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Ryan et al.

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(54) **SWABBABLE NEEDLE-FREE INJECTION PORT VALVE SYSTEM WITH NEUTRAL FLUID DISPLACEMENT**

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(22) Filed: **Jan. 13, 2004**

(65) **Prior Publication Data**

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(51) **Int. Cl.**
F16K 59/00 (2006.01)
F16L 29/00 (2006.01)
F16L 37/28 (2006.01)

(52) **U.S. Cl.** **251/149.6**; 251/149.3; 251/149.8; 604/249; 604/256

(58) **Field of Classification Search** 251/149.1, 251/149.3, 149.4, 149.6, 149.8; 604/246, 604/249, 256, 95.04, 95.05, 523, 528, 533, 604/534, 535, 537, 538, 539, 905; 600/433, 600/434, 435, 585
See application file for complete search history.

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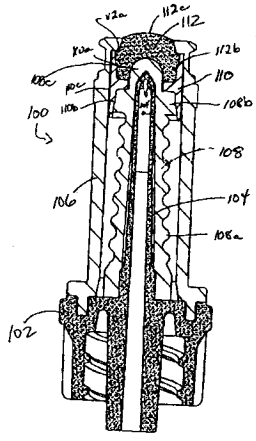
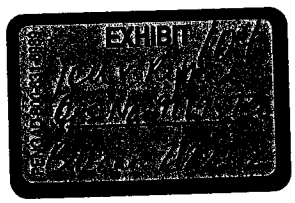
(57) **ABSTRACT**

An improved needle-free intravenous injection port assembly is disclosed. Embodiments include a boot valve with a helical surface, a boot valve and septum which mate with mechanical interference, a spike with a rough outer surface coated with a lubricant, a septum having a shoulder and a single continuous swabbable surface, a septum and a boot valve which are pre-punctured with a solid core steel needle, a septum with a frustroconical extension and a combination single piece septum and boot valve. The injection port assembly provides neutral fluid displacement during coupling and uncoupling.

30 Claims, 17 Drawing Sheets





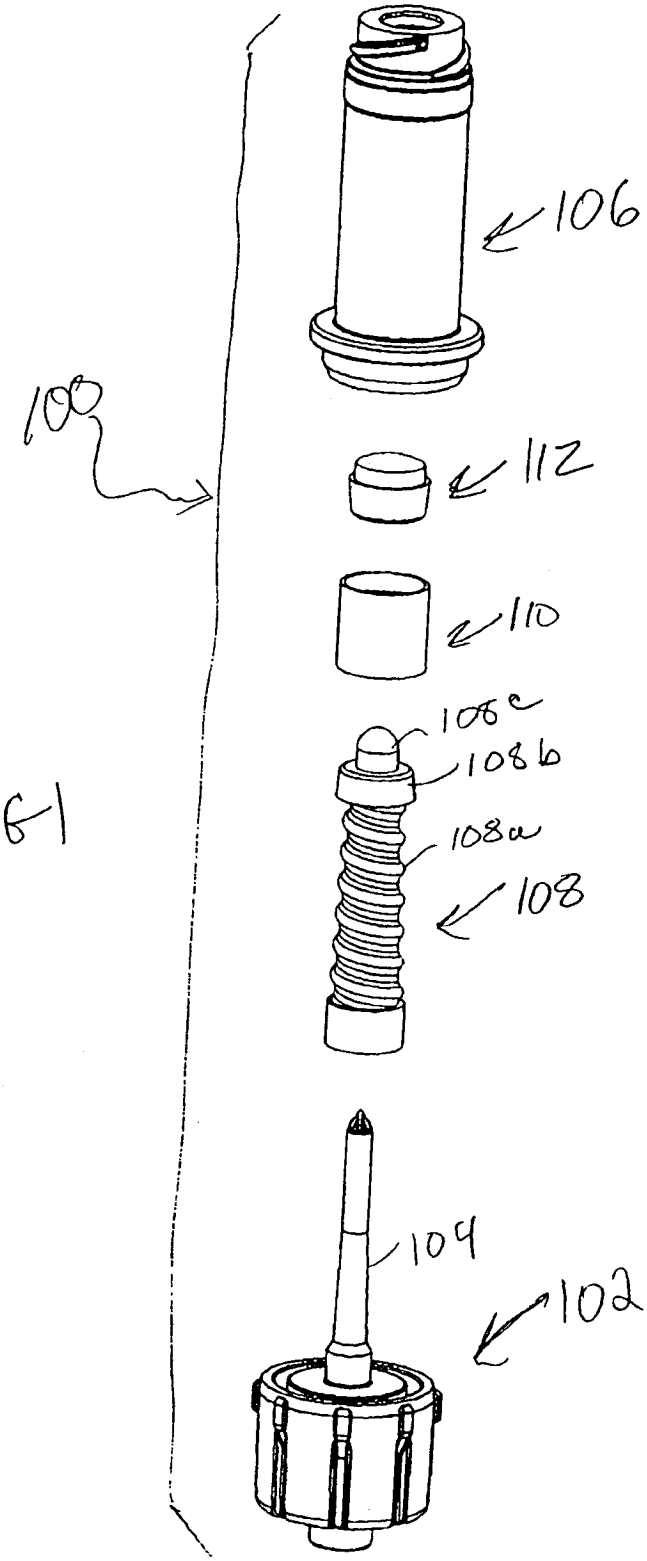
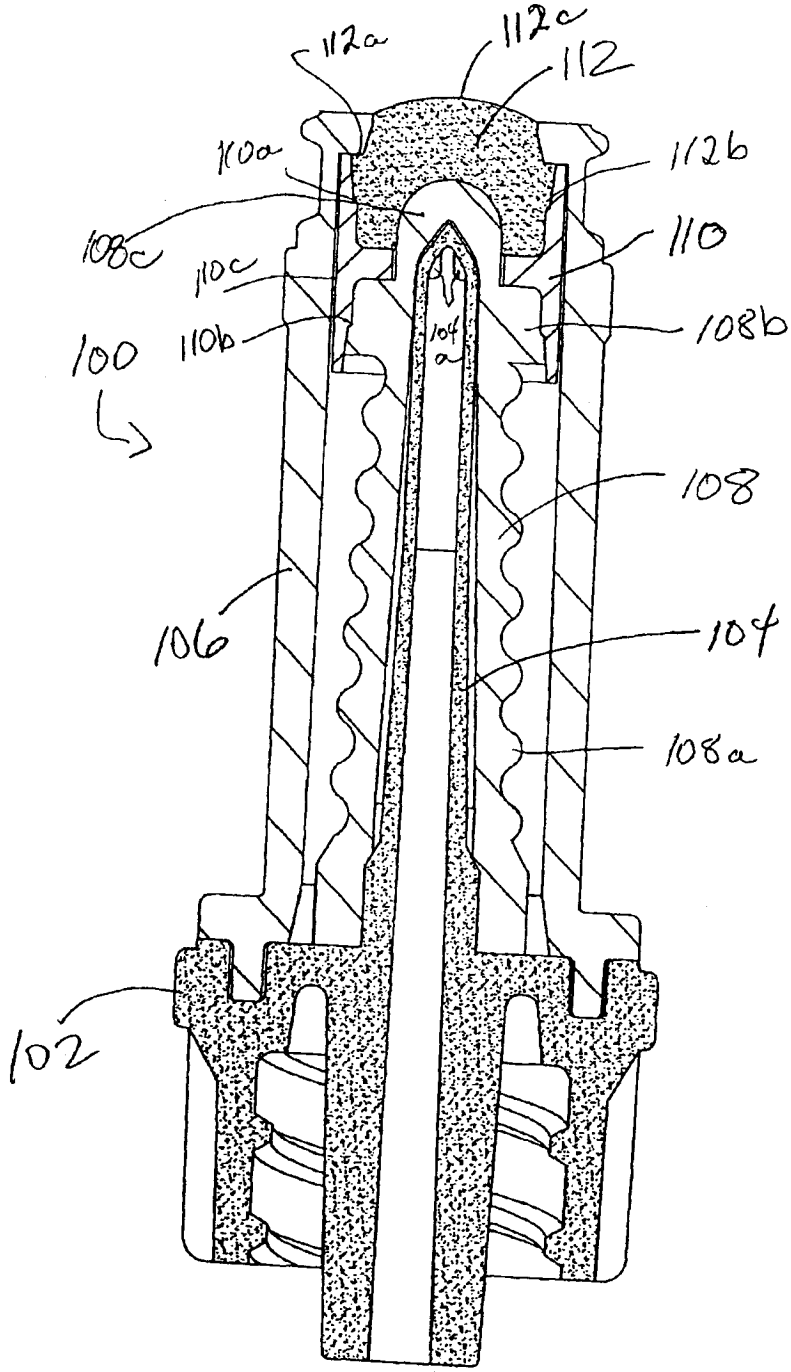


FIG 1


112a
112c
112
100a
112b
108c
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110
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104a
108b
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108
106
104
108a
102

FIG. 2

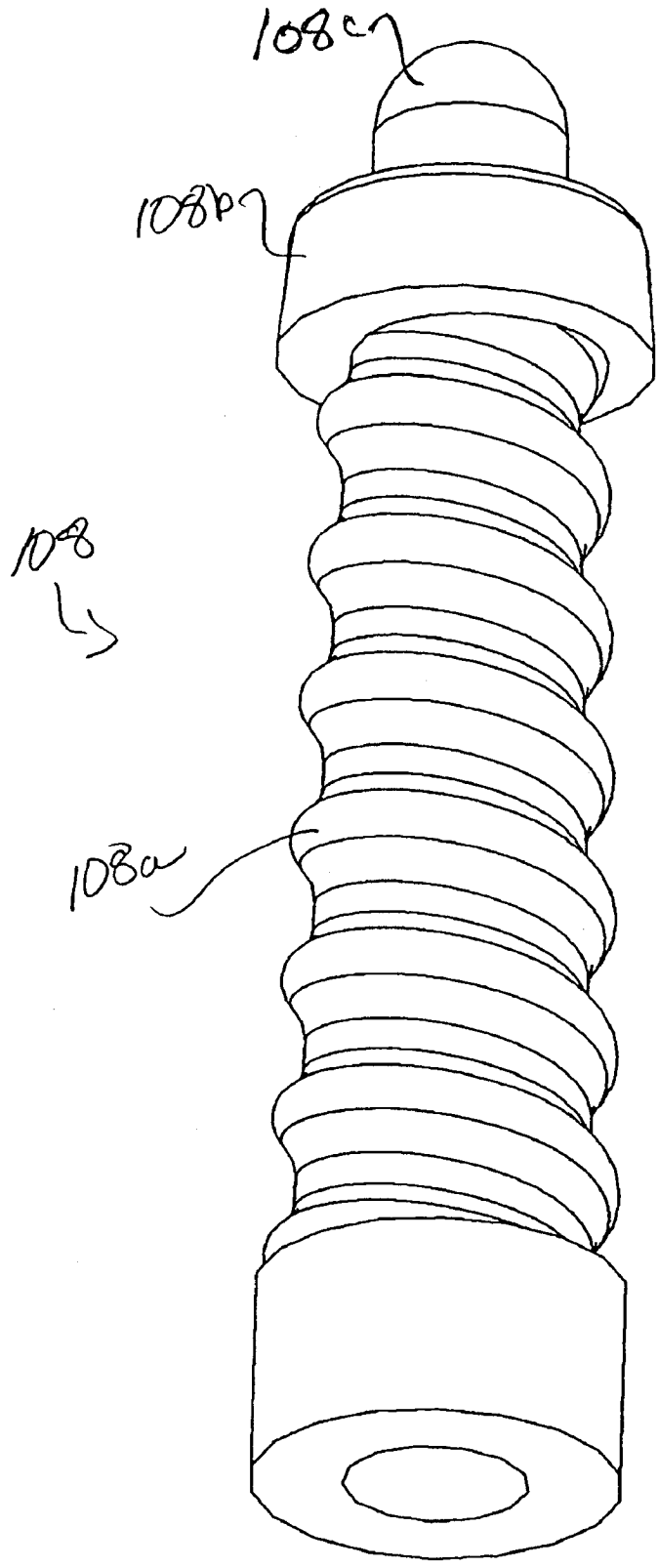


FIG. 3

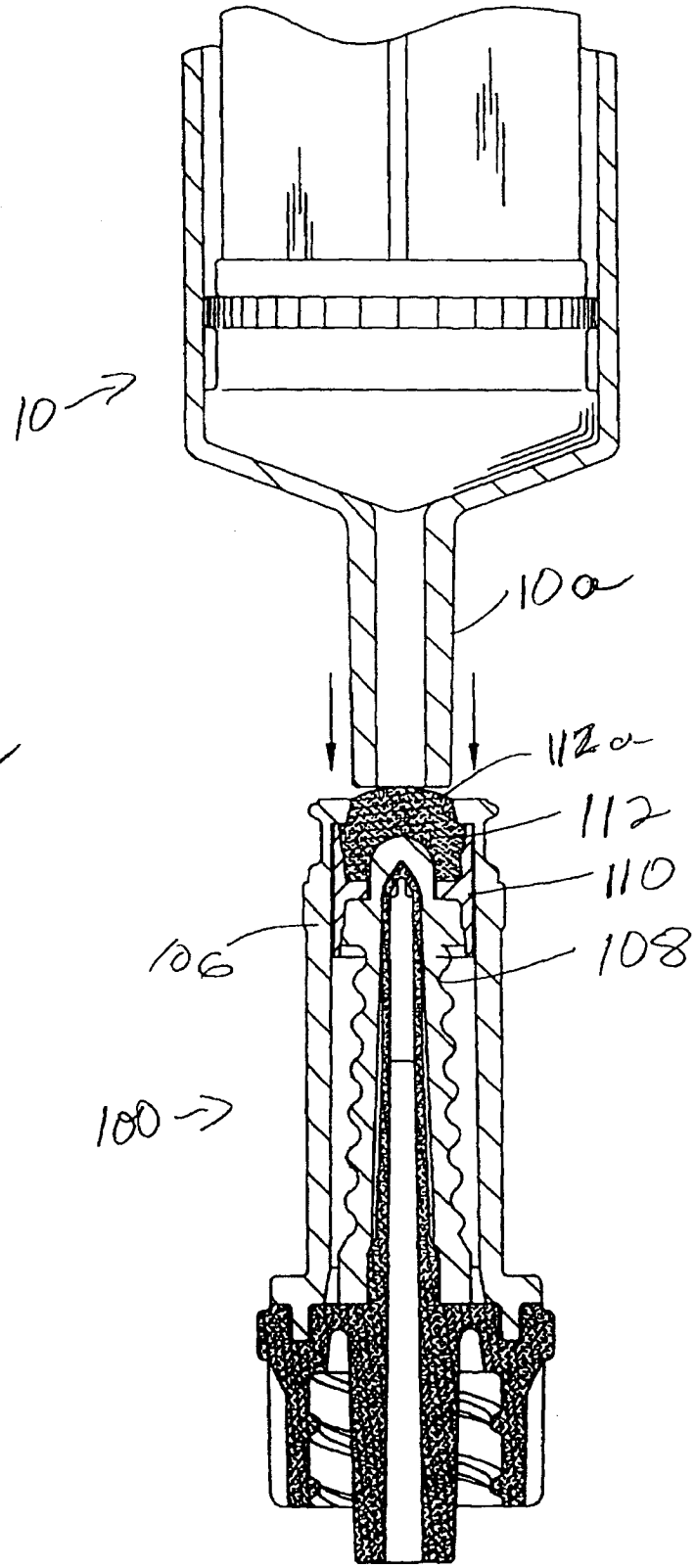
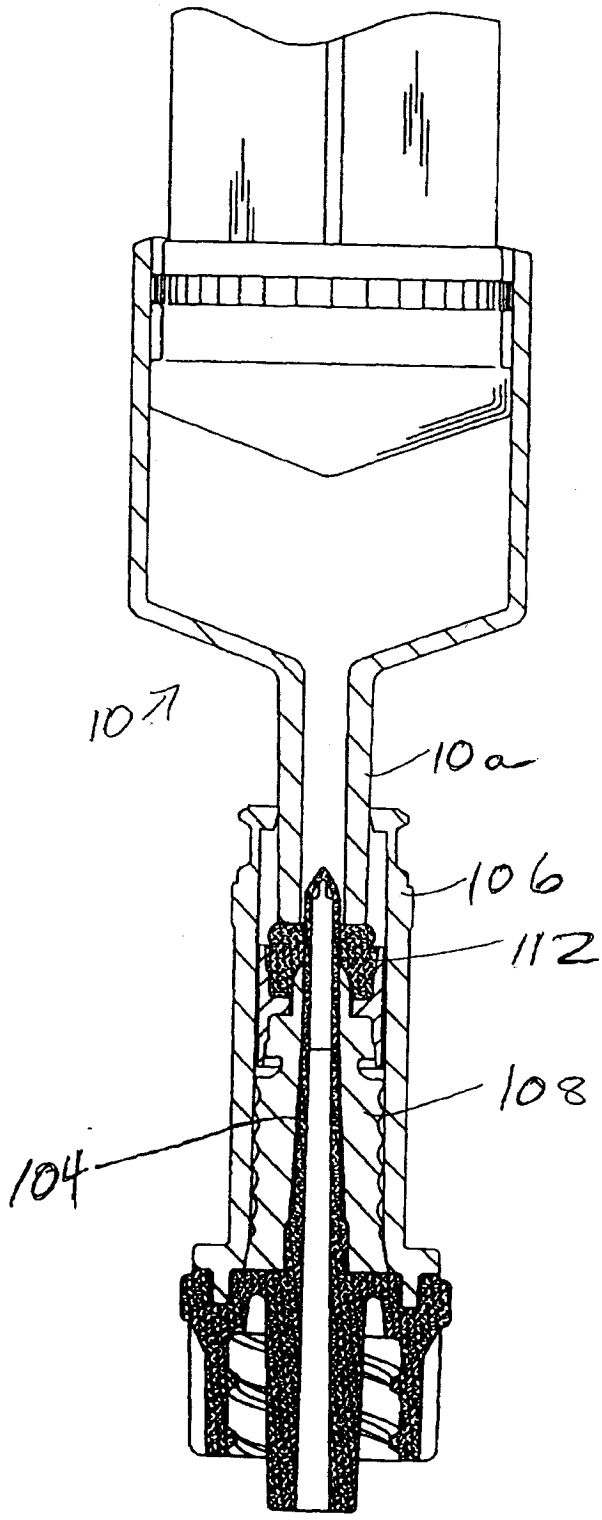


