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applications, but as medical devices become smaller and more compact, parylene certainly finds increasing value due to its molecular level deposition. … Parylene coatings protect a wide array of devices and components, including stents, cardiac assist devices, electrosurgical tools, cochlear and ocular implants, mandrels, and molds, catheters, elastomeric seals, needles and probes, neurostimulation devices, medical electronics, and more.

MPMN: What technical challenges had to be overcome in order for parylene to work for medical devices?

Gillespie: One of the first considerations in the medical industry is whether or not a material is biocompatible and biostable. Parylene coatings are inherently both. SCS Parylenes N, C and Parylene HT have been tested according to the Biological Evaluation requirements of ISO 10993. Further, the biocompatibility and biostability of SCS Parylenes have been demonstrated in a wide range of medical coating applications over the past four decades.

An additional technical challenge arises in the area of coating adhesion. Factors such as surface contamination, presence of oxide layers, and low surface energy substrates can lead to poor adhesion and the reduction in the effectiveness of coatings used in these devices. Optimal adhesion of parylene to a wide variety of substrates is commonly achieved by a treatment with A-174 silane prior to parylene coating. To address difficult metallic and polymeric substrates, newer adhesion technologies are available. …

MPMN: Any drawbacks around parylene? What should a medical device designer consider when deciding whether to use parylene?

Gillespie: Parylene coating is applied as a vapor in a vacuum deposition process. … Parylene coating service providers offer the most flexibility in terms of coating high production volumes in a timely and cost-effective manner. However, like all applications are not the same, coating service providers are not all the same. For medical customers, it is important to look for a partner who can not only help achieve the desired results via experienced applications engineering support, but also one who can meet your strict quality requirements and support your FDA submissions with biocompatibility test data.

Chris Newmarker is senior editor of MPMN and Qmed. Follow him on Twitter at @newmarker.

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A general term for thermoplastic film polymers produced from *p*-xylene and having the repeating structure $-(CH_2C_6H_4CH_2-)_n$, where *n* is approximately 5000; used as a pore-free coating and in ultrathin plastic films for capacitor dielectrics.

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News

A New Look at Parylene Conformal Coatings

Posted in Surface Treatment Coatings by mddiadmin on September 1, 2008

Parylene can enhance a number of cardiological and surgical devices.

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If you are not familiar with parylenes, you should be, especially if you make cardiovascular and surgical devices. This family of conformal coatings provides a number of benefits to medical devices.

Parylene conformal coatings have protected components in the medical device industry for over 35 years. Today more than ever, they are the ideal protection for leading-edge medical device technologies used in many critical cardiovascular and surgical applications, including orthopedic surgical tools.

Parylene is the generic name for a unique series of polymeric organic coating materials that are polycrystalline and linear in nature. They possess useful dielectric and barrier properties per unit thickness, and are chemically inert. Parylene coatings are ultrathin, pinhole-free, and truly conform to components due to their molecular level polymerization—basically "growing" onto the deposition surface one molecule at a time.

Parylenes provide unmatched moisture, chemical, and dielectric protection. They also provide surface lubricity. But the greatest benefit may be their biocompatibility, especially with the growth of new minimally invasive surgical procedures and implant technologies. Parylenes not only do not affect the body in any negative way, but they can be used on devices to enhance their acceptance within the body.

ISO biological evaluations have demonstrated very low levels of fibrous capsule formation, nearly nonexistent toxicological responses, and excellent hemocompatibility.[1]

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nonexistent toxicological responses, and excellent hemocompatibility.[1]

Parylene is also the only family of conformal coating materials that are applied via a vapor deposition process. This process ensures that the coating can provide 100% coverage. It means the coating can penetrate deeply into the smallest crevices where other types of coatings simply cannot reach, or would bridge over the area, leaving the potential for delamination of the coating or even damaging small devices, components, or electrical connections by the sheer weight of the coating material itself.

Vapor Deposition Polymerization

Devices to be coated are placed in a room-temperature deposition chamber. A powdered raw material, known as dimer, is placed in the vaporizer at the opposite end of the system. The double-molecule dimer is heated, causing it to sublimate directly to a vapor, then is heated again to a very high temperature that cracks it into a monomeric vapor. This vapor is transferred into the ambient temperature deposition chamber where it spontaneously polymerizes onto all surfaces, forming an ultrathin, uniform, and extremely conformal parylene film. The parylene coating process is carried out in a closed system under a controlled vacuum. The deposition chamber and parts to be coated remain at room temperature throughout the process. No solvents, catalysts, or plasticizers are used in the coating process. No curing process or added steps are required.

Because there is no liquid phase in this deposition process, there are no subsequent meniscus, pooling, or bridging effects as seen in the application of liquid coatings. As a result, dielectric properties are never compromised. The molecular "growth" of parylene coatings also ensures not only a uniform, conformal coating at the thickness specified by the manufacturer, but because parylene is formed from a gas, it penetrates into every crevice, regardless of how seemingly inaccessible. This assures complete encapsulation of the substrate without blocking, or bridging, even the smallest openings.

