient must not touch any electrically conductive objects, such as drip stands or the metal parts of the OR table.
- Avoid skin-to-skin contact points with the patient (e.g., hand / thigh)
- Do not install connecting cables on top of other cables or in places in the OR where they could cause someone to trip.
- Place instruments on the instrument table and not on or next to the patient.
- Be careful with disinfectants: electrical sparks can ignite the alcohol in these agents. For this reason, disinfectants must always be dried off completely.

OPERATIONS ON PATIENTS WITH PACEMAKERS

- Follow the pacemaker manufacturer's recommendations.
- Avoid allowing current to flow across the pacemaker, probe or cardiac muscle.
- The return electrode should be positioned as close as possible to the operating field but at least 15 cm from the pacemaker.
- Bipolar application is preferable to monopolar application.
- Select low settings.
- If possible, deactivate the pacemaker or ICD before electrosurgical application.
- Monitor the pacemaker before, during and after surgery for any potential malfunction.
- Brief activation bursts should be avoided. The pacemaker could interpret these as cardiac arrhythmias and generate stimulus signals in response.

Special recommendations for positioning the return electrode

With today's state-of-the-art technology, the risks incurred during monopolar electrosurgery are very low. Use of the return electrode does, however, give suggest questions and issues that we would like to clarify in this section.

In addition to carefully positioning the return electrode and ensuring contact across its entire surface, we also recommend observing the following safety rules.

- Check cables and plugs for any damage.
- Do not cut the return electrode.
- Position the return electrode with the long edge facing the operating field.
- The area of application should be dry and smooth with no disinfectant, body hair, skin folds or lesions
- Avoid air pockets between the skin and return electrode; do not use contact gel.
- Do not place the return electrode on scarred or inflamed areas of skin, on bony structures or near metallic implants that should not lie in the flow of current.
- Conductive muscular tissue with low electrical resistance is preferable to areas with subcutaneous fatty tissue. We recommend the upper arm or thigh (Fig. left page).
- Position the return electrode in such a way that ECG cables and electrodes do not lie in the flow of current.
- If the patient is repositioned, the placement of the electrode and the connection should be rechecked.
- The NESSY return electrode is not designed to be reused and should be replaced each time it is removed (e.g., when correcting its positioning).
- Position the return electrode as close to the operating field as possible (Fig. left page).
- When positioning the return electrode, implants must be taken into consideration. They must not lie in the flow of current.
- Arc flashes may occur during monopolar electrosurgery if uninsulated forceps are activated using a monopolar electrode (improper use!). Because their use is not uncommon in practice, we recommend using insulated forceps.
- ECG interference caused by electrosurgery can be avoided by using monitor-filter systems or accessories compatible with electrosurgery.

APPLICATION IN CHILDREN

- If the upper arm and thigh are too thin, the return electrode can also be placed on the patient's body.
- In infants, the return electrode should always be placed on the body. Whenever possible, work using the bipolar mode or only with low electrosurgical power (below 50 W).
- Return electrodes for children should only be used when a larger return electrode cannot be used. The larger the return electrode, the less the skin will warm up.

PROCEDURES ON PATIENTS WEARING JEWELRY (PIERCINGS, NECKLACES, RINGS, ETC.)

- We recommend always removing all jewelry (piercings, necklaces, rings, etc.).
- Performing electrosurgery on patients with piercings that cannot be removed is not contraindicated, however, provided the following rules are observed:
- Jewelry must not come into direct contact with the active electrode or return electrode.
- Neither the active electrode nor the return electrode may be used in the direct vicinity of piercings.
- The piercing must not be located in the flow of current between the active electrode and return electrode.
- Jewelry must not come into contact with electrically conductive materials.

AND AFTER THE PROCEDURE ...

- Carefully peel the return electrode off the skin to prevent injuries to the skin.

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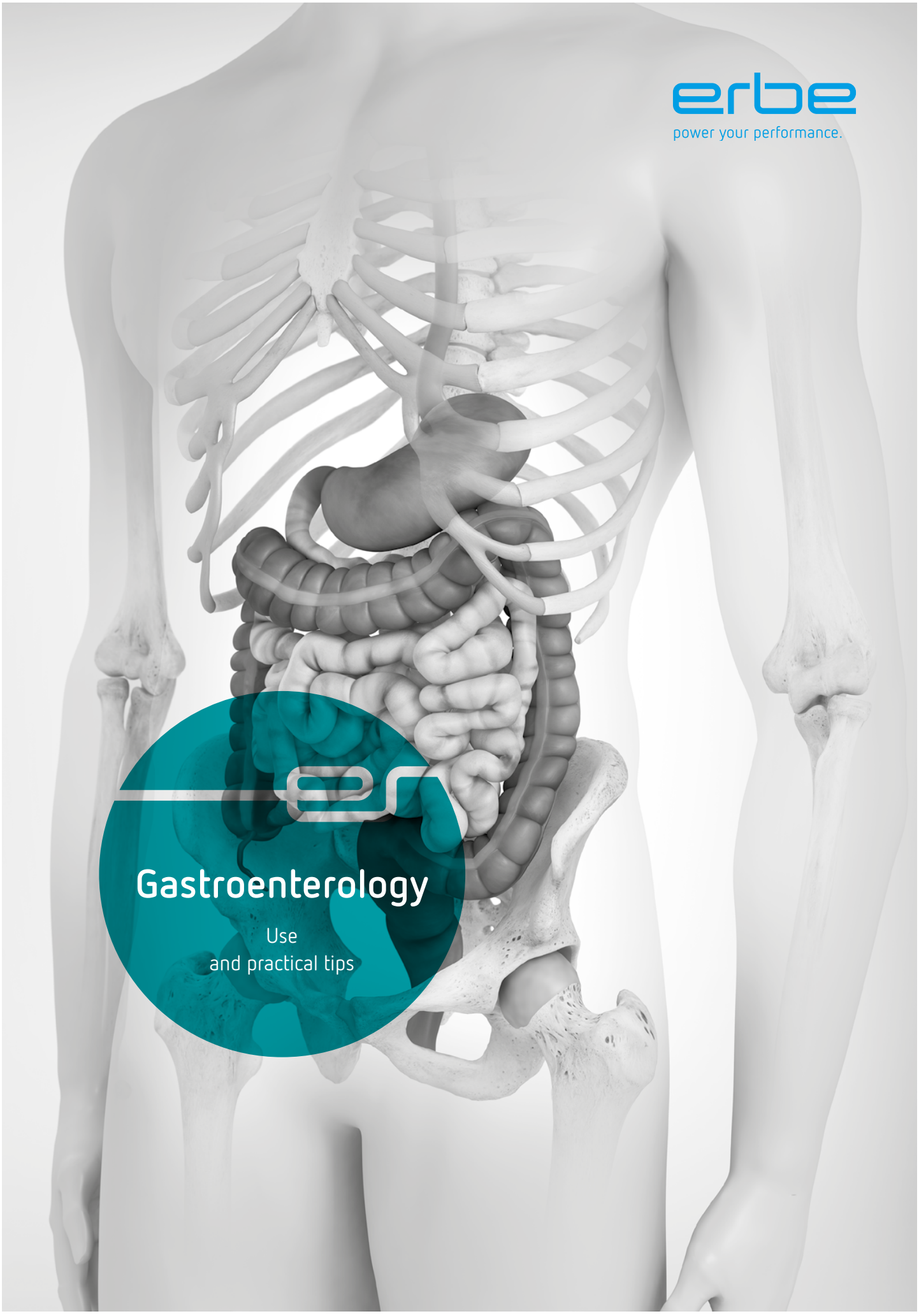


Gastroenterology

Use
and practical tips

E-SOFT_000180

TABLE OF CONTENTS

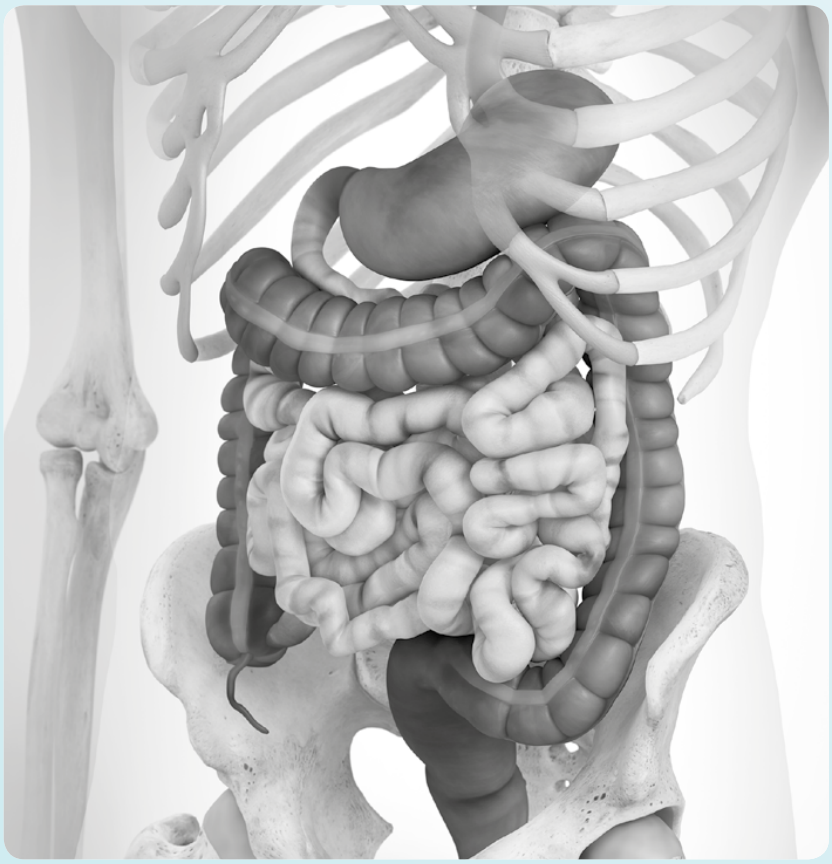
Important information

While Erbe Elektromedizin GmbH has taken the greatest possible care in preparing this brochure and compiling the recommended settings, we cannot completely rule out errors. The information and data contained in the recommended settings cannot be used to justify any claims against Erbe Elektromedizin GmbH. In the event of compelling legal justification for a claim, liability shall be limited to intent and gross negligence.

Although the information on recommended settings, application sites, duration of application and the use of instruments is based on clinical experience, individual centers and physicians also favor settings other than those recommended here. This information is intended only as a guideline and must be evaluated by the surgeon for applicability. Depending on individual circumstances, it may be necessary to deviate from the information provided in this brochure.

Medicine is constantly subject to new developments based on research and clinical experience.

This is another reason why departing from the information provided here may be appropriate.



Arrangement of the structures in the upper gastrointestinal tract (esophagus, stomach and duodenum) and lower gastrointestinal tract (jejunum, ileum, cecum, colon, sigmoid and rectum)

Endoscopic applications of electrosurgery

Electrosurgery, or HF surgery, plays an important role in interventional endoscopy. Diseases in the gastrointestinal tract are treated with electrosurgical cutting, coagulation and devitalization[1, 2]. In particular, argon plasma coagulation (APC), a special form of electrosurgery, has become established as a standard technique in many areas of applications over recent decades since the development of flexible probes. APC have proven to be a safe, effective and yet cost-efficient technique as compared to laser treatment, for example. Electrosurgery utilizes thermal effects whose impact on the targeted tissue differs dependent upon the temperature.

Waterjet technology is of growing importance in gastroenterology. The water jet separates and lifts tissue layers, so lesions can be safely resected while tissue is protected against thermal impact.

Gastroenterology workstation

The gastroenterology workstation offers a broad spectrum of electrosurgical applications in endoscopy. In the fully equipped version (Fig. 1) it consists of the electrosurgical unit (VIO 200 D), units for argon plasma coagulation (APC 2) and waterjet surgery (ERBEJET 2), as well as an endoscopy irrigation pump (EIP 2) used to flush the target region and thus improve visibility.

The workstation's software, hardware, unit modules and the wide range of instruments are configured for flexible endoscopy. The functions of the individual modules are described in the chapters on cutting and coagulation modes (starting on page 14) and on applications (starting on page 20).

Electrosurgery allows for cutting with minimal application of force, as well as effective coagulation and devitalization of the target tissue in the gastrointestinal tract. Argon plasma coagulation, a special form of electrosurgery, homogenously staunches bleeding and devitalizes tissue lesions without any direct contact between the instrument and tissue.

The waterjet function separates layers, lifts them apart and forms a thermal protective cushion. The HybridKnife and HybridAPC, both combination instruments, integrate these functions in one instrument and can be used alternately at any time.

01 **VIO® 200 D**

02 **APC 2**

03 **ERBEJET® 2**

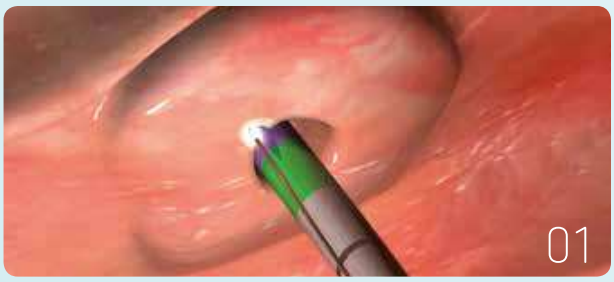
04 **EIP 2**

Fig. 1: Gastroenterology workstation: with units for electrosurgery, argon plasma coagulation, waterjet surgery and endoscopic irrigation

For more information, see the product brochures for the individual units

Effects of the technologies

Electrosurgery



Endoscopic cutting used to perform papillotomies, for example

A tissue lesion is marked with coagulation points, and bleeding is staunched using coagulation current

Example for the use of APC for tumor devitalization

CUTTING 01

Voltages of 200 V or more produce sparks between the electrode and the tissue. For cutting modes, temperatures of 100 °C and higher are generated by electrical energy. Intracellular and extracellular fluids vaporize so quickly that the cell membranes and cell layers rupture and the tissue is cut as a result.

COAGULATION 02

Coagulation current is used to staunch bleedings. Conversion of electrical energy into heat generates temperatures between 60 °C and 100 °C. The tissue dessicates and shrinks due to fluid vaporization. Tissue lesions can be marked with coagulation points.

DEVITALIZATION 03

This technique is used to target specific tumors and destroy them. Cell damage becomes irreversible at temperatures between 50 and 60 °C.

Waterjet surgery

THERMAL EFFECTS ON BIOLOGICAL TISSUE

37-40°C

None

From ~ 40°C

Hyperthermia:
initial tissue damage, edema formation,
depending on the duration of application, the tissue can recover or die (devitalization)

From ~ 60°C

Devitalization (destruction)
of the cells, shrinkage of the connective tissue through denaturation

~ 100°C

Vaporization of the tissue fluid, depending on the speed of vaporization:
- Tissue shrinkage through desiccation (drying out) or
- Cutting due to mechanical tearing of the tissue

From ~ 150°C

Carbonization

From ~ 300°C

Vaporization (evaporation) of the entire tissue

Source: J. Helfmann, Thermal effects. In: H.-Peter Berlien, Gerard J. Müller (eds.); Applied Laser Medicine. Published by Springer Verlag, Berlin Heidelberg, 2003.

Elevation of the mucosa during ESD

ELEVATION AND SEPARATION USING THE WATERJET 04

Needleless waterjet elevation can be used to create fluid cushions in the tissue. Anatomical layers can be separated from one another as well.

Argon plasma coagulation

	above approx.
1 Hyperthemia	40°C
2 Devitalization	60°C
3 Coagulation/Dessication	100°C
4 Carbonization	150°C
5 Vaporization	300°C

Tissue effects

In argon plasma coagulation the target tissue is heated using monopolar current flow. Dependent on three influencing factors, the following thermal effect zones arise and spread into deeper tissue layers (Fig. 05):

1. Hyperthermia
2. Devitalization
3. Coagulation/ Dessication
4. Carbonization
5. Vaporization

Factors influencing the tissue effect

The following main factors have an influence on the coagulation depth. They are listed in order of relevance:

1. Application duration (especially in cases of static application)
2. Power output (effect level)
3. Distance between probe and target tissue

APPLICATION DURATION – THE KEY FACTOR

The longer the APC is applied, the deeper the effect on the target tissue will be.
For this reason, we recommend starting with short activation times and increasing the duration step by step up until the desired effect is reached (e.g. PULSED APC, Effect 1). This holds in particular for APC applications involving thin-walled structures, such as in the right colon, and for children in general.

DIFFERENCES IN THERMAL SENSITIVITY 06

The structures in the gastrointestinal tract differ in sensitivity. This must be taken into account when selecting power output and application duration for electrosurgical interventions, particulary those involving APC.

POWER/EFFECT SETTING

Power output should be set dependent on localization and size (diameter, depth, elevation) and the lesion being treated. Low power settings are suitable for superficial, small lesions and for application in thin-walled tissue structures, such as the right colon or the duodenum. Medium power settings are ideal for devitalizing or reducing tumors and for staunching bleeding. High power settings are especially used for palliative tumor treatment, e.g. for tumor devitalization of larger exophytic tumors and for recanalization of stenoses.

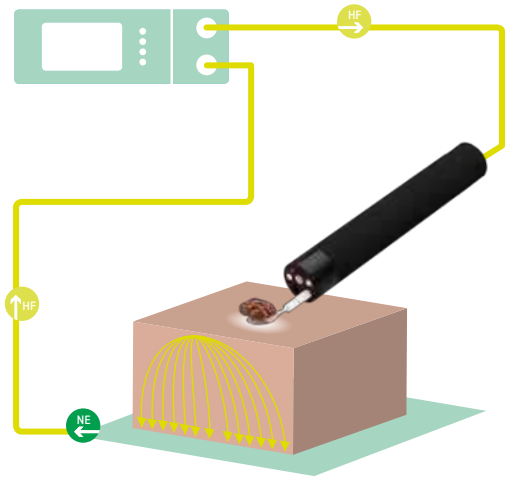
PROBE DISTANCE

Increasing the distance between the probe and tissue will result in a decrease in the tissue effect produced by PULSED APC and FORCED APC, with ignition ultimately disappearng.
The PRECISE APC mode is an exception: As a result of the plasma regulation, the tissue effect remains constant up to a distance of 5 mm. This can be advantageous, for example in cases of pronounced intestinal peristalsis.

STATIC AND DYNAMIC APPLICATION

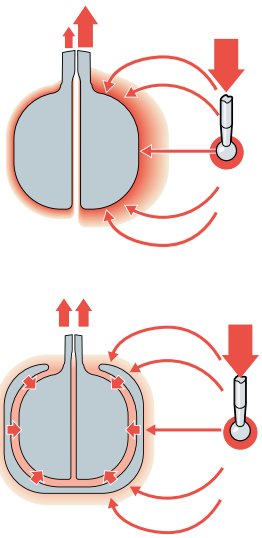
Static APC application for long durations increases, the depth effect considerably. If the application time is too long, this can lead to carbonization and perforation of the tissue. Thus for static application involving superficial lesions, we recommend short application times of 1 to 2 seconds.
For dynamic application, the APC probe should be moved across the target tissue using slow, controlled movements (brushstrokes) under visual control.

Techniques:
Electrosurgery



01

Circuit for monopolar electrosurgery



02

↑ High current density on the side closest to the operating field in the case of an incorrectly positioned conventional patient plate

↓ Distribution of current with no partial heat generation in case of NESSY Ω, which can be positioned independent of direction

MONOPOLAR TECHNIQUE 01

In monopolar electrosurgery, high-frequency current flows in a closed loop: from the unit to the instrument, then through the patient's body to the patient plate (PP), and from there back to the unit. The surgical effect is produced at the tip of the active electrode. Due to its relatively small contact surface, this is where the highest current density is reached. The second electrode, the patient plate, is placed on the patient's skin in a location which allows for conduction of the current over a large surface area.

