



SPECIALTY COATING SYSTEMS™



A higher level of protection for life's most critical devices.

SCS MEDICAL COATINGS

Specialty Coating Systems is the global leader in delivering innovative Parylene coating solutions for advanced technologies. For over three decades, customers have turned to SCS for planning, development, engineering and application of thin-film Parylene polymer coatings to their critical components.

A team of the world's foremost Parylene specialists, state-of-the-art laboratory facilities, and strict quality control systems across ten coating facilities worldwide ensure SCS customers the most innovative, precise and consistent coating processes . . . for components and applications where compromise is not an option.

Nowhere is this industry leadership more crucial than in the medical device industry. SCS has been developing and applying ultra-thin, pinhole-free Parylene conformal coatings to critical devices and components for nearly 40 years.



SCS Parylene Coatings

Ultra-thin and pinhole-free, SCS Parylenes offer exceptional properties for medical device protection. SCS couples the properties of Parylene with its years of experience, vast technology and worldwide resources to provide the medical device industry with coatings and services it can rely on.

The benefits of SCS Parylene include:

- Biocompatibility and biostability
- Controlled thickness down to 500Å
- Ultra-thin, conformal coating of all exposed surfaces
- Micro-encapsulation capabilities
- Superior chemical, moisture and electrical barrier
- Dry-film lubricity

Parylene Coating Properties that Protect Biostability and Biocompatibility

SCS Parylenes N, C and Parylene HT® comply with biological testing requirements for ISO-10993. Testing included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, implantation (2, 12 and 26 weeks), hemocompatibility (hemolysis and PPT) and pyrogenicity. In vitro tissue culture studies have shown that human cell types readily proliferate on Parylene C coated surfaces.^{1,2,3} SCS Parylenes N, C and Parylene HT are certified to comply with the biological testing requirements for USP Class VI Plastics.⁴

Specialty Coating Systems maintains Device and Drug Master Files with the U.S. FDA. These files, which include the results of biological studies on

SCS Parylenes, are available for reference by all SCS commercial coating service customers.

Barrier Properties

SCS Parylene coatings are excellent moisture and chemical barriers for medical device components. Applied much thinner than alternative coatings, Parylene provides a pinhole-free barrier to protect against body fluids as well as moisture, chemicals and common gases.

These barrier properties are demonstrated in a series of experiments with coated and uncoated rubber specimens. The specimens were autoclaved for one hour in one molar hydrochloric acid and the acid extracts were then analyzed for metals known to be present in the rubber's additive systems: calcium, aluminum and zinc. Figure 1 clearly shows that Parylene coatings on the test specimens markedly decreased extraction of these metals.

Dielectric Properties

SCS Parylenes also have excellent dielectric properties. Their high dielectric strength is attributable to the fact that they can be formed as thin, continuous, and uniform films free from defects and the fillers commonly found in conventional coatings, both of which tend to reduce dielectric strength.

Lubricity

SCS Parylenes possess excellent dry-film lubricity characteristics. Figure 2 illustrates how Parylene C significantly improves the lubricity of the rubber specimens. The coefficients of friction (COF) for Parylene HT and Parylenes N and C, as measured by ASTM D 1894, are 0.15, 0.25 and 0.29, respectively, for static observations.

Protection that Applies to Many Medical Devices

SCS can apply Parylene coatings to virtually any surface material, including metal, elastomer, plastic, glass, ceramic and paper. The thickness of a Parylene coating can range from a few hundred angstroms to several mils. Parylene polymerizes as a uniform, thin-film coating that conforms to all surfaces, edges and crevices of a substrate, including the interior of tubing. Because Parylene is not a liquid, the coating suffers none of the meniscus and edge effects of conventional liquid coatings. As a result of its ultra-thin application, Parylene adds little dimension or mass to critical, weight-sensitive components.

Numerous medical devices and device components benefit from Parylene coatings, including:

Implantable Medical Devices

Listed in the FDA's Biomaterials Compendium, SCS Parylene provides an ideal surface modification for implantable medical devices such as coronary stents and pacemakers. The coating protects medical devices and device components and serves as an acceptable surface for tissue contact.

It also serves as a surface primer, such as on drug-eluting stents, where a drug-containing copolymer is applied to a Parylene C coated metal coronary stent for human implantation.⁵

Elastomeric Products

Medical grade silicone and rubber products such as catheters and medical seals require a coating with a high degree of flexibility, which SCS Parylenes provide. Parylene coatings also reduce the coefficient of friction, eliminate surface tackiness and protect against discoloration and contaminant entrapment.