Parylene Variants and Capabilities

Parylene N is a carbon-hydrogen molecule, poly(para-xylylene), a completely linear, highly crystalline material. Parylene N is a primary dielectric, exhibiting a very low dissipation factor, high dielectric strength, and a low dielectric constant invariant with frequency. The penetrating power of Parylene N is second only to that of Parylene HT.

Parylene C is a carbon-hydrogen molecule with a chlorine atom on the benzene ring. It is produced from the same dimer as Parylene N but modified with the substitution of a chlorine atom for one of the aromatic hydrogens. Parylene C has a most useful combination of electrical and physical properties plus very low permeability to moisture and corrosive gases.

Parylene D is produced from the same dimer as Parylene N, modified by the substitution of chlorine atoms for two of the aromatic hydrogens. Parylene D is similar in properties to Parylene C, with the added ability to withstand higher use temperatures (up to 125°C). Parylene D is generally not used in the medical device industry, as it lacks the necessary biocompatibility credentials.

The newest formulation is Parylene HT, which was developed by replacing the alpha hydrogen atom of the Parylene N dimer with fluorine. This formula provides protection in high temperature

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environments up to 350°C (short-term, up to 450°C), and offers long-term UV stability not available with the other parylenes. It also has the lowest coefficient of friction, a very low dielectric constant and, because of its extremely small molecular size, it has the highest crevice-penetrating capability of all the parylenes. (Parylene HT is a registered trademark of Specialty Coating Systems.)

All parylene film coatings are free of fillers, stabilizers, solvents, catalysts, and plasticizers. They are extremely lightweight, offering excellent barrier properties without adding dimension or significant mass to delicate components. They are typically applied in thicknesses ranging from 500 Å to 75 µm. A 25-µm coating, for example, will have a dielectric capability in excess of 5,000 V. No other coating materials can be applied as thinly as parylene and still provide the same level of protection. One key benefit of parylene is that it can actually strengthen delicate wire bonds by an estimated factor of 10. Another attribute is parylene's transparency to visible light, enabling its use on optical devices and components.

Many electronic surgical systems now include various forms of memory communication and some of the newest systems are starting to interact with radio frequency (RF) and other forms of wireless communication. As precise and undistorted signals are becoming increasingly important, parylene coatings are particularly well suited for these high-frequency devices, given their extremely low dissipation factors and dielectric constants.

Common Applications

Parylene coatings can be applied to almost any material that is vacuum stable. They have been successfully applied to paper, ceramics, plastics, metals, polymers, and even feathers and powders. They are routinely applied to ferrites, nitinol, cobalt chromium, stainless steel, silicones, printed circuit boards, silicon wafers, and numerous other simple and complex components, devices, and systems. Here are some key applications in cardio and surgical areas.

ESU, RF Ablation. Electrosurgery (ESU) devices apply RF currents at frequencies in the range of 300 KHz to 5 MHz to tissue to achieve a surgical result. These processes require precise control of the RF energies to pinpoint only the target and the effects desired.

The active device contacts one surface of the target layer and positions the tissue to ablate through the layer or on its surface. Usually these tools require conductivity only at the tip or on the electrode/probe/hemostat where fulguration is to occur. The rest of the tool needs to be electrically insulated and able to withstand fairly high temperatures.

There are two basic parts to these systems—the RF generator powering the surgical tool, and the active tool that provides the cutting, coagulating, and ablation. Parylene coatings provide a secure moisture and dielectric barrier to protect the critical electronics in the generator and help to insulate and lubricate the active tool.

Electrostimulators: Implantable Cardioverter-Defibrillators (ICDs) and Pacemakers. An ICD is implanted in patients at risk for recurrent, sustained ventricular tachycardia, or fibrillation. The device is connected to leads positioned inside or on the heart's surface, which are used to sense the heart rhythm and deliver electrical shocks to stimulate the heart as needed. The various leads are tunneled to the pulse generator, which is implanted in a pouch beneath the skin of the chest or

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tethered to the pulse generator, which is implanted in a pocket beneath the skin of the chest or abdomen.

A pacemaker also uses electrical impulses to regulate the beating of the heart.

These devices require highly precise and reliable internal circuitry. Life literally depends on it. Parylene coatings provide moisture barrier, dielectric barrier, and biocompatibility properties that are critical to these devices. They prevent short circuit failures. Yet parylene does not add weight or compromise circuitry in any way.

There are, on occasion, patients who are allergic to the enclosure/case metal, titanium, of the pacemaker or ICD. A parylene coating solves this issue quite nicely.

Another scenario where parylene coatings have helped is not one where lives hang in the balance, but one involving discomfort and annoyance for the patient. When the enclosure of a pacemaker also serves as the return electrode, the stimulation signal can cause the adjacent muscles to contract. Coating the entire enclosure, save for a coin-sized space on the chest wall side, with parylene eliminates the muscle twitch.

Pumps: Heart-lung Bypass Pump and Intra-Aortic Balloon Pump. Cardiopulmonary bypass (CPB) is a form of extracorporeal circulation.

