Diamond-MT
Conformal Coating

The Truth about Parylene Coating & Medical Devices

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Introduction

Parylene is the generic name for members of a unique polymer series. Parylene conformal coatings represent a distinct family of organic polymeric coating materials that are polycrystalline and linear in nature, with innumerable commercial applications. Resilient, dielectric, and pinhole-free, parylenes are frequently selected for use with products subjected to ongoing conditions of duress that might otherwise diminish their performance.

Parylene's adaptability can be applied for a wide range of specialized products. Highly bio-compatible within the body, it is exceptionally applicable for the highly-refined, function-focused purposes of internalized medical devices. Among numerous other uses, the most prominent are coronary stents, electrosurgical devices (ESUs), needles/syringes, and implantable sensors that generate real-time physiological recordings of organs and tissue, as well as related hybrid-flexible sensing platforms.

In addition to medical uses, parylene's other product applications include:

- Military/aerospace radar/detection equipment, satellite electronics, and ruggedized safeguarding for extended field-use supplies.
- Protection for such automotive products as computerized analytical-systems and sensors for emissions' direction and tire pressure.
- Numerous industrial/ electrical/consumer applications, including cellphones, inkjet printers, LED-devices, microelectromechanical system (MEMS) technology, sensors for power supplies, and consumer electronics like digital cameras, keyboards and mobile devices.

What's interesting is that this diversity of non-medical uses for parylene provides a basis for even further development of its specifically medical applications. For instance, the connection between development of MEMS technology and medical applications should grow significantly in the future.

Basics of Parylene

The basic parylene molecular model varies according to Type; carbon-hydrogen is typical for parylenes C and D; while chlorine replaces selective hydrogen atoms for parylene N and HT. Of these four prominent commercially viable parylene conformal coatings, only parylene D has proven unsuitable for medical purposes. In all, some form of parylene has been used as coating materials for medical products since the early 1970s.

The value and use of parylene protected medical instruments and procedures will proliferate, as technology develops. Much has to do with the deposition of parylene onto the substrate in comparison to competitive coatings.

Deposition

Vacuum deposition technology is used at ambient temperatures to apply parylene coatings. Other commercial conformal coatings are applied by either:

- spraying the coating material directly onto the substrate surface, or
- physically dipping the substrate into a liquid bath consisting of the coating substance

These methods are rather standard throughout the industry. Reliance on them separates parylene from its competitors, and adds to its effectiveness as a conformal coating for most products and components.

Parylene's application process is more complex. A vapor-phase, chemical-vacuum polymerization process unique to parylene is used, one which effectively eliminates the intermediate liquid deposition procedure common to competing coatings. Overall, cross-link polymerization stimulates the initial conversion of powdered parylene into a gaseous form at the molecular level. With this method, a powdery dimer is heated inside a closed-system vacuum chamber. The vapor is then reheated at a higher temperature to eliminate the substance's double-molecule structure, causing a single molecule vapor to be formed.

The resultant transparent, polymerized film is then applied directly to targeted substrate, coating it with an ultra-thin and uniform layer of parylene. Indeed, parylene's vapor polymerization process eliminates the bridging, pinholes, puddling, run-off, sagging or thin-out of coating surfaces common to competitors' liquid application processes. With the effects of gravity and surface tension eliminated, parylene achieves superior coating of even the most complex structures because of the vapor monomeric quality.

Advantages of Parylene

The result is equally superior medical product service. An advantage of parylene coatings is that they can be applied to virtually any vacuum-stable material, in a device-specific format that generates a surface coating conforming explicitly to the contours of the substrate. These features lead to both exceptional dry-fill lubricity and crevice/multi-layer penetration for all components and instruments.

Because of these properties, parylene safeguards covered materials through a wide range of extreme conditions very typical to medical component usage. Among the most important are:

- Parylene coatings are linear, polycrystalline, chemically inert, colorless and clear. Their lack of pigmentation minimizes their capacity leak into the bodily system during use, potentially infecting or irritating the blood stream and internal organs.
- Inaccurate or altered instrument readings are similarly less likely, and for the same reasons.
- Unlike many competitive coatings, parylene effectively meets and maintains accepted USP Class VI and ISO 10993 biocompatibility requirements, making it safe for use within the body, essential for many medical products.
- In addition to biocompatibility, parylene coatings are bio-stable, inert, non-toxic and meet FDA compliance guidelines, increasing antimicrobial protection during extended use.
- Parylene exhibits proven ability to withstand the negative effects of moisture, heat, organic debris, bodily fluids, and other contaminants on component functioning.
- Parylene conformal coatings add minimally to the weight and volume of the devices they protect, simultaneously generating a pinhole-free covering, unburdened by tin whiskers.
- Sterilization options for parylene include autoclave, E-beam EtO, and gamma.
- Parylene coatings generate resistance to extreme or unexpected shock, vibration, and environmental convulsions, within the body or external to it, further minimizing performance degradation.
- Factors such as humidity within the unit, or the impact of human handling as with wearable devices, also have diminished impact on component operation.
- These favorable physical/mechanical properties are combined with parylene's exceptional dielectric strength, which insulates the medical device while within the body, simultaneously transmitting electric current without conducting it.
- Parylene is versatile. Materials such as ceramics, chromium, paper, plastic and silicon are adaptable to parylene application.
- Parylene provides longer lasting protection; ensuring implanted devices perform as designed for greater durations of time.
- Types of parylene coating are rapidly evolving to match technological expansion in the medical industry. In this industry alone, parylene coating is used on countless devices, including cardiac-assisted technology, catheters, ESU devices, heart-pumps, pacemakers, and stents.

