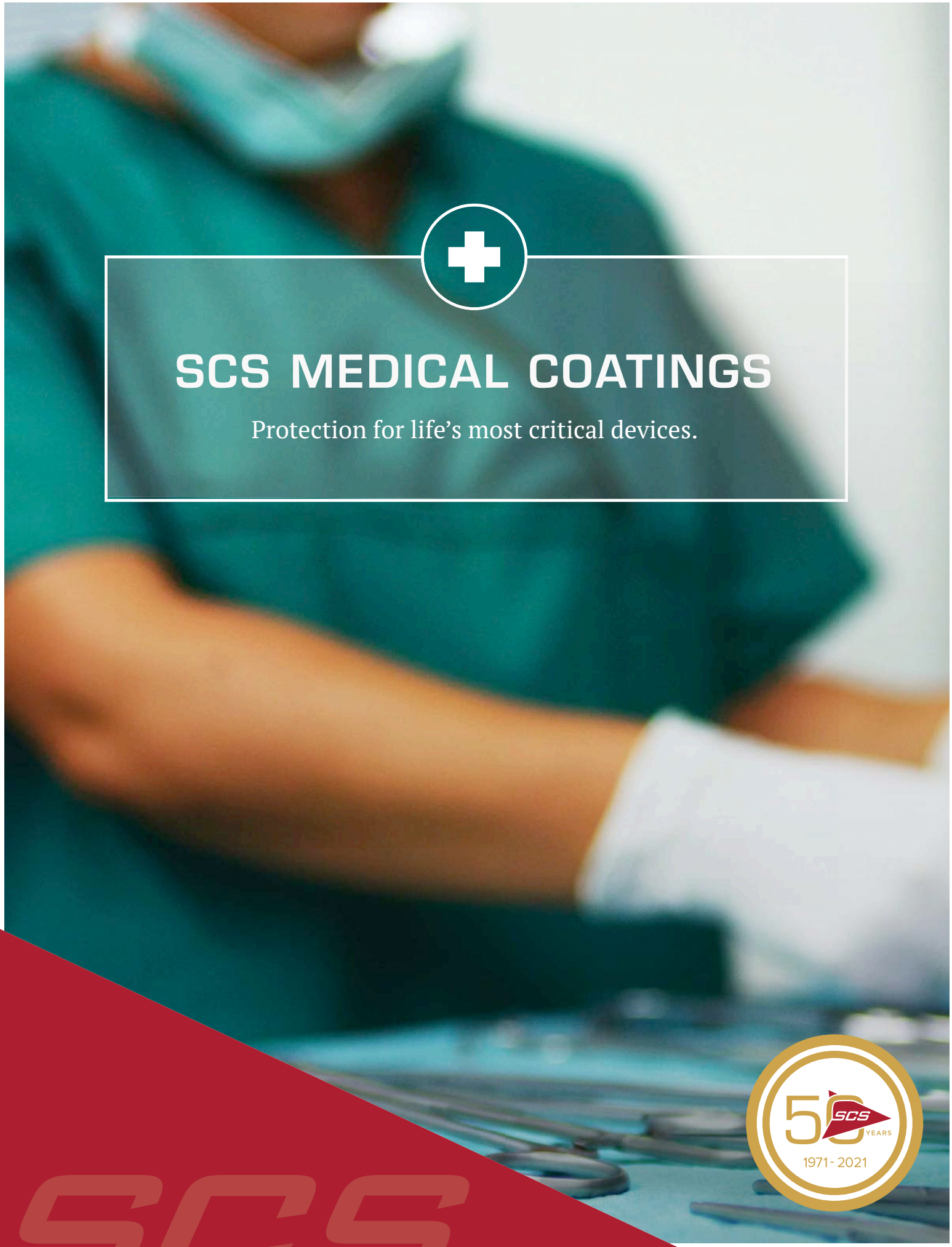


SCS MEDICAL COATINGS

Protection for life's most critical devices.

50 YEARS
1971 - 2021

SCS CONFORMAL COATINGS

SCS' industry-leading portfolio of conformal coatings includes Parylene coatings, liquid coatings, plasma polymerized coatings, atomic layer deposition (ALD) coatings and multilayer coatings. Combining the properties of these coatings with over 50 years of experience, vast technology and worldwide resources, SCS provides the medical device industry with reliable coatings and services that offer a host of beneficial attributes, including:

- Biocompatibility and biostability
- Nano and micro-level thicknesses
- Ultra-thin, conformal coating of all exposed surfaces
- Micro-encapsulation capabilities
- Superior chemical, moisture and electrical barrier properties
- Dry film lubricity

PROPERTIES OF SCS CONFORMAL COATINGS

Following is an overview of the most common properties and benefits of SCS conformal coatings. Because each coating maintains its own unique properties and every application requires specialized protection, SCS' sales and engineering teams stand ready to help customers select the best coating for their specific application based on environmental and performance requirements.