Figure 4

Figure 5



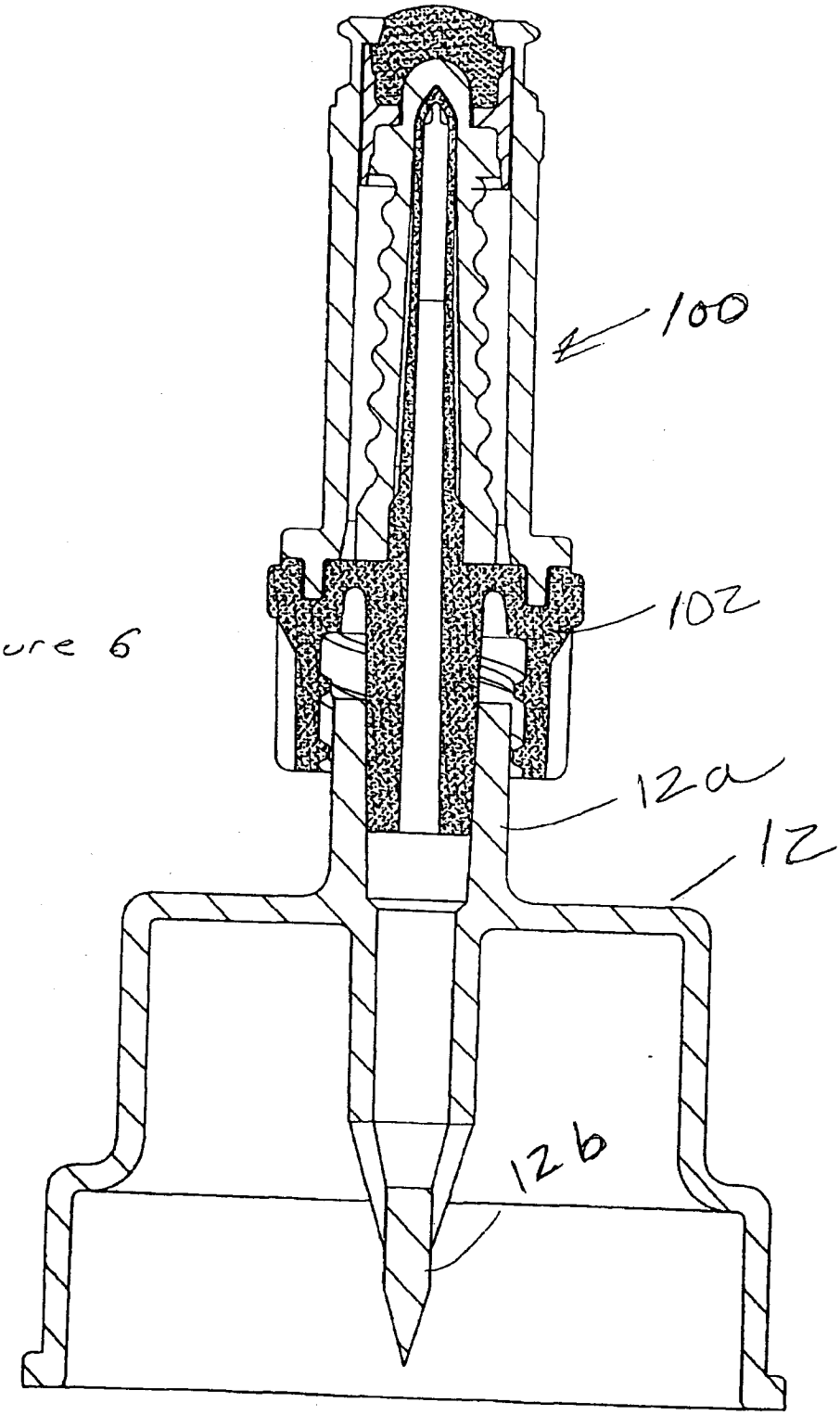


Figure 6

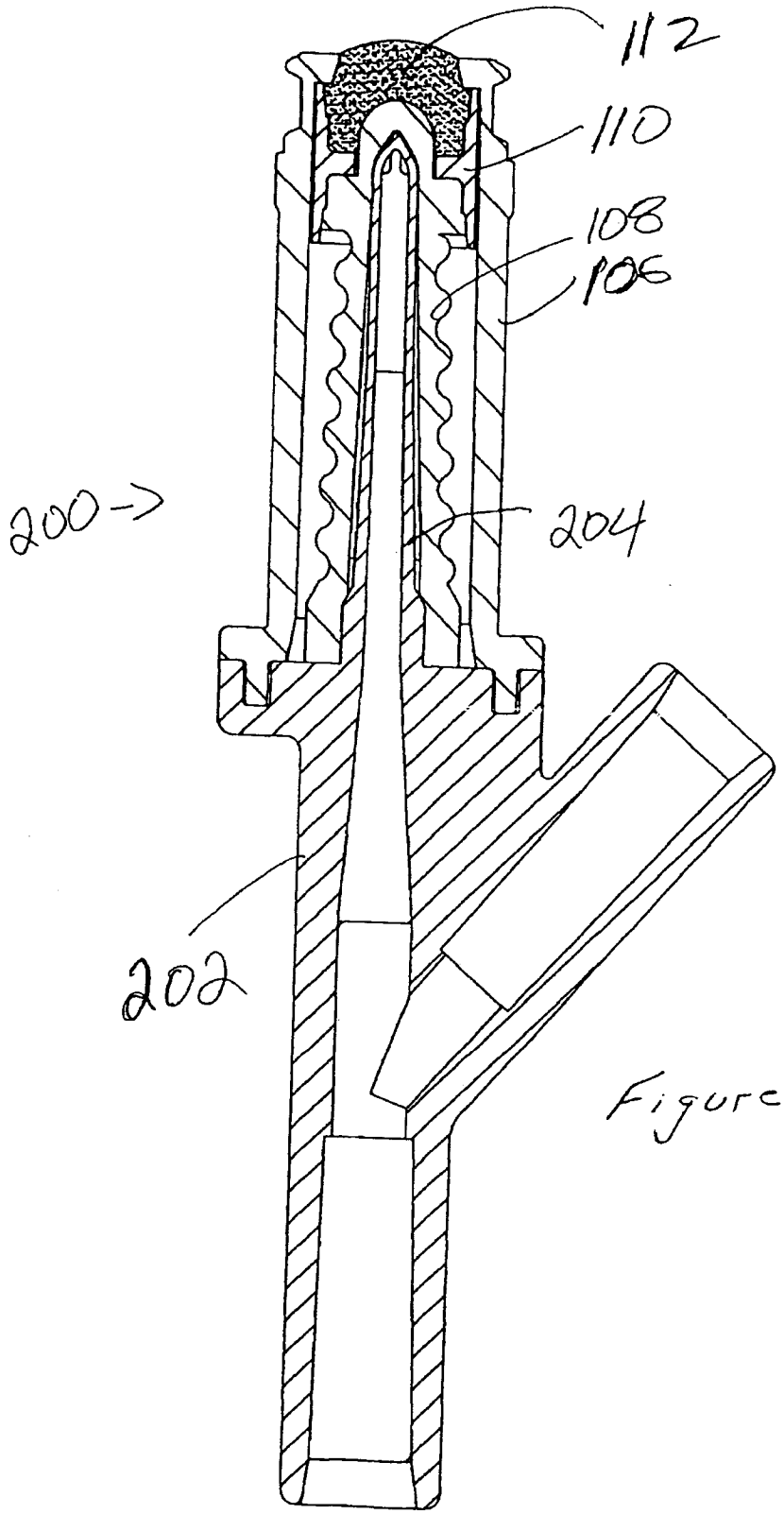


Figure 7

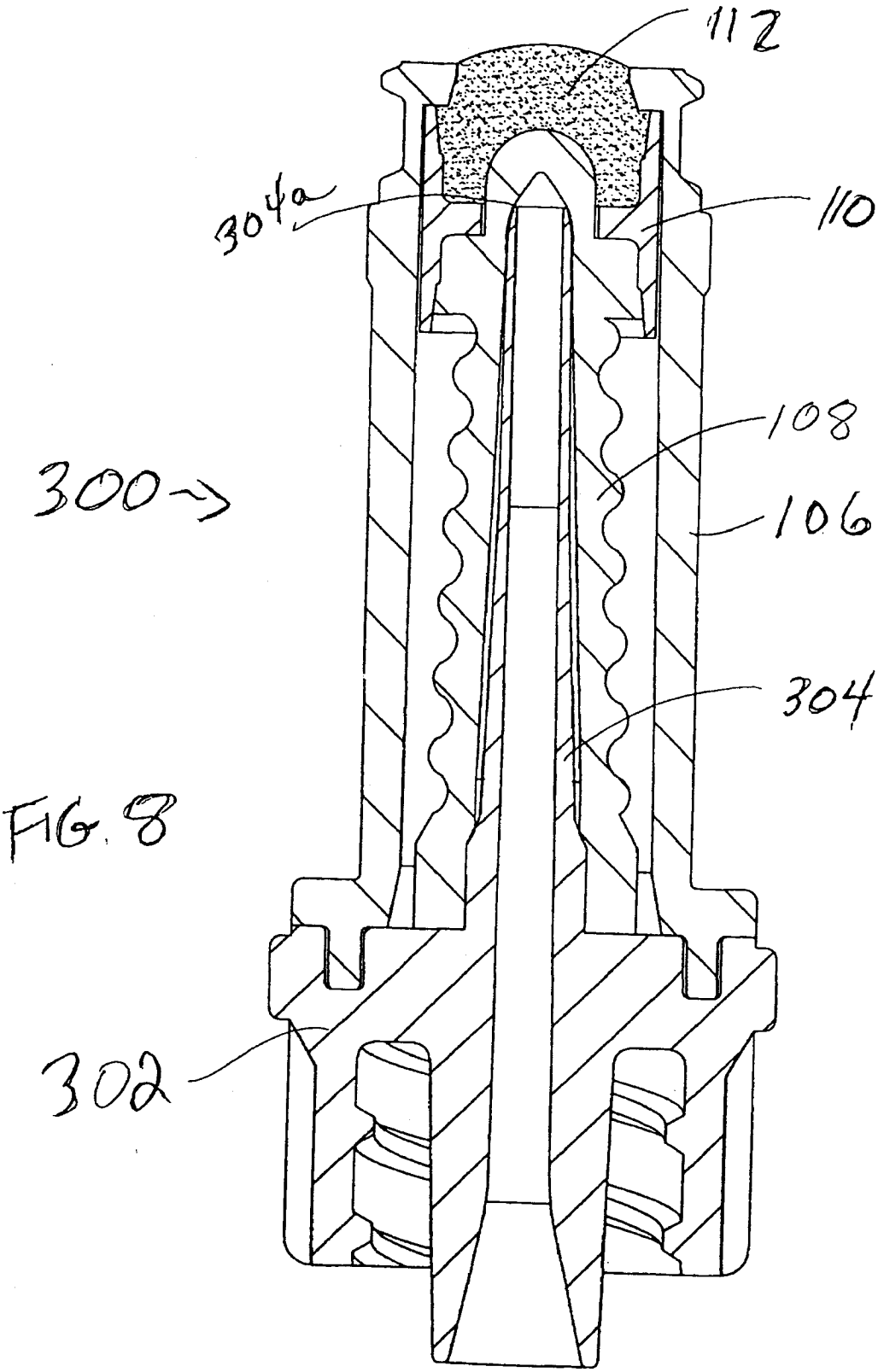


FIG. 8

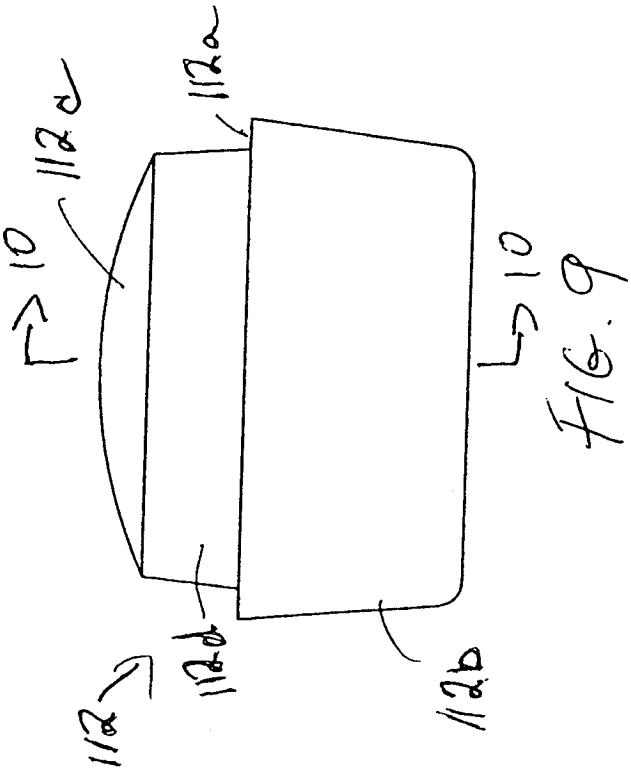


FIG. 9

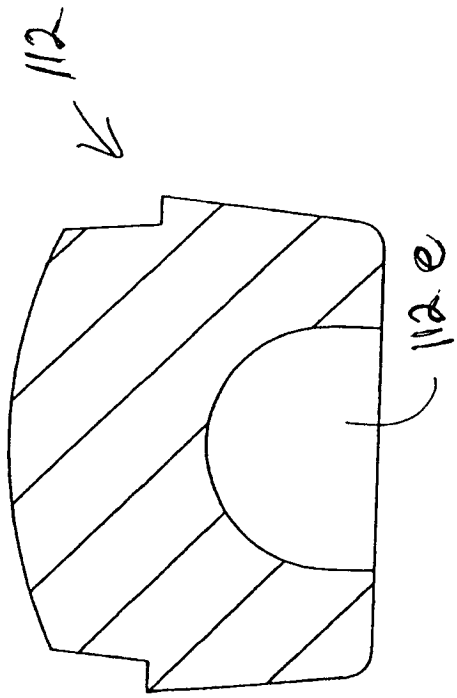


FIG. 10

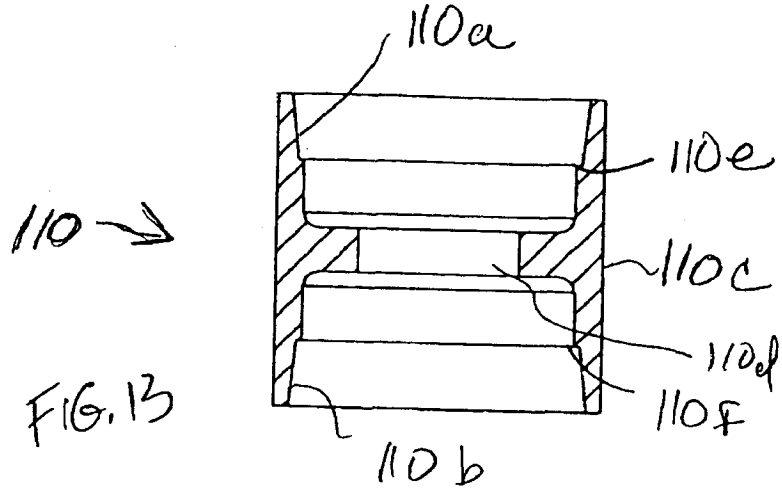


FIG. 13

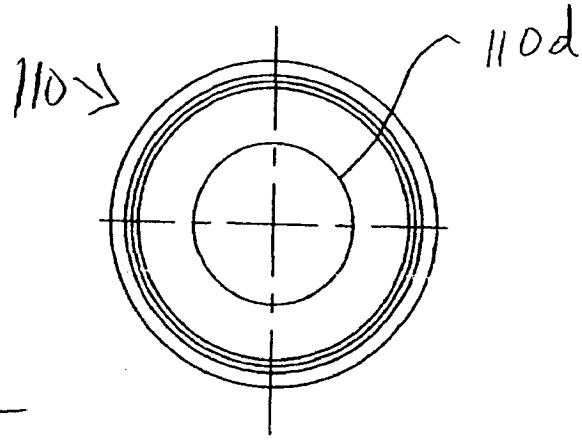


FIG. 12

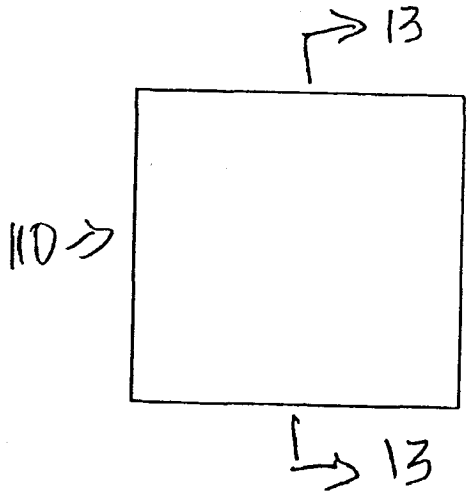


FIG. 11

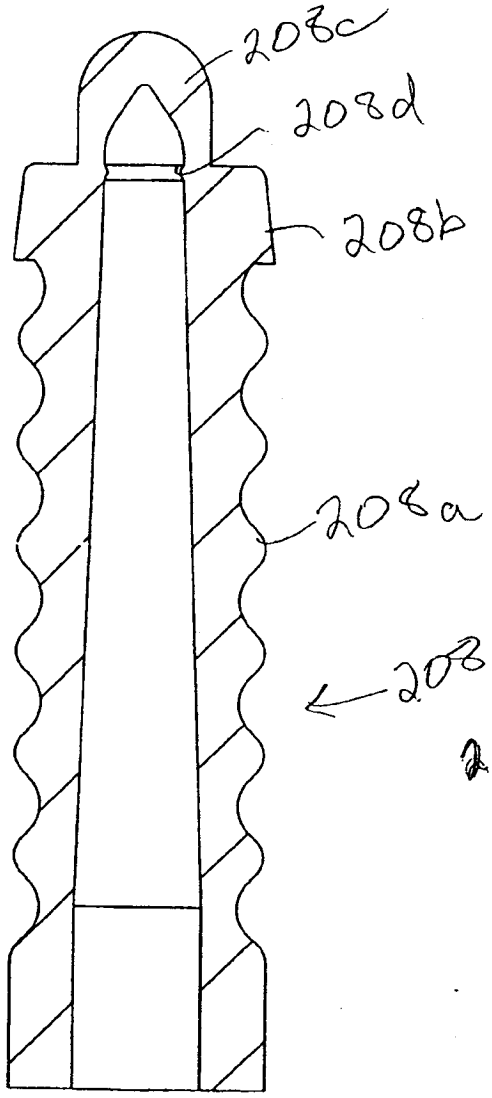


FIG. 15

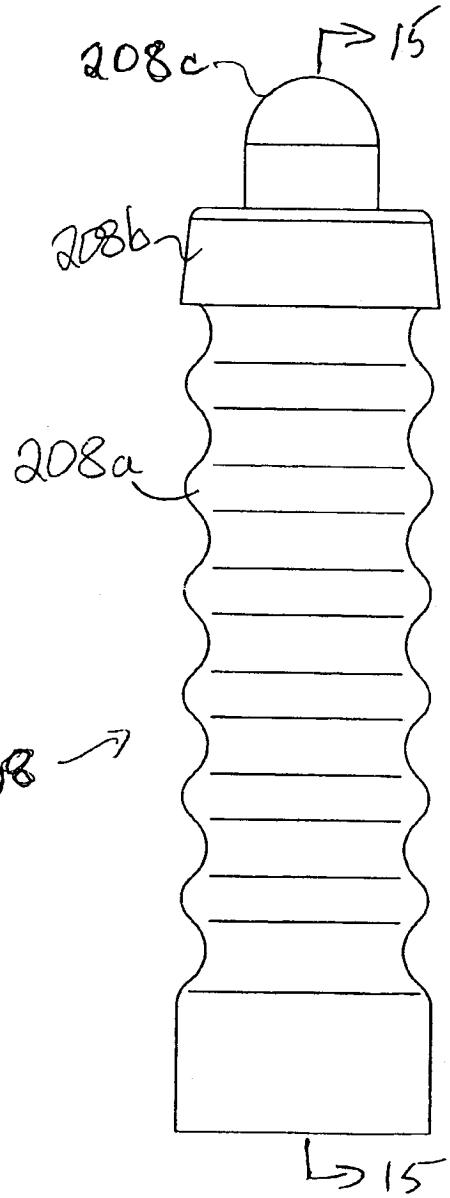
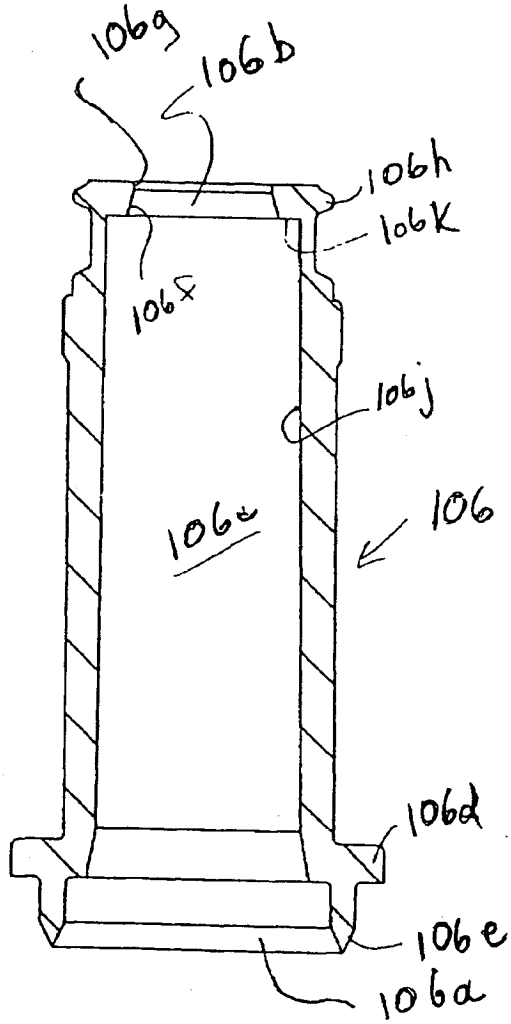


FIG. 14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106h
106K
106f
106j
106c
106
106d
106e
106a