Disadvantages of Parylene

In comparison, parylene's relative disadvantages to competitive coatings are fewer. However, they must be considered:

- Parylene is more expensive than most other conformal coatings. The deposition process and the nature of the raw materials used in manufacture/application contribute to cost. In addition, the process is labor intensive, adding to expense. In most cases, pricing for a parylene-coated item will be higher than for one coated by wet chemistry, or a similar, non-parylene process. In particular, parylene dimer is rather expensive, ranging from $200-$10,000+ per pound.
- Batch-processing inherent in parylene coating minimizes the quantity of chamber-space for every coating machine run, leading to generally lower production-runs and higher cost/item. Overall, the vapor deposition process is time-consuming; product masking and similar prep-work is necessarily very slow, adding to process inefficiency. Due to limited throughput, process-runs can be as long as twenty-four hours.
- Also, while parylene covers many materials efficiently, it exhibits poor adhesion to many metals, limiting wider scale adoption by the medical components industry.

While the benefits of parylene coating for medical instrumentation are considerable, the listed disadvantages are important to analyze when assessing its potential use for your medical care purposes.

Medical Device Applications of Parylene

Parylene conformal coatings commonly protect the highly-refined electrical circuitry known as printed circuit assemblies (PCAs). These have become a basic component of the microchip sensor technology essential to advanced and specialized medical equipment. Sensors measure the level and impact of such stimuli as digital impulses, motion, sound, temperature, or the presence of fluids within a bodily system, monitoring their introduction and impact. Applied as conformal coating, parylene retains compositional stability and performance consistencies in the presence of bodily fluids and tissues.

At the same time, parylene has no negative impact on bodily functions, and is generally used with medical devices that enhance organ/tissue performance, as well as ensuring the device's own acceptance within the body during use. Parylene's typically superior hemo-compatibility and lack of persistent fibrous capsule formation are instrumental in virtually eliminating patients' toxicological responses during use.

Exceptional Biocompatibility

Biocompatible, parylene conformal coatings protect medical instrument components from chemicals, fluids, and stray electrical charges, so the device operates as intended. Parylene coatings ensure the most reliable degree of uniform, biocompatible device-security for both patients and medical personnel, during the execution of cardiological and surgical procedures.

Instruments coated with parylene can be safely situated in less accessible, more-constricted regions of the body than those otherwise coated. It's extremely fine covering offers superior component protection, while adding minimal mass to the device. Extended product functionality and durability are a consequence of low dissipation factors, supporting improvements for both device performance and patient treatment. Equally as important, these factors are the source of enhanced device functionality in difficult-to-reach regions of the body often requiring critical monitoring and care.

Biocompatibility results from parylene's organic quality, which helps support devices use for most medical purposes, regardless where instruments may be situated within or on the body. In addition to protecting implanted devices' exteriors from potentially dangerous leakage, parylene also generates excellent dry-fill lubricity. Thus, the surface modification evident whenever a medical device has to react bio-actively to changes within the body is effectively minimized. Higher levels of surface lubrication improve device performance while diminishing patient discomfort and length of convalescence, simultaneously lowering overall treatment costs.

Recommended Medical Devices Protected by Parylene

Parylene coatings have provided exceptional surface protection for traditional medical devices like catheters, hearing aids, hypodermic needles and syringes, since the 1970s. Subsequent process and product evolution led to their successful application to numerous other instruments; circuits/printed circuit boards (PCBs) for medical devices Coronary stents, electrodes, medical probes, orthopedic devices, and pacemakers are among a wide range of products benefiting from parylene protection.