At the site of localized application, the high current density produces a thermal effect such as an incision or coagulation. Due to the low current density, generation of heat on the large surface of the patient plate poses no problem.

Safety factors pertaining to monopolar electrosurgery and endoscopy

Both components – the NESSY patient plate safety system of the Erbe VIO and the Erbe NESSY Ω patient plate - reduce the safety risks connected with monopolar electrosurgery in gastroenterology.

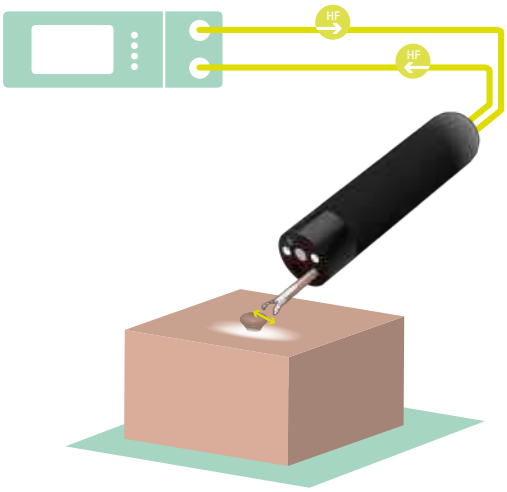
NESSY verifies whether the two-part patient plate has been positioned correctly and whether its entire surface is in contact with the patient, and it continuosly compares the currents of both patient plate surfaces.

In cases of slight deviation, activation is possible. In cases of significant deviance, activation is interrupted with a warning signal. To prevent burns, reactivation of the electrosurgical current is not possible until the patient plate has been correctly positioned.

Simple and safe application with NESSY Ω

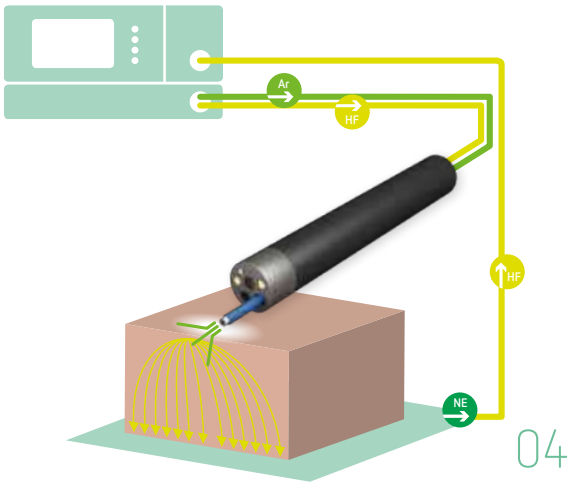
The NESSY Ω patient plate is equipped with a non-contact ring surface that surrounds the actual electrode surface. This equipotential ring distributes the current evenly across the inner contact surfaces and prevents the patient plate from only heating up on one side (leading-edge effect). As a result, it can be positioned in any direction. Compared with conventional patient plates, Nessy Ω (Fig. 2↑ and ↓) is easier to position; this enhances safety. The NESSY Ω is smaller than conventional electrodes, which makes it easier to attach to the patient's body. It is universally suitable for children and adults alike.

We therefore recommend using NESSY Ω to achieve maximum safety in monopolar electrosurgery.



03

Circuit for bipolar electrosurgery



04

Circuit for the monopolar APC technique

BIPOLAR TECHNIQUE 03

The bipolar technique offers the advantage of being able to limit the flow of current to the target area between the poles. Unlike monopolar electrosurgery, this technique prevents sensitive structures such as nerves that lie in the path of the current flow between the operating field and patient plate from incurring thermal damage inadvertently.

Bipolar electrosurgical instruments such as coagulation forceps have two integrated active electrodes. Current only flows through the tissue between the two poles of the branch and not through the patient's body. The bipolar technique does not require the use of a patient plate.

ARGON PLASMA COAGULATION (APC) 04

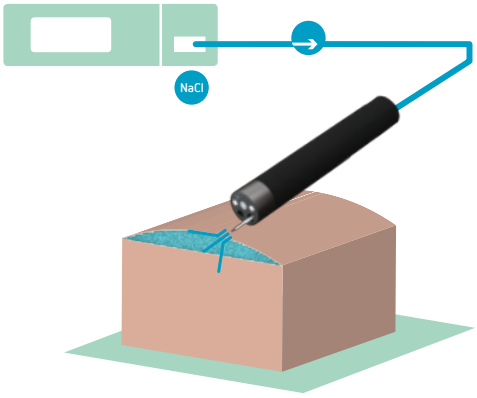
In APC, ionized argon gas conducts the electrosurgical current to the target tissue without contact between the probe tip and target tissue.

The procedure has few complications, staunches bleeding reliably, and facilitates effective and homogeneous surface coagulation and devitalization with adjustable penetration depth. Because it is a non-contact method, one advantage of APC is that the distal end of the instrument cannot adhere to the coagulated tissue and tear open the sloughing. Another advantage which is relevant for endoscopic use is the limited penetration depth of APC, which minimizes perforation.

The plasma stream and the tissue effect are determined by the type of probe, which defines the direction of application. APC can be applied axially and tangentially. The tissue effect is also influenced by the duration of the APC application and the APC mode.

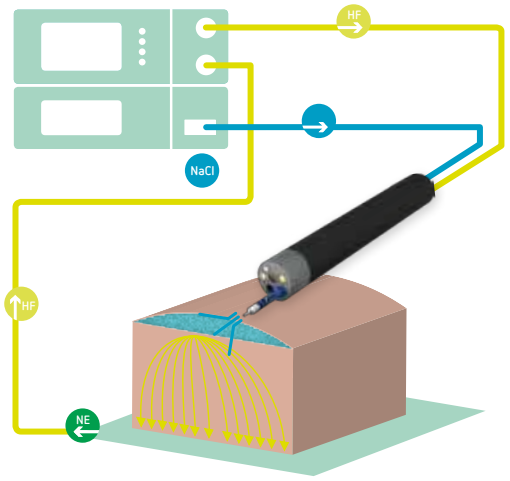
Techniques:

Waterjet surgery



05

The principle of waterjet surgery as illustrated by the flexible waterjet probe



06

The principle of waterjet surgery with combined monopolar circuit using the HybridKnife

WATERJET ELEVATION 05

The finely adjustable waterjet allows tissue types of various strength and elasticity to be separated. The expansion effect of the water jet is used to form fluid cushions, lifting tissue layers.

In gastroenterology, for example, the flexible waterjet probe is used to elevate tumor-bearing mucosa layers which are then resected using the snare technique.

WATERJET ELEVATION WITH ELECTROSURGERY OR WITH APC 06

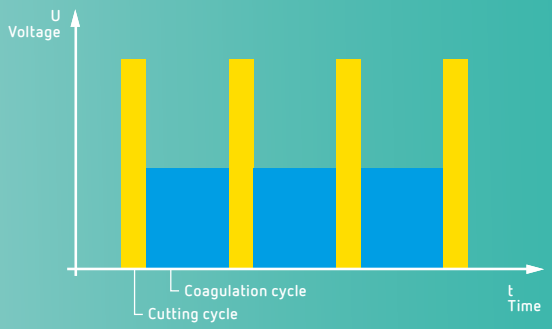
The HybridKnife probe integrates the waterjet and electrosurgery functions. Prior to resection of tumors in the gastrointestinal tract, a fluid cushion is created in the submucosa to elevate the mucosa at the site of the lesion. Subsequent electrosurgical cutting using the HybridKnife can thus be performed at a defined and higher resection level. Elevation thus reduces the risk of perforation.

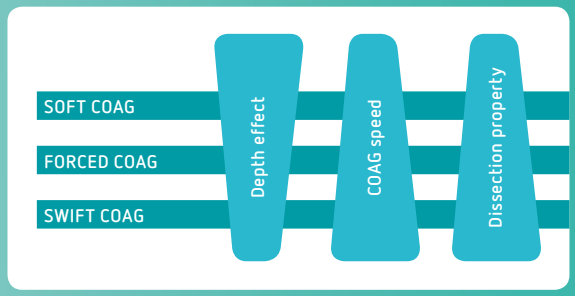
The HybridAPC probe employs the same principle of combining waterjet elevation with argon plasma coagulation.


Hyaluronic
acid

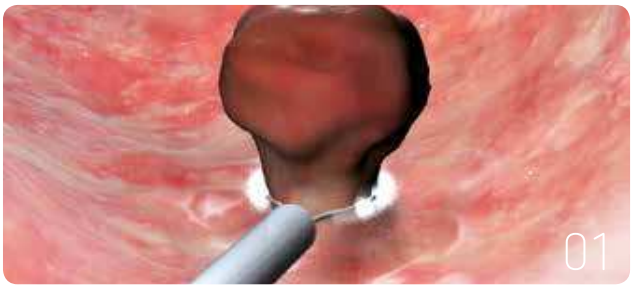
Cutting and coagulation modes

Fractioning of the process into cutting and coagulation intervals is performed automatically by the ENDO CUT mode. For the user this means: yellow pedal remains pressed (permanently activated); the rest is taken care of with ENDO CUT.

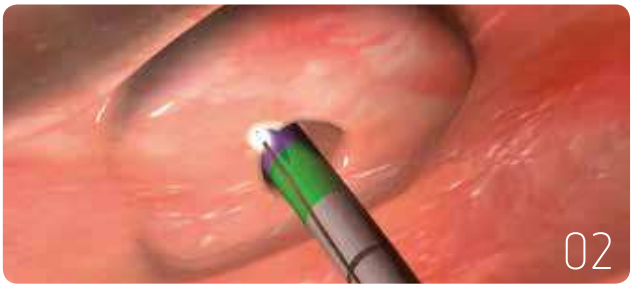




Properties of the COAG modes



Endoscopic polypectomy using ENDO CUT Q



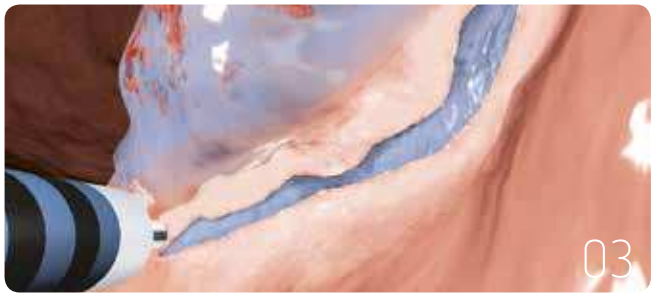
Endoscopic papillotomy using ENDO CUT I

ENDO CUT® Q 01

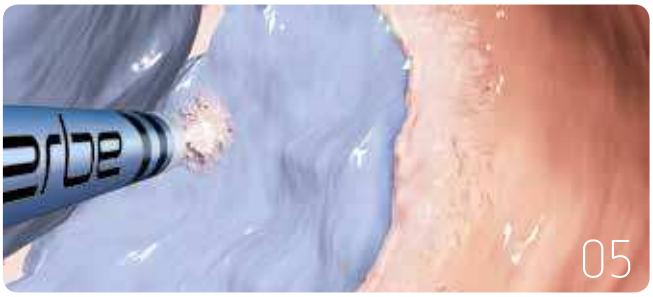
ENDO CUT Q fractionates the cutting process into controlled cutting and coagulation intervals, e.g. for endoscopic polypectomy using a snare and for EMR or ESD using the HybridKnife. Cutting and coagulation cycles can be adjusted individually to minimize the risks connected with polypectomies, such as bleeding if coagulation is insufficient, or perforation if coagulation is too intense.

ENDO CUT® I 02

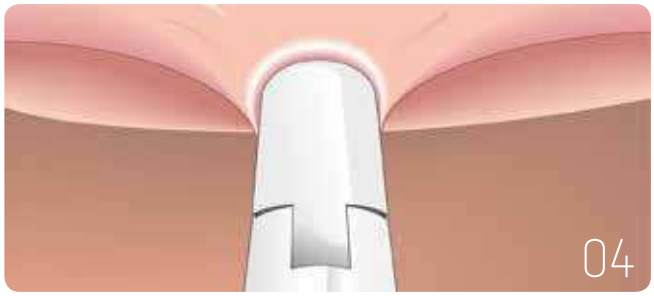
The fractionated cutting mode ENDO CUT I is used for papillotomies and other applications involving a needle or wire instruments in endoscopy. The cutting and coagulation cycles can be adjusted individually to minimize the risks connected with polypectomies and sphincterotomies, such as the zipper effect (uncontrolled incision into the papilla).



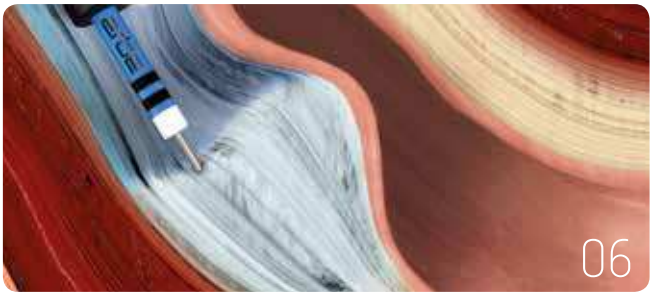
DRY CUT using ESD for a pronounced hemostasis effect



Example of a FORCED COAG application:
Coagulation after bleeding using ESD



Minor bleeding is coagulated with SOFT COAG



Tunneling of the submucosa with POEM using the HybridKnife

DRY CUT 03

The DRY-CUT mode cuts using modulated current forms with pronounced hemostasis. DRY CUT is the mode which offers optimal cutting performance for initial and circular incisions and resection during endoscopic submucosa dissection.

SOFT COAG 04

SOFT COAG is a sparing, conventional form of coagulation for deep tissue penetration. It minimizes adhesion between the electrode and the coagulated tissue. SOFT COAG is suitable for coagulating minor bleedings with a maximum application time of 1 to 2 seconds, for example.

FORCED COAG 05

This coagulation mode provides fast, effective standard coagulation in the entire gastrointestinal tract with medium thermal penetration depth.

SWIFT COAG 06

SWIFT COAG allows for effective and fast coagulation with pronounced hemostasis and is also suitable for dissection (such as submucosal tunneling involved in POEM and STER).

APC coagulation modes

Effective devitalization using FORCED APC

The PULSED APC mode is used for angiodysplasia in the colon

The PRECISE APC mode is used for angiodysplasia

FORCED APC 07

This mode offers effective coagulation and devitalization. The HF power is adjustable up to 120 Watt and is applied as continuous energy input. FORCED APC is used in the digestive tract for tumor resection (tumor debulking), as well as for coagulation of acute ulcer bleeding.

PULSED APC 08

This APC mode is based on pulsed (on-off) activation. PULSED APC can be used variably to devitalize or coagulate tissue. PULSED APC is easy to regulate, the result being homogeneous tissue effects. PULSED APC allows for power inputs ranging from 1 to 120 Watts. Effect 1 produces a higher energy output per pulse with longer pulse pauses, whereas Effect 2 produces higher pulse frequency with lower energy input. The mode is suitable for hemostasis of diffuse and widespread bleeding (GAVE, angiodysplasias) and for ablation Barrett's esophagus, for example.

PRECISE APC 09

In contrast to FORCED APC, PRECISE APC works in the lower energy range. This makes it possible to produce finely dosed, uniform coagulation effects in the target tissue, regardless of the distance between the probe and the tissue. PRECISE APC is suitable for treating angiodysplasias in the right colon and the cecum, for example. This mode is also used in the small intestine for double balloon enteroscopy.

Instruments

01

In the FiAPC probes,
the connecting cable and filter are completely integrated

02

Polypectomy snare

03

Papillotome

APC PROBE / FIAPC PROBE 01

Flexible APC probes are positioned at the target area of the gastrointestinal tract via an endoscope. The HF voltage ignites the chemically inert gas at the distal end of the probe and converts it into conductive argon plasma.

APC probes with different probe diameters, lengths and outlets are available for various applications in the gastrointestinal tract. They allow for non-contact tissue coagulation and devitalization.

FiAPC probes

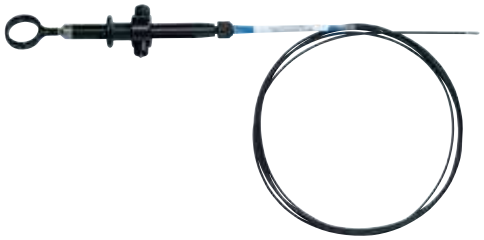
The integrated filter protects the sterile FiAPC probe against contamination which may be caused by secretion reflux. FiAPC probes are available in different versions (lengths, diameters) with axial, lateral and circular argon gas outlets. Erbe FiAPC probes are compatible with all common flexible endoscope types.

POLYPECTOMY SNARE 02

Polypectomy snares are inserted in to the endoscope and positioned at the polyp. The snare is placed around the base of the polyp, which is then resected using the ENDO CUT Q fractioning cutting mode. Polypectomy snares are available in different shapes and designs and as single-use and reusable products. The snare consists of either a monostrand or multistrand braided wire or ribbon and its shape can be varied symmetrically or asymmetrically.

PAPILLOTOME/SPHINCTEROTOME 03

A papillotome is a flexible probe with a cutting wire at the distal end designed to split papillae in the bile or pancreatic duct. Papillotomes come in various designs. Essential differences are the length of the cutting wire (20-30 mm long), the configuration of the tip (normal or filiform) and single- or multi-lumen design.



04

Coagulation forceps

05

Flexible waterjet probe

06

HybridKnife, complete instrument including handpiece and connecting cable

07

HybridAPC, complete instrument including handpiece and connecting cable

COAGULATION FORCEPS 04

Coagulation forceps are used to stop arterial bleeding by elevating the tissue slightly from the base and coagulating it by applying monopolar or bipolar high-frequency current.

FLEXIBLE PROBE (WATER JET) 05

The flexible probe allows for needleless elevation of the mucosa. The irrigation fluid forms a cushion in the submucosa that can be replenished as required. This prepares the lesion for subsequent EMR with optimal protection against perforation.

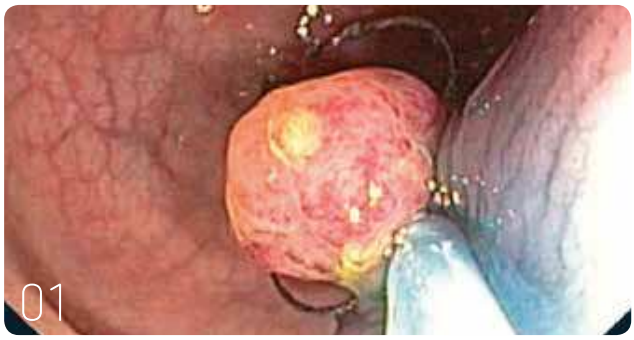
HYBRIDKNIFE 06

The HybridKnife is a multifunctional instrument which can be used for such procedures as Endoscopic Submucosal Dissection (ESD), Peroral Endoscopic Myotomy (POEM) and Submucosal Tunneling and Endoscopic Resection (STER). The integrated electrosurgery function and waterjet function are always available. All 4 steps required for ESD - marking, elevation, incision/dissection and coagulation - can be performed without a change of instrument.