FIG. 17

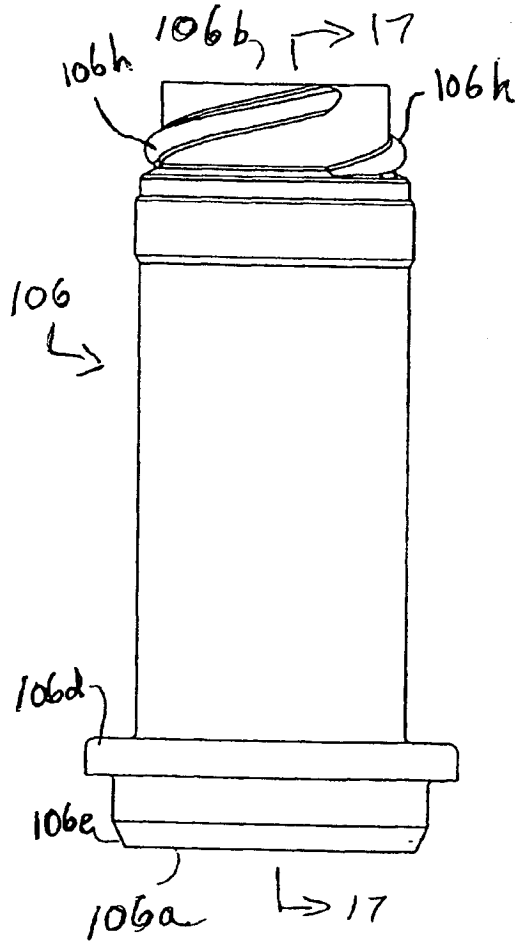

106h
106b
17
106h
106
106d
106e
106a
17

FIG. 16

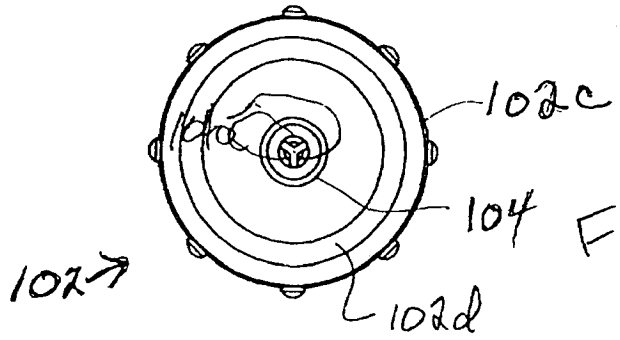


FIG. 19

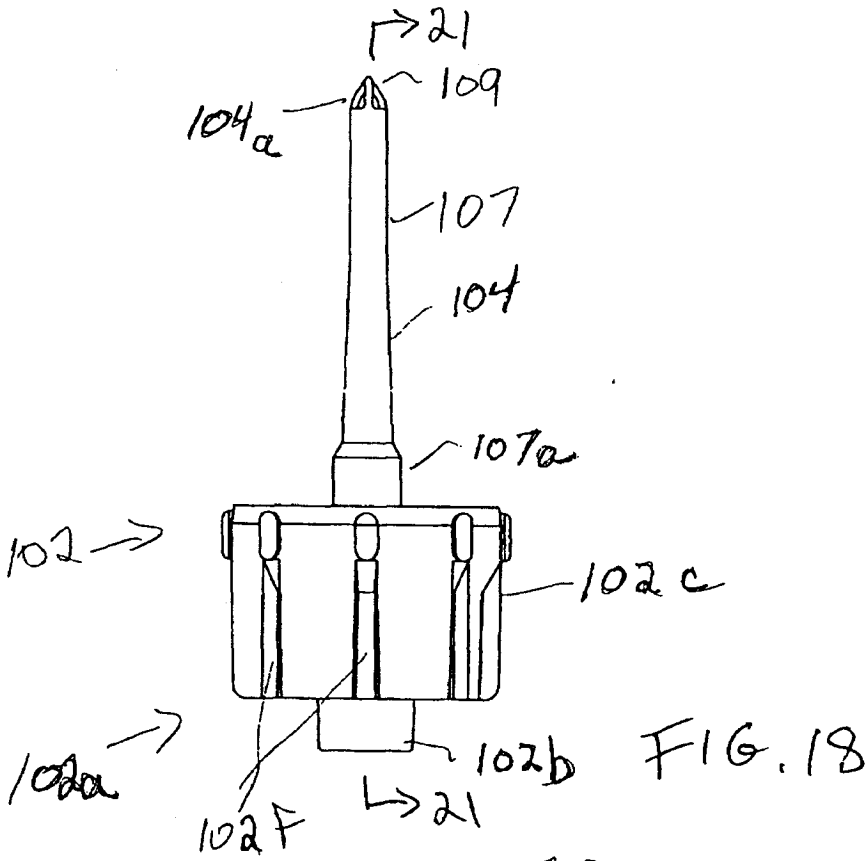


FIG. 18

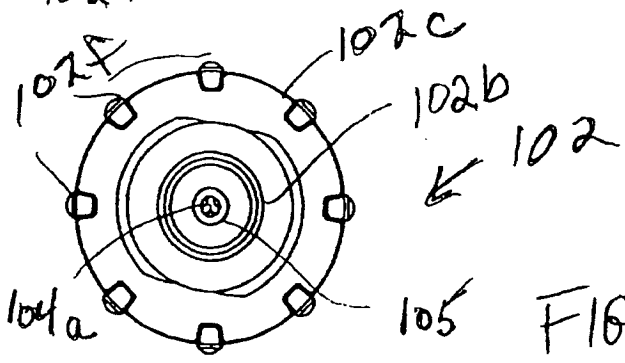


FIG. 20

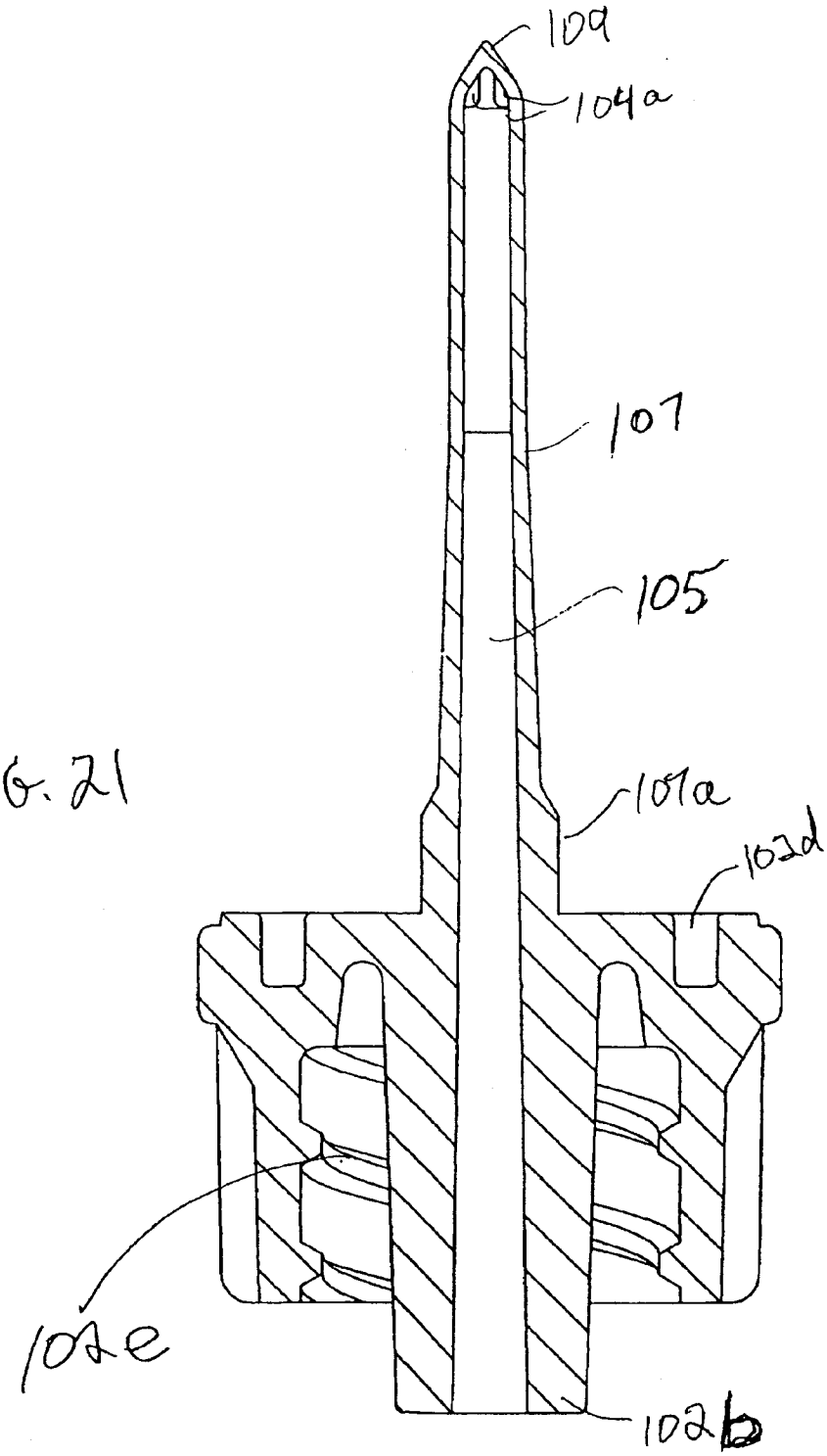


FIG. 21

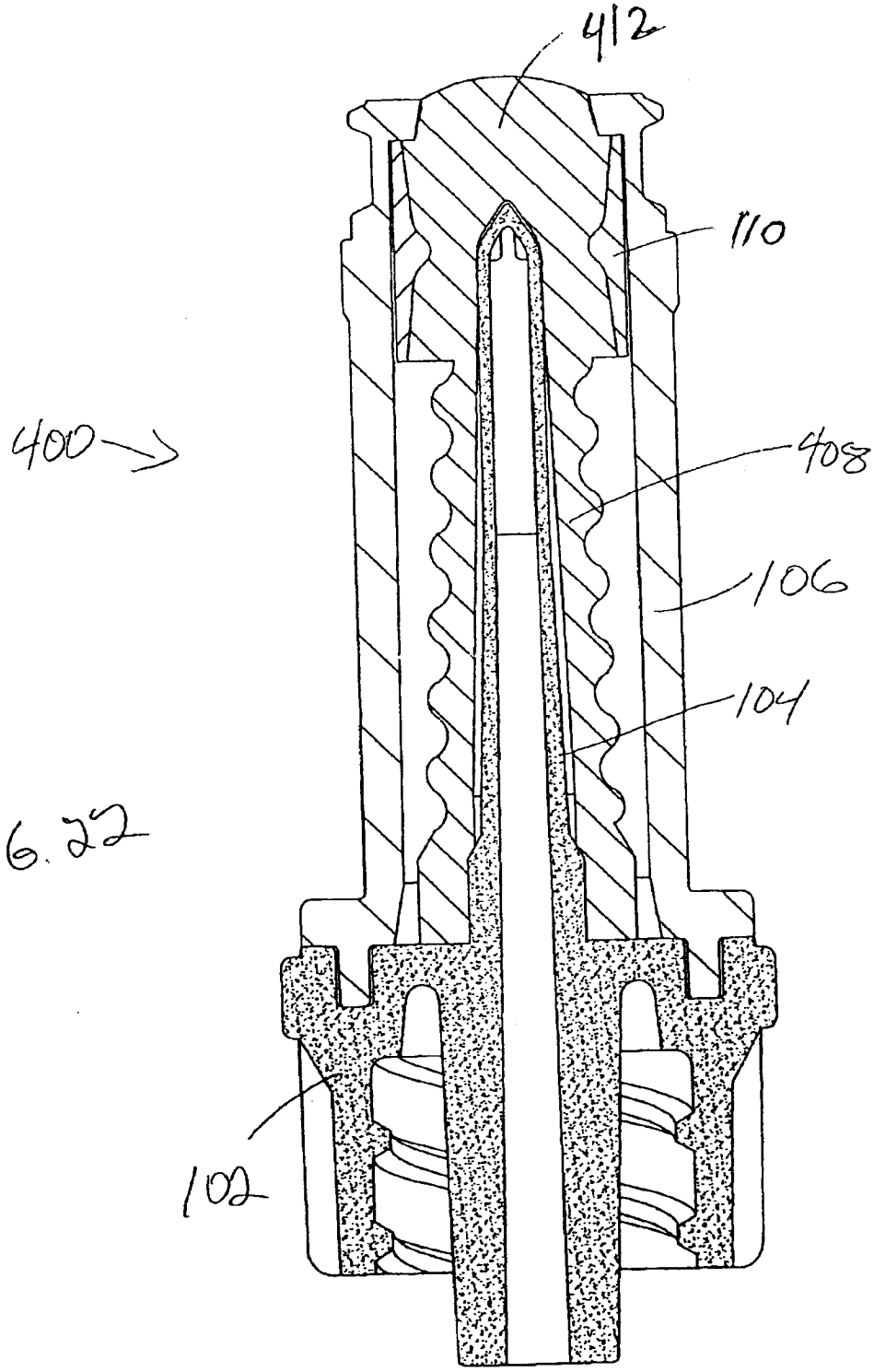


FIG. 22

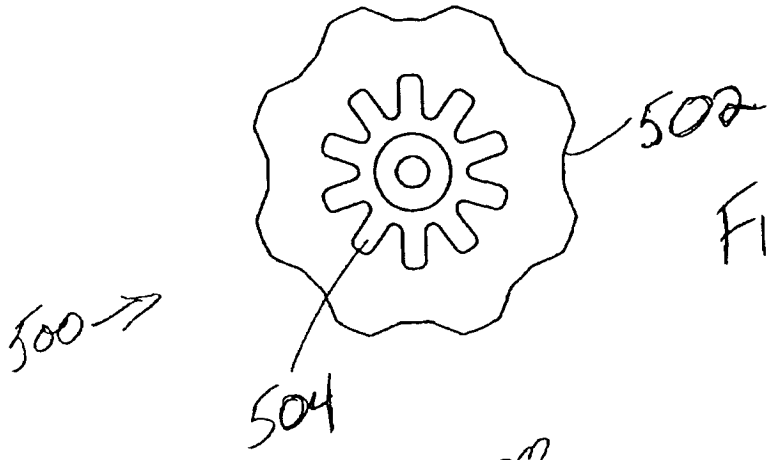


FIG. 24

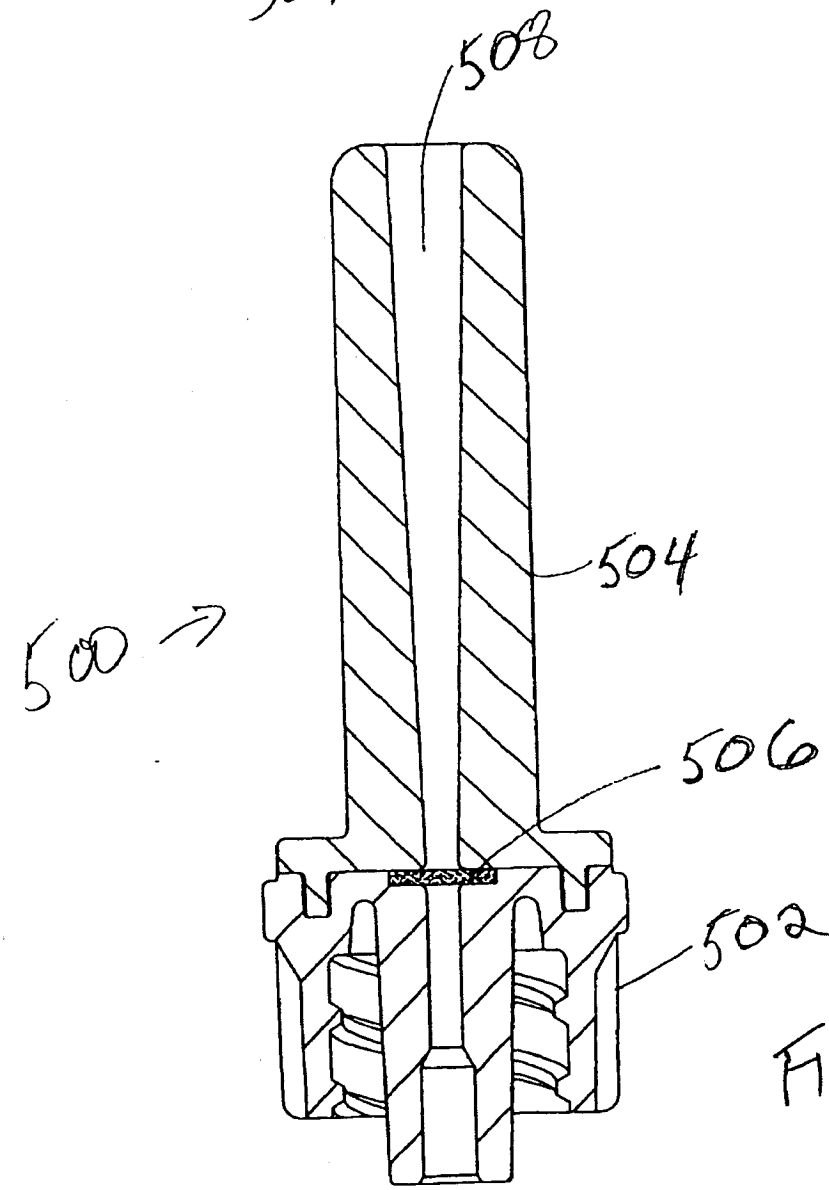


FIG. 23

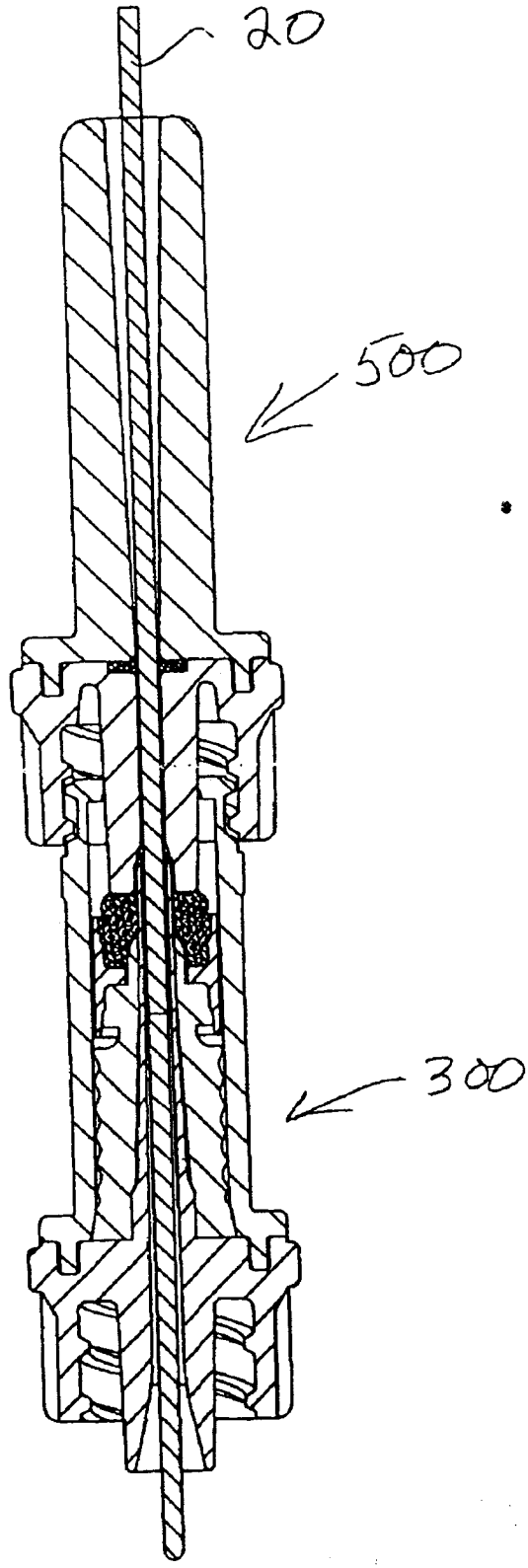


FIG. 25

SWABBABLE NEEDLE-FREE INJECTION PORT VALVE SYSTEM WITH NEUTRAL FLUID DISPLACEMENT

This application is related to U.S. Pat. No. 6,113,068, the complete disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to medical intravenous administration line connectors. More particularly, this invention relates to needle-free intermittent injection ports for the safe infusion and/or aspiration of fluids in intravenous and blood administration therapy.

2. State of the Art

Intravenous fluid therapy for parenteral administration or blood sampling in healthcare facilities routinely uses intermittent injection port connectors. These connectors or adapters are connected to a vascular access device such as a peripheral intravenous catheter, peripherally inserted central venous catheter, jugular, subclavian, and femoral central venous catheter, Huber needle, short-term needle, catheter and intravenous extension set, or intravenous administration set. The intermittent injection port connector allows the infusion therapist a means to infuse fluids or aspirate the patient's blood through the connector without having to stick the patient with a needle each time.

Traditionally, healthcare providers worldwide have used an intermittent injection port connector utilizing a latex septum or barrier requiring a hollow steel needle attached to a syringe or intravenous line set to pierce the resilient latex septum opening up a fluid channel to the patient. Since the discovery in the mid-1980's of the virus that causes AIDS, and the possibility of this virus being transmitted to the healthcare provider via an accidental needlestick injury, a major change within the medical device industry has taken place. Although hepatitis B and C are still the leading concern among healthcare professionals via an accidental needlestick injury, the emotional concern of the possibility of contracting AIDS through contaminated needles has been the catalyst for change in the industry.

Since the mid 1980's, various design innovations have solved the accidental needlestick injury crisis among healthcare professionals. Now that healthcare professionals are comfortable that they are protected from accidental needlestick injuries when they use these types of safety injection port systems, they are beginning to focus on the patient safety aspects of these products. It is clear that a new generation of intermittent injection port designs is needed to improve and resolve concerns such as microbial ingress, negative fluid displacement retrograding blood up into the catheter lumen, and other critical functional features.

Co-owned U.S. Pat. No. 6,113,068 focuses on improving upon the critical microbial barrier performance and functional attributes important for overall patient safety. After manufacture, it effectively provides a single piece injection port with standard male-luer connectors, i.e. universal access. No extra adapters, components, or end caps are required, thereby reducing the overall cost to deploy the system throughout the healthcare facility. The upper septum is swabbable and easy to disinfect. There are no gaps between the septum and the outer body opening. This prevents gross particulate contamination from entering into the internal body of the valve, thereby minimizing downstream contamination. The injection port cannot be used

with non-safety hollow bore needles, thereby complying with OSHA guidelines and mandates. The double microbial barrier design is an effective barrier to pathogen ingress. The combination of the double resilient barriers (the upper resilient septum and the lower resilient boot valve) and their association with the hollow bore spike and centering component significantly reduce the negative fluid displacement to a negligible 0.0035 mL. The plastic centering component captures both barriers allowing the double barriers to move freely along the inner wall of the outer body and to keep the slits axially aligned with the spike tip and shaft. The straight-through fluid path eliminates the torturous paths found in some prior art devices. Priming volume is reduced to only 0.034 mL of fluid which is one of the smallest volumes for swabbable injection port connectors. Activation force to fully access the valve is approximately 5.5 lbs, an acceptable amount for the clinician while providing excellent snap-back. In the device described in my prior patent, fluid flow at gravity averaged 7,500 mL per hour thereby exceeding the ISO standard of 6,000 mL per hour with the fluid source at one meter above the valve. In the manufacturing process, after assembly of all the components and the sonic-welding of the two outer bodies, an ISO male luer fixture could be used to initially pre-puncture the two silicone barriers. As the male luer fixture is attached to the injection port assembly, the internal spike punctures the two silicone barriers and distributes the liquid silicone lubricant along the puncture axes in the two barriers.

Although the invention which is described in U.S. Pat. No. 6,133,068 improved upon many of the desired patient safety attributes for a swabbable injection port connector system, the prior design may be improved.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide a needle-free medical valve injection port which is safe, efficacious, and easy to use.

It is also an object of the invention to provide an injection port valve system which is swabbable and provides an excellent microbial ingress barrier protection.

It is another object of the invention to provide an injection port valve system which has a neutral fluid displacement to minimize blood being refluxed or retrograded into a vascular access device lumen during both the "connection to" and "disconnection from" the medical valve.

It is a further object of the invention to provide an injection port valve system which has improved snap-back characteristics in repeated use over the life cycle of the product to minimize fluid leakage and/or microbial ingress.

Another object of the invention is to provide an injection port valve system which minimizes dead space within the fluid pathway thereby reducing the probability of downstream contamination and improving the flushing capabilities of the medical valve.

A further objective of the invention is to provide an injection port valve system which has excellent leak resistant characteristics of repeated use during its life cycle.

An additional object of the invention is to provide an injection port valve system which improves the lubrication of the spike shaft, spike tip, and the puncture axis geometry to minimize coring of the two resilient microbial barriers during repeated use.

Yet another object of the invention is to provide an injection port valve system which has improved high back-pressure leak resistant capabilities.

It is even a further object of the invention to provide an injection port valve system which is easy to use and activate by reducing the overall activation force required.

In accord with these objects, which will be discussed in detail below, an injection port valve system according to the invention has five total components: an upper plastic outer body with ISO compliant threads ("the female luer body"), a lower plastic outer body with an integrally formed unitary hollow spike and an ISO compliant male luer lock in fluid communication with the spike ("the spike body"), an upper resilient barrier ("the septum"), a plastic centering and barrier cage ("the H-guide"), and a lower resilient barrier ("the boot valve").

The septum and the boot valve are designed to minimize fluid leakage from the patient side of the valve at high pressure (e.g. when the IV tubing is kinked or clogged) and to prevent microbial ingress from the outside environment into the patient's bloodstream. The septum and the boot valve are joined at the H-guide. The valve also includes a hollow spike having an open tip. The spike preferably has a bullet-nose bridge structure with at least two fluid opening channels or an unobstructed opening. The boot valve completely covers the spike giving the valve the first barrier of defense against fluid leakage to the outside environment and the second barrier of defense against microbial ingress from the outside environment into the patient's bloodstream. The septum provides the first barrier of defense against microbial ingress from the outside environment into the patient's bloodstream, and the second barrier of defense against fluid leakage to the outside environment. There is no dead space between the septum and the boot valve. There is also no dead space between the spike tip bridge and the inner wall of the boot valve. According to one embodiment, there is an internal ring seal protruding from the inner wall of the boot valve positioned just below the spike tip opening that has an interference fit with the spike shaft to prevent fluid blow-by down the outer surface of the spike. There is preferably an interference fit between the septum and the boot valve, as well as an interference fit between the H-guide and the two resilient barriers. The boot valve is sufficiently resilient to move the two resilient barriers and the H-guide immediately back to the original decompressed state upon the removal of a male luer connector from the female luer. The septum is preferably provided with an outer shoulder or flange, a tapered end facing the boot valve, a matching contour mating surface for mating with the boot valve, and a single continuous swabbable surface facing away from the boot valve and exposing the septum surface to the outside. The boot valve is preferably provided with a spring-like "helical" external surface. The septum and the boot valve are preferably pre-punctured with a solid core needle having a diameter of approximately 0.072 inches which is lubricated with a fluorosilicone liquid formulation. The surface of the spike is preferably roughened and coated with a fluorosilicone lubricant.

The medical valve of this invention has many features; no single one is solely responsible for its improved microbial and functional attributes. The system achieves a neutral fluid displacement and an improved microbial ingress barrier. There is no retrograde of the patient's blood up into vascular access devices such as a central venous catheter either during the "connection to" or the "disconnection from" the female luer.

Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING

FIG. **1** is an exploded perspective view of a first embodiment of the invention;

FIG. **2** is a longitudinal cross-sectional view of the assembled components of FIG. **1**;

FIG. **3** is a perspective view of a first embodiment of a boot valve according to the invention;

FIG. **4** is a broken longitudinal cross-sectional view of the assembled components of FIG. **2** and a standard male luer syringe positioned to activate the valve;

FIG. **5** is a view similar to FIG. **4** showing the valve activated by the standard male luer syringe;

FIG. **6** is a view similar to FIG. **2** showing the assembled components in conjunction with a multiple-dose drug vial adapter;

FIG. **7** is a longitudinal cross-sectional view of a Y-injection port according to the invention;

FIG. **8** is a view similar to FIG. **2** illustrating an alternate spike body;

FIG. **9** is an enlarged side elevational view of a septum according to the invention;

FIG. **10** is a section taken along line **10**—**10** in FIG. **9**;

FIG. **11** is an enlarged side elevational view of an H-guide according to the invention;

FIG. **12** is a top view of the H-guide of FIG. **11**;

FIG. **13** is a section taken along line **13**—**13** in FIG. **11**.

FIG. **14** is a side elevational view of a second embodiment of a boot valve according to the invention;

FIG. **15** is a section taken along line **15**—**15** in FIG. **14**;

FIG. **16** is an enlarged side elevational view of a female luer body according to the invention;

FIG. **17** is a section taken along line **17**—**17** in FIG. **16**;

FIG. **18** is a side elevational view of a spike body according to the invention;

FIG. **19** is a top plan view of the spike body of FIG. **18**;

FIG. **20** is a bottom plan view of the spike body of FIG. **18**;

FIG. **21** is an enlarged section taken along line **21**—**21** in FIG. **18**;

FIG. **22** is a view similar to FIG. **2** illustrating a single piece combination septum and boot valve;

FIG. **23** is a longitudinal sectional view of a guide wire adapter for use with the injection port system of the invention;

FIG. **24** is a top plan view of the guide wire adapter of FIG. **23**; and

FIG. **25** is a longitudinal sectional view of the guide wire adapter of FIG. **23** coupled to an injection port system of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to FIGS. **1**–**3**, a first embodiment of a needle-free intravenous injection port assembly **100** according to the invention generally includes a spike body **102** provided with a hollow spike **104**, a female luer connector component **106** (preferably a luer lock), a flexible and resilient boot valve **108**, an H-guide centering member **110**, and a resilient septum **112**. As seen best in FIG. **2**, the boot valve **108** extends over the spike **104**, the H-guide **110** is provided over a portion of the boot valve **108**, and the septum **112** is provided between the H-guide **110** and an end of the female luer connector component **106**. The spike body **102** and the female luer connector **106** are preferably made from a hard plastic material such as polycarbonate. The

H-guide **110** is preferably made from a soft plastic such as high density polyethylene. The boot valve **108** and the septum **112** are preferably made from a rubber-like material, such as polyisoprene or silicone rubber, having an approximately 60 Shore A Durometer.

According to the illustrated embodiment and as shown in larger view in FIG. **3**, the boot valve **108** is preferably configured with a helical external surface **108***a* and a radially enlarged portion **108***b*. The septum **112** is preferably provided with a shoulder **112***a*, a tapered end **112***b* facing the boot valve, and a single continuous swabbable surface **112***c* facing away from the boot valve as described in more detail below with reference to FIGS. **9** and **10**. The septum and the boot valve are preferably pre-punctured with a solid core steel needle approximately 0.072" diameter by aligning the septum and the boot valve in the H-guide in a subassembly and puncturing the septum and the boot valve in a pre-assembly manufacturing process as described below. The H-guide **110** is preferably provided with a tapered internal surface **110***a*, **100***b* at both ends and its outer surface **110***c* is polished very smooth as described in more detail below with reference to FIGS. **11–13**. The surface of the spike **104** is preferably roughened and is coated with a fluorosilicone lubricant. The roughened finish may be achieved by several methods including, but not limited to, EDM, sandblasting, media blasting, chemical etching, mechanical means, etc. The roughened finish helps to "entrap" the lubricant. The radially enlarged portion **108***b* of the boot valve **108** is preferably tapered to match the taper of the H-guide **110**. The boot valve **108** and the septum **112** are preferably mated with mechanical interference.

Turning now to FIGS. **4** and **5**, a needle-free syringe **10** has a male luer tip **10***a* which is matable with the female luer **106** of the invention. The male luer tip **10***a* is pressed against the swabbable surface **112***a* of the septum **112** and pushed down in the direction of the arrows shown in FIG. **4**. As the male luer **10***a* is moved into the female luer **106**, the septum **112** and the boot valve **108** are moved over the spike **104** as shown in FIG. **5**. This opens a fluid path between the interior of the luer **10***a* and the interior of the spike **104** due to holes in the top of the spike as discussed below with reference to FIGS. **18–21**.

FIG. **6** illustrates how the invention can be used with a multiple dose drug vial adapter **12**. The drug vial adapter **12** has a female luer **12***a* at one end and a hollow spike **12***b* at the other end. The male luer **102** of the injection port system **100** engages the female luer **12***a* of the drug vial adapter and the spike **12***b* of the vial adapter pierces the septum of a drug vial (not shown).

FIG. **7** illustrates a Y-site **200** incorporating an injection port according to the invention. The Y-site **200** has a Y-site base **202** which includes a spike **204** which is the same or similar to the spike **104** described above. The remaining components are the same as described above. Those skilled in the art will appreciate that the Y-site is useful when incorporated into an intravenous extension or administration set to allow injections via the same intravenous line through the injection port.

FIG. **8** illustrates an alternate embodiment of an injection port **300**. The injection port **300** has a spike body **302** with a spike **304** which does not have a point. It has, instead, an open tip **304***a*. The remainder of the components are the same as described above. This embodiment allows for the passage of guide-wires and other implements through the valve as described below with reference to FIGS. **23–25**.

FIGS. **9** and **10** illustrate enlarged views of the septum **112**. The septum **112** has an upper frustrum **112***d* and a lower frustrum **112***b* of larger diameter defining a shoulder **112***a*. The upper end of the upper frustrum **112***d* is a continuous convex surface **112***c*. The lower frustrum **112***b* defines a concavity **112***e* which is dimensioned to fit the tip of the boot valve with mechanical interference.

The upper resilient septum **112** provides the first line of defense against pathogen ingress into the fluid pathway from outside the injection port, and the second line of defense against fluid leakage due to high back pressure from inside the injection port. The septum is held in the "H-Guide" **110** as shown in FIG. **2** with a dimensional interference causing a circumferential mechanical force to assist in resealing the pre-puncture (not shown) in the center of the septum during numerous activations. The outer shoulder or flange **112***a* has a larger diameter than the opening of the female luer component **106** and the upper frustrum **112***d* preferably makes an interference fit with the female luer opening as seen in FIG. **2**.

As previously mentioned, the septum is preferably pre-punctured prior to assembly of injection port with a lubricated piercing device. The pre-puncturing process is performed with the septum, H-guide, and boot valve sub-assembly and a piercing device which moves through the two independent and adjacent resilient barriers until the piercing device is totally through the sub-assembly. The piercing device, preferably a 0.072 inch diameter solid core stainless steel needle (but other appropriate piercing devices would be acceptable), pre-punctures both the boot valve and septum in a smooth, in-line, axis geometry. This new smooth, in-line, axis geometry coupled with the fluorosilicone lubricant has reduced the required activation force to approximately 3.8 lbs, making it easier to use. This manufacturing process modification eliminates the jagged cuts, tears, and coring that was observed in the original process utilizing the internal spike tip. The piercing device is lubricated preferably with a fluorosilicone lubricant which assists in a smooth pre-puncture-axis geometry. The fluorosilicone formulation also minimizes the "cross-linking" of the silicone molecular structure. It is understood that other FDA approved lubricants could be acceptable for this application. In addition, in order to improve the decompression "snap-back" characteristics of this new injection port, and to minimize frictional abrasions within the silicone septum and boot valve during the compression or activation phase when the septum and boot valve move down over the internal spike tip and shaft, an inert lubricant is molded within the silicone septum and boot valve formulations. Silicone is the preferable material in this injection port due to its inertness, abrasive resistance, sealing and internal memory characteristics, and its sterilization capability. It is understood that other inert resilient materials could be used for this application.

