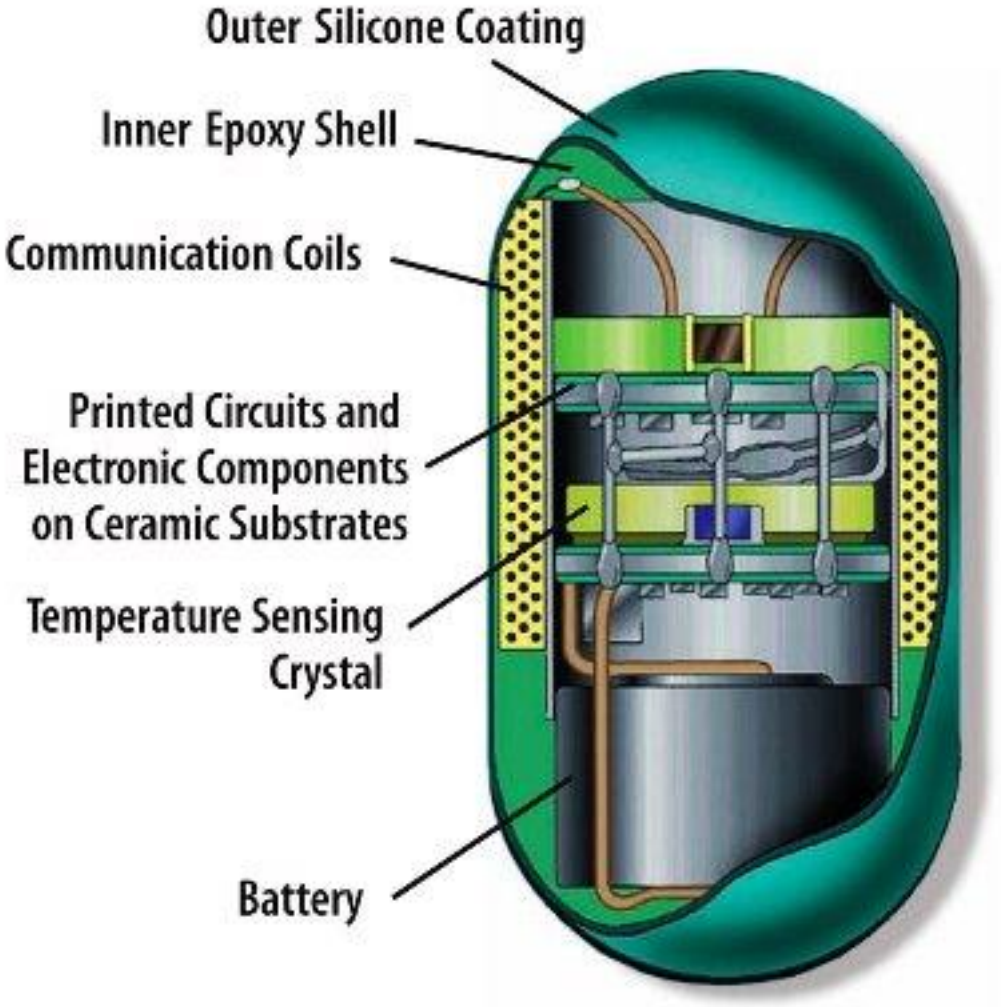
Coating for Consumption

Lonny Wolgemuth, Sr. Medical Market Specialist, and Juan Gudino, Medical Market Manager, Specialty Coating Systems

Ingestible medical devices offer a convenient, non-invasive method of delivering therapeutics, enabling diagnostic procedures, or performing imaging tasks. However, ensuring that the sensitive electronics within the device are protected is a challenge. This article will highlight a coating technology that is being used to guarantee such protection is provided.



Ingestible medical devices come in a variety of shapes and sizes, from encapsulated “pill cameras” to sensors that are smaller than a grain of rice. While capsule endoscopy and esophageal cameras are relatively common these days, the technology has progressed from strictly passive devices with a camera, power supply, and transmitter to highly sophisticated devices able to be controlled as to location and orientation within the body.

A capsule endoscopy, for example, starts when the patient swallows the pill-like

device. The device travels through the digestive tract, capturing images and transmitting data to an external recording system. A similar ingestible device, one that is compatible with MRIs, is currently in development. With this new device, the MRI equipment will actually steer the device within the digestive tract to position it for better imaging of areas of interest.

Microchip sensors, another example of currently developing technology, are no larger than a grain of sand. These sensors will be embedded in pills, capsules, or tablets to monitor when the patient takes their medication and how that medication reacts within the body, all the while transmitting information to the physician. Physicians will then be able to monitor patient compliance with the prescribed medication regimen.