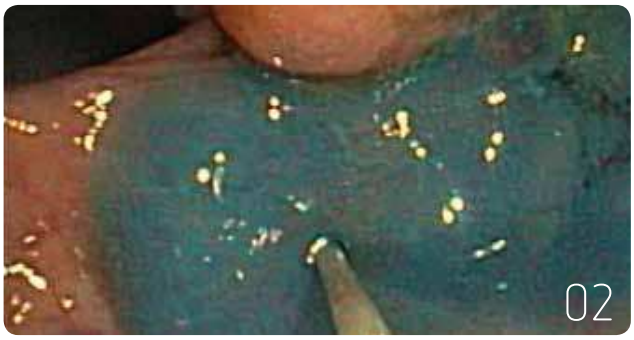
HYBRIDAPC 07

The HybridAPC, like the HybridKnife, is a waterjet assisted probe. Waterjet elevation is carried out prior to APC ablation. The HybridAPC is suitable for treating Barrett's Esophagus.

Electrosurgical applications



Safe removal of polyps using the ENDO CUT Q cutting mode



Layer-specific elevation of the mucosa using needleless waterjet elevation

POLYPECTOMY 01

Polyps with a diameter of up to 20 mm are removed using a polypectomy snare when availability of the required snare size and the clinical situation allow for this. The ENDO CUT Q fractioned cutting mode is ideally suited for removing tumors in the gastrointestinal tract using such procedures as polypectomy and mucosa resection.

The alternating cutting and coagulation intervals can be adapted to the gastroenterologist's working style, the shape of the polyp or lesion and the polyp snare. Controlled cutting performance with reliable hemostatic results are ensured during the entire sequence following the principle: as much coagulation as necessary (bleeding prophylaxis), as little as possible (perforation prophylaxis).

PAPILLOTOMY

Papillotomies are performed to treat choledocholithiasis and bile tract stenoses. In a papillotomy, the papillary orifice of the bile duct (where the duct drains into the duodenum) is split over a length of 1 to 2 centimeters electrosurgically.

Bile duct stones can be removed endoscopically through this papillary orifice, for example. The ENDO CUT I mode, which fractionates the cutting sequence into cutting and coagulation intervals, prevents uncontrolled incisions, the undesired zipper effect. Dependent on the form of the instrument, the surgical site and the gastroenterologist's working style, the intervals can be individually optimized.

ENDOSCOPIC MUCOSAL RESECTION (EMR) 02

EMR is an endoscopic procedure for resecting sessile or flat lesions that are limited to the mucosa and submucosa. EMR is usually carried out in combination with supportive techniques, such as elevation or suction[5].

When high pressure elevation using the flexible waterjet probe is performed, fluid accumulates in the submucosa and forms a fluid cushion. This selective cushion, which is limited to the submucosa, creates a safety distance to the muscularis, thus minimizing the risk of perforation during snare resection. The fluid can be replenished as required.

Only lesions up to approx. 20 mm in size can be resected en bloc using the EMR snare technique – dependent on the snare size. For larger diameters, the snare must be applied several times employing a piecemeal technique.
The disadvantage of the piecemeal technique are the higher recurrence rate for some tumor types and the fact that it makes histological evaluation more difficult for the pathologist.

EFTR = ENDOSCOPIC FULL THICKNESS RESECTION

Using this method it is also possible to resect small, muscle-invasive tumors in the gastrointestinal tract endoscopically. Further indications are recurrences with non-lifting sign and polyp residues that can be resected after an incomplete polypectomy.

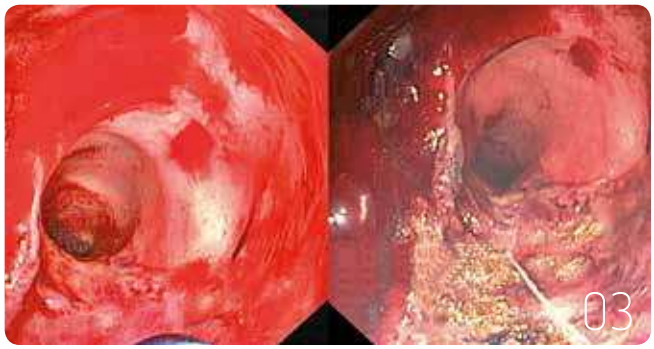
Once the tumor has been marked with the FORCED COAG mode, the cap of the resection system is placed on the lesion, held by coagulation forceps and pulled or sucked in along with the intestinal wall. Once the clip is applied, snare resection is performed using the polypectomy snare integrated in the system. ENDO CUT Q ensures reliable hemostasis of the cutting edge. The resected tissue is then removed en bloc and the resection line is visually inspected. The procedure can be repeated if corrective treatment is required.

ZENKER'S DIVERTICULOTOMY

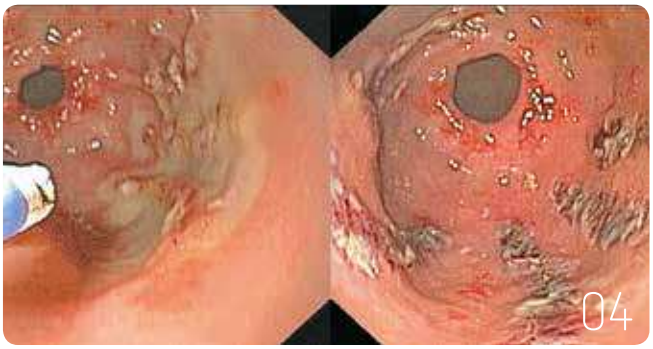
Flexible endoscopic myotomy is a minimally-invasive procedure with good success rates for treatment of Zenker's diverticulum. When performed transorally, the surgeon begins by exposing the diverticular bridge (connecting muscle) and then severing it, for example using an electrosurgical needle knife in a second session, if necessary. The incision of the septum usually extends down to the lower third of the diverticulum. Good hemostasis of the cutting edges can be achieved with ENDO CUT Q or DRY CUT.

APC (argon plasma coagulation) can also be used for severing the connective muscle, offering a suitable alternative to myotomy performed with a needle knife. Good hemostatic effects are achieved with the FORCED APC mode. Diverticulotomies performed using APC can require up to 4 sessions and are thus somewhat more time-consuming.

APC applications



Hemostasis using APC



Large-area coagulation of a watermelon stomach using APC

ACUTE BLEEDING 03

APC is one of the standard treatments for acute bloody oozing and post-biopsy bleedings in the entire gastrointestinal tract.

Acute bleeding, ulcer bleeding

APC coagulates bleeding ulcers safely and effectively using the FORCED APC mode. In case of Forrest Ib-IIa-IIb bleeding it can be combined with injection.

Diffuse bleeding

Widespread, diffuse bleeding requires coagulation over a large area. In case of mucosal fissures (Mallory-Weiss syndrome) at the gastroesophageal junction, PULSED APC is the perfect APC mode, which limits the coagulation depth to a minimum and preserves the underlying tissue layers. **APC probes with A, C and SC beam forms are all suitable for this application.**

CHRONIC BLEEDING 04

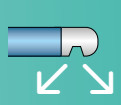
Angiodysplasia, GAVE syndrome, radioproctitis

All kinds of vascular malformations in all sections of the gastrointestinal tract can be treated successfully using APC. The aim is to avoid recurrent bleeding. Depending on the indication, APC is used in combination with proton pump inhibitors and other medications. Usually a low power setting is sufficient to stop all bleeding. A low power setting is also helpful for keeping down the risk of perforation in the thin-walled parts of the intestinal tract (e.g. in the small intestine or right colon). Angiodysplasias often occur here. **APC probes with A and C beam forms are suitable for this application.**

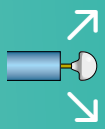
Vascular malformations in the small intestine can be treated with excellent results using endoscopic methods, such as double balloon enteroscopy. A cap can also be used to demarcate the area under treatment in order to generate an optimal argon gas atmosphere and a safety margin. **APC probes with A and C beam shapes are suitable for performing angiodysplasias; for the double balloon technique the A beam form can be used.**

Beam forms

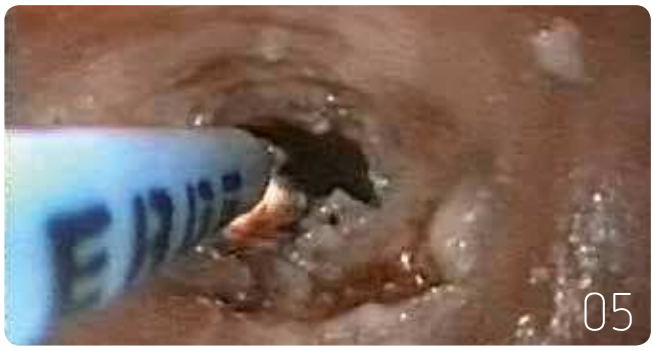
Axial Beam A



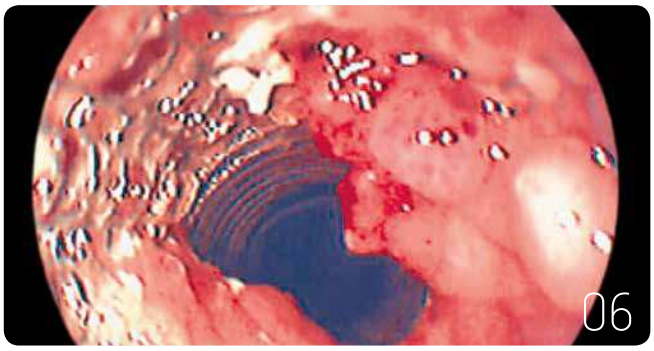
Side Fire Conical Beam SC



Circumferential Beam C



Angiodysplasia with APC



APC application with stent ingrowth/overgrowth

DEVITALIZATION/RECANALIZATION OF STENOSES / TUMOR DEBULKING 05

The FORCED APC mode can be used for tumor recanalization and other indications. When removing large tumors using APC this is usually done through vaporization at very high power settings (FORCED or PULSED APC, > 60 W).

Tumor resection, recanalization of stenoses

When APC is used to reduce large tumor masses, the following effects are produced: The tissue shrinks during the APC application itself as a result of desiccation and carbonization. The necrotic tissue disintegrates in the days following the procedure. In cases of stenoses, it may be advisable to combine APC with other endoscopic methods (e.g. bougienage) to allow the passage of food in the esophagus, for instance. Due to the risk of accumulation of explosive gases, sections with filiform stenosis or blockage should be mechanically dilated first before applying APC.

Due to the advantages it offers for this application, safe and effective APC has largely replaced laser ablation in the area of flexible endoscopy. **The APC probes with A and SC beam forms are suitable for this application.**

APC AND STENTS 06

Stent implantation

The FORCED APC mode can be used to open stenoses and recanalize them over a large area to facilitate subsequent stent insertion (see Tumor recanalization).

Devitalization of stent ingrowth and overgrowth without stent damage

Tumor ingrowth in non-coated metal stents can be devitalized and removed using APC without damage to the stent. The FORCED APC mode at a medium setting or PULSED APC at a higher power setting puts little strain on the stent. **The APC probes with A and C beam forms are suitable for this application.**

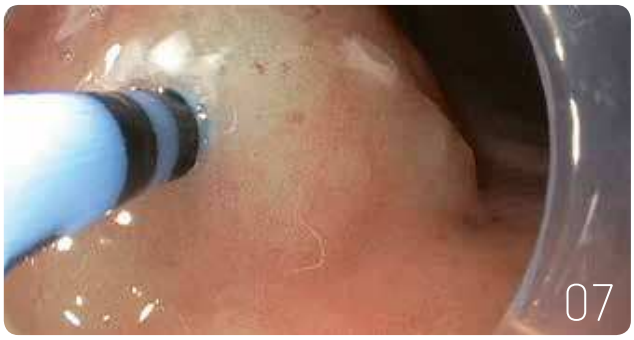
Metal stent extraction

To remove the stent with ease, the tissue which has grown into the metal mesh has to be removed first, if possible 1 day before stent extraction ("two-stage" approach). The modes used for this are FORCED APC or PULSED APC (as for recanalization).

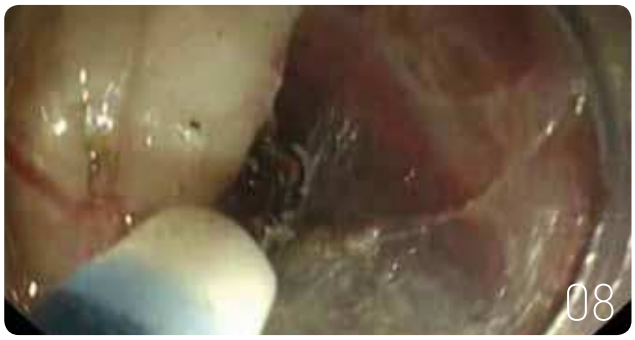
Stent shortening ("trimming")

If only partial removal of stents is desired, the protruding ends can be shortened using APC (trimming). FORCED APC mode should be set at a high power setting and applied to the trim line of the stent while being moved across its entire circumference in a non-contact fashion, so that the wire mesh heats up and melts due to the high electrical conductivity. The protruding end of the stent can then be retrieved and removed using the forceps. **(CAUTION: The PRECISE APC mode is not suitable for this application.)**

Applications using hybrid technology



Elevation prior to resection for ESD using the HybridKnife: 4 work steps, 1 instrument



En-bloc resection of the tumor

ENDOSCOPIC SUBMUCOSA DISSECTION (ESD) 07

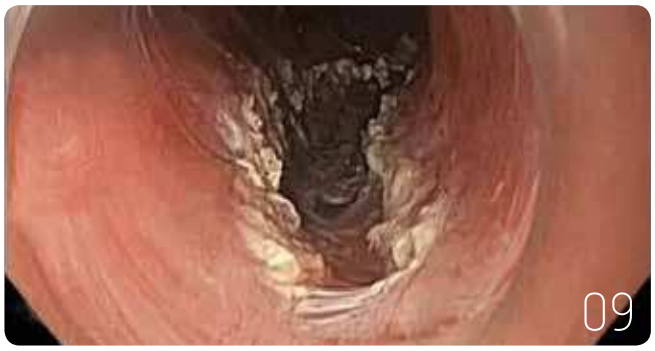
The ESD technique is used in the gastrointestinal tract for en bloc resection of lesions (> 2 cm). Only histologically verified, complete resection of the lesions, so-called R0 resection, provides optimal conditions for the success of curative treatment.

The first step is to lift the mucosal lesion using the waterjet function of the HybridKnife. The separating medium accumulates in the submucosa and forms a fluid cushion as a safety buffer for the outer organ wall, the muscularis. The tissue is resected using the electrosurgery function of the HybridKnife, supported by the modes of the VIO system[3,4].

Both functions – water jet and electrosurgery – are available at all times in the HybridKnife combination instrument. This 2-in-1 function constitutes the essential advantage of the HybridKnife procedure for ESD. The individual steps – marking, elevation, incision/dissection and coagulation – are performed in the safest possible way without a change of instrument. All 3 HybridKnife types I, T and O are suitable for ESD, dependent on the working style and the target region.

SUBMUCOSAL TUNNELING, ENDOSCOPIC RESECTION (STER) 08

According to the principle applied for POEM, the HybridKnife is also used for STER (Submucosal Tunneling and Endoscopic Resection). Following elevation, incision and tunneling, the submucosal tumor is resected and removed en-bloc[10].



POEM: Myotomy of the sphincter muscle of the esophagus using the HybridKnife

APC is suitable for both ablation of Barrett lesions as well as for small Barrett islands

PERORAL ENDOSCOPIC MYOTOMY (POEM) 09

The cause of achalasia is impairment or absence of reflexive relaxation of the lower esophageal sphincter during swallowing. This disease can be effectively treated with POEM (Peroral Endoscopic Myotomy), which involves incising the lower annular muscles[6-9].

HybridKnife lifts up the esophagus mucosa using the waterjet function and forms a submucosal cushion. Following the incision (2 cm long, approx. 5 cm above the stenosis) the tunnel is prepared using the electrosurgery function and elevation to approx. 2 cm below the gastroesophageal junction. The mucosa is needed for subsequently covering the myotomy line and must therefore be preserved.

Using the HybridKnife, a myotomy is then performed on the sphincter muscle, beginning at around 3 cm below the site of the incision down to approximately 2 cm beneath the gastroesophageal junction. The myotomy can proceed from here towards the proximal – depending on the user's preference.
Any bleeding can be immediately coagulated using the HybridKnife. Following the myotomy, the incision is covered using the intact mucosa and the incision site is closed using clips. **HybridKnife I and T types are suitable for POEM (in certain cases: O type).**

ABLATION OF BARRETT'S ESOPHAGUS 10

For ablation of Barrett's esophagus, APC is combined with a waterjet function. Prior to ablation, the waterjet function of the HybridAPC probe lifts the mucosa. The Barrett's esophagus can now be treated at the necessary depth with higher energy input by means of the APC function with no change of instrument. Ablation takes place successively, alternating with elevation. The protective fluid cushion practically rules out damage to the muscularis or risk of strictures.

APC is applied along the Barrett structure from distal to proximal in a non-contact fashion. APC is suitable for both large Barrett lesions (up to 8–10 cm), and in particular for small Barrett's islands[11-14].

