SCS MEDICAL COATINGS

Protection for life's most critical devices.

SCS

SPECIALTY COATING SYSTEMS™

A KISCO Company

INNOVATIVE SOLUTIONS FROM THE LEADER IN PARYLENE

With 50 years of experience in Parylene engineering and applications, Specialty Coating Systems (SCS) is the world leader in Parylene 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 Parylene 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.

50 years

4 continents

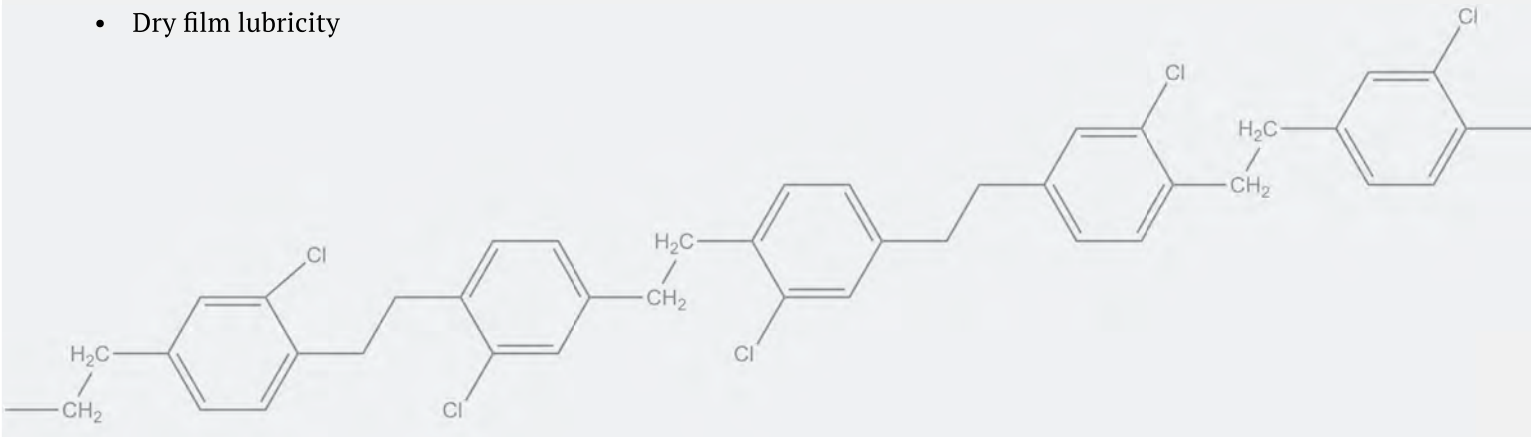
>1,000 employees

11 countries

SCS PARYLENE COATINGS

SCS combines the properties of Parylene with its years of experience, vast technology and worldwide resources to provide the medical device industry with reliable coatings and services. Ultra-thin and pinhole-free, SCS Parylene conformal coatings offer exceptional properties, including:

- 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 properties
- Dry film lubricity



PROPERTIES OF SCS PARYLENE COATINGS

BIOSTABILITY AND BIOCOMPATIBILITY

SCS Parylenes N, C, Parylene HT® and ParyFree® 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 PTT) and pyrogenicity. As a result, SCS Parylenes N, C, Parylene HT and ParyFree are certified to comply with the biological testing requirements for USP Class VI Plastics.

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 FDA reference on behalf of submissions made by SCS commercial coating service customers. SCS also works with the Notified Bodies of coating service customers to furnish necessary documents as they pursue approvals in Europe and the rest to the world.

BARRIER PROPERTIES

SCS Parylene coatings are excellent moisture and chemical barriers for medical device components. Applied much thinner than alternative coatings, Parylenes provide 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. 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 coating on the test specimens markedly decreased extraction of these metals.

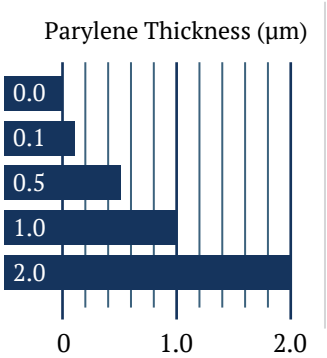
DIELECTRIC PROPERTIES

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 the defects and fillers commonly found in conventional coatings that tend to reduce dielectric strength.