An ingestible vibrating capsule, which provides chemical-free and safe treatment for constipation, is another type of device that uses advanced micro-scale technology. The high tech electronics notwithstanding, these devices are disposable and provide far less costly treatment than many alternative methods. They do their job and then are simply discarded.

[1]Regardless of how they work, each device does basically the same thing; it views, monitors, and/or treats something of interest within the body and then records that data for download or transmits it in real-time to be viewed, read, analyzed and used by a

medical professional. These devices enhance or replace more costly, invasive, and time consuming medical procedures.

In light of the growth in this medical area, it will not be surprising to see these wireless devices morph into self-contained diagnostic laboratories, capable of complete medical records communication and eventually becoming remote treatment delivery vehicles for physicians. There is already research in progress for chronic diseases that would utilize ingestible devices to deliver and adjust targeted therapies for specific disease states. Eventually, these devices will work in concert with established technologies and new “smart” micro-sized implanted technologies to dispense multiple medications and transmit patient data remotely to the medical provider. Ingestible technology will be designed to work with, enhance, and, perhaps in some cases, even replace more long-term invasive devices.

Ingestible devices require technology similar to other electronic devices in order to perform their functions. The difference, however, is that all of this capability must be small enough to fit inside a standard capsule configuration and be easy to swallow. The devices also need an energy source. Some provide their own energy generation—such as one which works by contact of stomach fluids on dissimilar conductive materials—while others require a patient to wear a patch or other form of energy generation device. Much depends on what task the ingestible device is designed to perform, how long it needs to be in the body, and its power requirements.

Although these devices are quite small and not intended to remain in the body much longer than a 24-hour period, they still face all the challenges of a permanently implanted device. They must function within a hostile environment where they encounter bodily fluids, acids, humidity, and moisture. Signals must remain clear and sufficiently strong for images and data to be transmitted properly without interference from outside sources. Additionally, the device itself must “do no harm.”

How does one protect such devices? Standard conformal coatings routinely used in and on many electronic devices are too thick, not uniform, and add too much weight and dimension to be used on these devices. Also, many may not be suitable for ingestion. What works to protect a circuit board in an electronic device is typically not appropriate for a human to swallow.

Parylene conformal coatings represent a solution applicable to many of these micro-devices. Parylene coatings have been used for implantable devices, such as drug eluting stents, pacemakers, cochlear implants, and ocular implants, for nearly 40

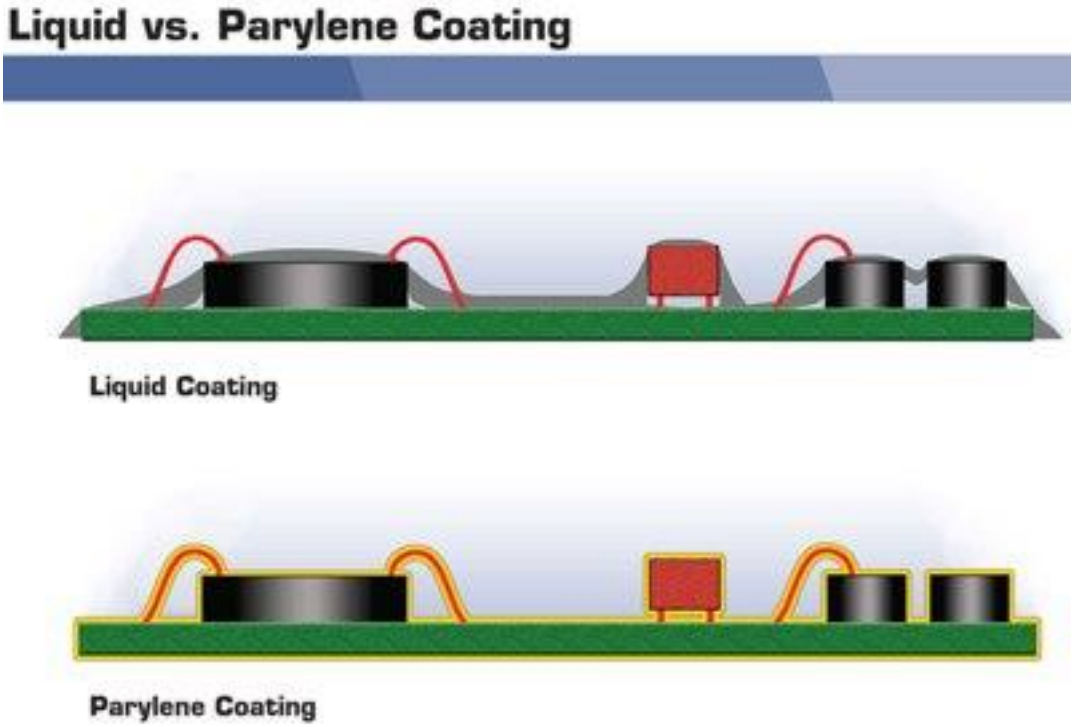
years. They are the perfect coating to protect ingestible medical devices and electronics, particularly as they grow in complexity and signal integrity becomes ever more important. Following are the basic benefits Parylene conformal coatings provide:

- High dielectric barrier protection per unit thickness
- Excellent moisture, fluid, and gas barrier capability
- Documented biocompatibility and biostability
- Minimal dimension or mass addition to a device
- Parylene can be applied selectively to a device, such as one that needs to be exposed to or activated by bodily fluids, while still protecting the electronics, data acquisition, and signal transmission.

Understanding Parylene

Parylene is the name for a unique series of chemically inert, organic polymeric coatings. Several types of Parylene exist to suit a variety of applications. All are free of fillers, stabilizers, solvents, catalysts, and plasticizers. As a result, Parylene presents no leaching, outgassing, or extraction issues.

Devices to be coated with Parylene are placed in an evacuated, room-temperature deposition chamber. A powdered raw material, known as dimer, is placed in the vaporizer at the opposite end of the coating system. The double-molecule dimer is heated, sublimating it directly to a vapor. The dimer vapor is then heated to a very high temperature that cracks it into a monomeric vapor. This vapor then travels into the room temperature deposition chamber where it spontaneously polymerizes onto all surfaces, forming the ultra-thin, 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 the items being coated remain at room temperature throughout the process. No curing process or added steps are required.



The molecular "growth" of Parylene coatings from a vapor ensures not only a uniform, conformal coating at the thickness specified by the manufacturer, but also excellent penetration into crevices and very small openings, regardless of how seemingly inaccessible. This assures complete encapsulation of the substrate without blocking, or bridging, even the smallest openings. For devices that need an open area free of the coating, such as ingestible devices that are powered by stimulation from stomach fluids, selective coating is provided by a variety of masking techniques.

There are three common forms of Parylene: C, N, and Parylene HT. Each has unique properties that suit it to particular medical coating applications. Parylene C, with its particularly low permeability to moisture, fluids, and corrosive gases, is the most often selected Parylene. Parylene N has particularly high dielectric strength and a dielectric constant that is independent of frequency. Because of its high molecular activity in the monomer state, Parylene N has great penetrating capability, enabling it to coat deep recesses and blind holes.

Finally, Parylene HT is unique among the Parylenes with its ability to withstand exposure to ultraviolet light, its ability to accommodate temperatures up to 450°C (842°F), and a coefficient of friction lower than many PTFEs.

All formulations of Parylene offer excellent lubricity properties and all are biocompatible and biostable. Since ingestible devices and the components within them are, by necessity, very small, multiple components/products can be coated simultaneously in deposition chambers. The nature of the deposition process ensures that every item within the chamber is uniformly and totally coated, absent Parylene only in those areas that have been masked. Parylene vapor deposition polymerization is uniform, totally conformal, and precise.

Challenges of Extremely Small Devices

There are at least two areas of interest when contemplating protection for these

devices. The first is focused on coating the exterior of the device to ensure it is not affected by bodily fluids and that the coating material has no adverse effect on the body. The second is the protection of the high tech and extremely miniaturized electronics in order to ensure continued operation and transmission of clear electronic signals for review and recording of data.

The exterior coating is the first line of protection. The internal components benefit from Parylene's capabilities, but foremost from its moisture and dielectric barrier properties. At the same time, because this protection is provided with very thin coatings, neither mass nor dimensions are significantly impacted.

Parylene provides its protective properties in coatings as thin as several hundred angstroms up to a seventy-five microns. As these device packages shrink, the power density increases. More power into a smaller space means it is increasingly important that a thin coating can accommodate increasingly rigorous thermal performance requirements. Parylene excels in such environments.

Looking Toward the Future

As technologies advance, new uses for unique ingestible devices are already under development. These devices will need protection to ensure their uninterrupted performance. Only biocompatible and biostable Parylene coatings can provide such protection without adding mass or dimension to the devices, while at the same time ensuring adequate barrier and dielectric protection to the device and patient.

For more information, visit http://scscoatings.com/ [2].

Source URL (retrieved on *03/11/2014 - 2:53pm*):
http://www.mdtmag.com/articles/2013/06/coating-consumption

Links:
[1] http://www.mdtmag.com/sites/mdtmag.com/files/legacyimages/SCSDepositionFULL.jpg
[2] http://scscoatings.com/