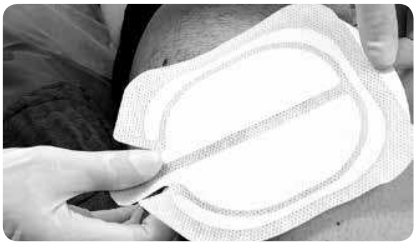
Recommended settings

Application	CUT	COAG	JET
Polypectomy/EMR			
Coecum, right colon Snare electrode	ENDO CUT Q, Effect 1 Cutting duration 1, cutting interval 6	FORCED COAG, Effect 2, 60 Watt	
Duodenum Snare electrode	ENDO CUT Q, Effect 2 Cutting duration 1, cutting interval 6	FORCED COAG, Effect 2, 60 Watt	
Esophagus, stomach Snare electrode	ENDO CUT Q, Effect 3 Cutting duration 1, cutting interval 6	FORCED COAG, Effect 2, 60 Watt	
Rectum, stalked polyps Snare electrode	ENDO CUT Q, Effect 4 Cutting duration 1, cutting interval 6	FORCED COAG, Effect 2, 60 Watt	
Papillotomy			
Sphincterotome	ENDO CUT I, Effect 2, cutting duration 3, cutting interval 3	FORCED COAG, Effect 2, 60 Watt	
Needle knife	ENDO CUT I, Effect 2, cutting duration 3, cutting interval 3	FORCED COAG, Effect 2, 60 Watt	
Full thickness resection			
	ENDO CUT Q, Effect 1, cutting duration 4, cutting interval 1	**Marking:** FORCED COAG, Effect 1, 20 Watt	
Zenker's diverticulum			
The APC probes with A and C beam forms	PULSED APC, Effect 1, 40-50 Watt		
Electrosurgical knife/instrument	ENDO CUT Q, Effect 1, cutting duration 3, cutting interval 1		
Diffuse bleeding			
In the right colon / duodenum APC probes with all beam forms		PRECISE APC, Effect 4–5	
In the remaining colon and rectum APC probes with all beam forms		PULSED APC, Effect 2, 10-30 Watt	
Acute ulcer bleeding			
Forrest Ib – IIa APC probes with all beam forms		FORCED APC, 30–60 Watt	
Forrest IIb APC probes with all beam forms		FORCED APC, 20–40 Watt	
Acute, non-varicose bleeding			
APC probes with all beam forms		PULSED APC, Effect 2, 20–40 Watt FORCED APC, 30–60 Watt	
Chronic bleeding			
GAVE/radioproctitis APC probes with all beam forms		PULSED APC, Effect 2, 10-30 Watt	
Angiodysplasia APC probes with all beam forms		PULSED APC, Effect 2, 10–30 Watt	
Tumor reduction APC probes with all beam forms		**Tumors >15 mm:** FORCED APC, >60 Watt **Tumors < 15 mm:** FORCED APC, 20–50 Watt	

Application	CUT	COAG	JET
Stent ingrowth/overgrowth			
APC probes with all beam forms		PULSED APC, Effect 2, 40–60 Watt FORCED APC, 20–40 Watt	
Stent trimming			
APC probes with all beam forms		FORCED APC, 30–60 Watt	
ESD			
HybridKnife, I, T, O types	**Incision/Dissection:** ENDO CUT Q, Effect 2, cutting duration 3, cutting interval 3 DRY CUT, Effect 2, 80 Watt (improved hemostasis)	**Coagulation:** FORCED COAG, Effect 2, 60 Watt	**Mucosa elevation:** Esophagus: Effect 30–50 Stomach: Effect 30–50 Right colon: Effect 10–15 Left colon/Rectum: Effect 20–30
STER			
HybridKnife, I, T, O types	**Incision/Exposure:** ENDO CUT Q, Effect 2, cutting duration 3, cutting interval 3	**Exposure:** SWIFT COAG, Effect 3–4, 70 Watt	**Mucosa elevation:** Effect 30–50
Peroral Endoscopic Myotomy (POEM)			
HybridKnife, I, T types	**Incision/Exposure/Myotomy:** ENDO CUT Q, Effect 2, cutting duration 3, cutting interval 3	**Exposure/Myotomy:** SWIFT COAG, Effect 3–4, 70 Watt **Coagulation:** FORCED COAG, Effect 2, 50 Watt	**Mucosa elevation:** Effect 30–60
Barrett's esophagus			
APC probes		PULSED APC, Effect 2, 50 Watt	
HybridAPC		PULSED APC, Effect 2, 60 Watt (first ablation) PULSED APC, Effect 2, 40 Watt (follow-up ablation)	**Mucosa elevation:** Effect 40–50

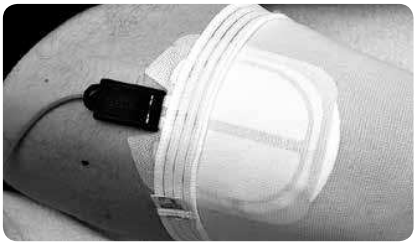
Information

on safe use of electrosurgery and APC



Select a suitable patient plate

Attach the patient plate free of creases



The patient plate can be placed under the antithrombosis stocking

1. PLACE THE PATIENT IN AN ELECTRICALLY INSULATED POSITION

- Place the patient on an electrically insulated OR table pad in a dry condition
- Remove body jewelry (piercings, rings, chains, watches, bracelets, removable dental prostheses); taping over jewelry is not sufficient
- Position arms and legs so that they are insulated from the body by positioning them at an angle or by applying layers of gauze; avoid skin-to-skin contact if there are skin folds or breast folds (by interposition of dry gauze)
- The patient must not come into contact with any electrically conducting objects (e.g. drip stands, tubes)

2. SELECTING A SUITABLE PATIENT PLATE (PP)

- Self-adhesive divided PPs are preferable to undivided PPs and silicone electrodes
- For infants, use an appropriate PP
- As far as possible, always use divided PPs, as only these can be monitored by the safety system

3. SELECTING THE POSITION FOR THE PATIENT PLATE (PP)

- The PP can be positioned on the thigh, the upper arm or the side of the abdomen
- Affix the PP as close as possible to the operating field, but with a minimum distance of 15 cm
- The monopolar current should not be conducted via the body's electrical "bottlenecks" (e.g. elbow, knee)
- If possible, position the PP over electrically well-conducting tissue (muscle tissue)
- Do not affix the PP on fatty tissue, on bones/joints, on skin folds or on the head
- If possible, affix the PP on healthy tissue. Avoid scars, hemorrhages and tattoos
- The patient should not lie on the PP, on cables or on the cable connection
- When repositioning the patient, take care to ensure that the PP and the cable do not become detached or lie under neath the patient

Patients with active or passive implants

- For patients with a cardiac pacemaker or other conductive implants, use bipolar instruments wherever possible
- For monopolar instruments, apply the PP away from the implant and in such a way that the current is not conducted via the implant. Minimize the effect number (voltage) and power limitation (max. watts)

4. PREPARE THE SURFACE FOR ADHESION

- Do not attach the PP to hair. Shave the PP application site
- The PP application site must be dry and free of grease

5. ATTACHING THE PATIENT PLATE CORRECTLY

- Do not trim the PP
- Always attach oblong PPs with the long side facing the operating field
- Apply the PP over its entire surface without forming any creases; avoid air bubbles
- In the case of patients with antithrombosis stocking the PP can be affixed under the stocking with the connector and cable exposed
- Do not re-use self-adhesive PPs

6. AVOIDING IGNITION OF COMBUSTIBLE SUBSTANCES

- Avoid inflammable and combustion-supporting gases in the surgical field (e.g. anesthetic or endogenous gases)

Important rules
for the application of APC

1. HIGHER EFFICIENCY OF THE VIO GENERATION

When using VIO/APC-2 technology, it is important to consider that it offers a 50% increase in efficiency over that of the ICC/APC-300 technology.

2. APC PROBE ALWAYS IN THE FIELD OF VISION

In order to prevent damage to the tip of the endoscope and the instrument channel, the APC probe should protrude at least 10-15 mm from the endoscope, i.e. the first distal black ring of the APC probe must be visible. During dynamic application, the endoscope must always be moved back and forth together with the APC probe, never on its own.

3. ONLY WORK WHERE THERE IS ADEQUATE VISIBILITY

Good visibility must be ensured for all APC applications. Even though application of APC "around the corner", e.g. behind a fold, is permitted, such application should only be undertaken with sufficient practice and experience.

4. OBSERVE THE PENETRATION DEPTH AND DOSAGE

The penetration depth of the APC thermal effects depends on various factors (see above). When performing APC, energy should be applied with special care when working on thin-walled structures, especially the ascending colon; here a low power setting and short activation time should be used (also see recommended settings).

5. AVOID TISSUE CONTACT

The special tip of the APC probe should not be pressed into the mucous membranes during application to prevent the argon gas which is emitted from causing an emphysema. When in direct contact with the tissue the probe can cause contact coagulation or perforation on activation as well. During dynamic application, it is recommended that APC is only activated while the endoscope together with the probe are withdrawn. Especially in the case of very thin - walled structures, such as the right colon and the duodenum, the probe should be kept at a sufficient distance from the tissue (> 1 mm) and it should not be pointed perpendicular to the wall. High current concentrations and localized thermal effects can arise that may lead to perforation.

6. AVOID PROXIMITY TO METAL OBJECTS

Do not bring the distal end of the activated APC probe into the proximity of metal clips, as a spark could jump across and cause inadvertent coagulation.
For this reason, where metal stents with exposed wires are involved it is important to keep the probe at a sufficient distance from them. Spark contact can cause accidental charring of the wire. In other cases this effect is desirable, for instance for shortening of metal stents ("stent trimming").
Caution: when using the PRECISE APC mode, contact with metal is not permitted due to the special plasma regulation.

7. DEFLAGRATION / GAS EXPLOSION

Given inadequate intestinal cleansing, any combustible, endogenous gases in the intestine can deflagrate and in the worst case explode. To avoid this, the following preventive measures should be considered:

- Avoid laxatives containing sugar
- Carry out orthograde colonic irrigation just before the planned intervention
- Remove residual feces close to the APC application site
- Remove gases by drainage or suction (using intestinal tube or insufflation of air, if necessary suctioning several times)
- Insufflation of inert gases such as CO_2 or argon
- Do not open up filiform stenoses or filiform closures primarily with APC

Glossary

Active electrode
The part of the electrosurgical instrument that delivers the electrosurgical current to the area of patient tissue where the tissue effect is required

Argon plasma coagulation
Monopolar non-contact coagulation. Electrically conductive argon plasma delivers the current to the tissue. Acronym: APC (Argon Plasma Coagulation)

Bipolar electrosurgery
Electrosurgical procedure in which both electrodes are integrated into a single instrument

Dessication
Drying out of biological tissue

Devitalization
Destruction of biological tissue

Diathermy
Synonym for electrosurgery or HF surgery

Electrosurgery
A synonym for HF surgery

Electrode
Conductor that transmits or receives current, e.g. active electrode, patient plate

Frequency
Number of periods per second during which the current direction changes twice. Unit: Hertz (Hz). 1 kHz = 1000 Hz

Hemostasis
Staunching of bleeding

HF surgery
Use of high-frequency electric current on biological tissue with the goal of using heat to generate a surgical effect. Synonyms: HF surgery, diathermy, radio frequency (RF) surgery

High frequency
In terms of HF surgery (standard: IEC 60601-2-2): frequency of at least 200 kHz. Acronym: HF; also radio frequency (RF)

High frequency generator
Device or device component that converts direct current or low-frequency alternating current into high-frequency electrosurgical current

Carbonization
Carbonization of biological tissue

Coagulation
1. Protein denaturation. 2. Electrosurgical effect in which proteins coagulate and tissue shrinks, promoting blood clotting significantly in this way

Lesion
Damage, injury or disruption to an anatomical structure

Power
Energy per second. The electrical power is the product of current and voltage. Unit: Watt (W)

Monopolar electrosurgery
Electrosurgical procedure during which the active electrode is used at the operative site and the electrical circuit is closed by a patient plate

Necrosis
Pathological cell death

Patient plate
Conductive surface, which is attached to the patient during a monopolar application in order to reabsorb the HF current. It feeds the current back to the electrosurgical unit in order to close the electrical circuit. Acronym: PP (patient plate). Synonyms: dispersive electrode, neutral electrode, return electrode

Cutting
Electrosurgical effect in which the intracellular fluid is explosively vaporized and the cell walls burst

Incision quality
The nature of the incision, especially the extent of coagulation at the incision margin. The desired cutting quality depends on the application

Current density
Current flow amount per cross-section area. The higher the current density, the more heat is generated

Thermofusion
Sealing of tissue or vessels through coagulation

Vaporization
Vaporization of tissue

Burning under patient plate
Burning of the skin due to extreme generation of heat as a result of excessive current density under or at the patient plate

Additional references

PUBLICATIONS ON THE NEW APPLICATIONS – EXCERPT

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13. Manner H, Neugebauer A, Scharpf M, Braun K, May A, Ell C, Fend F, Enderle MD: The tissue effect of argon-plasma coagulation with prior submucosal injection (Hybrid-APC) versus standard APC: a randomized ex-vivo study, United European Gastroenterology Journal, Oct 2014, vol. 2 n° 5, 383–390
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LEAFLETS AND BROCHURES

85800-103	Fundamentals of Electrosurgery
85800-127	Application of Electrosurgery with Practical Recommendations
85800-117	User brochure: Polypectomy
85800-119	User brochure: Papillotomy
85100-158	Leaflet: HybridKnife product
85100-140	Leaflet: FiAPC probes
85140-190	Leaflet: VIO product range
85110-107	Flyer: POEM – Peroral endoscopic myotomy using HybridKnife
85110-108	Flyer: Ablation of Barrett's esophagus with HybridAPC
85110-118	Flyer: Waterjet elevation prior to EMR or ESD
85810-126	Info folder for gastroenterology

Additional information:

Up-to-date product and application information, such as our accessories catalog, is available at www.erbe-med.com.
Up-to-date user videos are available at www.medical-video.com

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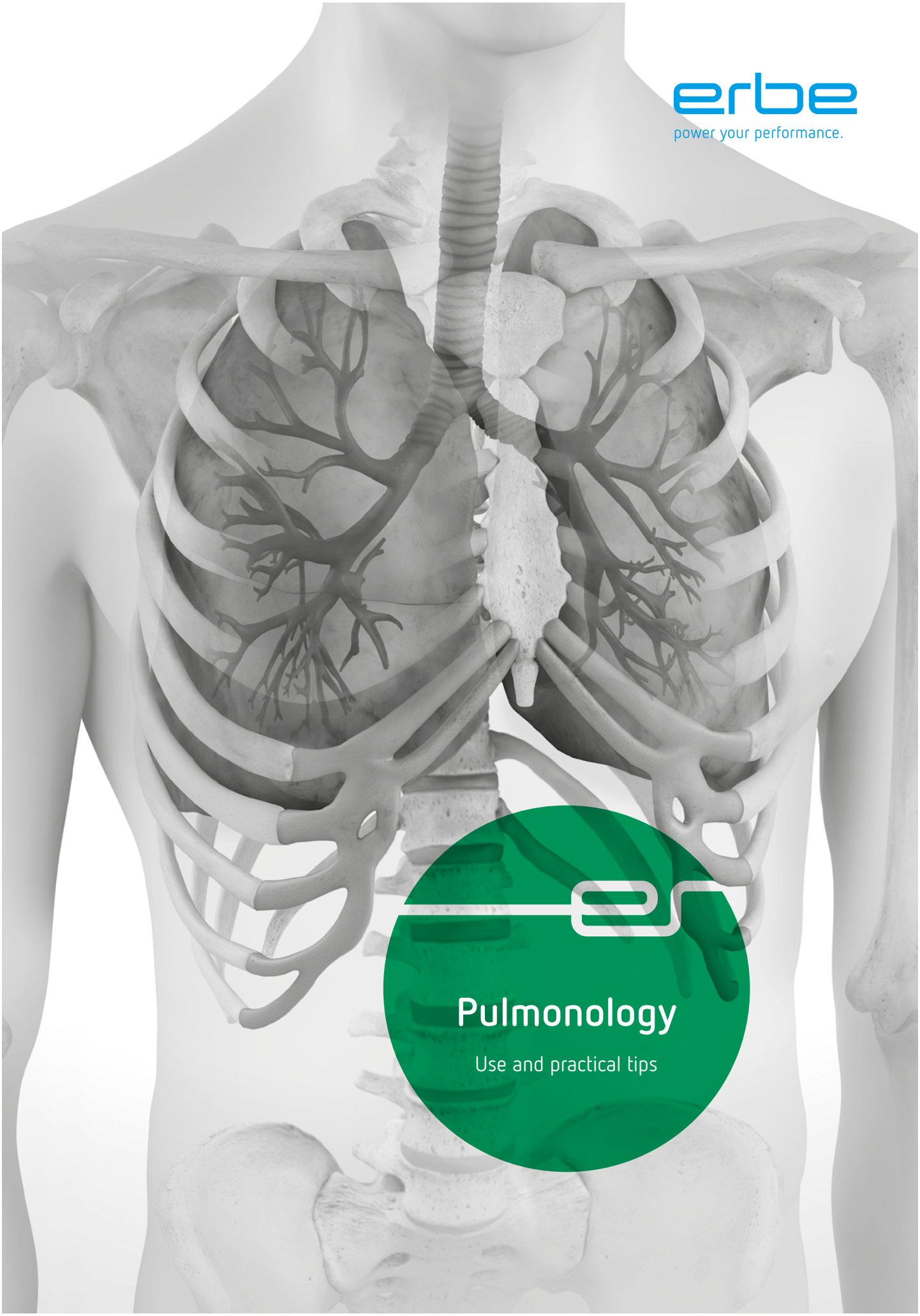


Pulmonology

Use and practical tips

E-SOFT_000212

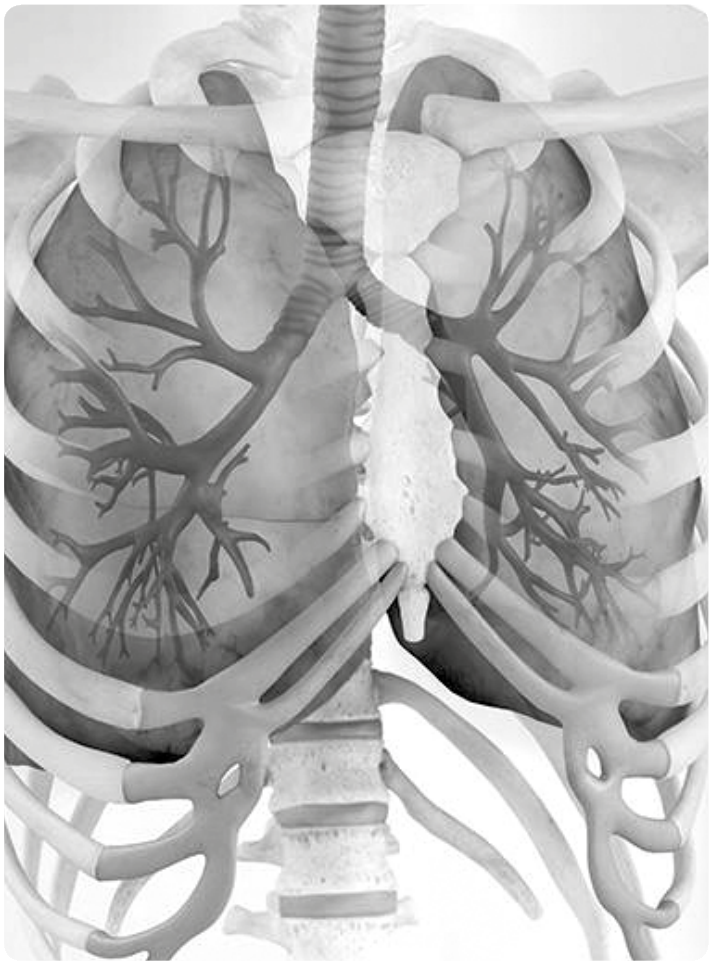
TABLE OF CONTENTS

Important information

While Erbe Elektromedizin GmbH has taken the greatest possible care in preparing this brochure and the recommended settings, we cannot completely rule out errors. The information and data contained in the recommended settings cannot be used to justify any claims against Erbe Elektromedizin GmbH. In the event of compelling legal justification for a claim, liability shall be limited to intent and gross negligence.

Although the information on recommended settings, application sites, duration of application and the use of instruments is based on clinical experience, individual centers and physicians also favor settings other than those recommended here. This information is intended only as a guideline and must be evaluated by the surgeon for applicability. Depending on individual circumstances, it may be necessary to deviate from the information provided in this brochure.

Medicine is constantly subject to new developments arising from research and clinical experience. This is another reason why departing from the information may be appropriate.



Erbe technologies for bronchoscopy are described in this brochure. A workstation with cryotechnology is mainly used for diagnosis and for immediate recanalization of stenoses in the tracheobronchial tract.

Tissue can be devitalized both by cold temperatures, as in cryotechniques, as well as by heat, as in the electrosurgical system.

The focus of electrosurgical applications is on staunching bleeding, but also on shrinking and devitalizing tumors. Cryosystems and electrosurgery systems complement one another, but can also be used individually.

01 VIO® 200 D

02 APC 2

03 ERBECRYO® 2

Workstations

Electrosurgery workstation for pulmonology

The electrosurgery workstation for pulmonology consists of a master module – we recommend VIO 200 D – as well as a unit for argon-plasma coagulation, the APC 2. The complete system consists of the electrosurgery workstation with a selection of probes and applicators for interventional bronchoscopy. The applications are supported by the cutting and coagulation modes of the VIO electrosurgery system. The VIO 200 D and APC 2 are coordinated and backed up with practice-oriented plug-and-play settings.

Cryosystem for pulmonology

The system for cryosurgical procedures and diagnostic cryobiopsy in bronchoscopy consists of ERBECRYO® 2 and an equipment cart (optional) with integrated gas cylinders. The flexible cryoprobes have a diameter of 1.9 or 2.4 mm and variable length compatible with all conventional bronchoscopes. They can be used in the central lung region through to the outer lung periphery. The display provides the user with information on the connected probe, the freeze effect and the duration of freezing.