It is a technique wherein a device temporarily takes over the function of the heart and lungs during surgery, maintaining the circulation of blood and its oxygenation. The CPB pump itself is often referred to as a heart-lung machine or heart-lung pump.

Oxygen-deficient blood withdrawn from the venous circulation is collected (by gravity siphon) in a reservoir. From there, the blood is pumped through an artificial lung, or oxygenator. This is designed to exchange carbon dioxide in the blood for oxygen. As the blood passes through the oxygenator, the blood comes into intimate contact with the surfaces of the exchange membrane. Oxygen and carbon dioxide move across the membrane, permitting the blood cells to release carbon dioxide and absorb oxygen. The oxygen-rich blood is pumped throughout the patient's body.

The heart-lung pump circuit is a continuous loop. As the oxygenated blood goes into the body, oxygen-depleted blood returns from the body, and is reoxygenated and returned to the patient, completing the circuit.

An intra-aortic balloon pump is a mechanical device that is used to decrease myocardial oxygen demand while at the same time increasing cardiac output. Increasing cardiac output also increases coronary blood flow and thereby myocardial oxygen delivery. The system consists of a cylindrical balloon that is positioned in the aorta where it counterpulsates.

Parylene coatings provide the moisture and dielectric barriers necessary to prevent short circuits in the control console circuitry of these devices. A shorted circuit in the control console would be a life threatening event.

Surgical Tools: Electrically & Pneumatically Powered Surgical Instruments. Surgeons rely on powered instruments for bone surgery. Even when the surgery is not on the bone itself, the need to access a critical area may mean going through or removing bone. Pneumatic and electric power

access a critical area may mean going through or removing bone. Pneumatic and electric power sources, along with the development of interchangeable accessories, have revolutionized this surgical instrument field. Procedures are now safer, faster, and less traumatic for the patient.

All electrical and pneumatic powered surgical tools require protection of the motors and circuits that keep them running, and pneumatic tools typically require a hose for connection to the gaseous power supply. Sophisticated control consoles allow the surgeon to precisely control the instrument.

Parylene coatings provide the moisture and dielectric barrier protection required to prevent shorted circuits. Additionally, the pneumatic gas supply hoses are often made of silicone, notorious for its tacky surface and propensity for soiling. These hoses do not have a good hand (feel) and tend to be hard to clean once contaminated. Parylene coatings give these hoses a smooth, nonporous, no-tack hand that facilitates easy cleanup.

Stents, Cardiac Catheters, and NonCoiled Guidewires. Drug-eluting coronary stents come in a variety of sizes and materials, most laser-cut from hypotubes into their intricate spring-like configurations. Stent delivery systems invariably include a guidewire.

As in balloon angioplasty, the coronary stent physically opens the lumen of the narrowed or collapsed coronary artery where it prevents that artery from further collapse.

A parylene coating on the bare-metal stent facilitates drug/polymer combo applications and adherence to the stent. As parylene adheres well to the bare-metal stent material, it in turn provides a surface to which the drug/polymer combo can effectively adhere. In this application, a parylene coating serves as a tie-layer, or primer, for the drug. In addition, parylene can also be applied over a drug to function as a release-control agent.[2] It can even be used to control the release of multiple drugs to provide more complex therapeutic activity.[3]

The lubricity afforded by a parylene coating can enhance the advancement and withdrawal of guidewires and catheters. However, parylene may not be a good candidate for coating coiled guidewires. If the coils actually contact one another, the contact points will remain uncoated. The coating will tend to encapsulate the touching coils into one homogenous construct, reducing the flexibility for which the coiled guidewire was designed. And when the coil is flexed sufficiently to separate the encapsulated coils, uncoated contact points and fractured parylene edges will be exposed.

Intravascular ultrasound (IVUS). IVUS is a medical imaging method that uses a specially designed catheter with a miniaturized ultrasound probe constructed into its distal end. The proximal end of the catheter is attached to computerized ultrasound equipment. Such a catheter allows the application of ultrasound technology to see from inside blood vessels, enabling the doctor to see the vessel's inner wall.

Intravascular ultrasound systems are comprised of the electronic control console and the catheter containing the ultrasound transceiver sensor. Parylene provides the ultimate moisture and dielectric barrier protection. It helps minimize failures in the console electronics, display circuitry, and components, while providing the same favorable biocompatibility and excellent lubricity to the catheter and its ultrasound sensor elements.

Keeping Pace With New Technology

Isolating instruments, tools and devices from contact with moisture, gases, corrosive biofluids, and chemicals is becoming more important every day—for the devices and for the patients into which many are implanted. Parylene will continue to play an important role in these futuristic devices, its applications limited only by the imaginations of the engineers who use it. The family of parylene coatings also continues to evolve as it keeps pace with the demands of the medical device industry.

Lonny Wolgemuth is the senior medical market specialist for Specialty Coating Systems Inc. (Indianapolis).

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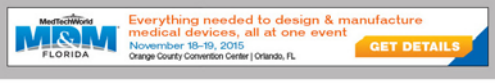
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