Turning now to FIGS. **11–13**, the H-guide centering member **110** includes a generally tubular outer portion **110***c* and an annular inner portion defining a hole **110***d*. The outer portion **110***c* is sized to stably axially slide within the central portion of the female luer component **106** as shown in FIG. **2**. The outer portion **110***c* and inner portion together define first and second substantially identical receiving areas **110***a*, **110***b*. These areas have an outer tapered portion and an inner non-tapered smaller diameter portion. This assists in mating with the boot valve and the septum. The receiving areas **110***a*, **110***b* are preferably provided with annular rings **110***e*, **110***f* which assist in sealing the interface s between the septum and the boot valve.

FIGS. **14** and **15** illustrate a second alternate embodiment of a boot valve. There are two differences between this

embodiment and those described above. One is that undulations **208***a* are not helical but consist of a plurality of non-tapering rings arranged along the axis of the boot valve **208**. The other is the presence of an interior sealing ring **208***d*. Although this boot valve may not perform as well as the boot valve **108** in terms of snap back, it does retain the advantages of the frustrum **208***b*, the dimensions of the tip **208***c*, and the sealing ring **208***d* which helps seal the space between the boot valve and the spike shaft.

FIGS. **16** and **17** illustrate enlarged views of the female luer component **106**. The female luer connector component **106** is tubular and includes a first open end **106***a*, a female luer second end **106***b*, and a central portion **106***c* therebetween. The first end **106***a* includes a flange **106***d* which is preferably provided with an annular mating ridge **106***e*. The ridge defines an enlarged diameter relative to the central portion **106***c*, and is provided on the flange **106***d* directed away from the second end **106***b*. The mating ridge **106***e* is sized and shaped to be received in the annular mating slot of the spike body **102** (described below with reference to FIGS. **19** and **21**). The second end **106***b* includes an opening having a reduced (relative to the rest of the component **106**) with a tapered portion **106***f* and a non-tapered portion **106***g*. The tapered and non-tapered portions provide a better sealing fit with the septum **112** as shown in FIG. **2**. A luer lock thread **106***h* is preferably provided about the second end **106***b*.

The internal wall **106***j* of the component **106** is preferably smooth and slightly tapered up to a perpendicular wall **106***k*, leading to an opening approximately 0.180 inch diameter which preferably tapers to approximately a 0.164 inch diameter in the second end **106***b* of the female luer body component. The internal wall is preferably smooth to allow the H-guide component to axially move without obstruction during the compression and decompression phases. It is understood, that a fluted internal wall structure could also be acceptable.

FIGS. **18** through **21** illustrate the spike body **102** in greater detail. The spike body includes a first end **102***a* having a male luer connector **102***b*, the spike **104** preferably integrally formed with the body **102** and coaxially directed opposite the male luer connector **102***b*, and a base **102***c* at the juncture of the male luer connector **102***b* and the spike **104**. A fluid path **105** is provided through the spike **104** and male luer connector **102***b*. The spike **104** has a tapered shaft **107** leading to a bullet-nose arched tip **109** which defines a second end of the spike body **102**. The tip **109** includes a plurality of slots (e.g., three slots) **104***a* which provide access into the hollow **105** of the spike **104** from outside the spike. The shaft **107** includes a base portion **107***a* which has an enlarged stepped diameter for holding the boot valve thereabout. The base **102***c* of the spike body **102** also includes an annular groove **102***d* which receives the mating ridge **106***e* of the female luer component **106**. The base **102***c* preferably also includes a plurality of internal threads **102***e* which together with the male luer connector **102***b* function as a male luer lock. In addition, the periphery of the base **102***c* includes a plurality of molded longitudinal ridges **102***f* to facilitate engagement of the periphery of the spike body by human fingers.

As mentioned above, a preferred embodiment of the integral spike shaft and spike tip used in the present invention is configured with a roughened finish external surface and a fluorosilicone liquid lubricate used along the shaft and tip. The roughened finished external surface creates a roughened surface with approximately 0.001 to 0.002 inch depth areas allowing for a circumfluent flow of the liquid lubricant along the spike shaft and spike tip. The previously incorporated co-owned invention had a very smooth external spike shaft surface with a Dow **360** silicone lubricant. This smooth surface caused on occasion a "suction" affect between the internal wall surface of the boot valve component and the spike shaft. The roughened finish allows the lubricant to flow into the 0.001–0.002 inch impressions on the spike shaft, eliminating the "suction" effect seen in the prior invention, and maintaining adequate lubrication between the internal wall of the boot valve and spike shaft during numerous compression and decompression cycles of the valve. This surface improvement also enhances the "snap-back" feature of the valve.

From the foregoing, it will be appreciated that the female luer **106**, the septum **112**, the H-guide **110**, the boot valve **108**, and the spike **104** interact as described below to obtain numerous advantages. The septum **112**, by being properly dimensioned and entrapped within the female luer component when in the decompressed state passes a 60 psi back-pressure test, thus improving the prevention of fluid leakage from the injection port in high pressure situations (e.g. when the IV tubing is kinked or clogged). It also provides a primary seal surface to further prevent gross particulate contamination from entering into the body of the injection port, thus preventing pathogen ingress into the patient's blood stream. The interference fit between the septum and the female luer increases the circumferential mechanical force to improve the resealing of the pre-puncture in the center of the septum in the decompressed state.

The taper of the lower frustrum **112***b* assists in the assembly of the septum in the H-guide **110**. The lower frustrum **112***b* also has a larger diameter than the matching inside wall diameter of the H-guide causing a mechanical interference. This mechanical interference frictionally holds the septum into the H-guide.

The interior cavity **112***e* of the septum has a matching contour to the tip of the boot valve **108**. The diameter of this cavity is smaller than the tip of the boot valve, causing a circumferential mechanical fit against the pre-puncture in the boot valve. This new design eliminates any interstitial cavity chamber or dead space between these two interfaces thus assisting in achieving a "neutral fluid displacement" when the valve is moved from the decompressed state to the compressed state. The interference fit between the septum and the tip of the boot valve also improves the performance of the injection port in the decompressed state in the following ways. There is improved resealing of the pre-puncture in the center of the boot valve, improved prevention of pathogen ingress into the patient's bloodstream through the pre-puncture in the boot valve, and improved prevention of fluid leakage from the patient's side of the injection port due to a high pressure situation (e.g. when the IV tubing is kinked or clogged).

Another design modification that improves the overall performance of this new injection port is the provision of a single continuous swabbable surface on the proximal side of the septum. In addition all of the external surfaces of the septum that come in contact with the H-Guide and the boot valve are smooth to assist in the sealing characteristics between these component interfaces.

The new H-guide centering component assists in the new design enhancements and improvements. The H-guide contains both the upper resilient septum and the lower resilient boot valve. The outer diameters of the septum and the boot valve are larger than the inner wall diameters of the H-guide where they interface, giving a frictional fit between all components. The H-guide centering component is also shaped similar to the lead-in tapers of the septum and the

boot valve for ease of assembly. The dimensional mechanical interference between the septum and the H-guide applies a mechanical pressure against the pre-puncture axis of the two independent and adjacent resilient barriers, thereby improving microbial ingress prevention, improving fluid leakage prevention during high pressure situations (e.g. when the IV tubing is kinked or clogged), and assisting in eliminating the dead space between the septum/boot valve and boot valve/spike tip interfaces to achieve neutral fluid displacement during the compression and decompression cycle. The H-guide also prevents the two resilient barriers from coming in contact with the female luer inner wall, thereby eliminating any frictional abrasion during the compression and decompression cycle of the resilient barriers rubbing against the inner wall of the female luer body element, thereby, improving the "snap-back" capability of the valve. The H-guide also keeps the septum and boot valve in-line puncture axis geometry "centered" over the stationary spike tip and shaft, preventing jagged cuts, tears, or coring of the two resilient barriers. The outer diameter of the H-guide is slightly smaller than the inside diameter of the female luer body, allowing for a smooth axial movement of the valve during compression and decompression cycle. A preferred material for the H-guide is high-density polyethylene due to its lubricity characteristics, but other plastic materials could function in this application.

FIG. **22** illustrates another embodiment of an injection port **400** according to the invention. This embodiment differs from the first embodiment in that the boot valve **408** and the septum **412** are a single piece. All of the other components are the same as the first embodiment.

FIGS. **23** and **24** illustrate a guide wire adapter for use with an injection port according to the invention. The guide wire adapter **500** includes a male luer base **502** and an elongated female luer body **504** coupled to the male luer base with a thin silicone resilient disk **506** therebetween. The disk is preferably pre-punctured in its center. The silicone disk prevents air ingress into the patient's blood stream and prevents blood egress from the device. The female luer body **504** has a tapered inner bore **508** which is coaxial with the bore of the male luer **502**. The exterior of the female luer body **504** is fluted as shown in FIG. **24**. When the guide wire adapter **500** is coupled to an injection port **300** of FIG. **8** as shown in FIG. **25**, a guide wire **20** may be inserted through the adapter into and through the injection port.

There have been described and illustrated herein several embodiments of medical intravenous administration injection ports. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow. Thus, it will be appreciated by those skilled in the art that the term "intravenous fluid" is intended to be understood in a broad sense to include parenteral fluids including drug solutions, blood, blood products, dyes, or other fluids and the term "administration" is used in its broad sense to include the dispensing or collection of the "intravenous fluid". Further, while the injection port is illustrated as preferably having a female luer lock on one end, and a male luer lock on the other end, it will be appreciated that, although not preferred, simple luer slips could be utilized in lieu of luer locks. Furthermore, while a ridge and groove are disclosed for mating the female luer component and spike body together, it will be appreciated that other mating means may be used. For example, a plurality of mating tabs and slots, or ridges and grooves, or the like, may be used. Moreover, while a particular plastic material has been disclosed for the spike body, female luer component, and centering member, it will be appreciated that other rigid materials may likewise be used for these components. Also, in each embodiment the spike may be unitary with or of a separate construction than the body. Furthermore, while particular rubber-like materials have been disclosed for the boot valve and septum, it will be appreciated that other rubber-like materials of different Durometers may also be used. Further yet, while the boot valve and septum are described as preferably being pre-punctured with a solid core needle, it will be appreciated that, if desired, neither the valve nor the septum need be pre-punctured, or only one of them might be pre-punctured. Alternatively, although not preferred, the boot valve and/or septum may be pre-slit; i.e., formed with a horizontal slit therein. Pre-slitting the boot valve and/or septum is not preferred as during use the pre-slit boot and/or septum will not accommodate the spike as well as a pre-punctured boot and/or septum. It will therefore be more prone to tearing, thereby leaving the pre-slit device more prone to undesirable microbial migration. Also, while a boot valve having an outer helical surface and a smooth and tapered inner surface has been shown, it will be appreciated that the boot valve could also have a helical inner or other non-smooth or non-tapered surface. Therefore, it will be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as so claimed.

What is claimed is:

1. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for coupling to a device provided with a second connector so as to provide a fluid connection between the first and second connectors, said injection port assembly comprising:

a first mating structure adapted to mate with the first connector and a second mating structure coupled to said first mating structure and adapted to mate with the second connector,

a resilient barrier located between said first and second mating structures and movable from a first position in which fluid flow between said first mating structure and said second mating structure is blocked to a second position in which fluid flow between said first mating structure and said second mating structure is permitted,

said resilient barrier includes a boot valve and a septum, and

said septum has a lower frustrum and an upper frustrum of different diameter defining a shoulder, said upper frustrum having a continuous convex surface.

2. An injection port assembly according to claim **1**, wherein:

said resilient barrier has a generally helical surface pattern.

3. An injection port assembly according to claim **2**, wherein:

said boot valve and said septum are pierced with a solid core needle prior to assembly of said injection port.

4. An injection port assembly according to claim **3**, wherein:

said needle has a diameter of approximately 0.072 inches.

5. An injection port assembly according to claim **1**, further comprising:

a body incorporating said first and second mating structures.

6. An injection port assembly according to claim **2**, wherein;

said boot valve and said septum are mated with mechanical interference.

7. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for coupling to a device provided with a second connector so as to provide a fluid connection between the first and second connectors, said injection port assembly comprising:

a first mating structure adapted to mate with the first connector and a second mating structure coupled to said first mating structure and adapted to mate with the second connector,

a resilient barrier located between said first and second mating structures and movable from a first position in which fluid flow between said first mating structure and said second mating structure is blocked to a second position in which fluid flow between said first mating structure and said second mating structure is permitted, and

a spike mounted within said resilient barrier, said spike having a roughened surface which is covered with a lubricant.

8. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for coupling to a device provided with a second connector so as to provide a fluid connection between the first and second connectors, said injection port assembly comprising:

a first mating structure adapted to mate with the first connector and a second mating structure coupled to said first mating structure and adapted to mate with the second connector,

a resilient barrier located between said first and second mating structures and movable from a first position in which fluid flow between said first mating structure and said second mating structure is blocked to a second position in which fluid flow between said first mating structure and said second mating structure is permitted, wherein said resilient barrier includes a boot valve and a septum having a lower frustrum, and

a centering means for axially centering said boot valve and said septum, said centering means having a first tapered opening dimensioned to accommodate said lower frustrum and a smooth outer periphery.

9. An injection port assembly according to claim 8, wherein:

said boot valve has a frustroconical extension and said centering means has a second tapered opening dimensioned to accommodate said frustroconical extension.

10. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end;

b) a hollow spike defining a shaft having a first end coupled to said body and a second end provided with a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient barrier extending over said spike and having a tip portion about said tip of said spike, said resilient barrier being pre-punctured with a solid core steel needle prior to assembly; and

d) a hollow component having a first end and a second end, said first end being coupled to said body, said hollow component extending around at least portions of said spike and said resilient barrier, and said second end being provided with a second mating structure adapted to removably couple to the second connector, wherein

when the second connector is coupled to said second mating structure, said second connector forces said tip portion of said pre-punctured resilient barrier over said spike such that said second connector and said first connector are in fluid communication with each other through said hollow spike and said first mating structure.

11. An injection port assembly according to claim 10, wherein:

said needle has a diameter of approximately 0.072 inches, and said spike has a roughened surface which is covered with a lubricant.

12. An injection port assembly according to claim 10, wherein:

said resilient barrier includes a boot valve and a septum mated with mechanical interference.

13. An injection port assembly according to claim 12, wherein:

said septum has a lower frustrum and an upper frustrum of different diameter defining a shoulder, said upper frustrum having a continuous convex surface.

14. An injection port assembly according to claim 13, further comprising:

e) a centering means for axially centering said boot valve and said septum relative to said spike, said centering means having a first tapered opening dimensioned to accommodate said lower frustrum.

15. An injection port assembly according to claim 14, wherein:

said boot valve has a frustroconical extension and said centering means has a second tapered opening dimensioned to accommodate said frustroconical extension.

16. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end provided with a second mating structure adapted to removably couple to the second connector;

b) a hollow spike coupled to and at least partially surrounded by said body, said hollow spike having a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient first barrier extending over said spike and having a tip portion about said tip of said spike; and

d) a resilient second barrier provided over and contacting said tip portion of said first barrier, said first and second barriers being mated with mechanical interference, wherein

when the second connector is coupled to said second mating structure, said second connector forces said second resilient barrier and said tip portion of said first resilient barrier over said spike with neutral fluid displacement and such that said second connector and said first connector are in fluid communication with each other through said hollow spike and said first mating structure.

17. An injection port assembly according to claim 16, wherein:

said resilient second barrier has a lower frustrum and an upper frustrum of different diameter defining a shoulder, said upper frustrum having a continuous convex surface.

18. An injection port assembly according to claim 16, further comprising:

e) a centering means for axially centering said first barrier and said second barrier relative to said spike, wherein said resilient second barrier has a lower frustrum and said centering means has a first tapered opening dimensioned to accommodate said lower frustrum.

19. An injection port assembly according to claim 18, wherein:

said resilient first barrier has a frustroconical extension and said centering means has a second tapered opening dimensioned to accommodate said frustroconical extension.

20. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end provided with a second mating structure adapted to removably couple to the second connector;

b) a hollow spike coupled to and at least partially surrounded by said body, said hollow spike having a shaft having a roughened outer surface and coated with a lubricant and a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other; and

c) a resilient barrier extending over said spike and having a tip portion about said tip of said spike;

when the second connector is coupled to said second mating structure, said second connector forces said tip portion of said resilient barrier over said spike such that said second connector and said first connector are in fluid communication with each other through said hollow spike and said first mating structure.

21. An injection port assembly according to claim 20, wherein:

said lubricant is a fluorosilicone.

22. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end provided with a second mating structure adapted to removably couple to the second connector;

b) a hollow spike coupled to and at least partially surrounded by said body, said hollow spike having a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient first barrier extending over said spike and having a tip portion about said tip of said spike; and

d) a resilient second barrier provided over and contacting said tip portion of said first barrier, said second barrier having a lower frustrum and an upper frustrum of different diameter defining a shoulder, said upper frustrum having a single continuous swabbable surface, wherein

when the second connector is coupled to said second mating structure, said second connector forces said second resilient barrier and said tip portion of said first resilient barrier over said spike such that said second connector and said first connector are in fluid communication with each other through said hollow spike and said first mating structure.

23. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end;

b) a hollow spike defining a shaft having a first end coupled to said body and a second end provided with a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient barrier extending over said spike, wherein when the second connector is coupled to said second mating structure, the second connector forces said resilient barrier over said spike with neutral fluid displacement and such that the second connector and the first connector are in fluid communication with each other through said hollow spike and said first mating structure.

24. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end;

b) a hollow spike defining a shaft having a first end coupled to said body and a second end provided with a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient first barrier extending over said spike and having a tip portion about said tip of said spike;

d) a resilient second barrier provided over and contacting said tip portion of said first barrier, wherein

there is no dead space between said first barrier and said second barrier and no dead space between the tip portion of the first barrier and the tip of the spike.

25. An injection port assembly according to claim 24, further comprising:

e) a multiple dose drug vial adapter coupled to said first end of said hollow spike.

26. An injection port assembly according to claim 24, further comprising:

e) a y-site adapter coupled to said first end of said hollow spike.

27. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end;

b) a hollow spike defining a shaft having a first end coupled to said body and a second end provided with a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient barrier extending over said spike, wherein said penetrating tip is truncated with an open tip; and

a guide wire adapter including

a male luer adapted to be coupled to said first end of said body;

an elongated member having a tapered throughbore, said elongated member being coupled to said male luer; and

a pierceable fluid barrier mounted between said male luer and said elongated member.

28. A method for coupling and uncoupling a device to a fluid pathway, said method comprising:

coupling an injection port assembly having a valve to the fluid pathway,

coupling the device to the injection port assembly such that the valve is opened putting the device is in fluid communication with the fluid pathway with neutral fluid displacement during coupling.

29. The method according to claim **28**, further comprising:

uncoupling the device from the injection port assembly such that the device is no longer in fluid communication with the fluid pathway with neutral fluid displacement during uncoupling.

30. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for coupling to a device provided with a second connector so as to provide a fluid connection between the first and second connectors, said injection port assembly comprising:

a first mating structure adapted to mate with the first connector and a second mating structure coupled to said first mating structure and adapted to mate with the second connector,

a resilient barrier located between said first and second mating structures and movable from a first position in which fluid flow between said first mating structure and said second mating structure is blocked to a second position in which fluid flow between said first mating structure and said second mating structure is permitted, said resilient barrier being an integrally formed boot valve and septum, said septum having a pierceable portion which is substantially thicker than said boot valve and when said barrier is moved from said first position to said second position all of said septum is moved.

* * * * *

ABOUT US

MISSION

To provide excellence in delivering health care products and solutions, both proactive and preventative, with a focus on increased patient health and safety.

COMPANY OVERVIEW

RyMed Technologies, Inc., founded in 1994, specializes in the development and marketing of innovative safety products in the field of intravenous catheter care management.

With patented technology, RyMed has set a new industry standard with its **InVision-Plus® Neutral® I.V. Connector System** designed to reduce the possibility of Intraluminal Thrombotic Catheter Occlusions as well as reduce the possibility of Intraluminal Catheter-related Bloodstream Infections. The **InVision-Plus® Neutral®** is the first neutral movement injection port developed in the medical field.

The **InVision-Plus® Neutral®** has widespread applications in virtually all hospitals, care centers, in-home services and doctor offices where I.V. catheter therapies are implemented. The products' universal fit properties and ease of operation provide institutions and individual users with maximum opportunity to employ the **InVision-Plus® Neutral® Connector System.**

PRINCIPALS

Dana Wm. Ryan is a Director and Chairman of the Board of Directors of the Company. Mr. Ryan also holds the positions of President and Chief Executive Officer. Mr. Ryan has 33 years of experience in the disposable I.V. and O.R. medical device industry with Johnson & Johnson, Deseret Medical, Ryan Medical, Symbiosis and RyMed Technologies Inc. He is recognized as being one of the pioneers in "safety-oriented" medical product design, with over 35 patents to date worldwide to his credit.

James M. Kaiser is a Director of the Company and holds the position of Vice-President of Operations. Mr. Kaiser brings to RyMed over 33 years experience in the high volume, disposable medical devices in the areas of manufacturing, regulatory affairs, quality control & assurance, and sterilization; Cutter Labs, Deseret Medical, HealthTech, Ryan Medical, Isomedix (Steris) and RyMed Technologies, Inc.

RyMed TECHNOLOGIES, INC

EXHIBIT 15

InVision-Plus® Neutral™ I.V. Connector System

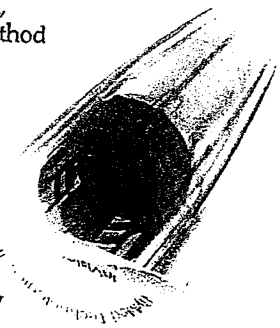
Improved Aseptic Technique Package Delivery

The patented **Touch-Free℠ Package Container** minimizes potential contamination of the catheter hub or vascular access device during the replacement of the **InVision-Plus® Neutral™**.

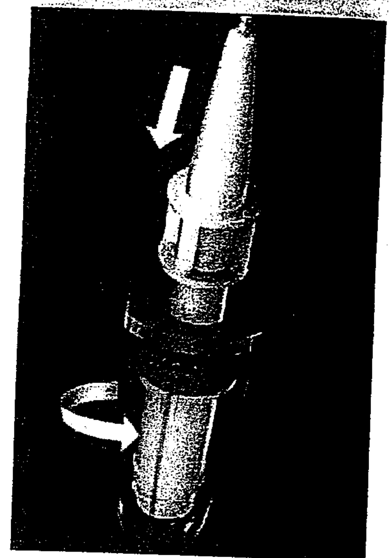
When the **InVision-Plus® Neutral™ I.V. Connector** is to be replaced, RyMed Technologies offers the healthcare provider an improved method of attaching a new sterile replacement valve to each catheter hub or access port.

Simply peel back lid on the Package Container. Without touching the male-luer tip of the **InVision-Plus® Neutral™**, attach it to the desired vascular access device female-luer hub by twisting the Package Container in a clockwise direction until secure.

The **InVision-Plus® Neutral™ I.V. Connector** is packaged in this new **Touch-Free℠ System** and peel pouch for sterile field procedures.



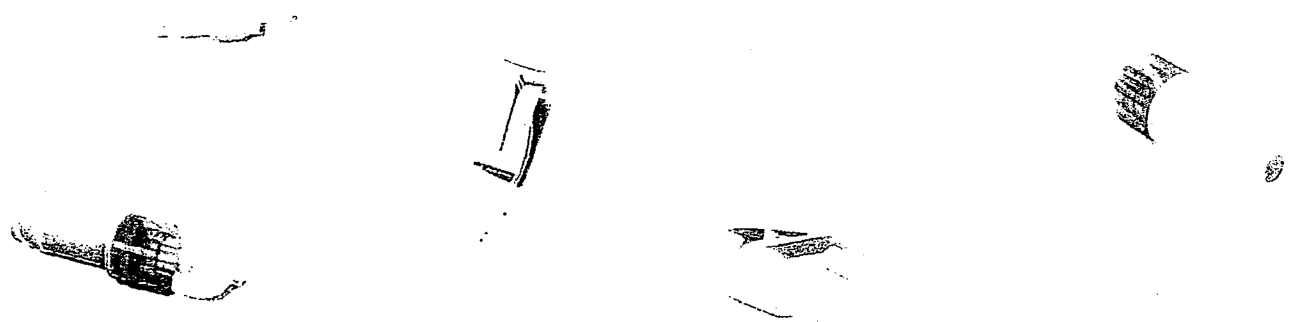
5 Year Shelf Life



The **Touch-Free℠ Package** ensures a sterile connection when attaching the **InVision-Plus® Neutral™ I.V. Connector** to a catheter hub or access device.

InVision-Plus® Neutral™ Catheter Extension Sets

The **InVision-Plus® Neutral™ I.V. Connector System** is available in various catheter and I.V. extension sets to meet your every need improved total catheter management. The sets are made from clear, soft, kink-resistant NON-DEHP PVC microbore and standard size tubing. Either removable slide clamps or pinch clamps are available with rotating male-luer-lock connectors for security and ease of attachment to your vascular access device hub.



CAUTIONS
- Do not use any needles with InVision-Plus® Neutral™;
- Do not put a cap, plug, or obturator of any sort on the InVision-Plus® Neutral™;

It is recommended that the InVision-Plus® Neutral™ I.V. Connector be changed per CDC Guidelines or per validated facility protocol.

