The Next Evolution of Parylene Coating

Parylene is an excellent option for medical device manufacturers seeking a device coating for their product. Unfortunately, specific factors limit its use in certain applications. A new variation offers benefits that address these concerns. This article examines Parylene HT and the advantages it offers to device makers while addressing these previously limiting factors.

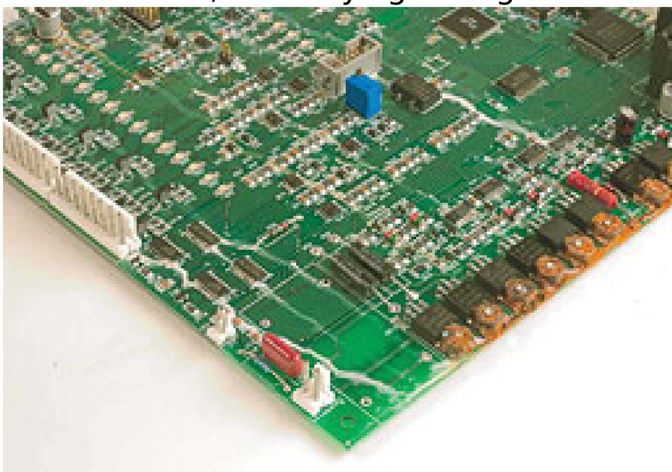
By Lonny L. Wolgemuth
Medical trends show a rapid expansion in the areas of minimally invasive diagnostic and surgical methods, many of which require various levels of instrument-embedded electronics to carry out procedures. Examples of such devices include capsule endoscopy, intravascular ultrasound catheters, and numerous other electrophysiology devices.

Collage of medical devices that benefit from protective parylene coating.

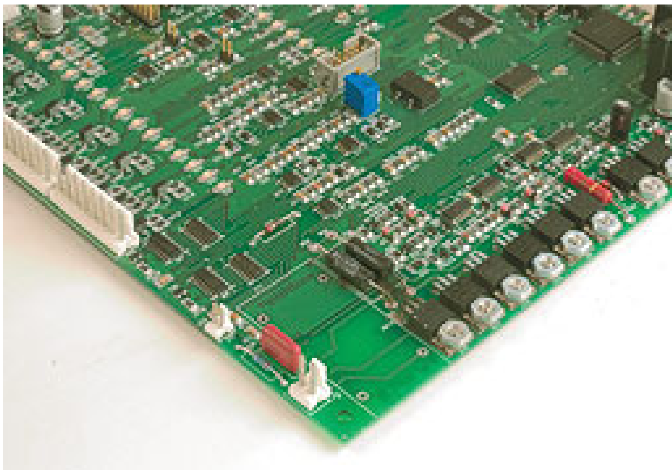
The implantable electronic device market has grown from the basic pacemaker to multiple-capability implantable defibrillators, and is rapidly moving into areas of neuro and spinal stimulating implants. As the size of these and other complex devices shrinks while their electronic capabilities expand, protection of these microelectronics devices and their biocompatibility are foremost issues. A protective coating is needed to isolate them from contact with moisture, gases, corrosive biofluids, or chemicals. Additionally, biocompatible coatings also protect patients from contact with device surfaces, ensuring biocompatibility of implanted devices.For over 35 years, parylene has been that reliable coating solution, providing biocompatibility and excellent barrier properties to protect medical devices. Today, however, while the standard formulations for parylene still meet the coating requirements of most medical devices, a new variant offers some added benefits for medical device manufacturers.

Parylene Review

While many manufacturers are aware of existing parylene formulations, it pays to recap exactly what parylene is and what makes it different from any other type of protective coating available. In the medical device industry, two of the most beneficial properties of parylene are its excellent barrier qualities and its inherent biocompatibility and biostability.Parylene is the generic name for a unique series of polymeric organic coating materials. They are polycrystalline and linear in nature, possess useful dielectric and barrier properties per unit thickness, and are chemically inert. Parylene coatings are ultra-thin, pinhole-free, and truly conform to components due to their molecular level polymerization—basically “growing” on the deposition surface one molecule at a time.



Comparison of uncoated *(above)* to coat *(below)*board after identical testing



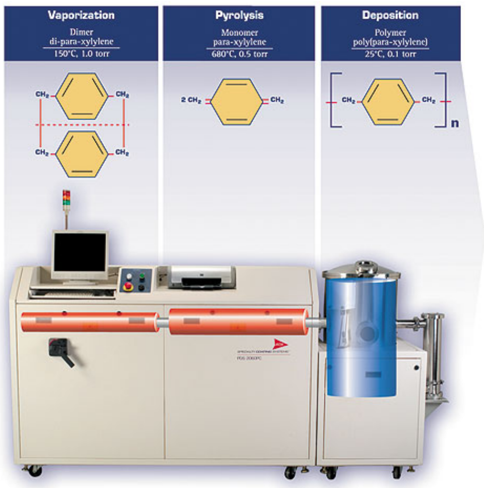
Due to the method by which they are deposited, parylene coatings are extremely lightweight, offering excellent barrier properties without adding dimension or significant mass to delicate components. Parylene is typically applied in thickness ranging from 500 angstroms to 75 microns. A 25 micron coating, for example, will have a dielectric capability in excess of 5,000 volts. While few medical devices operate at 5,000 volts, a 10 micron coating can provide most devices with the electrical and moisture protection they require. No other coating materials can be applied as thinly as parylene and still provide the same level of protection.Parylene coatings are applied via a vapor deposition process rather than as a spray, brush, or dip process. The parts to be coated are placed in the deposition chamber. The powdered raw material, known as “dimer,” is placed in the vaporizer at the opposite end of the deposition system. The dimer is heated, causing it to sublimate to a vapor, then heated again to break it into a monomeric vapor. This vapor is then transferred into an ambient temperature chamber where it spontaneously polymerizes onto the parts, forming the thin parylene film. The parylene process is carried out in a closed system under a controlled vacuum, with the deposition chamber remaining at room temperature throughout the process. No solvents, catalysts, or plasticizers are used in the coating process.