BIOSTABILITY AND BIOCOMPATIBILITY

SCS offers a variety of advanced and traditional conformal coatings for the medical market. For applications requiring biocompatibility, it is vital to clearly understand the level of biocompatibility required so that the optimum coating can be specified. Plasma polymerized coatings can meet ISO 10993 skin contact requirements such as sensitization, while the Parylenes, used for decades on medical devices including long-term implants, satisfy the key aspects of ISO 10993, addressing a range of medical applications from surface and tissue contacting devices to long-term implants. In addition, SCS Parylenes N, C, Parylene HT® and ParyFree® are certified to comply with the biological testing requirements for USP Class VI Plastics.

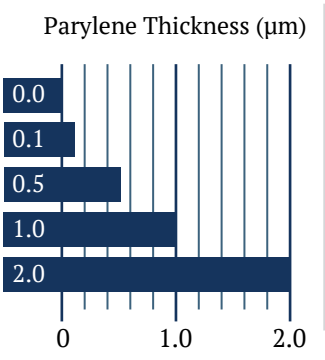
SCS maintains Device and Drug Master Files with the U.S. FDA. These files, which include the results of biological studies on SCS coatings, are available for FDA reference on behalf of submissions made by SCS commercial coating service customers. SCS also works with Notified Bodies and other regulatory agencies to furnish necessary documents in support of submissions around the globe.

BARRIER PROPERTIES

A selection of SCS conformal coatings provides excellent moisture and chemical barrier protection for medical device components. Pinhole-free coatings provide barrier protection against body fluids as well as moisture, chemicals and common gases.

These barrier properties have been demonstrated in a series of experiments with Parylene-coated and uncoated rubber specimens. The specimens were autoclaved for one hour in 1 molar hydrochloric acid. The acid extracts were then analyzed for metals known to be present in the rubber compound's additive system: calcium, aluminum and zinc. Figure 1 shows that Parylene conformal coating significantly decreased extraction of these metals from the test specimens.

FIGURE 1: The effect of Parylene C coating thickness on extractable metals in rubber specimens.[8]



Parylene Thickness (µm)	Calcium (ppm)	Aluminum (ppm)	Zinc (ppm)
0.0	0.17	4.2	50
0.1	0.15	1.8	35
0.5	0.03	0.1	12
1.0	<0.002	<0.05	0.2
2.0	<0.002	<0.05	<0.05

DIELECTRIC PROPERTIES

SCS coatings can provide a range of dielectric protection, even at extremely low thicknesses. The high dielectric strengths of biocompatible Parylenes, for example, are a result of the film being formed as a thin, continuous and uniform coating, free from the defects and fillers commonly found in conventional coatings. For certain electronics applications, traditional liquid coatings may also provide electrical insulation.

For decades, SCS has been solving the electrical insulation needs of medical electronics, including PCBs and flex circuits, electrosurgical tools, cardiostimulation and neurostimulation systems, neurosensing needles and probes, and sensors of all types.

LUBRICITY

Coatings that provide lubricious surfaces can also be key to the success of some medical devices. The selection of lubricious coatings available continues to grow as new solutions are developed. SCS coatings have imparted dry film lubricity characteristics to a number of components, including introducers, elastomers, cables and medical forming devices, additionally improving cleanability and the ability to undergo sterilization processes.

PROTECTION FOR MEDICAL DEVICES

SCS can apply conformal coatings to virtually any surface material, including metals, elastomers, resins, plastics and ceramics, in thicknesses ranging from a few hundred angstroms to several mils. By definition, conformal coatings conform to surfaces, edges and crevices of a substrate. Ultra-thin coatings and nanocoatings also conform to the interior of multi-layer electronic packages and add little dimension or mass to critical, weight-sensitive components.

IMPLANTABLE MEDICAL DEVICES

For the most critical medical devices requiring a coating, Parylene has long been a preferred solution due to its inherent biocompatibility and biostability. SCS Parylenes provide an ideal surface modification for implantable medical devices such as coronary and neurovascular stents, shunts, cardiostimulation and neurostimulation/neurosensing devices and electronics for smart orthopedics. The coatings protect medical devices and device components and serve as a tissue-friendly surface for contact.

Parylenes are used on stent technology, serving one of two key purposes. One is its use as a surface primer, such as on drug-eluting stents. In this case, a metallic coronary stent is coated with Parylene C, onto which a drug-containing copolymer is applied. Another case is the application of an ultra-thin Parylene coating onto a bioabsorbable stent in order to manage the dissolution rate of the bioabsorbable material.

MEDICAL FORMING DEVICES

The dry film lubricity properties of SCS coatings make them an ideal release agent for molds and forming devices such as wire mandrels, significantly improving the safety and utility of such components by eliminating flaking and delamination.