Flush InVision-Plus® Neutral™ after each use per institutional protocol using normal saline, or normal saline and heparin.

Federal (USA) law restricts this device to sale by or on the order of a physician.

RyMed Technologies, Inc., CORPORATE HEADQUARTERS, Franklin, Tennessee 37064
Customer Service: (512) 301-1949

Patents #6,113,068 #6,299,131 #6,994,315 and other U.S. and foreign patents pending
InVision-Plus® is a registered trademark of RyMed Technologies, Inc.
Neutral™ is a trademark of RyMed Technologies, Inc.

EXHIBIT

RyMed TECHNOLOGIES, INC.
DESIGNED WITH PATIENT SAFETY IN MIND

www.RyMedTech.com

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InVision-Plus® EPI™

with Neutral Advantage™ Technology

The **InVision-Plus® EPI™** with **Neutral Advantage™ Technology** is the only intraluminal protection system specifically designed to to address morbidity and mortality association with medication delivery errors through epidural catheters. While other products may claim to be intended for use for this delivery, the **EPI™** is the only one which offers the 10 – Point Standard, along with an ultra-low priming volume of 0.022 mL.

10-Point Standard Comparison Chart

10-Point Standard	InVision-Plus®	Brand X
1.	✓	
2.	✓	
3.	✓	
4. Straight-through fluid pathway	✓	
5. Zero dead space	✓	
6. Zero fluid displacement	✓	
7. Low priming volume	✓	
8.	✓	
9.	✓	
10.	✓	

InVision-Plus® EPI™

The **Neutral Advantage™** (*adj*) **1.** Having ten system features designed to work in conjunction with one another to maximize *intraluminal fluid pathway protection*. **2.** RyMed's **InVision-Plus®** Intraluminal Protection System technology.

RyMed's **Neutral Advantage™** Technology sets the new 10-Point Standard for intraluminal fluid pathway protection with a revolutionary combination of ten propriatary and superior design features specifically designed for both patient protection and improved patient outcomes - CR-BSI prevention and intraluminal thrombotic occlusion reduction.

Why ten? It takes the combination of all ten features to deliver what no other product can. The 10-Point Standard features have a sequential and cumulative effect, and are dependent upon one another in providing the real and effective intraluminal catheter protection of **Neutral Advantage™** Technology.

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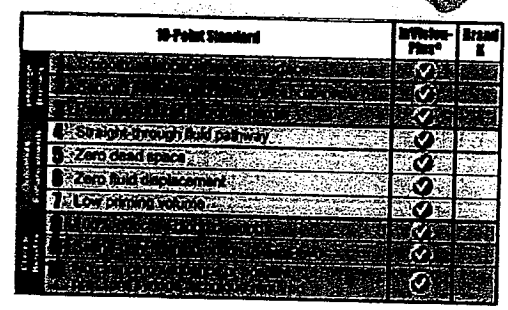
InVision-Plus® RED™ with Neutral Advantage™ Technology



The **InVision-Plus® RED™** with **Neutral Advantage™** Technology was created to address the Joint Commission Sentinel Event, Issue 36, April 3, 2006 "tubing misconnections," and for clinicians who desire an alternately colored needlefree connector for visual identification. The **InVision-Plus® RED™** carries RyMed's **10-Point Standard** and offers the same catheter care and maintenance, and patient fluid pathway protection benefits that all **InVision-Plus®** products do.

Easy Swabbing & Flushing

Independent studies performed by Nelson Laboratories, Inc. have shown that the **InVision-Plus® RED™** can be effectively swabbed with either 3 to 5 back and forth motions or 3 to 5 clockwise and counter-clockwise rotations, and the fluid pathway is **100% cleared** of blood with only four 1 mL flushes of 0.9% normal saline.

InVision-Plus® RED™

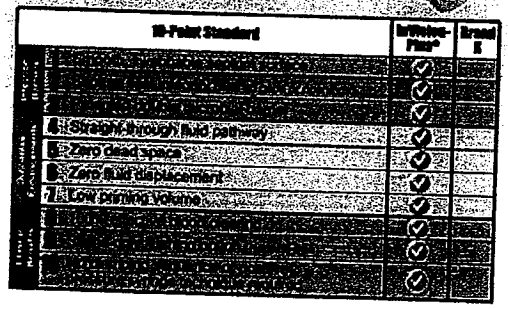
The **Neutral Advantage™** (*adj*) **1.** Having ten system features designed to work in conjunction with one another to maximize *intraluminal fluid pathway protection*. **2.** RyMed's **InVision-Plus®** Intraluminal Protection System technology.

RyMed's **Neutral Advantage™** Technology sets the new 10-Point Standard for intraluminal fluid pathway protection with a revolutionary combination of ten propriatary and superior design features specifically designed for both patient protection and improved patient outcomes - CR-BSI prevention and intraluminal thrombotic occlusion reduction.

Why ten? It takes the combination of all ten features to deliver what no other product can. The 10-Point Standard features have a sequential and cumulative effect, and are dependent upon one another in providing the real and effective intraluminal catheter protection of **Neutral**

InVision-Plus® Junior™

with Neutral Advantage™ Technology



The **InVision-Plus® JUNIOR®** with **Neutral Advantage™** is the only intraluminal protection system specifically designed to prevent CRBSI and minimize intraluminal thrombotic occlusions in pediatric and neonatal patients. While other products may claim to be intended for use in this population, the **JUNIOR®** is the only one which offers the 10 – Point Standard, along with an ultra-low priming volume of 0.022 mL.

The **JUNIOR®** is also unique in that it is the only product available with a demonstrated flushing effectiveness of 99.96% after only a single 1 mL saline-only flush, according to an independently conducted in vitro blood clearing analysis by Nelson Laboratories, Inc. The same study also found that another similarly marketed product contained nearly four times as much residual blood, and a leading positive pressure mechanical valve contained more than 100 times more residual blood after a 1 mL flush.

Flow Rates*
4.6 L/Hr Gravity
10.2 L/Hr 300mmHg
13.0 L/Hr 500mmHg

InVision-Plus® Junior®

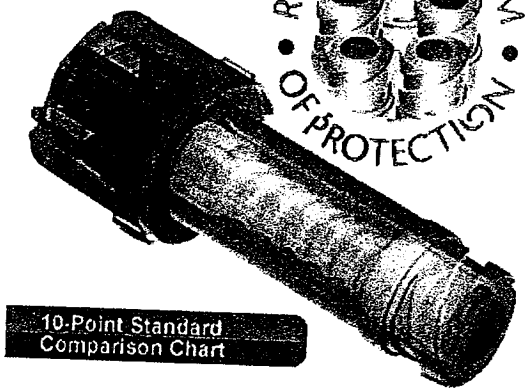
The **Neutral Advantage™** *(adj)* **1.** Having ten system features designed to work in conjunction with one another to maximize *intraluminal fluid pathway protection*. **2.** RyMed's **InVision-Plus®** Intraluminal Protection System technology.

RyMed's **Neutral Advantage™** technology sets the new 10-Point Standard for intraluminal fluid pathway protection with a revolutionary combination of ten propriatary and superior design features specifically designed for both patient protection and improved patient outcomes -

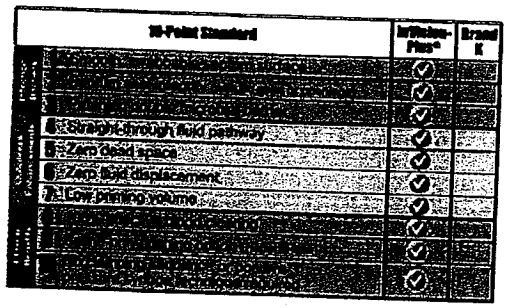
InVision-Plus®

with Neutral Advantage™ Technology

In 2005, RyMed Technologies, Inc. (Franklin, TN) introduced the **InVision-Plus® Neutral®**. With more than ten years of research and development behind it, today's **InVision-Plus®** with **Neutral Advantage™ Technology** is not just another needlefree connector; it is an *intraluminal protection system* and the only one of its kind specifically designed to address intraluminal thrombotic catheter occlusions and catheter-related bloodstream infections (CR-BSI).



10-Point Standard Comparison Chart



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Neutral Advantage™ *(adj)* **1.** Having ten system features designed to work in conjunction with one another to maximize *intraluminal fluid pathway protection*. **2.** RyMed's InVision-Plus® Intraluminal Protection System technology

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RyMed TECHNOLOGIES, INC.

Education Series

Volume 1, Number 1 *June 2009*

Special Considerations in Preventing Thrombotic Catheter Occlusions And CR-BSI in the Alternate Care Setting

Frances Powers, R.N., M.A., M.Ed., CRNI
National Director, IV Services, PharMerica (2003-2009)

Any patient setting other than the acute hospital setting is referred to as "Alternate Care". This includes Long-Term Care Nursing Homes, Skilled Nursing Facilities and Home Care.

Many changes have occurred in alternate care in the past two decades with regards to infusion therapy.

The Medicare Prospective Payment System (PPS) began in October 1984 as a means of reducing patients' length of stay in the hospital. In place of fee-for-service, which was the reimbursement method used prior to 1974, hospitals and alternate care settings are now reimbursed based on the amount and type of care a given condition is expected to require. PPS was instituted with the expectation of significantly reducing Medicare costs for patients.

After PPS and the DRG (Diagnostic Related Groupings) system was instituted, hospitals saw a reduction in length of stay of patients, but skilled nursing facilities and home health agencies saw an increase in number and acuity of Medicare patients (Hadley and Swartz 1989; Feder, Hadley, and Zuckerman 1987).

With the increase in high acuity patients, came an increase in the number of infusions both in skilled facilities and home care.

However, the increase in alternate care infusions was not accompanied by the development of national monitoring systems to measure outcomes and adverse events or with the establishment of formal infection control programs for standardization in the prevention, diagnosis, and treatment of complications. Although patients increasingly receive intravenous infusion therapy at home and in long term care and skilled facilities, study of infections and occlusions in these settings is difficult and few data are available. (Marcia Ryder JPEN, Journal of Parenteral and Enteral Nutrition Dec 31, 2005)

We will examine the special concerns and risk factors present in alternate site infusions.

Background

In general, nursing home residents are over the age of 65 and have functional difficulty and memory loss, dementia or other cognitive problems. The most frequently occurring conditions among this population are heart disease, stroke, or other chronic and degenerative diseases.

Skilled facilities often have residents with less chronic conditions and with fewer cognitive deficits. Residents in these homes include accident victims who enter for shorter extended stays needing care and rehabilitation, head injuries, strokes, spinal cord injuries, amputation, orthopedic and neurological impairment, arthritis, wound care, hip replacement surgery, heart conditions needing rehab services and pain management.

In the home setting, patients range in age from children to elderly.

Some of the most common therapies in the home setting are:

- **Total Parenteral Nutrition (TPN):** The administration of nutrition via central venous catheters to patients who are either already malnourished or have the potential for developing malnutrition.
- **Drug Therapy:** The intravenous administration of drugs including antibiotics, antivirals, chelating agents, growth hormones, and Colony Stimulating Factors (Neupogen, Epogen) etc.
- **Pain Management:** The intravenous administration of narcotics and other drugs designed to relieve pain.
- **Hydration Therapy:** The intravenous administration of fluids, electrolytes, and other additives. *(University of Virginia Health Systems)*

It is estimated that approximately 93% of patients receiving home intravenous therapies have a long-term central venous access device (CVAD) in place. Despite technologic advances, the risk for catheter-associated infection and obstructive complications is unchanged since the first tunneled catheter was placed in 1969 (Herbst, Kaplan, & McKinnon, 1998). Catheter occlusion is the most common non-infectious complication seen with long-term central venous access devices (Cunningham & Bonam-Crawford, 1993; Krzywda, 1998; Whitman, 1996). An obstructed CVAD may result in delayed treatment, increased risk for infection, patient discomfort, and increased cost of care. Loss of access places the patient at risk for further complications associated with placement of a new device or may lead to the inability to regain access altogether (Bagnall-Reeb & Ruccione, 1993).

Alternate care settings have less available resources than a hospital should an occlusion or CR-BSI occur and delay of treatment can occur more frequently. In addition, many facilities are ill-equipped to handle IVs primarily due to a lack of experience and training of nurses.

Risk Factors in Alternate Care

There are several risk factors for CR-BSI and occlusions that are more prevalent in alternate care sites.

Lack of standardization of care:

Each skilled facility or long-term care nursing home develops its own IV policies and procedures. While policies and procedures are developed based on standards of practice and state guidelines, there are policies such as "saline-only" flushing for all catheters that are not standardized. What is policy in one facility may not be the policy in another. Because nurses frequently work in several different facilities or may work for more than one home care agency, the lack of standardization of care can result in confusion and improper procedures.

Nurses may also not be familiar with state regulations, which increases the risk for errors.

Many nursing homes use agency nurses who may be unfamiliar with the supplies or policies in facilities.

Lack of Standardization of Supplies:

Hospitals generally use standardized supplies and equipment. This is not always true in the alternate care setting. Facilities use different pumps, IV catheters, needleless IV connectors, etc., which can all require a different procedure. This can be a tremendous problem when using anything that requires correct technique such as a positive-pressure IV connector.

Different home care agencies may also use different supplies and equipment.

For nurses who work in more than one alternate care site, this can lead to confusion and mistakes.

Also, supplies are often different in the same facility: Not all pharmacies are standardized as to supplies sent to facilities or home care patients. A facility may use one type of needleless IV connector one time and the next time they have an IV patient, they will be sent a different one.

Lack of education/experience of nurses:

Hospitals are staffed with RNs around the clock who care for patients with IVs on a regular basis. Nursing homes are staffed with few RNs and rely on LPNs for staffing, who may not have the experience caring for IV patients. Therefore, anything that depends on proper technique for success puts the resident at higher risk for complications. For instance, flushing using a positive-pressure displacement needleless IV connector is technique dependent as the nurse must clamp the catheter after she/he disconnects the flush syringe, or there is a risk of the IV connector valve mechanism not resealing itself, and a subsequent occlusion and/or fluid leakage could occur. The risk increases if the nurse works at several facilities utilizing different types of needleless IV connectors requiring different techniques, or the facility has a high rate of staff turnover. This setting is ideal for the use of a "zero fluid displacement" IV connector (RyMed Technologies, Inc. ***InVision-Plus® with Neutral Advantage™ Technology***), as it is not technique dependent.

Home Patients' Lack of Understanding

Patients sometimes do not understand catheter care and maintenance. In the home setting, the nurse may assume that the patient or family understands the instructions, but they may not or they may forget. Sterile technique may be difficult for patients to maintain and catheter contamination can occur more frequently. The ***InVision-Plus® with Neutral Advantage™ Technology*** with its patented "double microbial barrier" allows for more effective disinfection thereby lowering the risk of CR-BSI from touch contamination.

A general lack of understanding regarding positive-pressure / negative pressure/positive fluid displacement and zero fluid displacement IV connectors

Positive-pressure IV connectors require the opposite flushing / clamping techniques than those used for years prior to their development. The pre-pierced synthetic rubber diaphragm IV connectors and the early valve type IV connectors such as ICU Medical Clave® caused negative fluid displacement (blood reflux into the catheter) as the flush syringe was disconnected. Nurses were always taught to perform a positive-pressure syringe flush (i.e. keep thumb pressure on syringe plunger) and then clamp the catheter before disconnection. With positive-pressure IV connectors, such as the Medegen MaxClear®, B.Braun UltraSite® or ICU Medical CLC2000®, a positive fluid displacement occurs only on disconnection from the these type of IV connectors. This immediate and temporary positive fluid displacement

prevents blood reflux upon disconnection. If the nurse clamps the catheter before the syringe is removed, the positive fluid displacement feature is negated. Without constant reminders, nurses tend to revert to old techniques which results in blood reflux and possible occlusion.

Nurses also will sometimes mistakenly attach a dead-end connector to the positive-pressure IV connector when it is not in use, which will also result in blood reflux into the catheter.

While positive fluid displacement occurs on disconnecting from a positive-pressure IV connector, negative fluid displacement occurs immediately upon connecting a syringe, IV tubing, etc., resulting in blood reflux into the catheter.

The ***InVision-Plus® with Neutral Advantage™ Technology***, being a "zero fluid displacement" IV connector does not cause blood reflux either on connection to or disconnection from the **InVision-Plus®** and is not impacted by clamping. Because the ***InVision-Plus® with Neutral Advantage™ Technology*** is not technique dependent, there is minimal risk of blood reflux into the catheter and subsequent occlusion.

Infrequency of IVs:

This is especially true in long-term care facilities where the number and frequency of IVs are much lower than in the hospital setting. Nurses do not have the opportunity to perfect their skills, and will often forget the procedure for using a particular piece of equipment. In this situation, the use of anything that relies on proper technique for success, will often result in a higher risk to the patient of IV related complications.

Impact of Occlusions in Long Term Care/Skilled Facilities

Considerations	Impact on resident and/or nursing home
Residents with a Peripheral Catheter. These residents could be getting fluids for hydration, or short term antibiotics.	
Elderly have very poor veins. It is often very difficult to re-start IV.	Traumatic to resident who is already emotionally and physically fragile. Because the elderly have veins that are difficult to access, the procedure can be painful and emotionally stressful.
If the nurses who work in the facility cannot re-start IV, the resident may need to be sent to hospital, or an IV agency nurse may be called. (Many pharmacies that service nursing homes contract with IV nursing agencies to perform IV starts.)	If a Medicare or Medicaid resident, this incurs added expense to the facility. If a private pay resident, the patient will need to pay for the expense. Most likely this will result in delay of treatment. Transport to hospital involves a wait for the ambulance, a wait in the ER, and transport back to the facility.
If catheter that occluded is a midline catheter, and nurses in facility are not trained to insert midlines, the resident will need to be sent to hospital, or agency nurse will be called.	Agencies typically have a 4 hour turn-around time for visits, but if nurse is already involved in a visit, that could be longer.

Considerations	Impact on resident and/or nursing home
Central Venous Catheter:	
Catheter may need to be de-clotted.	Catheter de-clotting is an additional procedure which can be stressful to the resident. Incurs added expense to either facility or resident. tPA (de-clotting agent) is expensive and not all insurance covers it. Will result in delay of treatment.
Facility nurses may not be trained to administer tPA (de-clotting agent). Resident will need to be transported to hospital, or agency nurse may be called. If tPA does not resolve occlusion, central line may have to be replaced.	This is an invasive procedure which has high risk of complications, i.e. infection; bleeding; collapsed lung; blood clot, especially in the elderly. Incurs added expense for patient or facility.

Impact of Occlusions in Home Care

Considerations		Impact on Patient/Company
Peripheral:		
(Short and midline)	Home care nurse will need to re-start IV. Nurse may not be readily available.	Incurs added expense to patient or company depending on insurance coverage. Results in delay of treatment.
Central:	Catheter may need to be declotted.	Incurs added expense to patient or company.
If tPA does not resolve occlusion, central line may have to be replaced.		Will result in delay of treatment. Transport to hospital may involve a wait for the ambulance, a wait in the ER, and transport back to home. Added expense. Can be traumatic to patient, both emotionally and physically. This is an invasive procedure which has high risk of complications, especially in the elderly and those patients with a poor immune system.

Impact of CR-BSI in Long Term Care/Skilled Facilities and Home Care

Considerations	Impact on Resident/Patient
Often requires admission to hospital.	Increased risk of severe illness and death. Incurs added expense. Traumatic to resident/patient both emotionally and physically.

Considerations	Impact on Resident/Patient
Antibiotic administration.	Increased risk of antibiotic-induced toxicity. Elderly patients often have multiple chronic disorders and receive numerous medications. Adding an antibiotic to the patient's regimen poses a further risk for a drug-drug interaction. Specific examples of adverse antibiotic-related events that appear to occur more commonly in the elderly include the following: kidney problems; loss of hearing, severe diarrhea.
Home Care/LTC patients often have very poor immune systems.	Increased risk of severe illness and death.

Prevention of Catheter Occlusions and CR-BSI in the Alternate Care Setting

With the increased risk of device-related complications and the lack of standardization of care in alternate sites, it is important to identify key strategies for the care and maintenance of vascular access devices.

Standardization of supplies and equipment:

It is important that nurses are familiar with the supplies being used. This is more readily accomplished when supplies and equipment are standardized.

Better education of nurses:

Nurses need to know state regulations, policies and procedures in each facility or home care company they work for, and they need to have a thorough understanding of caring for the resident/patient receiving infusion therapy.

Nurses need to be educated about catheter occlusions, types, causes, and prevention. They need to understand the relationship between catheter occlusions and CR-BSI, and preventative measures.

This education process needs to be formalized and ongoing.

The higher the level of overall skills the staff possesses the better. Many infusion therapy patients will also need physical therapy (PT), occupational therapy (OT), rehabilitation or ventilator care. The nursing home must have the staff, equipment, and facilities to provide those services. (American Medical Association Publication Name: Archives of Internal Medicine Subject: Health ISSN: 0003-9926 Year: 1989)

Change to non-technique dependent needleless IV connector:

Because technique dependant supplies pose a greater risk to the patient, the use of non-technique dependent supplies such as the RyMed Technologies ***InVision-Plus® with Neutral Advantage™ Technology*** which removes the human error component, is recommended.

Institute the "bundle approach" of catheter care: The Central Line Bundle is a group of evidence-based interventions for patients with intravascular central catheters that, when implemented together, result in better outcomes than when implemented individually. (Institute for Healthcare Improvement, 2005). The key elements of the central catheter bundle are:

- Hand Hygiene;
- Maximal Barrier Precautions Upon Insertion;
- Chlorhexidine Skin Antisepsis;
- Optimal Catheter Site Selection, with avoidance of the Femoral Vein for Central Venous Access in Adult Patients;
- Daily Review of Line Necessity with Prompt Removal of Unnecessary Lines;

Other elements may include:

- A dedicated lumen for total parenteral nutrition (TPN);
- Access the CVC lumens aseptically;
- Review and documentation of entry site for inflammation daily and with every change of dressing;
- Use a "zero fluid displacement" needleless IV connector and "saline-only" flushing.

Implementation of the RyMed Technologies InVision-Plus® with Neutral Advantage™ Technology in a Long Term Care Pharmacy

Due to the increasing concerns with the use of heparin, PharMerica, the nation's second largest institutional pharmacy, with 100 pharmacies across the country servicing nursing homes, decided to pursue a "Saline Only" option for all catheters. At this time, the PharMerica pharmacies were using a positive displacement connector.

PharMerica conducted a one-month long trial of saline only flushing for all catheters except implanted ports in several high acuity skilled facilities. One facility had 17 PICC lines. Using the positive displacement connector and saline only flushing, the facility experienced 9 occlusions during that period of time. The other facilities also experienced PICC occlusions. PharMerica then trialed the RyMed Technologies ***InVision-Plus® with Neutral Advantage™ Technology*** in the same facilities using saline only flushing. With ***InVision-Plus® with Neutral Advantage™ Technology*** and saline only flushing, the same facilities saw their occlusions drop to 0.

In May 2005, PharMerica implemented the use of the ***InVision-Plus® with Neutral Advantage™ Technology*** and "saline only" flushing in all 100 pharmacies across the country. The following flushing procedures were implemented:

CATHETER TYPE	PRE-MED FLUSH	POST-MED FLUSH (or anytime blood has backed up into catheter)	FLUSH SOLUTION (Lumens not use)
Peripheral length less than 3 inches	10 ml saline	10 ml saline	10 ml saline every 8 hours +PRN
Midline up to 8 inches	10 ml saline	10 ml saline	10 ml saline every 8 hours + PRN
PICC Peripherally Inserted Central Catheter (tip in SVC)	10 ml saline	10 ml saline	10 ml saline every 8 hours + PRN (Flush all lumens)
Percutaneous (non tunneled) short term subclavian / jugular	10 ml saline	10 ml saline	10 ml saline every 8 hours + PRN (Flush all lumens)
Tunneled Catheter (Hickman/Broviac,/ Hohn/	10 ml saline	10 ml saline	10 ml saline every 8 hours + PRN (Flush all lumens)
Implanted Port (venous)	10 ml saline	10 ml saline 5 ml heparin (100 unit / ml)	20 ml saline /5 ml heparin (100 units/ml) every month if not accessed 10 ml saline /5 ml heparin (100u/ml every 24 hrs if accessed and not used)
All Valved Devices (Midline, PICC, Tunneled or Implanted Port)	10 ml saline	10 ml saline	10 ml saline every 8-24 hrs + PRN (Flush all lumens)

Flush with 20 ml saline following Parenteral Nutrition, Transfusion, or any Blood Reflux into a midline or any type of central line. Follow with heparin flush if indicated for specific device)

Because of the ***InVision-Plus® with Neutral Advantage™ Technology*** patented "zero fluid displacement", meaning no blood reflux occurs either upon connection and/or disconnection from the cap, it took the "human error component" out of the flushing situation. Additionally, there was no clamping sequence required.

PharMerica has been using the ***InVision-Plus® with Neutral Advantage™ Technology*** since 2005 with excellent results. Occlusion rates have been significantly reduced, virtually eliminating the costs associated with de-clotting or replacing central lines. Using this device has also allowed for the elimination of the use of heparin (except for implanted ports) utilizing best practice and reducing costs.

Summary

In addition to the cost issues associated with catheter occlusions and CR-BSI, most nursing home residents are psychologically fragile and easily traumatized and confused. Any change in routine or stressful situation can negatively impact them.