Among the most prominent specific examples of application of parylene conformal coatings for medical devices are:

- **Cardiac-Assist Devices (CADs)**: Parylene coatings effectively safeguard such electronic CADs as implantable cardioverter-defibrillators (ICDs), which detect and stop arrhythmias (abnormal heartbeats), and pacemakers, which maintain a steady heartbeat for those suffering from arrhythmias. These implantable devices benefit from parylene's superior encapsulation of their delicate but complex medical electronics, which are essential to ensure the life-critical monitoring and regulation of the patient's heart functions. Potentially corrosive effects of bodily fluids circulating near the heart are repelled by the instrument's parylene seal, ensuring its performance is not jeopardized. At the same time, the body's exposure to any threat of hazardous electrical charges or materials leaking from the implanted CAD is similarly negated by parylene's coating. Its dielectric properties generate an electrical barrier between the CAD's internal electronics and the electrical charges normally produced by the activity of surrounding bodily systems, further protecting the patient.

- **Catheters**: Parylene's proven biocompatibility and exceptional barrier properties lend themselves to use for catheters, which are inserted into the body for a variety of medical purposes. The lower frictional coefficient typical of parylene coatings results in enhanced lubricity, exceeding the levels performance of PTFE. The outcome is less difficulty navigating the body's internal passages, a major benefit for correctly situating catheters for appropriate use. Other coatings cannot generate this level of mobility while providing exceptional conformal protection.
- **Electrosurgical devices (ESUs)/pneumatically-powered surgical instruments (EPSIs)**: Parylene protective surfaces are essential to the operative of these medical technologies feature, which often rely on wireless or radio-free (RF) memory communication. Applied to tissue at frequencies between 300 KHz through 5 MHz, RF currents are instrumental to ESUs obtaining appropriate surgical results. The conformal parylene coating's dielectric and secure moisture properties safeguard critical electronics in the ESU's generator, while insulating and lubricating the component's active tool, positioning the targeted tissue for ablation. These processes require precise control of the RF-energies to pinpoint only the targeted region of the body and generating proper treatment. Parylene coatings provide moisture and

dielectric barriers, as well as the biocompatibility critical to these devices, preventing short circuits. The motors and circuits of EPSIs require similar protection, to ensure they maintain functionality. Parylene provides a necessary coating for the silicone frequently used for EPSI's pneumatic gas supply hoses, which would otherwise become too tacky for effective surgical implementation.

- **Intravascular ultrasound (IVUS)**: A medical imaging method, IVUS employs a miniaturized ultrasound probe at its distal end. Computerized ultrasound technology is attached to the device's proximal end by means of a specialized catheter facilitating visualization of conditions inside blood vessels. As with other medical technology, parylene coatings generate biocompatible dielectrical barriers and moisture controls, maintaining functionality of the device's electrical components, while offering excellent lubricity to the catheter and its ultrasound sensor elements.
- **Microelectromechanical systems (MEMS)/nanotechnology**: The use of MEMS' implantables is expected to grow significantly for a wide range of devices. These include cardioverter defibrillators, heart-lung bypass pumps, intra-aortic balloon pumps, non-coiled guide wires, pacemakers and sensors for diagnostic monitoring of patients' conditions. Parylene conformal coatings assure these medical devices remain safely functional during their specialized applications. These devices represent just a sampling of the growing list of efficient parylene-based or assisted medical applications. In conjunction with MEMS, use of nanotechology for ESU/EPSI, and similar tools or implanted devices is expected to markedly expand for biochemical and tissue engineering. Neurosurgery, spinal, ocular and cardiac surgeries increasingly rely on nano-technological processes. In all cases, parylene provides the most reliable conformal coating; its ultra-thin yet secure covering represents best-practice solutions for the minute component and process protection of micro/nano applications.
- **Needles/syringes**: Parylene provides a suitable coating for syringe components and needles. Methods of making syringes, needles, their cartridges and similar articles directly deposit parylene on the object or its intervening layers via chemical vapor deposition; this process simultaneously articulates and separates both the external and internal sliding surfaces of the products. Parylene's enhanced lubricity diminishes the incidence of the static friction within the device's plunger (stiction) that can cause product malfunction. The

parylene coating also produces superior barrier and protection properties to the assembly's distinct components. Parylene has been especially beneficial as a coating for pre-filled syringes, which often are kept in storage or on retail display until their sale. In these cases, the parylene protects the syringe's container from the effects of unplanned deposits or contamination potentially caused by the item's contents, the drugs themselves.