ELASTOMERIC PRODUCTS

Medical grade silicone and rubber products (e.g., catheters, valves, septa, seals and infusion components) require a coating with a high degree of flexibility. As noted earlier, SCS coatings reduce the device's coefficient of friction, but they can also eliminate surface tackiness and protect against discoloration and contaminant extraction. In the case of electrical cables, reduced friction, sealing porosity and electrical barrier protection are all benefits provided by a conformal coating.

PHARMACEUTICAL CONTAINERS

Whether an application requires barrier capabilities or dry film lubricity, USP Class VI certified conformal coatings can benefit technologies such as prefilled syringes, pharmaceutical containers and inhalers. Applied in micron-level thicknesses, Parylene coatings can contain extractables and leachables when container surfaces are in contact with the harshest of drug formulations. Additionally, the inert coatings eliminate break-out force due to similar static and dynamic coefficients of friction.

MEDICAL ELECTRONICS

SCS conformal coatings protect medical electronic components from moisture, biofluids, biogases and sterilization processes that can cause assemblies to fail prematurely. Such protection not only extends assembly life and prevents costly repairs, it also reduces the risk of failure at the most critical times. Coatings are used to protect a wide range of technologies, including electromechanical and electrosurgical devices, infusion and fluid heating technologies, robotic surgical systems and ultrasound and x-ray imaging platforms.

INNOVATIVE SOLUTIONS FROM THE LEADER IN CONFORMAL COATINGS

With over 50 years of experience in conformal coating engineering and applications, Specialty Coating Systems (SCS) is the world leader in Parylene, liquid, plasma polymerized, ALD and multilayer conformal coating technologies. We're a direct descendant of the companies that originally developed Parylene, and we leverage that expertise on every project – from initial planning to process application.

SCS employs some of the world's foremost conformal coating specialists, highly experienced sales engineers and expert manufacturing personnel, working in state-of-the-art coating facilities around the world. Our extensive, proactive approach to production and quality requirements gives our customers peace of mind and minimizes the resources they need to meet even the most challenging requirements and specifications.

As worldwide industry requirements and directives continue to evolve, SCS is at the forefront, ensuring our facilities, products and services comply with relevant regulatory and environmental standards.

- AS/EN 9100 and ISO 9001 certifications
- Biocompatibility per ISO 10993
- USP Class VI certification
- Medical Device Regulation (MDR)
- Requirements of IPC-CC-830
- REACH and RoHS compliance
- California Proposition 65

For additional standards and certifications to which SCS and/or SCS coatings comply, please visit SCScomplies.com or contact SCS.

REFERENCES

1. M. Kaminska, W. Okrój, W. Szymanski, W. Jakubowski, P. Komorowski, A. Nosal, H. Szymanowski, M. Gazicki-Lipman, H. Jerczynska, Z. Pawlowska, B. Walkowiak. "Interaction of Parylene C with Biological Objects." *Acta Bioengineering and Biomechanics* 11.3 (2009): 19-25.
2. M.C. Demirel, E. So, T. Ritty. S.H. Naidu, A. Lakhtakia."Nanoengineered Sculptured Thin Films for Fibroblast Cell Attachment and Growth." *Journal of Biomedical Materials Research Part B* 81B (2007): 219-223.
3. T. Chang, V. Yadav, S. De Leo, A. Mohedas, B. Rajalingam, C. Chen, S. Selvarasah, M. Dokmeci, A. Khademhosseini. "Cell and Protein Compatibility of Parylene-C Surfaces." *Langmuir* 23.23 (2007): 11718-11725.
4. N. Pereira-Rodrigues, P-E. Poleni, D. Guimard, Y. Arakawa, Y. Sakai, T. Fujii. "Modulation of Hepatocarcinoma Cell Morphology and Activity by Parylene-C Coating on PDMS." *PLoS ONE* 5.3 (2010): e9667.
5. F.R. Tittmann, W.F. Beach. "Parylene Coated Polypropylene Microfibers as Cell Seeding Substrates." *Synthetic Biomedical Polymers: Concepts and Applications* (1980): 117-131.
6. Summary Certificates of Biological Evaluation of Medical Devices. NAMSA Inc., Norwood, OH.
7. "Instructions for Use: Cypher Sirolimus-Eluting Coronary Stent on Raptor Over-the-Wire Delivery Systems." FDA, Rockville, MD (2005). Accessed online at www.accessdata.fda.gov/cdrh_docs/pdf2/P020026c.pdf.
8. V.G. Romberg, et al. U.S. Patent 4,808,453. (February 28, 1989).

SCS
SPECIALTY COATING SYSTEMS™
A KISCO Company

7645 Woodland Drive, Indianapolis, IN 46278 United States

TF 800.356.8260 | **P** 317.244.1200 | **W** scscoatings.com