In home care, we see patients who are getting chemotherapy, AIDS patients, pediatric patients, patients receiving nutrition through a Central Venous Catheter, or patients recently discharged from the hospital on some kind of IV therapy. In home care, even if the patient is not elderly or frail, any change in routine, or transport to the hospital is stressful and can increase morbidity.

Alternate care sites provide unique challenges but with the implementation of proper preventative strategies outlined above, the risk of infusion therapy complications, especially catheter occlusions and CR-BSI can be minimized.

RyMed Technologies, Inc.
Corporate Headquarters, Franklin, TN 37064
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How "NEGATIVE" Fluid Displacement Contributes to Intraluminal Thrombotic Catheter Occlusions

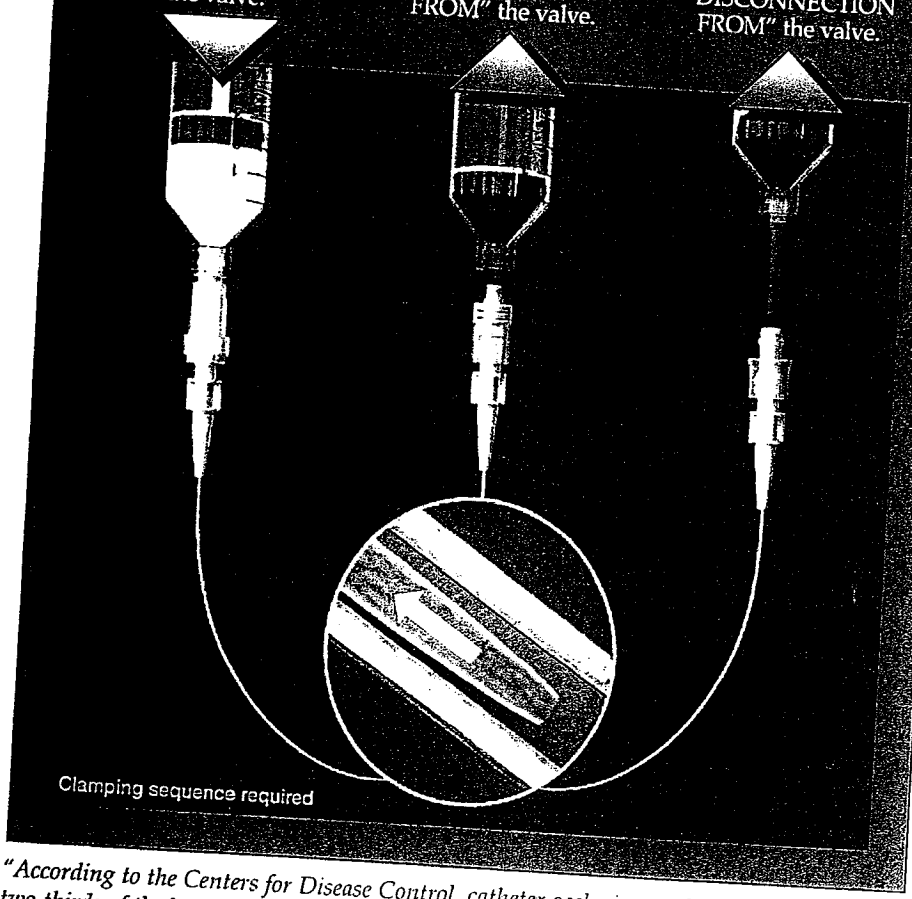
Intraluminal thrombotic catheter blockages can occur when blood is allowed to flow into the catheter lumen. This can cause a residual buildup resulting in, not only occlusions, but the growth of microorganisms, both of which can then flow into the patient's bloodstream.

The smaller the catheter lumen, the further up the catheter the blood is drawn.

Recent generation universal access I.V. connector designs that have a "Positive-Push" feature all exhibit a "Negative Fluid Displacement" and a retrograde of blood into the catheter lumen immediately upon the "CONNECTION TO" the valve.

Early generation universal access I.V. connector designs, that are swabbable or require a sterile end cap, all exhibit a "Negative Fluid Displacement" and a retrograde of blood into the catheter lumen immediately upon the "DISCONNECTION FROM" the valve.

The first generation I.V. connector designs that use hollow-bore needles, plastic cannulas or blunt steel cannulas all exhibit a "Negative Fluid Displacement" and a retrograde of blood into the catheter lumen immediately upon the "DISCONNECTION FROM" the valve.



"According to the Centers for Disease Control, catheter occlusions or biofilms account for two-thirds of the bacterial infections that physicians encounter."

Science News, 1-5, July 14, 2001.

Risk and Cost Reduction

occluded catheter and/or a related bloodstream infection can lead to an ease in the overall cost of patient

The **InVision-Plus® Neutral™ I.V. Connector System** from RyMed Technologies can reduce the risk of thrombotic occlusions and catheter-related infections, prevent disruption in therapy, keep costs under control and minimize the impact of catheterization on patient lifestyle.

Additionally, the **InVision-Plus® Neutral™ I.V. Connector System** reduces overall costs by providing a totally integrated catheter care system, with universal fittings to work with all standard infusion products and connectors, while eliminating the cumbersome additional components required with other systems.

ICT
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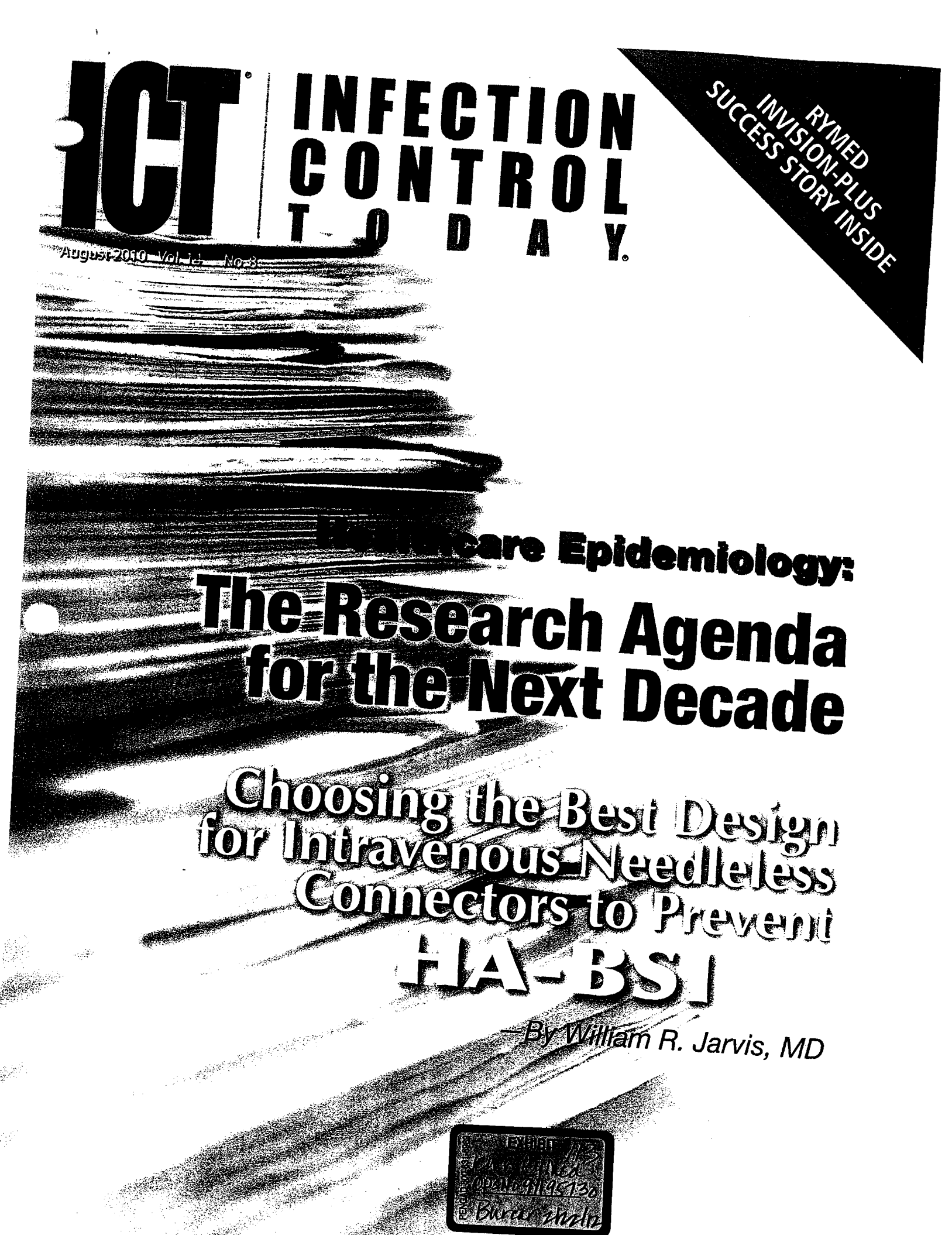
RYMED INVISION-PLUS SUCCESS STORY INSIDE



Healthcare Epidemiology: The Research Agenda for the Next Decade

Choosing the Best Design for Intravenous Needleless Connectors to Prevent HA-BSI

—By William R. Jarvis, MD

Choosing the Best Design for Intravenous Needleless Connectors to Prevent Healthcare-Associated Bloodstream Infections

By William R. Jarvis, MD

Healthcare-associated catheter-related bloodstream infections (HA-BSIs) remain a major cause of morbidity and mortality in the U.S. While the Centers for Disease Control and Prevention (CDC) recently reported a drop of 18 percent in the incidence of HA-BSIs, overall progress in reducing these infections has been a fraction of what is possible, and necessary.

The CDC had previously estimated that more than 80,000 HA-BSIs occur annually in intensive care unit (ICU) patients alone. Thus, an 18 percent drop in these infections means that tens of thousands of patients are still endangered by HA-BSIs each year. Many infection control experts believe that HA-BSIs can be markedly reduced, if not completely eliminated. Recognition of the preventability of HA-BSIs is one reason why the Centers for Medicare and Medicaid Services (CMS) and many health insurance carriers have eliminated enhanced reimbursement for these complications.

The design of intravenous (IV) needleless connectors (NCs) plays a substantial role in HA-BSI risk. These devices are used to connect catheters, administration sets, and/or syringes to deliver IV therapy. In the past two decades, connectors have evolved in a direction that has inadvertently increased the risk for HA-BSIs.

With some notable exceptions, the devices have become more complex in design. These complexities have made NCs harder to: disinfect, flush completely, and use correctly. This situation is compounded by the wide variety of NCs in the marketplace. Clinicians often are faced with several types of NCs in use at their hospital or healthcare system. Because each NC can require different routines for proper use (i.e., disconnection, clamping, disinfection and flushing sequence) such variety can be confusing to clinicians and endanger patients' lives. The confusion can lead to medical errors, and ultimately HA-BSIs.

This article provides a short history of IV needleless connectors, to show how the current situation developed, and then describes the crucial features of NCs that reduce the risk of HA-BSIs.

A Brief History of the Modern Connector

When healthcare workers (HCWs) use needles in conjunction with IV therapy, they risk accidental needlestick injuries and potential infection with bloodborne pathogens, e.g., hepatitis B or C viruses or Human Immunodeficiency Virus (HIV). In 1992, the Occupational Safety and Health Administration (OSHA) recommended that healthcare facilities use "engineering controls" to help protect HCWs from these pathogens. The use of such controls, including NC systems when applicable, became mandatory under the Needlestick Safety and Prevention Act in 2001.

The NCs that we see today evolved from industry's efforts to make devices that comply with OSHA regulations. They were primarily designed for HCW safety. Ironically, some NCs have had an unintended consequence of increasing patients' HA-BSI risk. In particular, two of the most widespread designs, so-called "positive" and "negative" pressure luer-access mechanical valve NCs, have been associated in a number of studies with increased HA-BSIs risk.[1-6] In general, the infection-related problems associated with these luer access mechanical valve NCs are related to their complicated design. They have complex internal surfaces – including in some instances, moving parts – that are difficult to disinfect and flush properly. The internal surfaces then can become contaminated and serve as a nidus for biofilm development and subsequent HA-BSI. Most NCs also require a specific routine clamping sequence for disconnection, either clamp and then disconnect or disconnect and then clamp. If the clamping-disconnection sequence is not executed correctly, the risk of inadequate disinfection and contamination increases HA-BSI risk.

The general design principle that "simple is better" applies to NCs. Simpler NCs are less likely to be associated with increased HA-BSI risk because there are fewer opportunities for HCWs to incorrectly use them and there are fewer parts or other design elements to function incorrectly or fail. In addition, the external and internal surfaces of simpler NCs are easier to completely and adequately disinfect and flush.

Connector Design Recommendations

Not all NCs have the same design prob-

— Photo provided by: RyMed Technologies, Inc.

lems, and some have design features that are desirable from an infection-control standpoint. Below is a guide to common features in NCs, including a discussion of potential problems and preferable alternatives.

Septum surface. Many current NCs have complex external septum surfaces that include gaps and openings. These gaps and openings create spaces that may not be reached by the clinician's disinfection routine, even if the appropriate routine – a 30-second, vigorous scrub with alcohol or chlorhexidine with alcohol – is performed meticulously. If the septum is not completely disinfected, then connecting a syringe or IV tubing to the NC can result in infusion of potentially contaminating pathogens into the patient's bloodstream.

Preferable: A NC with a smooth external septum surface with few if any gaps that can be more thoroughly disinfected.

Septum seal. Although there are no studies to confirm this, any opening between the septum and fluid pathway is, hypothetically, an area where biofilm can develop and a potential opening for pathogens to invade.

Preferable: A tight seal between the septum and the NC housing to reduce or eliminate space for contamination to occur and biofilm to develop.

Fluid pathway. Some NCs have a fluid pathway that is complex and indirect. If the pathway is indirect, flushing is less likely to remove blood or other nutrient fluids. When blood or other nutrient materials settle on a NC internal surface, they can serve as the nidus for biofilm development.

Preferable: A NC with a direct – that is, straight – fluid pathway that facilitates adequate flushing and reduces the internal surface for biofilm development.

Dead spaces. This issue is related to the directness of the fluid pathway. NCs with indirect or tortuous fluid pathways often have dead spaces that are not always reached by flushing. Contaminating organisms and proteinaceous material (i.e., blood) that enhances biofilm development can "hide" in these dead spaces, increasing HA-BSI risk.

Preferable: NCs with little or no dead space in the fluid pathway minimize the surfaces that infusates can contaminate and where biofilm can develop.

Internal mechanism. Some NC designs involve complicated internal mechanisms that open the fluid pathway when the NC is activated. As with dead spaces, moving parts in the fluid pathway provide surfaces for infusates to bind to and can serve as a nidus for biofilm development. Also, moving parts themselves often make the fluid pathway more complicated and indirect. Finally, moving parts may fail.

Preferable: NCs with the most direct and least tortuous fluid pathway, with preferably no moving parts, reduce the potential risk of HA-BSI.

Clamping sequence. Both positive and negative pressure luer access mechanical valve NCs require a sequence of clamping steps as part of the disconnection process. The sequence is performed to minimize blood reflux (blood flowing backwards into the distal end of the IV catheter). Different NC types require different sequences, however. With negative pressure NCs, the clinician clamps the IV catheter and then disconnects the NC. In contrast, with positive pressure NCs, one disconnects from the NC and then clamps the IV catheter. This opposite order of clamping and disconnection is seldom understood by clinicians, and thus often the correct clamp-disconnection sequence is not used. This is an even greater potential problem when both positive and negative pressure NCs are being used simultaneously in a facility or healthcare system.

Preferable: Use a needleless connector that does not require a clamping sequence. Or, alternatively, use only one NC type that requires a specific clamp-disconnection sequence (e.g., all negative pressure, all positive pressure or all neutral pressure) throughout the healthcare facility or system – and insure that all HCWs understand and are well trained in this clamp-disconnection sequence.

Visibility. Flushing NCs is critically important because it is the method by which blood or other contaminating infusates (glucose containing solutions, intralipid, etc.) is removed from the NC. Many NCs are opaque; thus, one cannot visualize the internal surface of the NC and determine whether flushing was complete. The ability to visualize the internal surfaces of the NC helps the clinician determine if flushing of the NC is complete. If blood or other contaminants remain in the NC after flushing, they will facilitate the development of biofilm on that surface.

Preferable: A transparent NC is preferable to one that is opaque.

Blood reflux. Theoretically, blood reflux into either the IV catheter or the NC increases both the risk of occlusion and biofilm formation. Both also increase the risk of HA-BSI. Blood reflux can occur with both positive and negative pressure luer access mechanical valve NCs.

Preferable: A luer access mechanical valve NC with little or no blood reflux.

Flushing solution. Some NC types are designed to be flushed with heparin to reduce the risk of occlusion. In some patient populations, there have been reports of increasing rates of heparin-induced thrombocytopenia or HIT. Thus, a NC that can be flushed with saline rather than heparin containing solutions should decrease the risk of HIT.

Preferable: A NC that can be flushed with saline-only rather than heparin containing solutions avoids the potential risk of heparin-induced side effects.

Many if not most of the aforementioned design features have not been specifically studied for their relative contribution to the risk of HA-BSIs associated with negative or positive pressure luer access mechanical valve NCs. Although their relationship to HA-BSIs is logical, it remains hypothetical. But it is strongly believed that because the origin of HA-BSIs is in biofilm development on the internal and external surfaces of NCs, it makes sense to select a type of NC that minimizes the risk of biofilm formation.

In addition, the association of both positive and negative pressure luer access mechanical valve NCs with increased HA-BSIs risk has been repeatedly reported in the scientific literature.[1-6] It is my experience in traveling to hospitals worldwide that far more facilities have had HA-BSI problems associated with these NCs than indicated in the literature. The Society for Healthcare Epidemiology of America (SHEA) has recommended against the use of positive pressure mechanical valve NCs without appropriate evaluation.[7] More recently, the CDC has recommended against use of either negative pressure or positive pressure luer access mechanical valve NCs.[8]

If, despite the SHEA and CDC recommendations, a facility decides to use such NCs, then they should stock just one type of NC, use it institution-wide, and insure that their clinicians understand and are well educated on its proper use. This will help prevent confusion about clamping-disconnection sequences and other recommended NC infection-control practices.

As we attempt to achieve zero tolerance for HA-BSIs, attention to both an insertion bundle and a maintenance bundle (including the type of NC used) is critical. The majority of published data illustrates that if such bundles are fully implemented, very low or zero rates of CVC-

3SI are achievable. Given the extent of the data, such insertion and maintenance bundles should be mandated by the Department of Health and Human Services in all ICUs in the United States today.

What are we waiting for? If prevention is primary, action is essential. If this were done, then the funding currently being used to "study" these bundles further in ICU settings (where most of the interventions have been tried and been successful) could instead be used to expand such prevention programs hospital-wide, where as many as 60 percent of HA-BSIs occur.

At least one hospital has demonstrated success in implementing an insertion and maintenance bundle hospital-wide. Sutter Roseville Medical Center (SRMC) in Roseville, California has completely eliminated HA-BSIs on peripherally inserted central catheters (PICCs) placed in the ICU by the PICC team.[9] This record of success has persisted for more than four years.[10] This should be a model for all U.S. hospitals. If patient safety is paramount, then implementation of insertion and maintenance bundles proven to prevent HA-BSIs should be a high priority for all hospital administrators. If these hospital administrators do not insure that such bundles are fully implemented, then Federal regulatory agencies should mandate it and insurance companies should refuse to reimburse for these preventable HA-BSIs

William R. Jarvis, MD, is president of Jason and Jarvis Associates, LLC, a private consulting company in healthcare epidemiology and infection control. Jarvis was the editor of Infection Control and Hospital Epidemiology. He is the former president of SHEA and former president of the Association of Professionals Infection Control and Epidemiology (APIC)'s Research Foundation board of directors. He previously served as acting director of the CDC's Hospital Infection Program (now the Division of Healthcare Quality Promotion), among other positions during his 23 years with the CDC.

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InVision-Plus® with Neutral Advantage™ technology Closed Medication Delivery Set

Wash hands thoroughly with bactericidal soap before each procedure. Use gloves if required by your Healthcare provider.

Inspect set. Discard set if end caps are missing or loose in package. Remove protective coverings as assembly progresses.

InVision-Plus® with Neutral Advantage™ technology

The **InVision-Plus®** is accessed by a standard male-luer syringe or I.V. set connector. It is recommended that a male luer-lock connector be used with the **InVision-Plus®** for a secure connection. The **InVision-Plus®** is bi-directional and luer-locking. The **InVision-Plus®** will automatically close when the syringe or male-luer I.V. set connector is removed.

Directions for Use

Single patient use only. Contents are sterile and fluid path non-pyrogenic unless package is opened or damaged.

Use aseptic technique

1. Remove sterile product from pouch. Close pinch clamp.
2. Close vent on tubing if spiking a fluid bag; open the vent if spiking a bottle.
3. Remove the spike protector and insert spike into bag or bottle.
4. Attach a syringe to the **InVision-Plus®** by positioning the syringe on the septum, push forward, rotate syringe clockwise until secure.
5. Turn stopcock OFF to the patient line. Open the pinch clamp and aspirate fluid into the syringe.
6. Turn stopcock OFF to the fluid source. Expel air out of the syringe, remove male-luer end cap and prime the line to the patient with the fluid.
7. Close pinch clamp prior to the administration of fluid.
8. Upon completion of fluid administration turn stopcock OFF to patient and prepare for next infusion.
9. To disconnect the syringe from the **InVision-Plus®** simply rotate counterclockwise. The **InVision-Plus®** will automatically close.
10. The **InVision-Plus®** has only 0.027mL in priming volume.

NOTES

Flush **InVision-Plus®** after each use per institutional protocol using normal saline, or normal saline and heparin. It is recommended that this device be changed per CDC guidelines or per validated facility protocol. The CDC recommends that tubing used to administer lipid emulsions and TNA solutions should be changed every 24 hours. The IV connector and extension set should also be changed at this time. Observe appropriate infection control procedures.

Federal (USA) law restricts this device to sale by or on the order of a physician.

CAUTIONS

The **InVision-Plus®** I.V. Connector may not be compatible with every male-luer connector. Some I.V. sets/syringes utilize a male-luer connector with a lumen opening diameter of 0.063" or less which may cause damage to the **InVision-Plus®** resulting in septum damage, reduction or loss of fluid flow. Do not use any male-luer device unless certain that the male-luer connector opening is 0.064" or larger. Do not use needles with connector. Do not use luer lock end caps on connector.

Product Information: (512) 301-1949 www.rymedtech.com

3RTCMC

InVision-Plus® with Neutral Advantage™ technology Closed Medication Delivery Set

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Inspect set. Discard set if end caps are missing or loose in package. Remove protective coverings as assembly progresses.

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Directions for Use

Single patient use only. Contents are sterile and fluid path non-pyrogenic unless package is opened or damaged.

Use aseptic technique

1. Remove sterile product from pouch. Close pinch clamp.
2. Close vent on tubing if spiking a fluid bag; open the vent if spiking a bottle.
3. Remove the spike protector and insert spike into bag or bottle.
4. Attach a syringe to the **InVision-Plus®** by positioning the syringe on the septum, push forward, rotate syringe clockwise until secure.
5. Turn stopcock OFF to the patient line. Open the pinch clamp and aspirate fluid into the syringe.
6. Turn stopcock OFF to the fluid source. Expel air out of the syringe, remove male-luer end cap and prime the line to the patient with the fluid.
7. Close pinch clamp prior to the administration of fluid.
8. Upon completion of fluid administration turn stopcock OFF to patient and prepare for next infusion.
9. To disconnect the syringe from the **InVision-Plus®** simply rotate counterclockwise. The **InVision-Plus®** will automatically close.
10. The **InVision-Plus®** has only 0.027mL in priming volume.

NOTES

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Product Information: (512) 301-1949 www.rymedtech.com

InVision-Plus® is a registered trademark of RyMed Technologies, Inc., Franklin, TN 37064
Neutral Advantage® is a trademark of RyMed Technologies, Inc., Franklin, TN 37064 U.S. Patents: #6,113,068 - #6,299,131 - #6,994,315 - #7,530,546B2 and other U.S. and foreign patents pending
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DIRECTIONS FOR USE
InVision-Plus® Closed Medication Delivery Sets
SPECIFICATION SHEET
RyMed Technologies, Inc.

Approximate Size: 5.50" x 8.50", White
Color of Type: Black

Notes:
1) Above label text are to be printed and cut to create two inserts

3RTCM
Revision: C

APPROVED BY:

Jim Kaiser

Jim Kaiser Date: April 6, 2011

Scott Chase Date: April 6, 2011

RYM001226

RyMed Technologies Inc.

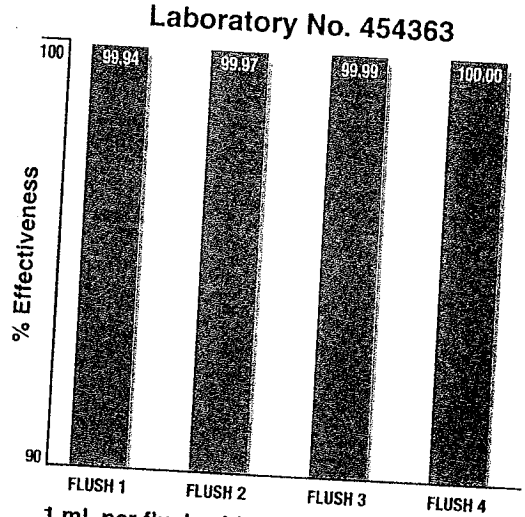
Blood Clearing Study for the InVision-Plus® with Neutral Advantage™ Technology

Nelson Laboratories, Inc. (Salt Lake City, UT), an independent laboratory facility, was contracted to conduct a blood clearing study on the **InVision-Plus® with Neutral Advantage™ Technology**, manufactured by RyMed Technologies, Inc.