Electrosurgery workstation for pulmonology with VIO 200 D and APC 2

Cryosystem for pulmonology with ERBECRYO 2 on equipment cart and storage basket (both optional)

EFFECT OF COLD (DEPENDENT ON THE TARGET TISSUE AND THE DURATION OF APPLICATION)

From -40°C

Tissue destruction
(at high cooling speed and low thawing speed)

THERMAL EFFECTS ON BIOLOGICAL TISSUE

37 – 40 °C

None

From ~ 40 °C

Hyperthermia:
initial tissue damage, edema formation, depending on the duration of application, the tissue can recover or die (devitalization)

From ~ 60 °C

Devitalization (destruction)
of the cells, shrinkage of the connective tissue through denaturation

~ 100 °C

Vaporization of the tissue fluid, depending on the speed of vaporization:
- Tissue shrinkage through desiccation (drying out) or
- Cutting due to mechanical tearing of the tissue

From ~ 150 °C

Carbonization

From ~ 300 °C

Vaporization (evaporation of the entire tissue)

Source: J. Helfmann, Thermal effects. In: H.-Peter Berlien, Gerard J. Müller (Ed.); Applied Laser Medicine. Published by Springer Verlag, Berlin Heidelberg, 2003.

Tissue effects

Cooling effects

Adhesion of the cryoprobe to the target tissue

The tissue, such as a benign tumor, is devitalized with the aid of the cryoprobe

ADHESION 01

In cryotechniques the target tissue containing water adheres to the distal end of the cryoprobe. The probe and target tissue have microscopically fine-pored surfaces in which liquid can penetrate. Freezing causes the crystals to interlock and thus adhere together.
As the tissue sticks to the probe, stenoses, for example, can be recanalized immediately[3], larger tissue segments biopsied[4] and foreign bodies removed[5-6].

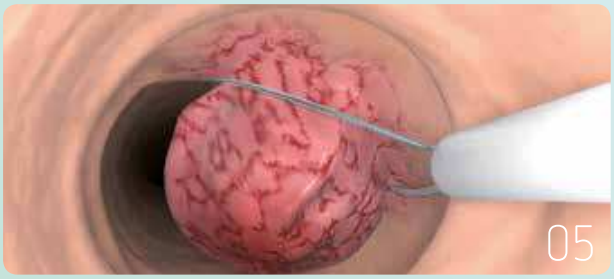
DEVITALIZATION 02

Cold leads to crystallization of intracellular and extracellular fluid. At a temperature of -40 °C and below, tissue is irreversibly damaged at a freezing speed of 10 °C/min[19]. The devitalization process is accelerated by repeated freezing and thawing cycles[7].
The devitalized, ablated tissue remains in situ or can be mechanically removed in a further bronchoscopy session.

Heating effects

Coagulation

Devitalization



Cutting

COAGULATION 03

Coagulation current is used to staunch bleeding. The conversion of electrical energy produces heat. The denaturization of proteins and heating of connective tissue causes a shrinkage effect, which is further reinforced by drying of the tissue and evaporation of tissue fluid[1].

DEVITALIZATION 04

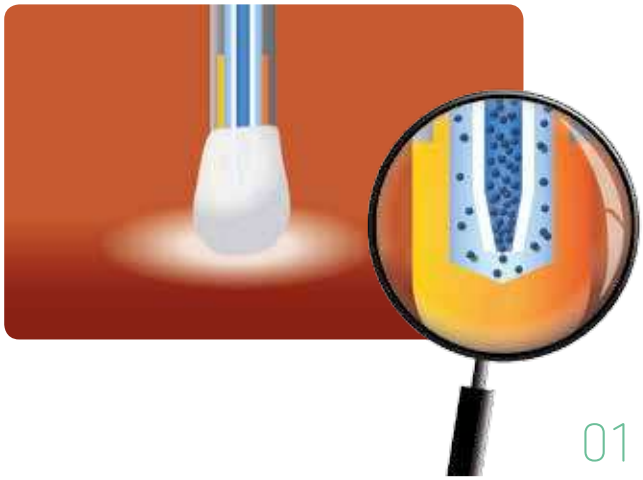
This electrosurgical technique (e.g. APC) is used to destroy specific tumors. Cell damage is irreversible at temperatures of 50 to 60 °C or more[1].

CUTTING 05

Voltages of 200 V or more produce electric arcs between the electrode and tissue. Cutting modes involve temperatures of 100 °C and higher. Intracellular and extracellular fluids vaporize so quickly that the cell membranes and cell layers rupture and the tissue is cut as a result[2].

Technologies

Cryo



01

Diagram of the gas flow in the cryoprobe

OPERATING PRINCIPLE OF CRYOTECHNIQUES 01

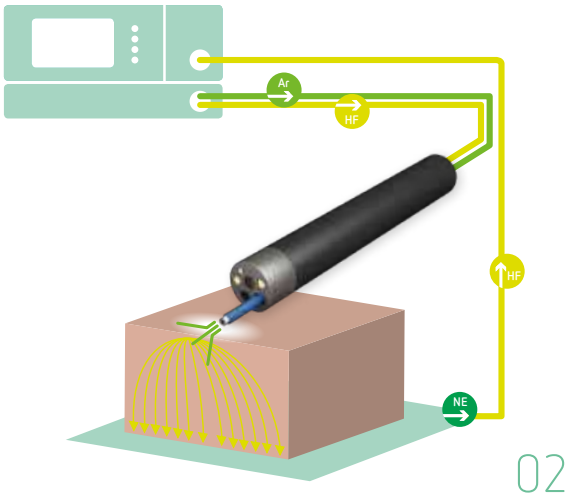
The ERBECRYO® 2 freezing effect is based on the Joule-Thomson principle: decompression of the coolant achieves the cooling effect.

Compressed carbon dioxide is used as the coolant, which freezes the probe tip on gas decompression.

Functionality of the probe

The coolant flows in the cryoprobe in a closed system from the inner lumen via a constriction at the tip of the probe. On decompression, the gas flows from here via the cryoprobe's outer lumen back to the device and diffuses into the room.
The cooling effect arises in the tip of the cryoprobe after the constriction where the gas is decompressed.

APC technique



02

Circuit for the monopolar APC applications

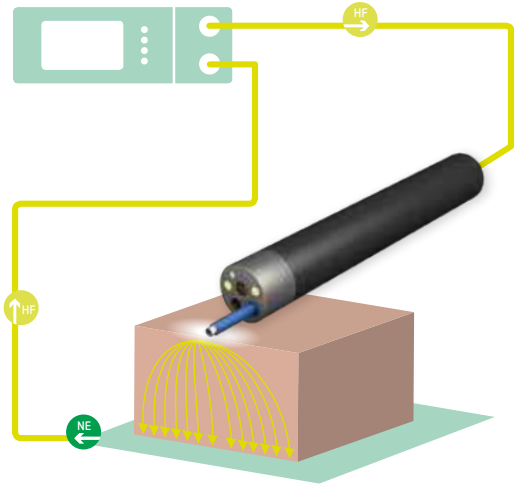
ARGON PLASMA COAGULATION (APC) 02

In APC, ionized argon gas conducts the current to the target tissue with no contact between the instrument and the tissue.

The process results in few complications, safely staunches bleeding, produces homogeneous surface coagulation and allows the surgeon to adjust penetration depth[8,9]. Because it is a non-contact procedure, one advantage of APC is that the distal end of the instrument cannot adhere to the coagulated tissue and tear open the scab that has formed. The plasma beam - as well as the tissue effect - depends on the type of probe. Other factors influencing this effect include the APC mode and the duration of the APC procedure.

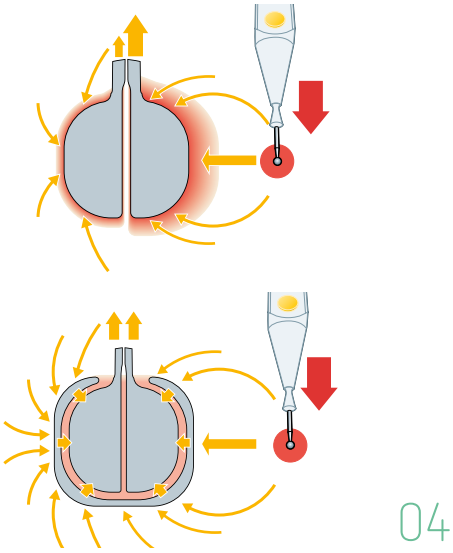
Further information and tips on the use of APC - see chapter "Information for safe application".

Electrosurgical technique



03

Circuit for monopolar electrosurgery



04

↑ Incorrectly connecting the patient plate generates high current density on the side closest to the operating field

↓ Distribution of current without a partial increase in temperature with NESSY Ω, which can be positioned in any direction

MONOPOLAR TECHNIQUE 03

In monopolar electrosurgery, current (I_{HF}) flows in a closed loop, first from the unit to the instrument, then through the patient's body to the return electrode, and finally from the return electrode back to the unit. The surgical effect is produced at the tip of the active electrode (AE), which, due to its relatively small contact surface, is the location where the highest current density is reached. The second electrode, the return electrode, has a large surface area and is placed on the patient's skin at an appropriate location in order to discharge the current.

At the points of application, the high current density and resulting heat produce effects such as an incision or coagulation. By contrast, the increase in temperature on the large surface of the return electrode is not significant due to the low current density.

Safety issues with monopolar electrosurgery in bronchoscopy

Two components - the NESSY return electrode safety system of the VIO 200 D and the Erbe NESSY Ω return electrode - reduce the safety risks involved in monopolar electrosurgery in bronchoscopy.

NESSY tests the split return electrode to determine whether it has been positioned correctly and whether its entire surface is in contact with the patient and also constantly compares the currents flowing through the two surfaces of the return electrode.

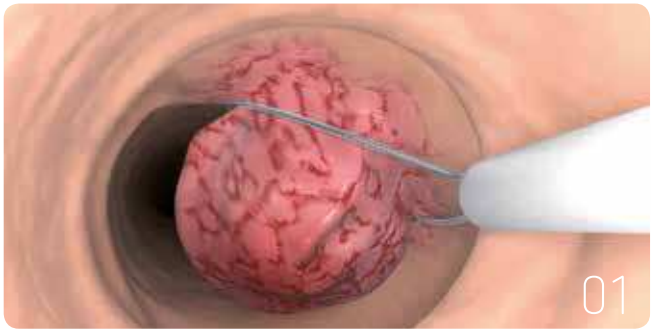
If there are only slight differences, activation is possible. If NESSY detects major differences, however, it will produce a warning signal and interrupt activation. To prevent thermal necrosis, the surgical system cannot be reactivated until the return electrode is correctly positioned.

Simple and safe application with NESSY Ω®

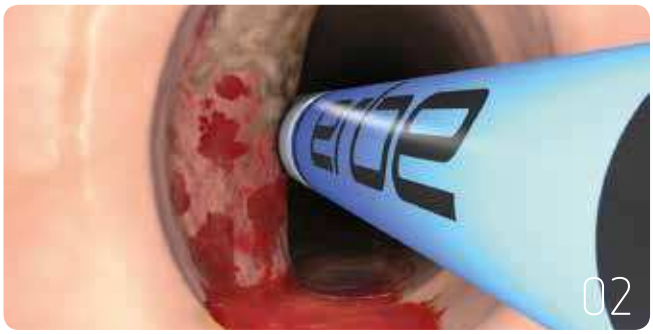
Compared with conventional return electrodes, NESSY Ω (Fig. 04 ↑ and ↓) simplifies positioning and therefore enhances safety. The surrounding, insulated equipotential ring of the NESSY Ω means that this return electrode can be positioned in any direction. Current is distributed evenly across the two inner contact surfaces. Because the overall contact surface is smaller than that of conventional electrodes, the NESSY Ω is easier to position on the patient's body, making it universally applicable for children and adults alike.
We recommend using NESSY Ω to maximize safety in monopolar electrosurgery.

Cutting and coagulation modes

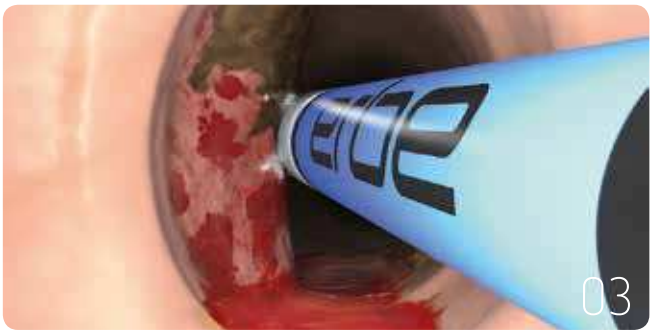
Electrosurgery modes



ENDO CUT Q



SOFT COAG



FORCED COAG

ENDO CUT® Q 01

ENDO CUT Q fractionates the cutting process into cutting and coagulation intervals. Cutting and coagulation cycles can be adjusted individually to minimize the risks in bronchoscopic incision, such as bleeding if coagulation is insufficient, or perforation if coagulation is too intense.

SOFT COAG 02

SOFT COAG is a gentle, conventional form of coagulation for deep tissue penetration, for example to devitalize target tissue. This minimizes adhesion between the electrode and the coagulated tissue (anti-sticking effect).

FORCED COAG 03

This mode of coagulation provides fast, effective standard coagulation with thermal penetration to a medium depth.

APC modes

FORCED APC

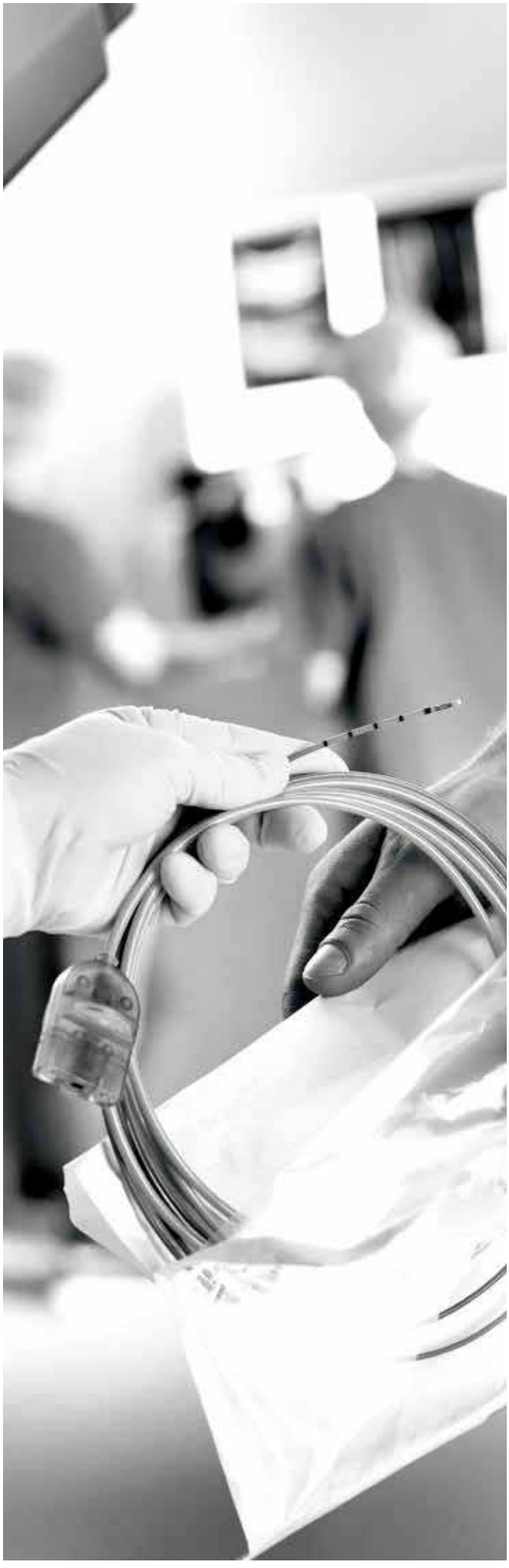
PULSED APC

FORCED APC 04

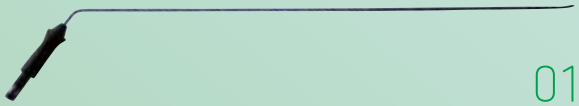
This argon plasma coagulation mode delivers high energy to the target tissue to effect deep coagulation and effective devitalization.

PULSED APC® 05

This APC mode is based on pulsed (on-off) activation. PULSED APC is versatile and can be used both for coagulation and for tissue devitalization. The favorable dosing characteristics of PULSED APC result in homogeneous tissue effects.

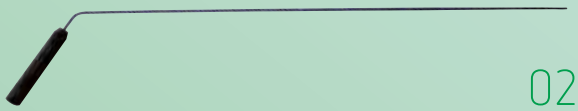


Instruments
Rigid



01

APC applicator, rigid



02

Coagulation probe, rigid

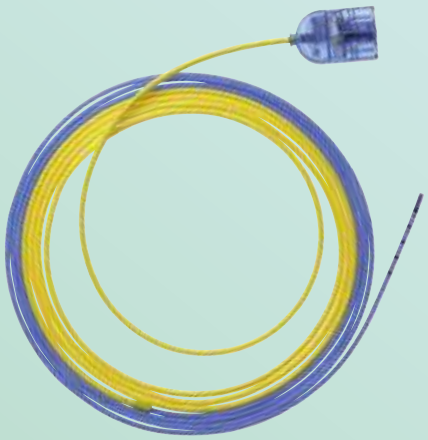
APC APPLICATORS 01

These APC instruments are designed for rigid bronchoscopy. The shaft length of the APC applicators is 300 mm or 500 mm.

COAGULATION PROBE, RIGID 02

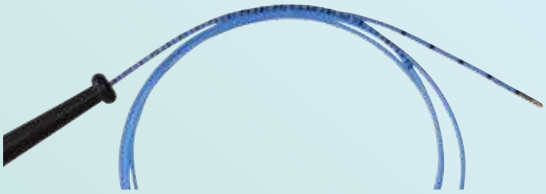
The coagulation probe is suitable for high precision contact coagulation with dosable hemostasis. The suitable mode for achieving a good depth effect is SOFT COAG. Contact coagulation is a technique for staunching hemorrhages and can be used as an alternative to APC. Together, the thermal coagulation effect and compression on the contact point provide a high degree of safety.

Flexible



03

Distal probe tip of most frequently used aperture configurations in bronchoscopy: axial and radial



04

Flexible cryoprobe

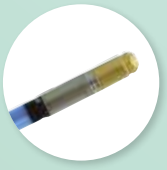
05

Coagulation probe, flexible

FIAPC PROBES 03

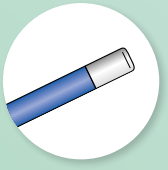
The FiAPC probes (patent protected) have a selectable probe diameter of 1.5 or 2.3 mm and are used in the central bronchial tract. The connecting cable and filter are completely integrated in FiAPC probe. This prevents any possible contamination of the APC unit due to the return flow of blood or secretion. The probes are flexible and have axial, lateral or radial beam exit nozzles and thus reach almost every intraluminal target area. Different modes, such as PULSED APC or FORCED APC, can be selected for the various applications like hemostasis, devitalization or tumor debulking.

CRYOPROBES 04



The cryoprobes have different lengths and diameters – dependent on the application. They are suitable for use in the central and peripheral lung regions. Probes with 2.4 mm diameter tend to generate larger biopsy samples, with 1.9 mm they tend to be smaller.