Medical Forming Devices

The dry-film lubricity properties of SCS Parylene make it an ideal release agent for molds and forming devices such as wire mandrels. The film significantly extends the useful life of such components by eliminating flaking and delamination. Solid and inert, there is no residue to contaminate molded products.

Medical Electronics

SCS Parylene protects medical electronic components from moisture, biofluids and biogases that can cause such 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. SCS Parylenes comply with the European Union's Restriction on the use of Hazardous Substances (RoHS) in Electrical and Electronic Equipment Directive 2002/95/EC.

The Parylene Process

SCS Parylene coatings are applied in a room temperature vacuum chamber via a vapor deposition polymerization (VDP) process. Components to be coated are only required to have a reasonable vacuum tolerance. There are no solvents, catalysts or plasticizers involved in the coating process and since Parylene coatings require no elevated temperature cure cycle, there are no associated cure stresses. Unlike Parylene coatings, conventional dipped, sprayed or brushed coatings may require catalysts and elevated temperature or UV cure cycles to improve coating properties.

SCS Parylene Properties						
		Parylene N	Parylene C	Parylene HT	Silicone (SR)	Polyurethane (UR)
Water Absorption (%)		<0.1	<0.1	<0.01	0.1	0.6-0.8
Gas Permeability @ 25°C cc·mm m ² ·day·atm	N₂	3.0	0.4	4.8	—	31.5
	O₂	15.4	2.8	23.5	19,685	78.7
	CO₂	84.3	3.0	95.4	118,110	1,181
	H₂	212.6	43.3	—	17,717	—
Coefficient of Friction	Static	0.25	0.29	0.15	—	—
	Dynamic	0.25	0.29	0.13	—	—
Rockwell Hardness		R85	R80	R122	40A-45A (Shore)	68A-80D (Shore)
Tensile Strength		7,000 psi	10,000 psi	7,500 psi	350-1,000 psi	175-10,000 psi
Thermal Usage w/o Breakdown	Continuous	60°C	80°C	350°C	260°C	121°C
	Short-Term	80°C	100°C	450°C	—	—
Penetration Ability*		40 x dia.	5 x dia.	50 x dia.	Dip or Brush	Dip or Brush
Dielectric Strength @ 1 mil.		7.0KV	5.6KV	5.4KV	2.0KV	3.5KV
USP Class VI Polymer		Yes	Yes	Yes	Not All	Not All

*Depth into tubing and crevices.

Note: For test methods and sources, see the SCS Parylene Properties brochure.

Figure 1: The effect of Parylene C coating thickness on extractable metals in rubber specimens.¹⁴

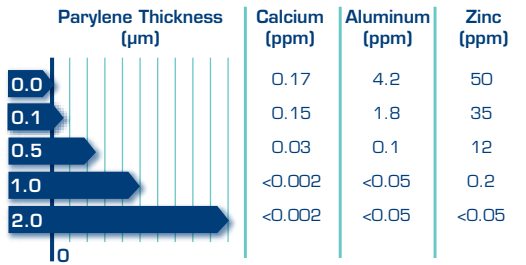
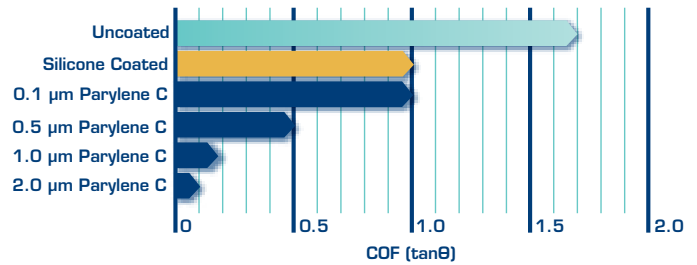


Figure 2: Coefficient of friction measurements for Parylene-coated rubber specimens.¹⁴



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Innovative solutions for advanced technologies.

Specialty Coating Systems leads the industry in providing Parylene solutions for its global customers' advanced technologies. SCS is a direct descendant of the companies that originally developed Parylene, and we have 40 years of experience and expertise that we leverage on every project for our customers—from the initial planning phases, to advanced engineering, to the development of application processes.

Our worldwide resources include highly experienced sales engineers, some of the world's foremost Parylene specialists, and expert manufacturing personnel, working in ten state-of-the-art coating facilities around the globe. In addition to Parylene coating services, we design and manufacture industry-leading Parylene deposition systems; liquid spray, dip and spin coating systems; ionic contamination test systems; and UV and thermal cure units. Our equipment is used in environments that range from university and research labs to high-volume production applications.

Our extensive and proactive approach to production and quality requirements—testing, validating, documenting and processing—provides our customers peace of mind and minimizes their resources needed to meet the most challenging industry specifications and quality requirements.



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