OBJECTIVE: Effective clearing of blood and medications from needlefree I.V. connectors is a critical catheter care and maintenance practice. It has also been suggested that fluid pathway design within I.V. connectors can impact flushing success. The ability to effectively flush the I.V. connector's fluid pathway with 10 mL (per facility protocol) is important. This test procedure was designed to determine the flushing effectiveness of the **InVision-Plus®** using only a 1 mL 0.9% normal saline solution after blood exposure.

METHODS: Citrated human blood was used in this study. A hemoglobin standard curve was prepared by diluting the hemoglobin standard (0.80 mg/mL) with cyanmethemoglobin (CMR) to give solutions at concentrations of 0.80, 0.60, 0.40, 0.30, 0.20, 0.10, and 0.01 mg/mL. The solutions were allowed to stand at room temperature for >5 minutes, and the absorbance was measured on a spectrophotometer at 540 nm. A standard curve was performed with the optical density readings and concentrations of hemoglobin. To establish plasma hemoglobin determination, 4 mL of blood were centrifuged at 700-800 times g for 15 minutes. 1 mL of plasma was added to 1 mL of CMR and allowed to stand at room temperature for >15 minutes, then measured for absorbance at 540 nm on a spectrophotometer. The amount of hemoglobin present was determined from the standard curve and multiplied by a factor of 251 to account for the dilution. The procedure was performed in triplicate.

TEST PROCEDURE: Each device was exposed to human citrated blood by filling a 1 mL syringe with 1 mL of blood. The blood was injected through the device and the residual blood that escaped was collected in a test tube. The device was then flushed by filling a syringe with 1 mL of 0.9% saline, injecting saline through the device, and collecting the saline in the same test tube as the residual blood. The flushing procedure was repeated for a total of four times. Each time the flushed solution was collected in a separate test tube. A total of three devices were injected with blood and flushed. A baseline control was performed by filling a 1 mL syringe with 1 mL of blood and dispensing the blood into a test tube with 1 mL of 0.9% saline. Three baseline tubes were prepared. Once the flushing procedure was complete the collected samples were analyzed for the amount of hemoglobin present as described above.



RESULTS: The following chart summarizes the effectiveness of each consecutive 1 mL flush on the **InVision-Plus®** which has a priming volume of 0.027 mL.

CONCLUSION: After a 1 mL flush of 0.9% normal saline, the RyMed Technologies, Inc. **InVision-Plus® with Neutral Advantage™ Technology** (Catalog No. RYM-5001) was **99.94% cleared**, which corresponds to initial residual percent hemoglobin of 0.06%. The **InVision-Plus®** fluid pathway was **100% cleared** with only four 1mL flushes of 0.9% normal saline.

The complete study protocol and final report on file at RyMed Technologies, Inc.

RYM001489

RyMed TECHNOLOGIES, INC.

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RyMed Technologies Inc.

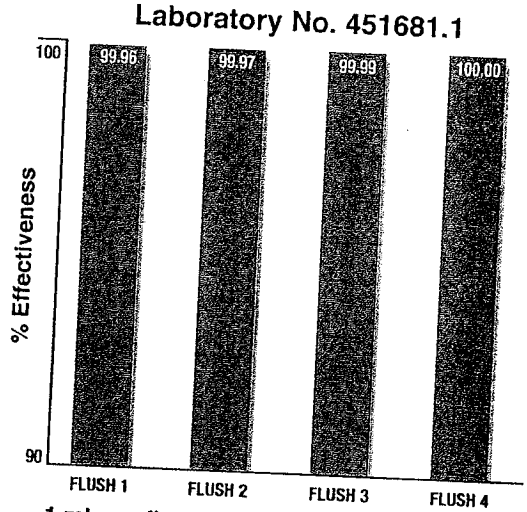
Blood Clearing Study for the InVision-Plus® Junior™ with Neutral Advantage™ Technology

Nelson Laboratories, Inc. (Salt Lake City, UT), an independent laboratory facility, was contracted to conduct a blood clearing study on the **InVision-Plus® Junior™ with Neutral Advantage™ Technology**, manufactured by RyMed Technologies, Inc.

OBJECTIVE: Effective clearing of blood and medications from needlefree I.V. connectors is a critical catheter care and maintenance practice. It has also been suggested that fluid pathway design within I.V. connectors can impact flushing success. In pediatric and neonatal patient populations, the ability to effectively flush the I.V. connector's fluid pathway with less than 5 mL is important. This test procedure was designed to determine the flushing effectiveness of the **InVision-Plus® Junior™** using only a 1 mL 0.9% normal saline solution after blood exposure.

METHODS: Citrated human blood was used in this study. A hemoglobin standard curve was prepared by diluting the hemoglobin standard (0.80 mg/mL) with cyanmethemoglobin (CMR) to give solutions at concentrations of 0.80, 0.60, 0.40, 0.30, 0.20, 0.10, 0.02, and 0.01 mg/mL. The solutions were allowed to stand at room temperature for >5 minutes, and the absorbance was measured on a spectrophotometer at 540 nm. A standard curve was performed with the optical density readings and concentrations of hemoglobin. To establish plasma hemoglobin determination, 4 mL of blood were centrifuged at 700-800 times g for 15 minutes. 1 mL of plasma was added to 1 mL of CMR and allowed to stand at room temperature for >15 minutes, then measured for absorbance at 540 nm on a spectrophotometer. The amount of hemoglobin present was determined from the standard curve and multiplied by a factor of 251 to account for the dilution. The procedure was performed in triplicate.

TEST PROCEDURE: Each device was exposed to human citrated blood by filling a 1 mL syringe with 1 mL of blood. The blood was injected through the device and the residual blood that escaped was collected in a test tube. The device was then flushed by filling a syringe with 1 mL of 0.9% saline, injecting saline through the device, and collecting the saline in the same test tube as the residual blood. The flushing procedure was repeated for a total of four times. Each time the flushed solution was collected in a separate test tube. A total of three devices were injected with blood and flushed. A baseline control was performed by filling a 1 mL syringe with 1 mL of blood and dispensing the blood into a test tube with 1 mL of 0.9% saline. Three baseline tubes were prepared. Once the flushing procedure was complete the collected samples were analyzed for the amount of hemoglobin present as described above.



RESULTS: The following chart summarizes the effectiveness of each consecutive 1 mL flush on the **InVision-Plus® Junior™** which has a priming volume of 0.022 mL.

CONCLUSION: After a 1 mL flush of 0.9% normal saline, the RyMed Technologies, Inc. **InVision-Plus® Junior™ with Neutral Advantage™ Technology** (Catalog No. RYM-8001) was **99.96% cleared**, which corresponds to initial residual percent hemoglobin of 0.04%. **InVision-Plus® Junior™** fluid pathway was **100% cleared** with only four 1mL flushes of 0.9% normal saline.

The complete study protocol and final report on file at RyMed Technologies, Inc.

RYM001491

RyMed TECHNOLOGIES, INC.

9RT036A

March 22, 2010

Contact: Liz Dowling, (800) 386-0157
Dowling & Dennis Public Relations
E-mail: Liz@DowlingDennis.net
www.dowlingdennis.net

At SHEA, Scientific Posters Show Effectiveness of InVision-Plus IV Connectors

Two Different RyMed Connectors Found To Be More Powerful than Competitors in Preventing Contamination

FRANKLIN, Tenn. – Two scientific poster presentations that demonstrate the infection prevention capabilities of InVision-Plus® with Neutral Advantage™ technology were featured at the annual conference of the Society for Healthcare Epidemiology of America (SHEA).

Both studies show InVision-Plus connectors to be more effective than other connectors in preventing contamination by bacteria known to cause catheter-related bloodstream infections (CRBSI). The SHEA meeting was held March 18-22 in Atlanta.

One study compared the ability of five needleless connectors, including InVision-Plus with Neutral Advantage technology, to prevent contamination by four different microorganisms that are significant causes of CRBSI. Each of the connectors was swabbed, filled with blood, flushed with saline and then repeatedly inoculated with the four bacterial strains throughout the four-day test period.

InVision-Plus outperformed the other connectors by having the lowest bacteria counts at the conclusion of testing.

"This study is significant for several reasons," said lead researcher Cynthia Chernecky, Ph.D., RN, AOCN, FAAN. "Needleless connectors are designed to protect the catheter's fluid pathway from bacteria that can cause CRBSI. Our study showed that InVision-Plus did this more effectively than a luer-activated split septum device and two other connectors whose manufacturers state they have anti-reflux technology.

"Prior to this, there have been very few comparative studies of needleless connectors," Chernecky added. "There have been even fewer studies under conditions that simulate actual clinical conditions when aspirating blood, as ours did. So this study's results may be more significant than those produced by less realistic research designs."

Chernecky is a Professor of Physiological and Technological Nursing at the Medical College of Georgia's School of Nursing.

Of the five connectors used in the study, one was a positive pressure mechanical valve device, meaning that blood will reflux negatively, or flow backwards into the catheter, initially upon connection to the catheter. One was a split septum device, and two are claimed by their manufacturers to prevent blood reflux. The InVision-Plus is designed to prevent blood reflux.

Blood reflux coats the inner walls of the catheter lumen with blood. This can lead to the formation of biofilm, the bacterial aggregation that is a precursor to CRBSI.

The second study presented at SHEA used similar methodology and compared another manufacturer's silver-coated connector to two different versions of the InVision-Plus. One version was the standard non-antimicrobial InVision-Plus, while the other was the InVision-Plus with chlorhexidine silver engineering. The latter device has not yet received FDA clearance.

Both InVision-Plus connectors significantly outperformed the antimicrobial connector with silver coating, which produced 2.5 to 200 times more bacteria over time than either of the InVision-Plus connectors. In fact, InVision-Plus with chlorhexidine silver impregnation produced no consistent bacteria during the test period.

"Technological design is a crucial factor in preventing CRBSI," said Chernecky, "as shown by the fact that even the non-antimicrobial InVision-Plus was more effective than the silver-coated (not silver-impregnated) connector.

"The other important finding here is that silver plus chlorhexidine may be the formulation needed to best prevent CRBSI. It has previously been established that silver treatment alone is not sufficient to prevent CRBSI. This study underlined that finding and may have identified a solution to the problem."

CRBSI are one of the leading hospital-acquired infections and one of the nation's leading killers overall. They are fatal in up to 25% of cases and cost tens of thousands of dollars to treat, driving up the cost of healthcare.

"These two studies confirm the careful thinking and research that have gone into InVision-Plus connectors," said Dana Wm. Ryan, RyMed's President, CEO and Chairman of the Board. "These presentations at SHEA will help spread the word about the value of the current InVision-Plus and the potential availability of an even more potent device to protect patients against CRBSI."

The studies, which documented testing that was conducted by an independent laboratory, were presented at SHEA's 2010 decennial meeting. InVision-Plus connectors are made by RyMed Technologies, Inc.

About RyMed Technologies, Inc.

RyMed Technologies, Inc., founded in 1994, specializes in the development and marketing of innovative safety products in the field of intravenous catheter care management. The company's products are designed to help reduce catheter-related infections associated with vascular access. More than 10 years of research and development have gone into its unique needleless connector, InVision-Plus with Neutral Advantage technology, and related products. The company is headquartered in Franklin, Tenn.

For more information, call (615) 790-8093 or access www.rymedtech.com.

-- END --

CareFusion

Patient Safety Council

The San Diego Patient Safety Council consists of county-wide representatives from acute care facilities across multiple disciplines including physicians, nurses, pharmacists and respiratory therapists. Council members review literature, apply process improvement tools, and share best practices to obtain consensus in building a comprehensive set of recommendations on specific topics. The Council has developed three tool kits – ICU Sedation Guidelines of Care, PCA Guidelines of Care and Safe Administration of High-Risk IV Medications. Current efforts focus on sepsis - helping to decrease the death rate with early recognition and aggressive treatment.

Congratulations to the Patient Safety Council

A 2009 ISMP Cheers Award winner!

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GENERAL INQUIRY

Tool Kit: ICU Sedation Guidelines of Care (Jan 2010)
An evidence-based standard for safe and effective management of pain, sedation, and delirium in the adult ICU ventilated patient. The Tool Kit contains clinical guidelines for adult, sedated ICU patients and a plan for implementing the guidelines in your institution.

The objectives are to:

- Decrease pain
- Decrease anxiety
- Decrease ventilator days
- Decrease ICU length of stay
- Reduce long-term cognitive decline
- Avoid heart, lung, liver, and kidney complications
- Reduce the incidence of PTSD
- Reduce occurrences of spontaneous extubation
- Reduce the occurrence of delirium and/or improve the management of delirium.

Tool Kit: Patient-Controlled Analgesia (PCA) Guidelines of Care (December 2008)
Managing post-operative pain has been a focus of the Joint Commission and is associated with some of the highest incidence of adverse drug reactions. It is also associated with wide variation in prescribing, administration, and monitoring.

Tool Kit: Safe Administration of High-Risk IV Medications (November 2006)
Standardization of intravenous (IV) infusion medication concentrations and dosage units with and across hospitals in San Diego County was identified as a significant opportunity to reduce morbidity and mortality due to preventable, high-risk IV-related adverse drug events. The 2006 Institute of Medicine (IOM) report, "Preventing Medication Errors," urges hospitals to take action to reduce the potential for errors.

In 2009, the IV task force published a follow up report in Hospital Pharmacy. The results showed that area-wide standardization of high-risk IV drug concentrations and dosage units significantly reduced variability in IV therapy, helping promote safer and more consistent practices in administering high-risk IV medications to patients.

- *"If every hospital adopted the recommended standards fully, variation in concentration and dosing units would be reduced by 94% and 100%, respectively."*
- *"It is expected that standardization will decrease the potential for medication errors within hospitals and on patient transfer to other health care facilities."*

Hospital Pharmacy - Reduction in Variation of Intravenous Drug Administration in Seventeen San Diego Hospitals with Standardized Drug Concentrations and Dosage Units
> Request a copy of the article

MicroPeak™

The precision Peak Flow Meter with an immaculate pedigree

CareFusion

MicroPeak

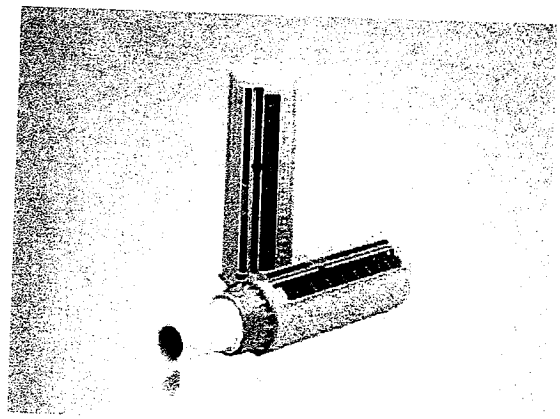
25 years experience of design, testing and improving the world's leading Peak Flow Meters (PFM) has led to the new generation MicroPeak™. Designed to meet the new ISO Standard (ISO23747) standards in performance and quality including a high visibility scale and in-built customisable Colour-Zone asthma management system that won't wash off (see illustration below).

Unlike other PFM's the advanced design of MicroPeak™ means dismantling is avoided, thus protecting the integrity of the internal mechanism, also an internal check valve avoids cross infection concerns.

MicroPeak™ comes complete with instructions and a 4 week recording chart, and can be offered fully customised for promotional purposes too.

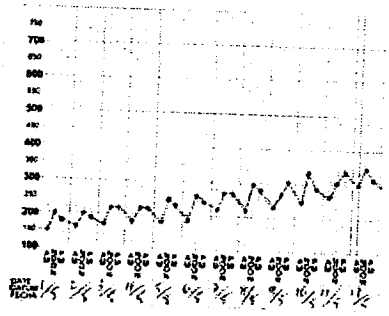
Available with a choice of either European or ATS scales, Catalogue numbers: MPE8200EU - EU Scale MicroPeak, MPE7200 - ATS Scale MicroPeak.

When accuracy is important in clinical asthma management, then compromise is not an option, choose MicroPeak™ the PFM with an immaculate pedigree.

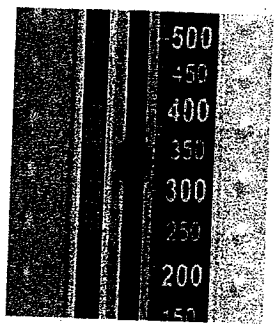


Features

- Designed specifically to meet ISO23747 scale standard
- Movable asthma management colour zones that won't wash off
- Large, high visibility scale
- In-built internal check valve, avoiding cross infection concerns
- Meets and exceeds all international performance standards
- Customisation possible for promotional purposes
- Available with either European or ATS scale



Peak flow record chart showing recovery from acute asthma with pronounced morning dips.



(Colour-Zone asthma managment system)

Specifications

MicroPeak™

Range	60-900 l/min (EU, EN13826/ ISO23747) 60-900 l/min (ATS)
Scale Increment	10 l/min
Accuracy	<+/ – 5% or 10 l/min
Repeatability	<+/ – 2%
Calibration	100% (individual unit)
Frequency Response	c100Hz @ 350 l/min
Dynamic State	Critically damped @ 350 l/min
Standard Compliance:	ISO 23747 AS/NZS 4237:1994 NAEP Guidelines 1991
Integral Check Value	Expiration only

International Sales:
CareFusion Germany 234 GmbH.
Leibnizstrasse 7,
D-97204 Hoechberg,
Germany.
+49 (0) 931 4972 0 tel
+49 (0) 931 4972 423 fax

U.K Sales:
CareFusion UK 232 Ltd.
The Crescent, Jays Close,
Basingstoke,
RG22 4BS, UK
+44 (0) 1256 388550 tel
+44 (0) 1256 330860 fax

Research and Design Office:
CareFusion UK 232 Ltd.
Quayside, Chatham Maritime,
Chatham, Kent,
ME4 4QY, UK
+44 (0) 1634 899599 tel
+44 (0) 1634 899598 fax

CE 0086

carefusion.com/micromedical

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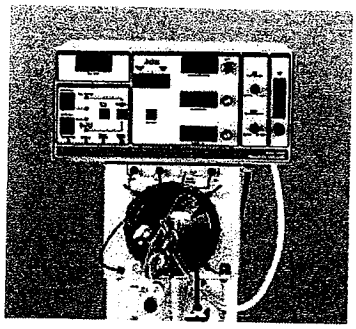
LOCATIONS: Worldwide Offices

SEARCH: CareFusion.com

SensorMedics 3100A High Frequency Oscillatory Ventilator

High Frequency Oscillatory Ventilator



The SensorMedics 3100A High Frequency Oscillatory Ventilator (HFOV) from CareFusion is the only high frequency oscillatory ventilator approved in the U.S. for early intervention in the treatment of neonatal respiratory failure. The SensorMedics 3100A provides the lung protective tools to treat your patients by inflating the lung with a continuous distending pressure and superimposing very small pressure and volume swings to achieve ventilation. Numerous publications have reported improved benefit and outcomes associated with the use of HFOV. The Alliance of Children's Hospitals, Inc. has awarded their prestigious Seal of Acceptance to the SensorMedics 3100A HFOV. The seal establishes Standards of Excellence for pediatric products and creates a new standard of expectations for pediatric product users.

THE CAREFUSION DIFFERENCE

Requires no conventional breaths to avoid stretch injury

The most studied and researched high-frequency ventilator on the market today

The only high frequency ventilator that is FDA cleared for early intervention in the treatment of neonates in respiratory failure

The standard of care in more than 90% of Level III nurseries in the US and 75% of the Pediatric Intensive Care Units

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Related Products & Services

AVEA Ventilator System

Infant Flow SIPAP System

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SensorMedics 3100B High Frequency Oscillatory Ventilator

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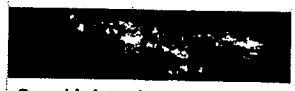
28th Conference on High Frequency Ventilation of Infants, Children, and Adults



Snowbird, Utah
March 29 - April 2, 2011

Call for Abstracts due on January 10, 2011

More information
Donald.Null@Imail.org

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CareFusion

MiniMe Nasal Mask

CPAP Mask

The MiniMe® Nasal Mask from CareFusion is the noninvasive answer, uniquely engineered by top professionals in the industry and hailed by numerous medical practitioners. This stylish sleep mask is designed for comfort and compliance. If you've ever had difficulty finding a sleep mask to fit a tiny nose, the MiniMe® Nasal Mask may the solution you've been looking for. Like its predecessor, the IQ®, the MiniMe® Nasal Mask has a bendable wire embedded in a flexible shell, allowing the mask to be reshaped instantly. Its skin-soft gel cushion that reduces the irritation commonly associated with nasal masks.

VIEW PRODUCT BROCHURE (1504 KB)

THE CAREFUSION DIFFERENCE

Our "Softer than Skin" gel helps seal masks without causing facial irritations and indentations.

The MiniMe® Nasal Mask is the true standard for your patients who need smaller masks.

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PureSom CPAP System

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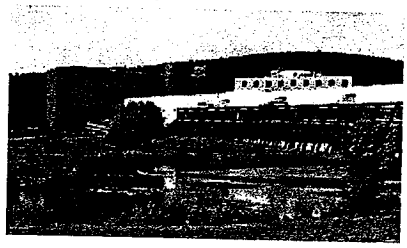
More Answers Than You'd Ever Imagine

What began in 1839 as a small-town pharmacy has now become a major healthcare company.



We are B. Braun. The new leading choice for a comprehensive offering of superior medical products and value-added services.

After 170 years our future is brighter than ever. Find out more about our rich heritage and our mission to continually develop medical technology that makes a difference.

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- IV Safety Infusion System barcode technology to reduce medication errors
- Passive needle-free IV system
- Positive pressure capless valve
- Capless IV system
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- Passive safety huber needle
- IV admixture outsourcing service, CAPS®
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For superior innovation that spans virtually all healthcare disciplines, B. Braun leads the way.

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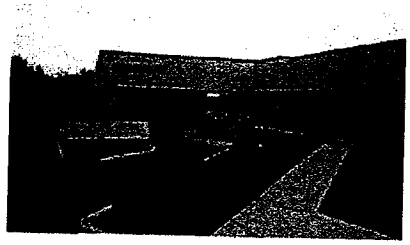
B. Braun is more than just a medical products company. We're your healthcare partner, too. When you want to improve safety for clinicians and patients, our needle-free IV systems and PVC-free & DEHP-free plastic IV containers deliver the answers. When you need professional pharmacy admixture assistance, our CAPS® outsourcing pharmacy program provides the cost-effective solution. We even offer customized products via Design Options, as well as clinical assistance with our RN Help Line, Clinical and Technical Support Programs.

World Class Professionals. A Wide Range of Products

As part of a global organization with 38,000 professionals worldwide, we are a full-line IV therapy and broadline healthcare supplier.



B. Braun offers customers everything from IV accessories to critical care products. We're also a major player in pain control, a worldwide leader in regional anesthesia devices and

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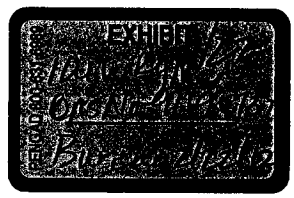
- Medication Error Reduction
- DEHP Risk Reduction
- Needlestick and Sharps Safety

USP <797> Compliance



we feature a growing vascular access and interventional product line. Plus, we provide a wide array of pharmaceutical devices and services, as well as non-acute focused products.

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Please complete the Grant Request Form, following the instructions on the form. You will need to print the completed form and submit it with the supporting documentation outlined below. We will not be able to consider any incomplete requests.

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For Charitable Donation Requests:
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- Statement of charitable mission
- Description of fundraising activity and levels of sponsorship

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Please send the completed Grant Request Form and supporting documentation via fax, mail or email to:

Fax:	**Mail:**	**Email:**
(610) 997-5510 B. Braun Medical Inc Attention: Compliance Specialist	B. Braun Medical Inc Attention: Compliance Specialist 824 Twelfth Avenue Bethlehem, PA 18018	grantrequests.us @bbraun.com

If the required supporting documentation does not accompany a grant request, it will not be considered. The review process may take up to four weeks once the completed grant request packet is received. We cannot guarantee approval of your request. If we approve your grant request, you will receive a letter in the mail stating our level of support, together with any applicable information relating to our support.

Please e-mail your questions to grantrequests.us@bbraun.com.

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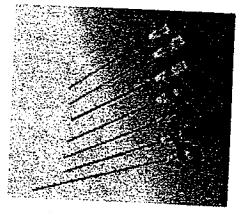
Trays



B. Braun is a market-leading supplier of regional anesthesia trays and needles. Our unparalleled selection of spinal needles enables us to offer you the widest possible choice of standard and custom spinal trays.

B. Braun standard spinal trays feature our Pencan, Spinocan, Atraucan, and Sprotte spinal needles with the following procedural drugs:

- Bupivacaine HCl 0.75% with dextrose 8.25% - 2mL
- Lidocaine HCl 5% with dextrose 7.5% - 2mL
- Tetracaine HCl 1% pre-mixed - 2mL
- Lyophilized Tetracaine HCl - 20mg

Convenience

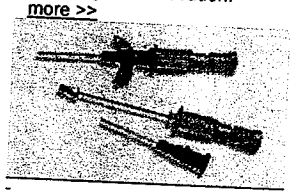
B. Braun also packages standard procedural trays with drug combinations so that you may only have to stock one tray for your facility. The P25LBK tray gives you 2mL ampules of hyperbaric lidocaine HCL 5% and hyperbaric bupivacaine HCl 0.75% in one tray. For utmost convenience, choose the P25LBTK tray, which adds in a 2mL ampule of tetracaine HCl 1% and 3mL of dextrose 10%.