COAGULATION PROBE, FLEXIBLE 05



The probe has a length of 1.5 m and a diameter of 1.5 mm. It is suitable for focused and precise contact coagulation in the central airways. Medium to high coagulation penetration depths can be achieved with the selection of the mode. The spectrum of applications extends from coagulation of smaller hemorrhages through to targeted and deep tissue devitalization.

Electrosurgery instruments

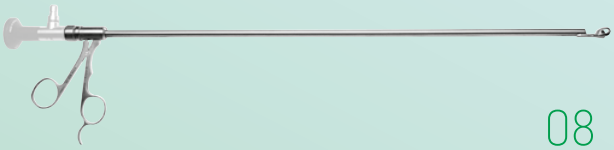
from third-party suppliers

06

Polypectomy snare, © medwork

07

"CoagGrasper" (COAG forceps)



08

XXL forceps, © Richard Wolf GmbH

SNARE 06

Electrosurgical resection with the snare is suitable for pedunculated lesions. The cutting-coagulating effect of the FORCED COAG mode is advantageous for this application. The tissue resected with this mode can be histologically evaluated.

MONOPOLAR FORCEPS 07

Monopolar forceps can be used to staunch arterial bleeding. The tissue is elevated slightly from the base and is coagulated with SOFT COAG.

XXL FORCEPS 08

Tissue fragments are removed with these forceps, for example following tissue devitalization with APC. As a result of the size of the XXL jaws, this instrument can only be used in rigid bronchoscopy. As, in contrast to thermal techniques, the target tissue is not frozen or coagulated by electrosurgery, the risk of hemorrhaging is increased with this technique. The hemorrhages can be coagulated with APC.

Applications

01

Cryoprobe vs. forceps (schematic representation)
A = Tissue sample of a forceps biopsy (standard size: 2.5 mm)
B = Biopsy size with 2.4 mm cryoprobe (frontal application)
C = Biopsy size with 2.4 mm cryoprobe (tangential application)

02

Immediate recanalization of an exophytic stenosis with cryotechniques

BIOPSY SAMPLING 01

Cryotechnology is extremely well suited for biopsy of tissue samples from the endobronchial and transbronchial lung regions[4, 10, 21, 22].

In cryotechniques the target tissue containing water adheres to the distal end of the cryoprobe. The probe and target tissue have microscopically fine-pored surfaces that interlock through the formation of crystals and cause adhesion. The freezing process can be followed and controlled visually in the central lung segment. The choice of probe, effect level and the freezing duration, as well as the contact pressure, allows the size of the biopsy sample to be influenced.

The morphological cell structure is preserved in the freezing process[7], as the tissue is not squashed as in forceps biopsy. The biopsy quality is not reduced due to hemorrhages. This procedure is also greatly superior to that of a forceps biopsy in terms of quantity, enabling biopsy samples that are three times larger without increasing the risk of hemorrhaging[4]. Both size and quality are essential for the high diagnostic value of the biopsy sample, enabling a clear diagnosis[12]. Repeat biopsies are reduced; the patient and budget are spared.

Another advantage is that almost every target tissue can be accessed, even in areas where forceps are not suitable. The probe can not only be applied frontally, but also tangentially.

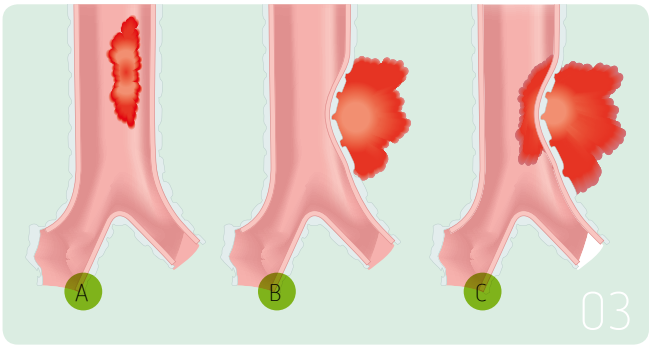
IMMEDIATE RECANALIZATION OF EXOPHYTIC STENOSES 02

For recanalization of respiratory tract stenoses of a benign or malignant cause, cryosurgery or cryoextraction are effective techniques.
The probe tip is placed on the tumor or cautiously pressed into the tumor. As a result of the cryoadhesion, the tumor sticks to the probe tip and can then be extracted together with the bronchoscope. The icing process can be followed visually in the central lung region and stopped in good time before reaching the bronchial wall.
The procedure is repeated as necessary until the complete tumor is removed from the endobronchial lung segment.
The risk of hemorrhages is minimized by freezing the tumor and the surrounding tissue[13]. The flexible probe can be placed frontally, as well as tangentially, so that almost every target area can be reached. This is an essential advantage of cryosurgery compared with other techniques such as the laser or forceps.
An important aspect: cryotechniques are especially advantageous in acute respiratory tract stenoses because they can be used immediately and uncomplicatedly without extensive preparation, and above all, allow the stenosis to be eliminated immediately[4].

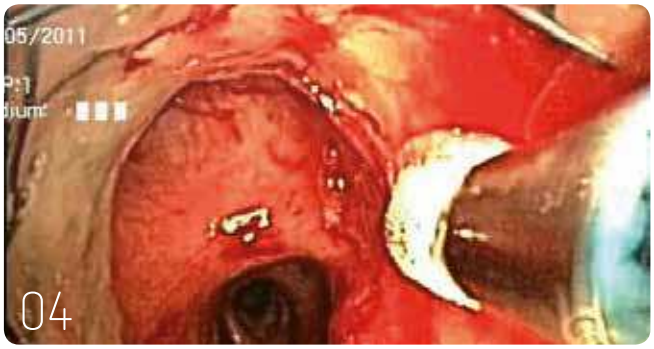
In contrast to energy-based techniques, such as electrosurgery, APC or laser, combustion of the respiratory mixture is ruled out with cryotechniques.

However, in consideration of the safety criteria, APC is ideally suited for shrinking or devitalizing endoluminal tumors[1]. The FORCED APC mode is suitable for tumor debulking. The immediate shrinkage effect arises by denaturing the protein structure and by further heating through desiccation. The stenosis can also be recanalized with immediate effect using an electrosurgical snare[8].

Applications



Tracheal stenosis configurations:
a) exophytic, b) through extraluminal compression from the outside, c) mixed



Devitalization of tissue using cryotechniques with the example of stent ingrowth

RECANALIZATION OF EXOPHYTIC STENOSES BY DEVITALIZING WITH CRYOTHERAPY OR ELECTROSURGERY 03

Recanalization with delayed effect

Various techniques can be selected for recanalization of respiratory tract stenoses. The therapy is dependent on the position, size and nature of the stenosis.
For stenoses caused by impression of tumors outside the lumen, see Fig. 3b) and c), plastic or metal stents can be inserted, for example. Cryosurgery[16], as well as contact coagulation and APC[17], are suitable for exophytic stenoses (Fig. 3a) and hybrid forms c).

Devitalization with cryosurgery

In devitalization, the target tissue remains in the bronchus and is resorbed by the body, ejected postoperatively (by coughing) or is removed mechanically[7].
The degree of devitalization in cryosurgery can be regulated and is dependent on the factors:

- ☑ Effect setting on the device
- ☑ Repetitions of the freezing and thawing cycles
- ☑ Freezing duration
- ☑ Freezing temperature
- ☑ Freezing speed

Devitalization with electrosurgery or APC

The target tissue can also be devitalized with APC (FORCED APC mode) or using contact coagulation with FORCED COAG. In these electrosurgical techniques, the coagulation mode and the activation duration influence the degree of devitalization.

STENT INGROWTHS AND OVERGROWTHS 04

Stent ingrowths and overgrowths are ideally treated with ablation or devitalization. All three techniques – cryosurgery, APC and contact coagulation – provide an effective basis for reducing the tumor tissue to the stent level[1,18].

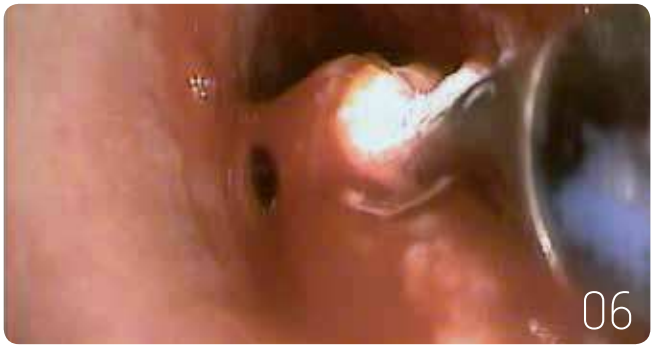
The approach is the same as recanalization with the ablative effect of devitalization (see left column). When using a stent, care should be taken in all techniques that damage to the stent is avoided.

With immediate effect

In case of highly obstructive stenoses, extraction or tumor debulking may also be necessary[17]. Tumor destruction is performed by APC or contact coagulation. For APC the FORCED APC mode is recommended; for coagulation, FORCED COAG.

The tissue can be frozen and extracted using cryotechniques[12]. The degree of icing can be followed visually and can be stopped in good time before reaching the stent.

Hemostasis with argon plasma coagulation



Extraction of a foreign body with cryoadhesion

HEMORRHAGES 05

Hemostasis with APC

Flexible APC is predestined for the coagulation of surface bleeding or diffuse hemorrhages in the entire bronchial tract[8-9]. Essential advantages: The thermal effects are achieved without contact with the tissue. This means that vessels are not ripped open again after coagulation, as is the case for contact coagulation, for example. The APC beam can be ignited frontal, lateral or "around the corner" depending on the exit of the probe. In this way, APC reaches almost every target area. Rigid APC applicators can be used with rigid bronchoscopy in the central lung segment. Flexible probes are advantageous in the distal lung segment.

Contact coagulation

The focal coagulation effect can be followed and controlled well visually in the central lung region[17].
Like APC, this technique can be applied using a rigid or a flexible probe - in order to better reach the target area.

Removal of blood clots

Blood clots can be recovered after icing in their frozen, solidified form with cryotechniques[7]. Recovery of soft or fluid consistencies is almost impossible with forceps. These substances can be iced over a large area and extracted with the flexible cryoprobe, even in deeper sections and narrower lumina.

REMOVAL OF SECRETION, FOREIGN BODIES CONTAINING WATER AND GRANULATION TISSUE 06

With cryotechniques, foreign bodies or secretion can be recovered simply and safely from the endobronchial region[5-6].
Fluid material freezes on the cryoprobe and can be recovered safely and completely with cold adhesion. Even solid foreign bodies, such as nuts, adhere in a freezing process as a result of the surrounding fluid. In order to optimize adhesion, it is recommended to wet the foreign body with fluid or to recover it with the surrounding secretion.

Porous foreign bodies can also be retrieved as a whole using cryoadhesion. Using forceps, porous foreign bodies can only be extracted in fragments.

Once the target tissue, such as a foreign body, granulation tissue or secretion, has adhered, the probe together with the flexible bronchoscope is retrieved from the rigid pipe or the flexible tube. As cartilage contains little water, penetration of the ice front into these structures is limited accordingly, which additionally increases safety.

Application overview

Application	CRYO	APC
Biopsy sampling		
	Flexible cryoprobe Effect 2, Freezing time 3 – 5 sec	
Immediate recanalization of exophytic stenoses		
	Flexible cryoprobe Effect 2, Freezing time 5 sec (and longer)	**FiAPC probe** **Trachea and bronchi** 1st order: FORCED APC, 30 – 50 W 2nd order: FORCED APC, 20 – 40 W
Recanalization of exophytic stenoses by devitalizing with cryotherapy (delayed effect) or electrosurgery (immediate effect)		
	Flexible cryoprobe Effect 2, Freezing cycles 2 – 3	
Stent ingrowth and overgrowth		
Devitalization	**Flexible cryoprobe** Effect 2, Freezing cycles 2 – 3	**FiAPC probe** PULSED APC, 20 – 30 W, Effect 2 FORCED APC, 30 W
Extraction	**Flexible cryoprobe** Effect 2, Freezing time 2 – 5 sec	**FiAPC probe** PULSED APC, 20 – 30 W, Effect 2 FORCED APC, 30 W
Hemorrhages		
		FiAPC probe 1st order: PULSED APC, 20 – 30 W (Effect 2) 2nd order: PULSED APC, 10 – 25 W (Effect 2)
Removal of secretion, foreign bodies containing water and granulation tissue		
	Flexible cryoprobe Effect 2, Freezing time 3 – 5 sec	

Overview of flexible cryoprobes and recommended application areas

			Pulmonary application area		
Article number	**Length**	**Diameter**	**Central**	**Peripheral**	**Biopsy sample size**
20402-032	900 mm	2.4 mm	■	■	●
20402-037	900 mm	1.9 mm	■	■	•
20402-040	1150 mm	1.9 mm	■	■	•

CUT	COAG
Snare ENDO CUT Q, Effect 2-1-6	
Snare ENDO CUT Q, Effect 3-1-6	**Coagulation probe for contact coagulation (rigid or flexible)** FORCED COAG, Effect 2, 40 W Activation time 1 – 2 sec
	Coagulation probe (rigid or flexible) SOFT COAG, Effect 4, 60 W Activation time 2 sec (and longer)
	Coagulation probe (rigid or flexible) FORCED COAG, Effect 2, 40 W Activation time 2 sec (and longer)
	Coagulation probe (rigid or flexible) FORCED COAG, Effect 2, 40 W Activation time 2 sec (and longer)
	Coagulation probe (rigid or flexible) SOFT COAG, Effect 4, 60 W Activation time 2 sec (and longer) FORCED COAG, Effect 2, 40 W Activation time 1 – 3 sec

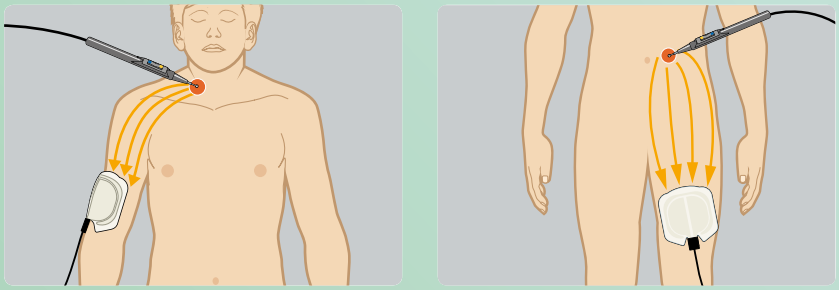
Information on APC application times:

FOR VERY SUPERFICIAL LESIONS / IN THIN-WALLED STRUCTURES:	1–3 SEC
STANDARD APPLICATION:	1-3 SEC
TUMOR ABLATION:	3 SEC AND LONGER

For further information on the recommended settings, please see the back side of individual brochures.

Safety information

for applying cryotechniques, APC surgery and electrosurgery



The return electrode is placed as close as possible to the operating field

PREPARATION, SEDATION, AIRWAY MANAGEMENT

The more complicated and complex a bronchoscopic intervention and diagnosis, the more important is good sedation. Either the patient is deeply sedated, intubated with a flexible tube and breathes spontaneously or he is given general anesthesia, is intubated using a rigid tube, and is artificially ventilated. Airway management should be ensured with a flexible or rigid tube, as the flexible bronchoscope has to be withdrawn from the patient's bronchial tract to take the biopsy sample.

TIPS FOR CRYOTECHNIQUES

- ☑ Prior to each application, check the instrument for function and leak tightness.
- ☑ For cryoapplication in the central lung region, observe the propagation of the freezing effect in the tissue.
- ☑ Take care that there is no damage to healthy tissue.
- ☑ The cryofunction should be activated until the probe used for biopsy or recanalization has been recovered safely.

TIPS AND RULES TO AVOID BURNS IN AN APC APPLICATION IN THE BRONCHIAL TRACT

When staunching bleeding and devitalizing with APC, a vapor mixture arises that can mix with oxygen and may become a highly combustible gas mixture. If possible, extract the gas mixture using a flexible or rigid endoscope with a suction channel of an APC applicator (we recommend the IES 2 device for fume extraction). Tip: The formation of vapor can be reduced with short activation times.

Information on the oxygen content: The higher the oxygen concentration, the higher the likelihood of combustion.
And the nearer the oxygen is to the vicinity of the APC applicator, as in high frequency jet respiration, the higher the risk of fire or explosion.

- ☑ If possible, activate APC in the apnoea phase. The oxygen content of the respiratory mixture should be below 40%.
- ☑ Just before or during APC application, do not introduce any oxygen or other combustible and flammable gases/fluids into the tracheobronchial system.
- ☑ All other gases, such as nitrogen, noble gases, atmospheric air or inhalation anesthetics are non-combustible.

GENERAL TIPS AND RULES FOR ELECTROSURGERY AND APC

If applied properly, electrosurgery is almost free of hazards to the patient and the operating personnel. This checklist is to alert the user to the risks in order to eliminate them.

General notes

- ☑ Familiarize yourself with system features and with how to operate the system properly before using it (see German Medical Devices Operator Ordinance, or MPBetreibV). In addition to its User Manual, Erbe also offers training and accompanying literature.
- ☑ Because the electrosurgery unit, instruments and accessories are designed to work together, use either recommended accessories and equipment that has, as far as possible, been obtained from a single manufacturer. See Erbe User Manuals for additional information.
- ☑ Inspect the electrosurgery unit, instrument and accessories before use to ensure they are in proper working condition and free of damage.

Patient positioning

- ☑ The patient must be dry and insulated when placed into position. OR table overlays or cloth covers that are wet must be replaced during surgery.
- ☑ Place a urinary catheter for relatively long procedures.
- ☑ The patient must not touch any electrically conducting objects, such as drip stands or the metal parts of the OR table.
- ☑ Avoid skin-to-skin contact points with the patient (e.g., hand/thigh)
- ☑ Do not install connecting cables on top of other cables or in places in the OR where they could cause someone to trip.
- ☑ Place instruments on the instrument table and not on or next to the patient.
- ☑ Be careful with disinfectants: electrical sparks can ignite the alcohol in these agents. For this reason, disinfectants must always be dried off completely.

Operations on patients with artificial pacemakers

- ☑ Follow the artificial pacemaker manufacturer's recommendations.
- ☑ Avoid allowing current to flow across the artificial pacemaker, probe or cardiac muscle.
- ☑ The return electrode should be positioned as close as possible to the operating field but at least 15 cm from the artificial pacemaker.
- ☑ Bipolar application is preferable to monopolar application.
- ☑ Select low settings.
- ☑ If possible, deactivate the artificial pacemaker or ICD prior to application.
- ☑ Monitor the artificial pacemaker before, during and after surgery for any potential malfunction.
- ☑ Brief activation bursts should be avoided. The artificial pacemaker could interpret these as cardiac arrhythmia and generate stimulus signals as a result.

TIPS FOR POSITIONING THE RETURN ELECTRODE

With today's state-of-the-art technology, the risks incurred during monopolar electrosurgery are very low. The use of the return electrode does, however, give rise to questions and issues that we would like to clarify in this section.

In addition to carefully positioning the return electrode and ensuring contact across its entire surface, we also recommend working through the following safety checklist.