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, thus dielectric properties are never compromised. The molecular “growth” of parylene coatings also ensures not only an even, conformal coating at the thickness specified by the manufacturer, but because parylene is formed from a gas, it also penetrates into every crevice, regardless of how seemingly inaccessible. This ensures complete encapsulation of the substrate without blocking small openings.

Why Was a New Parylene Needed?

While the existing parylene variants are quite able to meet many medical coating challenges, there are new technologies that need a little bit more capability.

The recent commercial availability of Parylene HT gives an extra advantage for medical device and medical electronic applications. Parylene HT possesses unique properties including increased dielectric capabilities and superior thermal and UV stability. The new variant of parylene was developed by replacing the alpha hydrogen atom of the Parylene N dimer with fluorine.



Stages of the parylene deposition process

Parylene HT was developed to provide protection in high temperature environments up to 350°C (short term up to 450°C), and long-term UV stability. It also has the lowest coefficient of friction, a very low dielectric constant, and the highest penetrating capability of all the parylenes. The coating is not limited to medical electronic applications, but also protects silicone, glass, composites, plastics, ceramics, and ferrite components.

All parylenes are applied in the same manner and provide the similar basic barrier and dielectric properties. Parylene HT just goes a step further.

Application Examples

Ultraviolet Resistance: Parylenes N and C are fairly susceptible to ultraviolet light and have only a moderate operating temperature. As such, these parylenes perform poorly in applications which require prolonged exposure to ultraviolet light, ultimately breaking down and degrading.

For device and implant manufacturers who are working in the ocular area, coating survival in the face of prolonged exposure to ultraviolet light is an absolute necessity. When designing an ocular implant to treat a disease or as a permanent solution to correct a physical defect of the eye, selecting a coating that provides biocompatible barrier protection is also important. Parylene HT solves these issues by providing barrier protection that is biocompatible and impervious to ultraviolet light.

High Operating Temperature: Parylene C has a higher operating temperature than Parylene N, but can still only operate at about 80°C long term (100°C short term). Parylene HT can operate continuously at 350°C and can also withstand short term exposures to 450°C.

Many ESU (electrosurgical) devices use RF energy to cut or coagulate tissue. The instantaneous temperatures during this cutting or coagulation process are well into triple digits. Parylene HT is an excellent coating for these types of instruments and acts as both an insulator and a bio-protective coating.

Sterilization is another issue. Although most “smart” catheter and probe applications are one-time use devices, the goal may be to move more into the multi-use category, offering lower cost and longer function. To do this, the device must be able to withstand repeated sterilization cycles. While parylene coatings handle other methods of sterilization quite well, some methods of autoclave sterilization have temperatures that challenge the survival of Parylenes N and C. Parylene HT, with its high thermal stability, is better suited to withstand steam autoclave temperatures.

Low Coefficient of Friction: Parylene HT is an ideal coating to protect devices that need to move easily into or through other instruments or through openings in the human body. It has a coefficient of friction that compares favorably with that of PTFE. It is very slippery, making it an ideal coating for devices that require dry film lubricity, including epidural probes, needles, catheter guidewires, and similar penetrating devices, as well as elastomeric seals. Parylene HT increases the lubricity on these devices without measurably changing the dimensions of the device.

High Penetration Ability: Parylene coatings are able to penetrate extremely small areas such as crevices on devices or the open end(s) of hypotubes. Compared to Parylene N and C, Parylene HT is able to penetrate 25% further into these openings. This penetration ability is extremely valuable on MEMS and nano–devices which enable a vast array of capabilities on the tip of a probe, an endoscope, or other diagnostic or surgical devices. Parylene HT opens the door for more opportunities where components are in nano dimensions and coatings must penetrate very small areas, providing complete coverage without compromising operational capabilities.

Lowest Dielectric Constant and Dissipation Factor: Parylene HT has the lowest dielectric constant and dissipation factor of the parylenes. These two terms refer to a material's distortion of the electrical signals in their presence. For Parylene HT, these are extremely low. With even more RF and other forms of wireless devices entering examination and treatment rooms and surgical areas, precise and undistorted signals are becoming increasingly important. While all parylenes are excellent candidates for use in medical electronic devices because of their bulk electrical properties, Parylene HT is particularly well suited for high frequency device applications due to its very low dielectric constant and dissipation factor.

Benefits for Device Manufacturers

Parylene HT is not intended to replace Parylenes N and C, but rather joins the family by bringing additional capabilities to a line of coatings that already has a lot to offer the medical device designer and manufacturer.

Parylene N and C, variants that have served the industry for over 35 years, are still the coating answer for many device manufacturers. However, when dealing with high temperatures, UV light, nanotechnology devices, or designs in the UHF RF arena, Parylene HT is available and provides exemplary protection for applications facing these challenges.

Finally, it is important to note that while Parylene N, C, and HT are biostable and biocompatible, not all parylene providers cater to the specific needs of the medical device industry. It is up to the user to check with the individual coating service provider to determine if GLP biological evaluations have been performed and to request specific test results and the relevant certifications.
Online
For additional information on the technologies and products discussed in this article, see MDT online at www.mdtmag.com or Specialty Coating Systems at www.scscoatings.com [1].
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