Safety

B. Braun's FILTER STRAW® particulate matter filter offers you a needle-free means to aspirate fluid from ampules. A clear plastic fenestrated drape is also standard to help you better visualize anatomical landmarks.

PRODUCT CATEGORIES

Support Trays | Custom Trays



Standard

Perifix® brand epidural catheters from B. Braun have set the pace for superior product performance since their introduction into the U.S. market in 1984.

Anesthesia providers easily distinguished what makes Perifix catheters outperform: kink-resistance, stretch resistance, threadability without a stylet, and a reliable catheter connector.

In just 6½ years after its introduction, the Perifix catheter emerged as market leader. It's a position that still holds true today.

Take a moment to review some of the product options we offer, and then talk to your local B. Braun representative to learn more.

Polyamide Catheter: Unique Recipe

Perifix Standard epidural catheters are made from a unique formulation of polyamide nylon.

Although other vendors may also claim to have "polyamide" catheters, their nylon recipe is different. The Perifix polyamide nylon offers you:

- unparalleled kink resistance
- stretch resistance
- easy threadability
- inert, bio-compatible material

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NEW! Perifix® Catheter Connector
Our current Tuohy-Borst connector is being replaced with a new low-profile, "click-to-close" connector. Click here to learn more about the connector and our conversion plans for your tray/set.

Introcan Safety® IV Catheter
Designed to minimize accidental needlesticks without requiring user activation.
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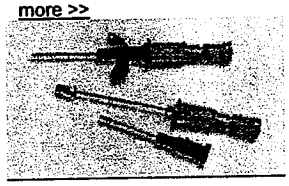

DUPLEX® Drug Delivery System
A two-compartment flexible plastic IV container that uses breakthrough technology to store both the diluent and the drug powder separately until the point of use.
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Admixture Products
Compounding and Nutrition Products
Dialysis Products
Duplex and Premixed Drugs
Infusion Pump Systems & Sets
Irrigation/Urology Sets & Solutions
IV Administration Sets & Access Devices
IV Solutions
LDL Apheresis
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Product Catalog

Technical Product Data
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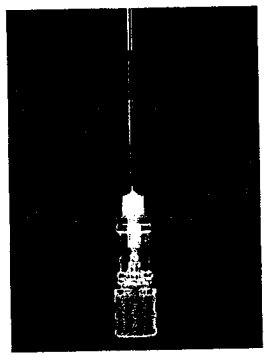
Products > Pain Control Products > Epidural Products Global and US Market Leader > Epidural Products > Needles (Perifix) > Needles > Standard - Features

Standard

The wide array of Perifix needles feature:



- precision ground, matched stylets to reduce the risk of tissue coring
- convenient 1cm depth markings making it easier to observe and control the exact depth of insertion
- polished inner bevel to smooth the edge and minimize the risk of catheter shearing
- clear polycarbonate hubs to offer easy visualization of blood or CSF
- fixed wings on most needles providing a stable surface for your fingers
- hourglass-shaped, ridged hub offering ergonomic placement of your fingers

Quality: Strength in Numbers

Needle	Buckling force [Newtons]
Perifix 17G O.D. 0.0589 in.	57.49
B-D 17G O.D. 0.0577	40.62
Perifix 18G O.D. 0.0532	40.32
AMI 18G O.D. 0.0502	27.07
Manan 18G O.D. 0.0499	28.58

B. Braun epidural needles were tested for stiffness and malleability along with a variety of epidural needles from other domestic manufacturers.(1)

The Perifix 17G epidural needle "was clearly the most durable of the needles tested."(2)

1. Dunn S.M., et al. **A Fractured Epidural Needle: Case Report and Study.** Anesth Analg 1992;75: 1050 - 52.

2. Dunn SM, Goolishian, WT. **All Epidural Needles Are Not Created Equal.** Anesth Analg 1996;83(3): 659.

The catheter's threading assist guide plugs into the polycarbonate hub of

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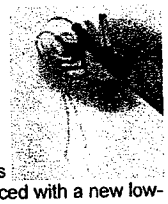

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Introcan Safety® IV Catheter
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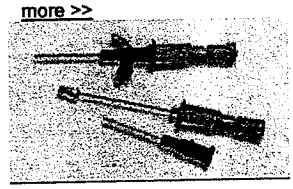

DUPLEX® Drug Delivery System
A two-compartment flexible plastic IV container that uses breakthrough technology to store both the diluent and the drug powder separately until the point of use.
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B. Braun and Venetec Partner to Reduce Risk of Accidental Needlestick Injuries and Exposure to Bloodborne Pathogens

Passive Introcan Safety IV Catheter and StatLock Securement System Offered Together to Enhance Patient and Clinician Safety

Bethlehem, PA (July 31, 2003) - B. Braun Medical Inc. and Venetec International today announced a landmark agreement to jointly market and sell a revolutionary sharps safety system combining the B. Braun Introcan Safety IV Catheter and Venetec StatLock IV catheter securement device to reduce the risk of accidental needlestick injuries and exposure to bloodborne pathogens.

Under the two-year agreement, effective immediately, B. Braun will offer its safety-conscious customers the passive-design Introcan Safety IV Catheter, with built-in securement through Venetec's innovative StatLock IV catheter securement device for Introcan Safety IV Catheter. The two companies have closely collaborated to create a peripheral vascular-access system that offers unparalleled patient safety through:

1. The StatLock securement device's improved clinical outcomes;

2. Introcan Safety IV Catheter's passive design needlestick injury protection; and

3. Conformity to international color-coding for patient safety, identifying a venous access device.

"This agreement represents a major achievement in establishing the new worldwide standard for peripheral IV catheter safety, benefiting patients and clinicians alike," said Steve Bierman, M.D., medical director and CEO of Venetec International. "A passive safety catheter (Introcan Safety) with built-in StatLock securement provides a system that is not only the easiest to use for clinicians, but also the safest for patients and caregivers. A new standard of care has been established."

"This partnership with Venetec International enhances our ability to offer technology that improves patient care while protecting healthcare workers from accidental needlestick injuries," said Caroll H. Neubauer, Chairman and Chief Executive Officer of B. Braun Medical. "The passive design of the Introcan Safety IV Catheter, partnered with the custom-designed StatLock IV catheter securement device for the Introcan Safety IV Catheter, is a unique combination developed specifically to reduce the risk of exposure to dangerous bloodborne pathogens."

The passive Introcan Safety IV Catheter is designed to minimize accidental needlesticks without requiring user activation of the safety mechanism. The passive design eliminates risk of inadvertent activation, yet the removable flash-plug and convenient syringe attachment allow the clinician to utilize the Introcan Safety IV Catheter much like a non-safety IV catheter design. Compliance is virtually assured without changing technique since the safety mechanism cannot be bypassed.

StatLock IV catheter securement device for Introcan Safety IV Catheter is the first peripheral IV securement device to be custom-crafted so it locks onto the catheter hub - preventing accidental dislodgements and movement-related complications. The device is also color-coded blue, signaling a venous access device, to further reduce medical errors. StatLock IV catheter securement device is

proven to reduce patient complications such as phlebitis and infiltration. Much easier and faster than tape securement, the StatLock IV catheter securement device also reduces unscheduled catheter restarts saving hospital nursing staff time that is now wasted on troubleshooting and restarting tape-secured IVs.

B. Braun and Venetec are members of the National Alliance for the Primary Prevention of Sharps Injuries (NAPPSI), a nonprofit organization dedicated to needlestick safety that includes more than 25 corporate members, more than 1,000 individual clinicians, and major clinician professional organizations. This collaboration in design, sales, and marketing reflects NAPPSI's call to manufacturers to work together to maximize safety protections for nurses and doctors.

This current agreement represents an approximately $20 million, two-year commitment from B. Braun to Venetec. Under agreements announced last year, B. Braun also includes the StatLock IV securement device with the B. Braun ULTRASITE Needle-Free IV System and includes Venetec's StatLock CV Plus catheter securement device in B. Braun's Certofix Central Venous Catheter kits.

About B. Braun
With more than 28,000 employees worldwide, B. Braun is a full line supplier of innovative healthcare products & programs designed to improve both patient and clinician safety. Through its People, Products, and Programs - "Working Together for Excellence in Safety™" initiative, B. Braun promotes best practices and products for continuous improvement of safety.

Founded 160 years ago, B. Braun is proud of its longstanding tradition and commitment to delivering innovative healthcare products and programs with unmatched quality, superior technology, and cost-effectiveness, while maintaining environmental responsibility. For more information about B. Braun or its safety healthcare products, call 800-854-6851, or visit B. Braun at www.bbraunusa.com.

About Venetec
Venetec International is a privately held, infusion-safety company dedicated to eliminating the dangers to patients and healthcare workers caused by suture and tape securement of IVs. Venetec's world-renowned StatLock product line includes devices for securement of virtually all of the 800 million medical tubes and catheters placed annually. Protected by more than 100 patents and patents pending, Venetec has established StatLock securement as the new worldwide standard, through its U.S. sales force and international alliances. StatLock is used in more than 30 countries and is part of the standard of practice in such eminent institutions as the David Geffen School of Medicine at UCLA, the National Institutes of Health, Beth Israel Deaconess Medical Center, and the Cleveland Clinic. StatLock is an integral part of catheter insertion trays made by most major manufacturers. For more information, call (800) 833-3895 or access www.Venetec.com.

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BD

Products

BD Nexiva Closed IV Catheter System

BD Nexiva™

Closed IV Catheter System

A New Standard in IV Therapy

An open-label, prospective, randomized, noninferiority study was conducted at a large academic, Magnet-designated, Level 1 trauma center to compare the peripheral intravenous catheter securement-related complication rates of 2 different stabilization systems. The control stabilization system included the StatLock device with a nonwinged catheter, and the investigational stabilization system included a closed catheter system with a specially designed Tegaderm dressing. Data from 302 subjects indicated that the investigational stabilization system was noninferior or similar to the control stabilization system with respect to the overall securement-related complications. The cost of the investigational stabilization system was approximately 75% of the cost for the control stabilization system.
View study »

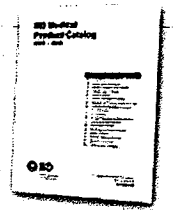
The first of its kind, this all-in-one system is designed to reduce insertion attempts for first-stick success, as well as reduce your exposure to blood though the innovative blood-containment system.

For more information on how you can get the BD Nexiva Closed IV Catheter System for your facility, simply send us an email or call us at 1.888.237.2762.

BD Instaflash™ Needle Technology

Designed to help clinicians improve first-stick proficiency by confirming immediate vessel entry at the point of insertion.

Learn More



BD Medical: Product Catalog

View Catalog

Features and Benefits

Techniques for Use

Product Animation

- Brochure
- Points to Practice
- Tips for Success
- Priming - Points to Practice
- Power Injection
- Reaching a Higher Standard
- Instructions for Use

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BD 2009 Sustainability Report

Health and Safety

BD considers providing a safe workplace to be a value, not a program or a goal. The health and safety of our associates is our priority. We seek to continuously improve our performance and to establish a zero mindset concerning occupational injuries and illnesses. This means that we want our associates to focus on staying injury free, rather than on hitting or missing a specified target at the expense of safety. BD's wellness programs help associates make healthy choices, improving their productivity and reducing absenteeism.

Management

BD's global health and safety standards, developed through collaborations with our onsite environmental, health and safety (EHS) specialists, provide guidance and define the standards we expect from each associate, including our senior leaders.

Our EHS teams coordinate health and safety training to help ensure that associates understand both BD's standards and their individual responsibilities. The teams also conduct awareness campaigns to highlight potential risks and to share best practices among sites.

Operations leaders are responsible for implementing our EHS requirements at BD facilities, and they set safety leadership expectations for their facilities managers. BD sites have Continuous Improvement (CI) leaders who are trained to improve operating performance by focusing on resource management, productivity changes and cost control measures. These CI leaders also work to ensure that EHS measures are considered when redesigning or improving manufacturing processes.

BD's EHS compliance program comprises local requirements and external standards. Compliance audits are conducted continuously by internally qualified auditors on a schedule of every three to four years, with onsite follow ups within 12 months of the original audits. Where appropriate, audit teams comprise external auditors who provide independent oversight and local expertise.

Safety Process Model

BD's Safety Process Model (SPM) is our global safety performance improvement program implemented in 2007. SPM includes a web-based database to track and measure performance in the following areas:

- Closing out findings from monthly safety inspections
- Identifying the root causes of first aid and recordable safety incidents
- Performing risk assessments for all machinery and processes
- Tracking and trending "near miss" incidents

The data are collected and the numbers are reported as a Monthly Safety Index score. The goal is for sites to improve their score each month as they improve their safety performance. Since we introduced the SPM, sites have reported increased levels of knowledge about safety hazards, as well as strong associate engagement in the safety process at the plants.

BD created the SPM to help improve our ability to identify and eliminate risks and to increase our associates' engagement in safety. We expect our performance, as reflected in a decrease in our illness and injury rate, to improve as we fully implement the model.

Health and Safety Risks

We have put in place measures to identify and control risks common to manufacturing facilities across sectors. Many of BD's manufacturing processes involve high-speed manufacturing and assembly of multi-piece plastic components, which can result in exposures to the following hazards:

- Points of operation of machinery
- Electrical safety hazards from equipment
- Slips and trips from working surfaces
- Musculo-skeletal disorders such as lower back pain, joint injuries and repetitive strain injuries from material-handling activities

To address machine-guarding exposures, an independent expert conducted systematic machine-guarding audits throughout our sites and identified corrective actions to eliminate these risks. We also developed a global Machine Safety Specification Standard to ensure new equipment built for our sites meets the highest safety standards in the world.

We conduct periodic evaluations of potential electrical hazards, develop work procedures and conduct training to minimize risks. We also work hard to manage housekeeping issues that can contribute to falls in our workplaces. In addition, we have programs to target risks from processes specific to our industry.

Chemical Exposure

We use solvents and inks to print and label our products, as well as in the lubrication process for our needles. These processes involve minimal chemical exposures. We monitor air quality to ensure that our associates are not exposed to airborne chemicals and that exhaust ventilation systems are working effectively.

Noise

We continually look for ways to reduce noise, including purchasing machinery with low noise levels when we buy new equipment. At our larger, high-speed manufacturing and assembly operations, we require associates to wear hearing protection equipment. We also conduct hearing tests annually on our associates to monitor any changes in their hearing and to enable us to take action to prevent the risk of damage to their health.

CASE STUDY **Double-duty equipment helps associates stay safe**

California, U.S. — At our BD Biosciences facility in San Diego, the packaging process involves multiple steps, including weighing boxes at a separate station after they are packed and before they are shipped. As a result, associates lift 20-pound boxes and twist their bodies to weigh them more than 40 times per shift.

To address this, we purchased pallet jacks with a built-in weight scale. Now, associates weigh packages as they are being transported to shipping containers. This has reduced handling time, as well as the number of handling steps, and has significantly relieved associates from having to go through repetitive motions of lifting and weighing boxes.

Hazardous materials

Many BD products must be sterilized before they are sold. To do this, we expose our products to radiation that eliminates any micro-organisms, bacteria or viruses. In the United States, where we use cobalt as a radiation agent, the process is highly regulated by the U.S. Nuclear Regulatory Commission and is completely automated so that there is no potential for human exposure.

At many of our other manufacturing sites in Asia, Europe, and North and South America, we use ethylene oxide sterilization chambers. We have a deep understanding of the hazards associated with this material and these processes, and we have developed a global safety standard that meets or exceeds the most stringent requirements for this material.

Performance

Please see the Performance section to read about BD's health and safety performance for 2009.

CASE STUDY **Associates Collaborate for Safety**

GLOBAL — When safety teams at eight of our **BD Medical** — Medical Surgical Systems plants in the U.S., Puerto Rico, Brazil and Mexico were issued a challenge by their operations leader to improve safety performance, they accepted enthusiastically, and the Medical Surgical Multi-Site Safety team was born. The challenge for the team was to learn from each other and develop best practices in order to drive continuous improved performance toward elements of the Safety Process Model.

The team members now participate in monthly conference calls to discuss recent incidents, investigation results and action items on which the plants are working. Each member is assigned an area of expertise on which to report back to the group.

As a result of this collaboration, every participating site has implemented new programs for all elements of the Safety Process Model. These include stronger incident investigations, on-time completion of internal audit findings, equipment risk assessments and engagement in tracking and addressing near misses.

In 2009, each of the eight sites reported improved safety performance. The average Safety Index score climbed from 68 to a current average score of 83. The members of the Multi-Site Safety team report that this cooperative focus has helped accelerate their progress at improving safety conditions at their respective sites.

Wellness

BD Healthy Lives

BD is a more productive company when our associates are healthy. *Healthy Lives*, our wellness program, encourages associates to stay healthy and provides them with the support and information they need to stay fit and make smart choices. Examples include smoking cessation programs, mental healthcare support, and "Maternal Link," which gives mothers-to-be pregnancy-related healthcare information.

Quiet Room

At our Franklin Lakes, New Jersey headquarters and in Singapore, a quiet room is available to all associates as a place to take a few moments for contemplation, reflection, meditation or personal prayer during the business day.

Ergonomics

The health and safety of our associates working in offices is as important as that of those working in our manufacturing plants, even though they are exposed to fewer hazards. Furniture, technical equipment and lighting are all designed to ensure associates are comfortable and to reduce the risk of repetitive stress injuries.

Many of our sites have multi-functional ergonomics teams to identify and reduce exposures that can contribute to repetitive stress injuries such as carpal tunnel syndrome. BD Biosciences employs a certified ergonomist to provide expertise and support to the teams throughout the entire company in addressing these issues.

In 2009, our BD Biosciences facility in San Jose, California received the U.S. Green Building Council's LEED Certification (Leadership in Energy and Environmental Design) for new construction. To become LEED-certified, buildings accrue a set number of points for having environmentally sustainable design, construction and operational practices. As part of the certification in San Jose, the site received a point for ergonomics, making it one of the first buildings in the United States to meet this requirement. The site received the point not only by designing work spaces to reduce the risk of repetitive stress exposures, but also by providing ergonomics education to associates who work in the building.

CASE STUDY

BD facility in Yishun honored by Singapore Human Resources Institute

SINGAPORE — Our manufacturing facility in Yishun, Singapore was honored by the Singapore Human Resources Institute (SHRI) at the 2009 Singapore HR Awards. Since 2001, this facility has taken a comprehensive approach to health by promoting holistic physical, social, spiritual, emotional and intellectual wellness.

Associates understand that even a minor accident can shut down the plant, and they are taught to view improper safety and health practices as more than injuries and illnesses. They understand that a simple problem of being over-stressed at work may lead them to make mistakes which can result in an accident that may disrupt business. They are also taught to consider their health and well being as intricately linked with the health and well being of the Company.

As a result of this holistic approach, and of associates' dedication to their physical well being, the percentage of the workforce with high cholesterol has decreased by 26 percent and the proportion of associates who are overweight has dropped by 2.7 percent since 2006. These improvements alone have contributed to a **13 percent reduction in medical costs per associate.**

WWW.BD.COM/SUSTAINABILITY/2009/OURASSOCIATES/HEALTHSAFETY.HTML

BD

Products

2000 Needlestick Safety and Prevention Act 1,2

The November, 2000 Needlestick Safety and Prevention Act requires employers to evaluate and implement effective and appropriate safety-devices in their facilities, including scalpels and blades.

1. What was the effective compliance date?

October 18, 2001

2. Who has to comply?

Hospitals, alternate site facilities, clinical laboratories and other facilities where employees may be exposed to blood or other potentially infectious material are covered by the Bloodborne Pathogens Standard. ER, OR and alternate site facilities that utilize scalpels are also covered.

View a safety scalpel demonstration

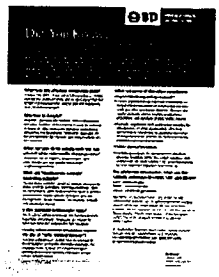
View Now

3. What can you do to comply with the scalpel and other non-needle sharps portion?

Adopt the use of scalpels and surgical blades with "engineering controls." "Engineering controls" isolate or remove exposure to blood or other potentially infectious materials. For example: scalpels with protective shields.

4. Is this standard enforceable? How?

Yes. It will be enforced through the traditional OSHA inspection procedures. Employers are subject to monetary fines for violating the BBP Standard.



Download OSHA FAQ

Numerous occupational safety and health studies demonstrate that the use of safety-engineered medical devices when part of an overall BBP risk-reduction program can be extremely effective in reducing accidental sharps injuries.

The BD Bard-Parker™ Protected Blade System has been designed to reduce accidental sharps injuries.

BD Bard-Parker Protected Blade System may be ordered through your BD Representative and Distributor.
For ordering information call: 1.888.237.2762.

1. CONGRESSIONAL RECORD, Vol. 146 (2000): Document ID f:publ430.106

2. United States Department of Labor, OSHA, Needlestick Safety and Prevention Act FAQ. http://www.osha.gov/needlesticks/needlefaq.html

3. CDC: Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program. http://cdc.gov/sharpssafety/wk_overview.html

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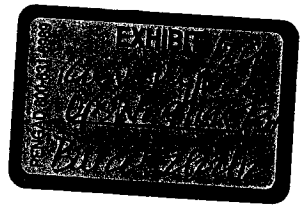

BD

Resource Center

Needlestick Safety and Prevention Law Frequently Asked Questions & Answers

Real Information: The Needlestick Safety and Prevention Law

On November 6, 2000, the Needlestick Safety and Prevention Act was signed into law. The new compliance deadline, mandated by this law has been moved to April 18, 2001. In an effort to assist your healthcare facility in understanding and complying to the law, BD has developed the following Frequently Asked Questions.

- In short, what does the new legislation accomplish?
- Is this directive enforceable? How?
- Exactly what medical procedures require the use of "safer medical devices"?
- What are "engineering controls"?
- Is a specific product technology or brand recommended in the revised regulation?
- When does the new legislation take effect?
- So, when do I have to be in compliance?
- What do I have to do to be in compliance?
- Who has to comply?
- Are there any "loopholes" or exceptions to the use of "safer medical devices"?
- For additional information, what are the website addresses of OSHA, CDC and NIOSH?

In short, what does the new legislation accomplish?
The new legislation serves to reinforce the BBP standard preventing legal challenges to the November 5, 1999 Federal OSHA Compliance Directive.

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Is this directive enforceable? How?
Yes. It will be enforced through the traditional OSHA inspection procedures. Employers are subject to monetary fines for violating the BBP standard.
Citations can be issued for:
- Failure to have an Exposure Control Plan.
- Failure to review and implement commercially available "safer medical devices."
- Failure to include procedures for documenting exposure incidents.
- Failure to review and update plan at least annually.
- Failure to follow universal precautions.
- Failure to comply with most current CDC recommendations for post-exposure evaluation and follow-up.

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Exactly what medical procedures require the use of "safer medical devices"?
Any time a healthcare worker may be exposed to blood or other potentially infectious material, the employer must evaluate and implement safer medical devices that eliminate exposures to the lowest feasible extent.

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What are engineering controls"?
The term "engineering controls" is now defined and means controls that isolate or remove the BBP hazard from the workplace. They are described as "safer medical devices used to prevent percutaneous injuries before, during or after use through safer design features." Examples include needleless devices, shielded needle devices, blunt needles, plastic capillary tubes.

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Is a specific product technology or brand recommended in the revised regulation?
No. As OSHA states in the Compliance Directive, "OSHA does not advocate the use of one particular device over another."

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When does the new legislation take effect?
- Federal Bill HR 5178 was signed into law by President Clinton on November 6, 2000. Publication of the legislation in the Federal Register took place on January 18, 2001, resulting in an April 18, 2001 compliance date.
- Please be mindful that throughout this time and until the time the legislation takes effect, the Federal OSHA Compliance Directive of November 5, 1999 remains in effect and fines are enforceable.

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So, when do I have to be in compliance?
April 18, 2001.

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What do I have to do to be in compliance?
- Update or create a BBP Exposure Control Plan.
- Evaluate and implement "safer medical devices" where they are found to be effective in eliminating or minimizing occupational exposures. Frontline healthcare workers are to be part of the evaluation and selection process.
- Continuously monitor the effectiveness of engineering controls.
- Update employee training to include training on HCV and the use of "safer medical devices."
- Review new Compliance Directive to determine other specific changes necessary for the needs of your facility.

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Who has to comply?
Hospitals, alternate site facilities, clinical laboratories and other facilities where employees may be exposed to blood or other potentially infectious material are covered by the BBP standard. Special rules apply in home health services and to personnel service firms that supply contract workers to hospitals and other healthcare facilities.

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Are there any "loopholes" or exceptions to the use of "safer medical devices"?
There is no list of exceptions. Employers must review and consider commercially available devices to determine whether they are effective in reducing occupational exposures to the lowest feasible extent.

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For additional information, what are the website addresses of OSHA, CDC and NIOSH?
CDC and NIOSH: www.cdc.gov/niosh
Federal OSHA: www.osha.gov

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For additional information regarding the Needle Safety and Prevention Law, contact your local BD Sales Consultant.

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