- ☑ Check cables and plugs for any damage.
- ☑ Do not cut the return electrode.
- ☑ Position the return electrode with the long edge facing the operating field.
- ☑ The area of application should be dry and smooth with no disinfectant, body hair, skin folds or lesions.
- ☑ Avoid air pockets between the skin and return electrode; do not use contact gel.
- ☑ Do not place the return electrode on scarred or inflamed areas of skin, on bony structures or near metallic implants that should not lie in the flow of current.
- ☑ Conductive muscular tissue with low electrical resistance should be preferred to areas with subcutaneous fatty tissue. We recommend the upper arm or thigh.
- ☑ Position the return electrode in such a way that ECG cables and electrodes do not lie in the flow of current.
- ☑ If the patient is repositioned, the placing of the electrode and all connections should be rechecked.
- ☑ The NESSY return electrode is not designed to be reused and should be replaced each time it is removed (e.g., when correcting its positioning).
- ☑ Position the return electrode as close to the operating field as possible.
- ☑ When positioning the return electrode, implants must be taken into consideration. They must not lie in the flow of current.

Application on children

- ☑ If the upper arm and thigh are too thin, the return electrode can also be placed on the patient's body.
- ☑ In infants, the return electrode should always be placed on the body. Whenever possible, work in bipolar mode only with at low power (below 50 W).
- ☑ Return electrodes for children should only be used when a larger return electrode cannot be positioned correctly. The larger the return electrode, the less the skin warms up.

General tips

- ☑ Arc flashes may occur during monopolar electrosurgery if the user activates uninsulated forceps using a single-pole electrode (improper use!). Because their use is not uncommon in practice, we recommend using insulated forceps.
- ☑ ECG interference caused by electrosurgery can be avoided by using monitor filter systems or compatible accessories.

Procedures on patients wearing jewelry (piercing, necklace, ring, etc.)

- ☑ We recommend always removing the jewelry (piercing, necklace, ring, etc.).
- ☑ Performing electrosurgery on patients with piercings that cannot be removed is not contraindicated, however, provided the following rules are observed:
- ☑ Jewelry must not come in direct contact with the active electrode or return electrode.
- ☑ Neither the active electrode nor the return electrode may be used in the direct vicinity of piercings.
- ☑ The piercing must not be located in the flow of current between the active electrode and return electrode.
- ☑ Jewelry must not come in contact with electrically conducting materials.

And after the procedure ...

- ☑ Carefully peel the return electrode off the skin to prevent injuries to the skin.

Glossary

Active electrode
The part of the electrosurgical instrument that transmits the current to the site of patient tissue where the tissue effect is intended Acronym: AE

Argon plasma coagulation
Monopolar non-contact coagulation. Electrically conductive argon plasma transmits the current to the tissue. Acronym: APC (Argon Plasma Coagulation)

Bipolar electrosurgery
Electrosurgical procedure in which both electrodes are integrated in a single instrument

Burning under return electrode
Burning of the skin due to extreme generation of heat as a result of excessive current density under or at the return electrode

Carbonization
Carbonization of biological tissue

Coagulation
1. Denaturation of proteins. 2. Electrosurgical effect in which proteins coagulate and tissue shrinks, thereby making an essential contribution to blood clotting

Cryoablation
Tissue rejection through previous devitalization by icing

Cryoadhesion
Adhesion of tissue (containing fluid) or materials by icing

Cryobiopsy
Tissue removal with cryoadhesion and subsequent extraction

Cryorecanalization
Elimination of a constriction (stenosis) with cryoadhesion and subsequent extraction of the stenosing tumor

Cryotherapy
Tissue devitalization/ablation by freezing

Current density
Current flow amount per cross-section area. The higher the current density, the more heat is generated

Cutting
Electrosurgical effect in which the intracellular fluid is explosively vaporized and the cell walls burst

Dessication
Drying out of biological tissue

Devitalization
Destruction of biological tissue

Electrode
Conductor that transmits or receives current, e.g. active electrode, return electrode

Electrosurgery
Use of high-frequency electric current on biological tissue with the goal of using heat to generate a surgical effect. Synonyms: HF surgery, diathermy, radio frequency (RF) surgery

Exophytic stenosis
Actually "growing out of a surface". In bronchoscopy: Endobronchial tissue growth

Frequency
Number of periods per second during which the current direction changes twice. Unit: Hertz (Hz). 1 kHz = 1000 Hz

Granulation tissue
Porous granulated tissue that temporarily arises in the wound healing process

Hemostasis
Staunching of bleeding

High frequency generator
Device or device component that converts direct current or low-frequency alternating current into high-frequency electrosurgical current

High frequency
In terms of electrosurgery (standard: IEC 60601-2-2): frequency of at least 200 kHz. Acronym: HF; also radio frequency (RF)

Incision quality
The nature of the incision, especially the extent of coagulation at the incision margin. The desired cutting quality depends on the application

Joule-Thomson effect
Temperature change due to pressure change of gases. In cryosurgery: cooling by decompression of gases

Lesion
Damage, injury or disruption to an anatomical structure

Monopolar electrosurgery
Electrosurgical procedure during which the active electrode is used at the operative site and the electrical circuit is closed by a return electrode

Necrosis
Pathological cell death

Power
Energy per second. The electrical power is the product of current and voltage. Unit: Watt (W)

Return electrode
Conductive surface, which is attached to the patient during a monopolar application in order to reabsorb the current. It feeds the current back to the electrosurgical unit in order to close the electrical circuit. Acronym: RE (return electrode). Synonyms: neutral electrode, return electrode

Stent ingrowth/overgrowth
Tumor tissue that grows into the stent or beyond the stent

Thermofusion
Fusion of tissue through coagulation

Vaporization
Vaporization of tissue

Additional reference materials

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LEAFLETS AND BROCHURES

85402-100	Product leaflet ERBECRYO® 2
85140-120	Product leaflet VIO® D
85134-100	Product leaflet APC® 2
85800-103	Fundamentals of electrosurgery
85800-127	Use of electrosurgery with practical tips

Additional information:
Up-to-date product and application information is available at www.erbe-med.com and in publications such as our accessories catalog.
Up-to-date user videos are available at www.medical-video.com

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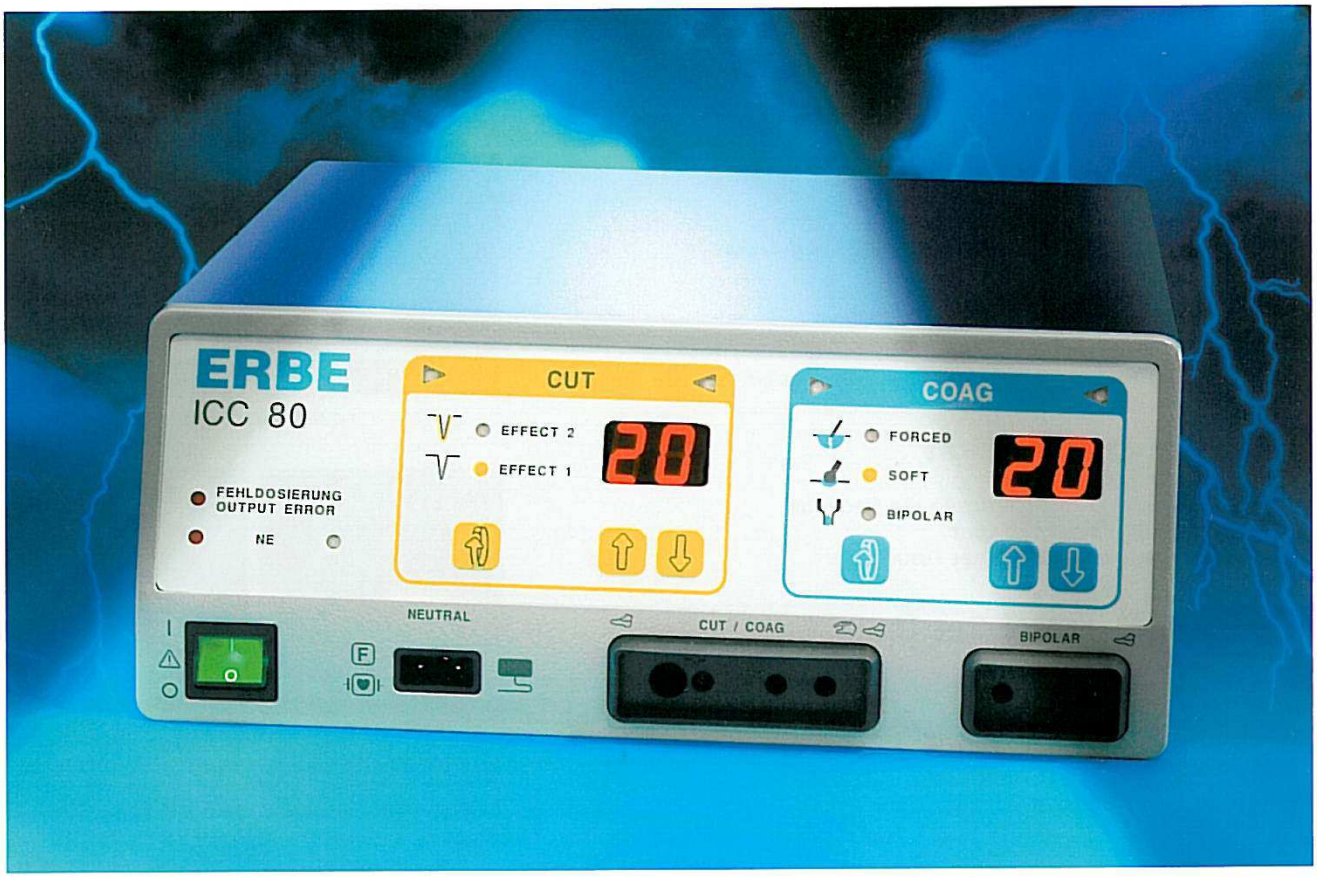
Mullarkey Exhibit I

ERBE ICC 80

The Electrosurgical Workstation for Minor Procedures



Multi-Function for Outpatient and Office Settings

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Mullarkey Exhibit J

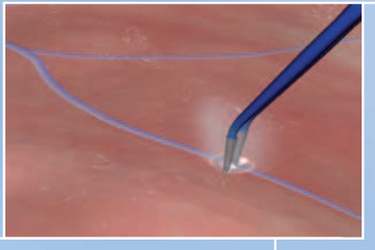
VIO® 100 C

VIO® 100 C

A COMPACT ERBE GENERATOR for less-invasive procedures.

FEATURES:

- Compact/Lightweight
- Up to 4 storable programs
- Return Electrode Monitoring (REM)



MODES AVAILABLE:

- AUTO CUT® – Electrosurgery (ES) cutting with minimal to medium hemostasis.
- DRY CUT – ES cutting with moderate to intense hemostasis.
- SOFT COAG – Non-sparking, gentle monopolar contact coagulation with minimal sticking and carbonization.
- FORCED COAG – Effective, fast, pinpoint coagulation.
- BIPOLAR SOFT COAG – Non-sparking, gentle bipolar contact coagulation with minimal sticking and carbonization.

INDICATIONS:

- BIPOLAR COAGULATION
- ES CUTTING
- ES COAGULATION

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ERBE VIO® 100 C
Product Data

DESCRIPTION	PART NUMBER
ERBE VIO® 100 C Electrosurgical Unit, 120 V / 60 Hz, UL-Version	10140-500 
VIO C Two (Double/Dual) Pedal Footswitch, AP and IP X8 Equipment	20189-107 
* Also Available: VIO C One (Single) COAG Pedal Footswitch, AP and IP X8 Equipment	20188-102

Technical Data

POWER OUTPUT

Maximum CUT output	Up to 100 Watts
Maximum COAG output	Up to 80 Watts

MAIN CONNECTION

System Voltage	100–120 / 220–240 V
Power Frequency	50 / 60 Hz

DIMENSIONS AND WEIGHT

Width x Height x Depth	280 x 135 x 300 mm
Weight	4 kg

STANDARDS

Classification according to EC Directive 93/42/EEC	IIb
Protective class according to EN 60 601-1	I
Type according to EN 60 601-1	CF

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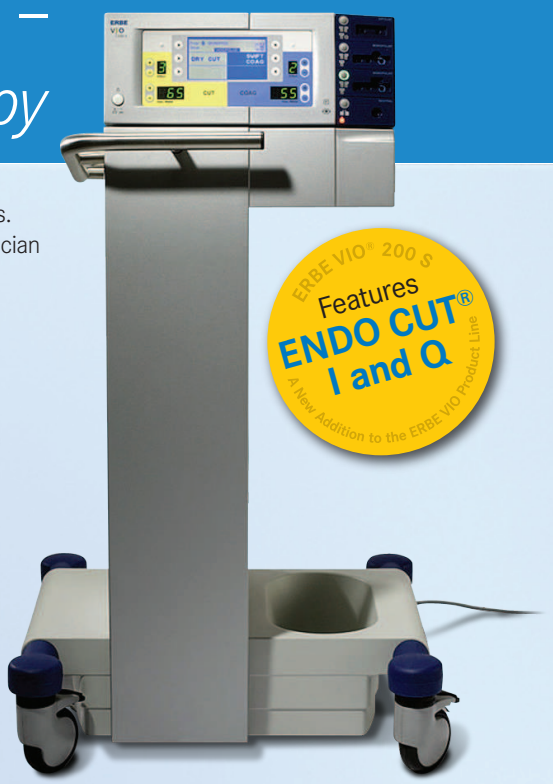
A New Generation from ERBE –
An Innovative Leader in GI Endoscopy



Introducing the **VIO® 200 S,** the newest addition to the ERBE VIO product line of generators. Offering various cutting and coagulation modes with defined effect levels to provide the physician flexibility in interventional applications. The ERBE VIO 200 S also offers improved voltage regulation and automatic power dosing, with as much as needed or as little as possible – millisecond to millisecond.

The new ERBE VIO 200 S unit offers automatic output dosage for all regulative technologies:

- ***Constant Voltage Regulation*** *– for reproducible cuts with optimally adjusted, automatic power output*
- ***Arc Regulation*** *– for reproducible, efficient cuts in tissue with an extremely low or high impedance*
- ***Power Dosing*** *– automatically delivers lowest effective power in all modes, including both Cut and Coag*

Features:

- **Power Peak System PPS™** – for optimal support during the initial cutting stage, especially low-contact impedance situations, allowing the electrode to start in contact with target tissue
- Effect settings for each Mode
- AUTO START™ and AUTO STOP™ features in BIPOLAR SOFT Mode
- Up to 9 storable programs
- User-Friendly Interface
  - **FocusView** *– reduces the visual information to the essentials, simplifying the operation of the unit*
- Audio and Visual Error Recognition System

Benefits:

- **New VIO technology** – Logical, simple, and easy to use
- **ENDO CUT® I and Q** for use with snare wires and sphincterotomes
- **Argon compatible**

Unit Includes:

CUT Modes

- AUTO CUT®
- ENDO CUT® I
- ENDO CUT® Q

COAG Modes

- BIPOLAR SOFT COAG
- SOFT COAG
- FORCED COAG

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E-SOFT_000352

ERBE VIO® 200 S
Product Data

DESCRIPTION	Part Number	
VIO® 200 S Electrosurgical Unit, 120V/60Hz UL	10140-400	
VIO Two Pedal Footswitch with Bracket, AP and IP X8 Equipment	20189-304	
Adapter for BICAP or Gold Probe™	20183-053	
OPTIONAL		
NESSY® Omega Monitoring Pad with Cable (50 per case)	20193-084	
ESU Cart	7910-1006	
VIO Cart with Footswitch Holder, Cable Wrap and 1 Tank Fixation Kit	20180-000	
VIO Cart Wire Basket	20180-010	
VIO/APC™ 2 to VIO Cart Fastening Set (with Grounding Cable)	20180-131	

General Technical Data

POWER OUTPUT

Maximum Cut output	200 Watts for 500 Ohms
Maximum Coag output	Up to 120 Watts
Safety system	NESSY
Frequency	350 kHz

MAIN CONNECTION

Supply voltage	100 V – 120 V/ 220 V – 240 V ±10 %
Frequency	50/60 Hz
Main current	Max. 8 A/4 A
Power input during stand-by	40 Watts
Power input during max. electrosurgical output	500 Watts/920 VA
Potential equalization connection	Yes
Fuse	T 8 A/T 4 A

DIMENSIONS AND WEIGHT

Width x Height x Depth	410 x 165 x 380 mm/ 16.1" x 6.5" x 15.0"
Weight	19 lbs., 14 oz.

AMBIENT TEMPERATURE DURING OPERATION OF THE UNIT

Temperature	+10° C to +40° C/ 50° F to 104° F
Relative humidity	15 % – 80 %

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MKT/5053/00 03/09

Mullarkey Exhibit L

Not Just a Purchase...
A Partner

ERBE offers leading edge technology which combines ease of use, with the highest safety standards in mind.

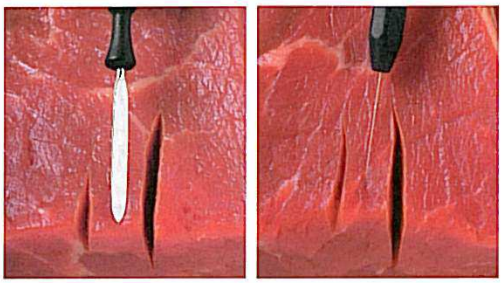
The ERBE ICC 80
Quality Technology for Ambulatory and Office Based Procedures

• Low Voltage Cutting

- *Two Different Cutting Effects*
  - *CUT EFFECT 1 for Reproducible Cutting Quality*
  - *CUT EFFECT 2 for Reproducible Cutting Quality with Maximum Hemostasis*
- *Maximum Performance, Minimal Necrosis*

• Multiple Coag Modes

- *FORCED COAG™*
  - *Covers Most Demands of Standard Coagulation*
- *SOFT COAG™*
  - *Minimal Necrosis with Little Carbonization*
  - *Reduced Tissue Adhesion*
  - *Self-Limiting Current Output — Preserves Life of Instruments*



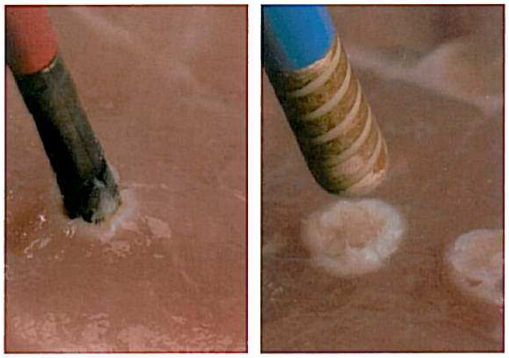
Low-Voltage Cutting

• Bipolar Coagulation

- *Minimizes Tissue Adherence to the Electrode*
- *Self-Limiting Current Output*
- *Low Voltage Effect to Target Tissue*

• Easy to Use and Set Up

- *Programmable Default Settings*
- *Automatic Initial Self-Check*
- *Easy to Understand Error Codes*
- *Compatible with Most Standard Accessories*



SOFT COAG BIPOLAR COAG

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MKT/50025/00 01/03

For More Information on How the ERBE ICC 80 Can Benefit Your Facility, Contact us at

1-800-778-3723

E-SOFT_000360

Mullarkey Exhibit M

ICC 200® E

Electrosurgical Workstation for Flexible Endoscopy

ERBE ICC 200® E with optional EIP 2 Pump >>

ENDO CUT® Mode for use with Snare Wires or Sphincterotomes

- Power on demand
  "As much as necessary, as little as possible."
- Consistent cutting quality
- Automatic output for controlled cutting and snare resections
- ENDO CUT® automatically controlled cutting

FORCED COAG™ Mode

- Conventional snare resectioning
- Hot biopsy

SOFT COAG™ - Proprietary Monopolar

- **Monopolar -** Hot biopsy with bipolar tissue effect

BIPOLAR Mode

- **Bipolar -** SOFT COAG™ for bipolar coagulation probes

Compatible with Common Accessories

- Snare wires
- Sphincterotomes
- Bipolar probes
- Hot biopsy forceps

<< See Reverse for General Technical Data

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E-SOFT_000361

ERBE ICC 200® E

General Technical Data

POWER CONNECTION

Rated supply voltage	120V +/- 10%
Rated supply frequency	50/60 Hz
Line current	6.0 A
Power input in standby mode	25 watts
Power input with max. HF output	450 watts

DIMENSIONS AND WEIGHT

Width x Height x Depth	11.0” x 6.0” x 14.5”
Weight	18.4 lbs.