- **Sensors/transducers**: Devices that detect and respond to environmental input, medical sensors monitor such biological conditions as heat, cold, motion, changes in bodily rhythms or the introduction of fluids. Frequently situated/deployed in areas of constant activity or high stress, properly functioning sensors efficiently measure the level and impact of variable stimuli on a specific bodily system. Medical transducers interpret a physical quantity such as blood pressure or bodily temperature, and express it as, for instance, an electrical signal that can be recorded graphically and monitored. Parylene coatings ensure these devices function as designed.
- **Stents**: Parylene's completely conformal, uniform coating ability is particularly adaptable to the complex geometries typical of stents. It facilitates adherence to the device and resistance to the drug/polymer combo applications the devices are subjected to once inserted. While its corrosion-resistant properties protect the metal-based device from bodily fluids, parylene's superior lubricity helps better position the stent, with lower resistance during insertion and placement. Equally as important, parylene enables controlled release of drugs as a bonding agent or tie-layer on drug-eluting stents; this function has been successfully enacted to control the release of multiple drugs to provide more complex therapeutic activity. Serving as a primer for drug release in this application, the parylene coating is leveraged because it adheres well to both the bare metal stent and the therapeutic agent.
- **Wearable Health Monitoring**: Increasingly sophisticated remote sensory monitoring of patients' conditions through wearable computer-assisted medical intelligence generates dependable healthcare data, collected from wearers' bodies. These sensory devices monitor the performance of bodily functions – and represent one end of the scale of parylene sensor applications, externally-placed medical devices. Innovative technologically, wearables provide real-time healthcare and disease-tracking, far more accurately than the paper-

written medical reports of the past. As such, they offer a far better picture of a patient's current condition. Wearables track personal health status, receiving inputs from home monitoring devices to assure verifiable, in-the-moment tracking and management data, instantaneously transmitted to healthcare providers. mHealth medical consumers use embedded digital tools to meaningfully improve quality and cost of healthcare, by focusing on treatment of real-time problems, as they are detected. Parylene coated components enhance wearables enormous utility for tracking diseases. In addition to remote data collection and everyday healthcare monitoring, wearables generate medical information previously unavailable to healthcare patients. In this way, they ensure healthcare consumers are no longer denied crucial knowledge about their particular condition and the conduct of its treatment. Parylene's protective properties help maintain the function of these externally-placed medical devices.

These items represent just a sampling of medical products benefiting from application of parylene conformal coatings. Among other practical uses of parylene for medical products, major examples include:

- Brain probes.
- Cochlear devices/hearing aids.
- Dermal drug delivery devices.
- Electrodes.
- Epidural probes.
- ISO biological evaluations.
- Mandrills.
- Medical bottles.
- Microfluidic reservoirs.
- Neurostimulators/pulse generators.
- Ocular devices.
- Orthopedic devices of all kinds.
- Radiation dosimeters.
- RFID devices.
- Seals, O-rings, tubing.
- Urological tools.
- Ventilators.

As this list indicates, the uses of parylene conformal coatings for medical purposes are both considerable and versatile, due to the polymer's superior coating characteristics and extensive product adaptability.

Comparison with Other Coatings

Parylene compares well as a conformal coating for medical devices. Because the properties of each coating substance varies considerably, with its own specialized set of capabilities and uses.

In parylene's case, much has to do with its unique vapor-phase polymerization process. Coatings such as acrylics, epoxy, polyperfluorocarbons like polytetrafluoroethylene (PTFE), silicones (e.g. polydimethylsiloxane [PDMS]) or urethanes use a wet chemistry; this liquid coating process leaves them ill-prepared for the strenuous bio-compatibility requirements of continual operation within bodily systems. Bio-medical surfaces typically require coating to protect them from chemicals, moisture, and temperature changes during operation.

Non-parylene coatings seldom generate the considerably longer-term protection implanted medical devices require due to their constant contact with sometimes corrosive bodily fluids, enzymes, lipids, and proteins. Wet chemistry coatings also cannot be applied with the same precision as parylene, making them less effective against the passage of contaminants from both the body to substrate or substrate to body.

Moreover, the fact that parylene films are usually applied between .0005” and .002”, compared to 002” and .005” for other coatings, make them more suitable for use with MEMS and nano-technologocial medical devices than their counterparts. Very simply, the much thinner but more durable conformal coatings provided by parylene improve their application and efficiency for these highly specialized medical purposes, requiring maximum coverage and protection in exceptionally minimal space.

Finally, despite their many uses, coating-layer thicknesses of PTFEs such as polytetrafluoroethylene can be over-molded during processing, leading to often significantly greater properties of physical stiffness. The probability of diminishing performance integrity and device malfunction increases under these circumstances, relative to similar surfaces coated with comparatively flexible parylene.

Conclusion

Because of the vapor-deposition polymerization process used for its application, parylene coatings are prized for being completely conformal, yielding a uniform thickness. Effectively isolating medical instruments and devices from exposure to chemicals' corrosive biofluids, gases, and moisture ensures both the operational efficiency of these devices and the safety of the patients into whom they are implanted. Parylene will continue to play an important role in creation and maintenance of these devices, with an ever-expanding range of applications reflecting the need to keep pace with developments in medical technology. The evolution of the entire family of parylene conformal coatings for use in medical device should endure well into the future.