AMBIENT OPERATIONAL CONDITIONS

Temperature	+10˚C to +40˚C/50˚F to 104˚F
Relative humidity	30%–75%, non-condensing

ACCLIMATIZING

If the unit has been stored or transported at temperatures below +10˚C/50˚F, in particular under 0˚C/32˚F, the unit will require approximately three hours to acclimate at room temperature.

STANDARDS

Classification according to EU Directive: IIb 93/42/EEC

CATALOG NUMBERS

ICC 200® Electrosurgical Generator with ENDO CUT®	10128-204
EIP 2 Irrigation Pump	10325-000
NESSY® Monitoring Split Pad	20193-074
NESSY® Omega Return Electrode	20193-084
ICC Double Pedal Foot Switch with Spacer	20189-027

Only ERBE offers NESSY® (Neutral Electrode Safety System), which monitors specific orientation and return electrode resistance for MAXIMUM patient protection during electrosurgical procedures.

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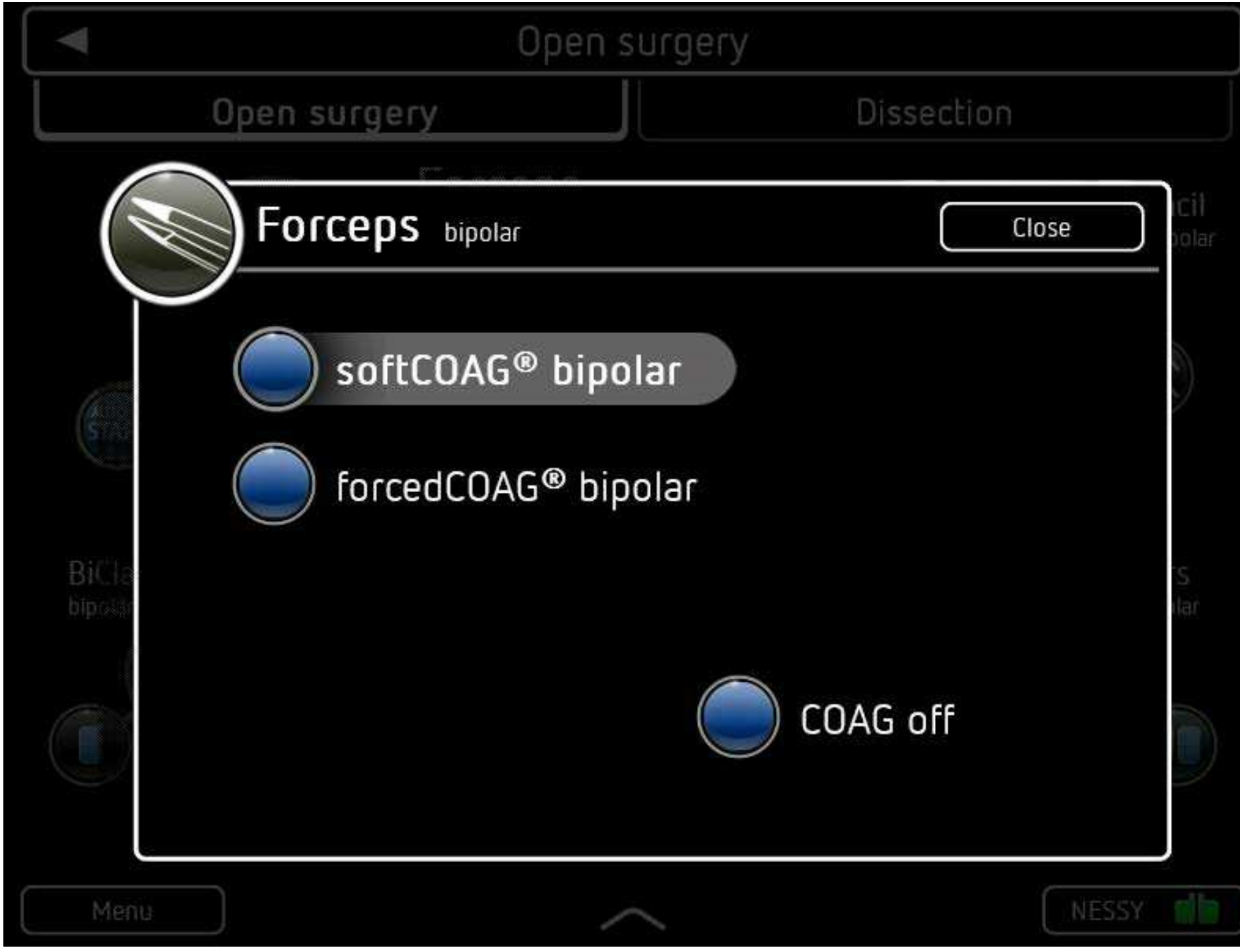
MKT/5024/01 09/06

Mullarkey Exhibit N



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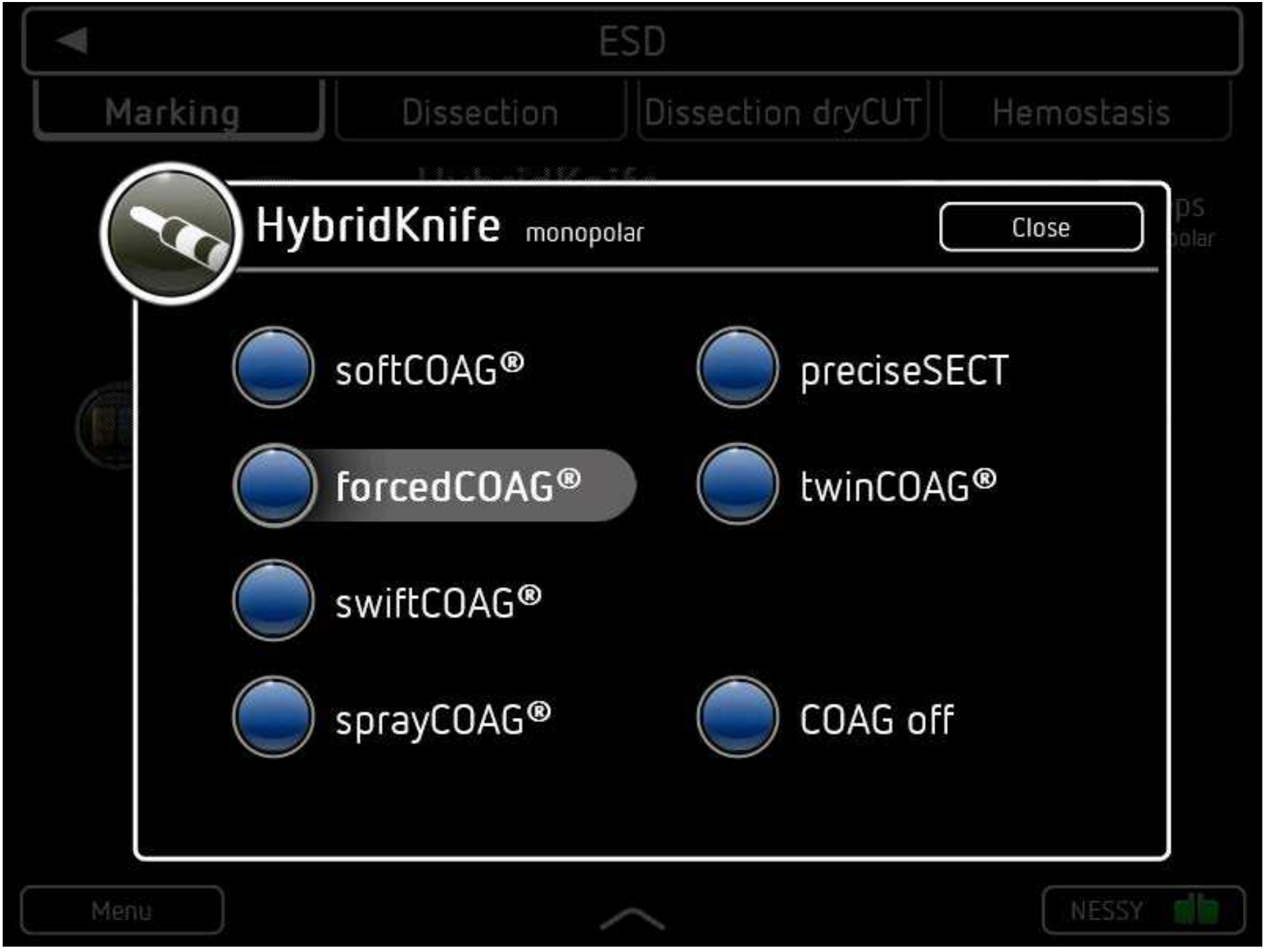
Mullarkey Exhibit O



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Mullarkey Exhibit P
Highly Confidential

Mullarkey Exhibit Q
Highly Confidential

Mullarkey Exhibit R
Highly Confidential

Mullarkey Exhibit S
Highly Confidential

Mullarkey Exhibit T
Highly Confidential

Mullarkey Exhibit U

ERBE ICC 200 E

The Electrosurgical Workstation for Flexible Endoscopy

Multi-Function Electrosurgery for Endoscopy

ERBE
USA INCORPORATED
Surgical Systems

E-SOFT-005032

Not Just a Purchase...
A Partner

ERBE offers leading edge technology which combines ease of use, with the highest safety standards available

The ERBE ICC 200 E
One Unit for All Your Endoscopic Needs!

- **ENDOCUT™ for Polypectomy and Sphincterotomy**
  - *Provides Less Bleeding and Perforation*
  - *Consistent Cutting Quality*
  - *Minimal Necrosis*

- **Multiple Coag Modes**
  - *FORCED COAG™*
  - *Conventional Polypectomy*

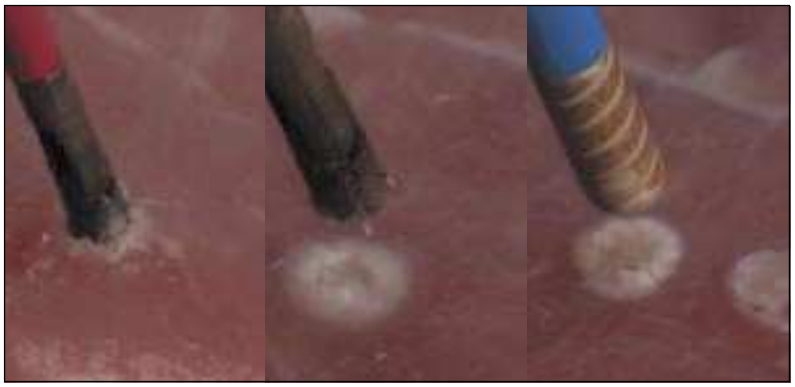
FORCED COAG - conventional electrocautery 20 Watts 1 second application

Ploypectomy Pre-Waye

Polypectomy Post-Waye

- **SOFT COAG™ - Proprietary Monopolar and Bipolar**
  - *Avoids unintended cutting effects and carbonization*
  - *Minimizes tissue adherence to the electrode*

- **Compatible with all your accessories, including**
  - *Snare Wires*
  - *Sphinctertoms*
  - *Bipolar Probes*
  - *Hot Biopsy forceps*



SOFT COAG monopolar 60 Watts, 3 seconds
Note: Energy delivery nearly absent at 3 seconds

ERBE SOFT COAG monopolar application (self-limiting current output)

ERBE bipolar application (self-limiting current output)

Identical power settings on both

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Only ERBE offers NESSY™ - Omega Neutral Electrode Safety System which constantly monitors patient plate resistance and proper orientation of patient return electrode for MAXIMUM patient protection during electrosurgical procedures.

E-SOFT-005033

Mullarkey Exhibit V

ICC 200® E

Electrosurgical Workstation for Flexible Endoscopy

ERBE ICC 200® E with optional EIP 2 Pump >>

ENDO CUT® Mode for use with Snare Wires or Sphincterotomes

- Power on demand
  "As much as necessary, as little as possible."
- Consistent cutting quality
- Automatic output for controlled cutting and snare resections
- ENDO CUT® automatically controlled cutting

FORCED COAG™ Mode

- Conventional snare resectioning
- Hot biopsy

SOFT COAG™ - Proprietary Monopolar

- **Monopolar -** Hot biopsy with bipolar tissue effect

BIPOLAR Mode

- **Bipolar -** SOFT COAG™ for bipolar coagulation probes

Compatible with Common Accessories

- Snare wires
- Sphincterotomes
- Bipolar probes
- Hot biopsy forceps

<< See Reverse for General Technical Data

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E-SOFT-005036

ERBE ICC 200® E

General Technical Data

POWER CONNECTION

Rated supply voltage	120V +/- 10%
Rated supply frequency	50/60 Hz
Line current	6.0 A
Power input in standby mode	25 watts
Power input with max. HF output	450 watts

DIMENSIONS AND WEIGHT

Width x Height x Depth	11.0” x 6.0” x 14.5”
Weight	18.4 lbs.

AMBIENT OPERATIONAL CONDITIONS

Temperature	+10˚C to +40˚C/50˚F to 104˚F
Relative humidity	30%–75%, non-condensing

ACCLIMATIZING

If the unit has been stored or transported at temperatures below +10˚C/50˚F, in particular under 0˚C/32˚F, the unit will require approximately three hours to acclimate at room temperature.

STANDARDS

Classification according to EU Directive: IIb
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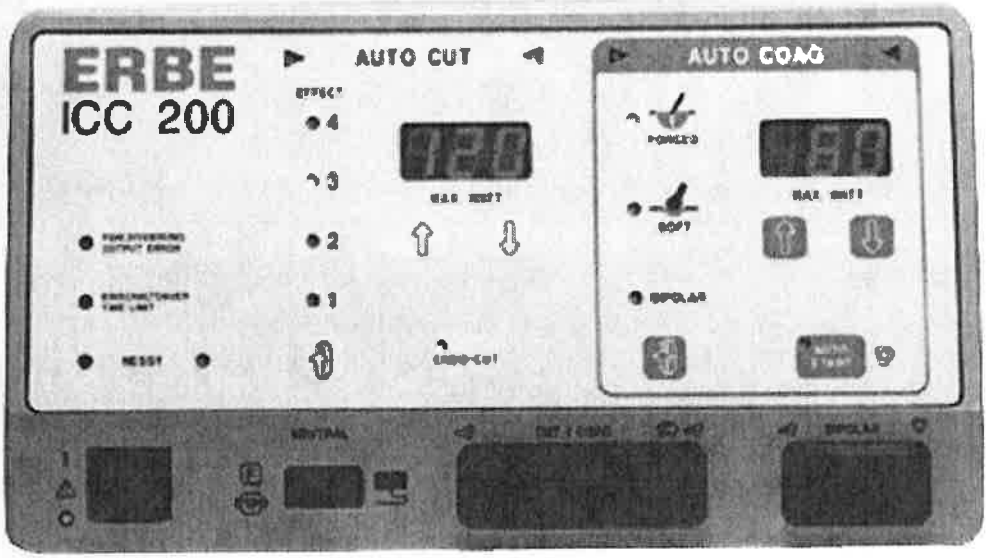
Mullarkey Exhibit W



ERBE ICC 200 E

> The Electrosurgical Workstation for Flexible Endoscopy

> Multi-Function Electrosurgery for Endoscopy

> Compatible with All Your Accessories

<< See back for product details

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E-SOFT-005034

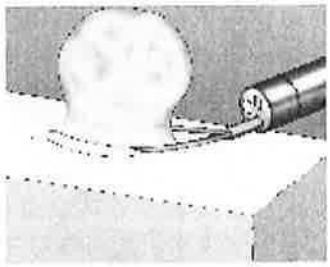
Not Just a Purchase...A Partner

ENDO CUT for Polypectomy and Sphincterotomy

> Provides Less Bleeding and Perforation

> Consistent Cutting Quality

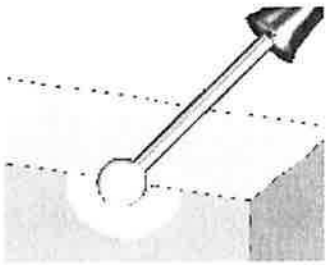
> Minimal Necrosis



SOFT COAG-Proprietary Monopolar and Bipolar

> Avoids Unintended Cutting Effects and Carbonization

> Minimizes Tissue Adherence to the Electrode



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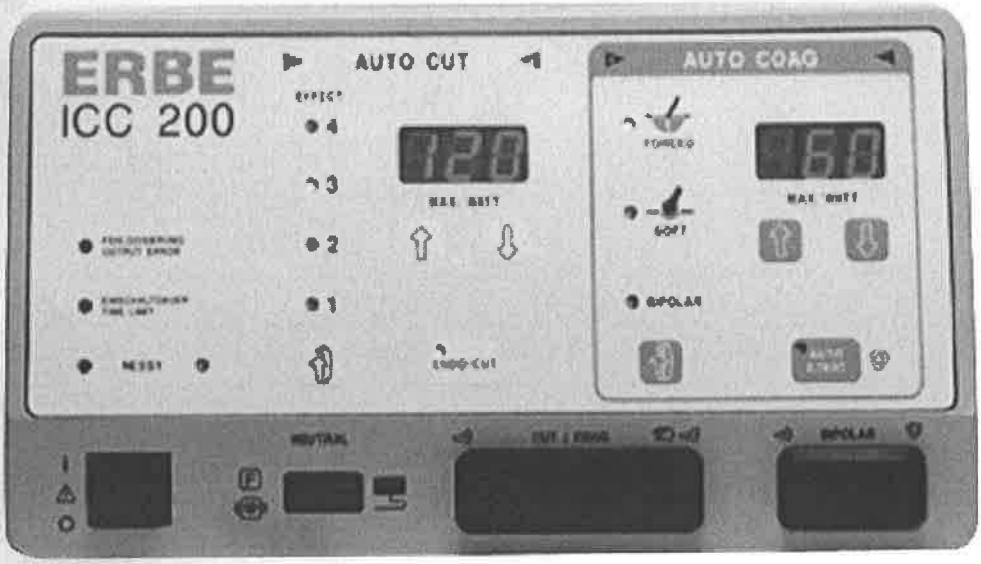
Mullarkey Exhibit X



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> The Electrosurgical Workstation for Flexible Endoscopy

> Multi-Function Electrosurgery for Endoscopy

> Compatible with All Your Accessories

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> *Provides Less Bleeding and Perforation*

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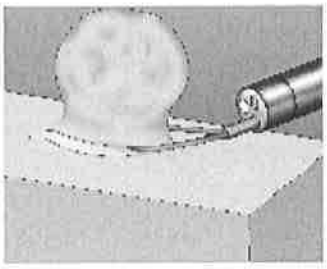
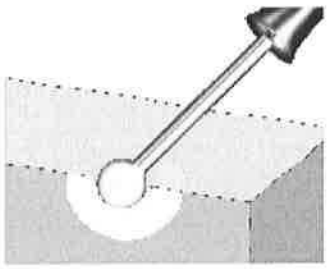


SOFT COAG-Proprietary Monopolar and Bipolar

> *Avoids Unintended Cutting Effects and Carbonization*

> *Minimizes Tissue Adherence to the Electrode*



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