LUBRICITY

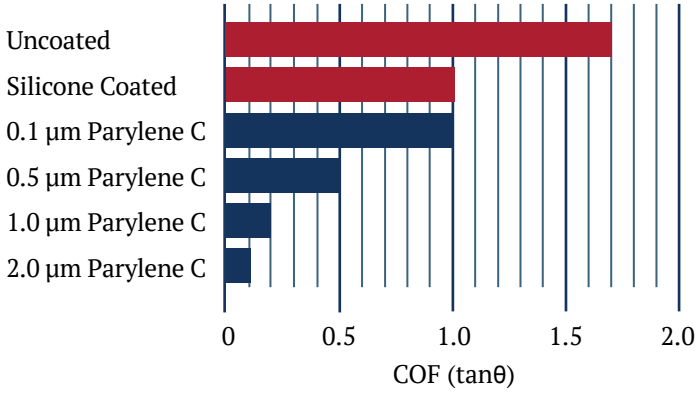
SCS Parylenes provide excellent dry film lubricity to components such as elastomers and medical forming devices, improving manufacturing flow as well as extending useful life. Tests completed per ASTM D 1894 indicate nearly identical static and dynamic coefficients of friction (COF) for Parylene HT at 0.15 and 0.13, ParyFree at 0.23 and 0.23, Parylene N at 0.25 and 0.25, and Parylene C at 0.29 and 0.29, respectively. Figure 2 provides an indication of improved dry film lubricity on rubber 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

FIGURE 2: Coefficient of friction measurements for Parylene-coated rubber specimens.[8]



PROPERTIES OF SCS PARYLENES

		Parylene N	ParyFree	Parylene C	Parylene HT	Silicone (SR)	Polyurethane (UR)
Water Absorption (% after 24 hrs)		<0.1	<0.1	<0.1	<0.01	0.1	0.6 – 0.8
Gas Permeability @ 25°C $\frac{cc \cdot mm}{m^2 \cdot day \cdot atm}$	**N_2**	3.0	<0.2	0.4	4.8	–	31.5
	O_2	15.4	3.4	2.8	23.5	19,685	78.7
	CO_2	84.3	7.8	3.0	95.4	118,110	1,181
	H_2	212.6	86.2	43.3	–	17,717	–
Coefficient of Friction	**Static** **Dynamic**	0.25 0.25	0.23 0.23	0.29 0.29	0.15 0.13	– –	– –
Rockwell Hardness		R85	R136	R80	R122	68A – 80D (Shore)	40A – 45A (Shore)
Tensile Strength (psi)		7,000	9,600	10,000	7,500	175 – 10,000	350 – 1,000
Thermal Usage w/o Breakdown	**Continuous** **Short-Term**	60°C 80°C	60°C 80°C	80°C 100°C	350°C 450°C	260°C –	121°C –
Penetration Ability*		40 x dia.	10 x dia.	5 x dia.	50 x dia.	Dip or Brush	Dip or Brush
Dielectric Strength @1 mil		7.0KV	6.9KV	5.6KV	5.4KV	2.0KV	3.5KV
USP Class VI Polymer		Yes	Yes	Yes	Yes	Not All	Not All

*Depth into tubing and crevices.

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

PROTECTION FOR MEDICAL DEVICES

IMPLANTABLE MEDICAL DEVICES

SCS Parylenes provide an ideal surface modification for implantable medical devices such as coronary stents, neurostimulation devices, cochlear and ocular implants, and pacemakers. The coating protects medical devices and device components and serves as an acceptable surface for tissue contact.

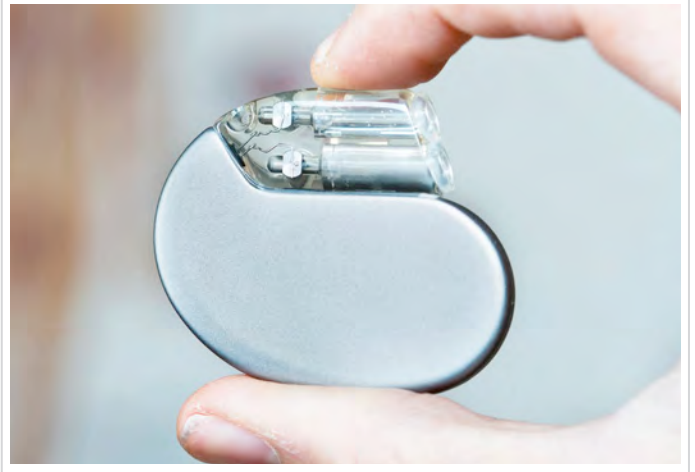
Parylenes also serve as a surface primer, such as on drug-eluting stents. In this example, a drug-containing copolymer is applied to a Parylene C-coated metal coronary stent for human implantation.

ELASTOMERIC PRODUCTS

Medical grade silicone and rubber products (e.g., catheters, medical seals and infusion components) 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 Parylenes make them an ideal release agent for molds and forming



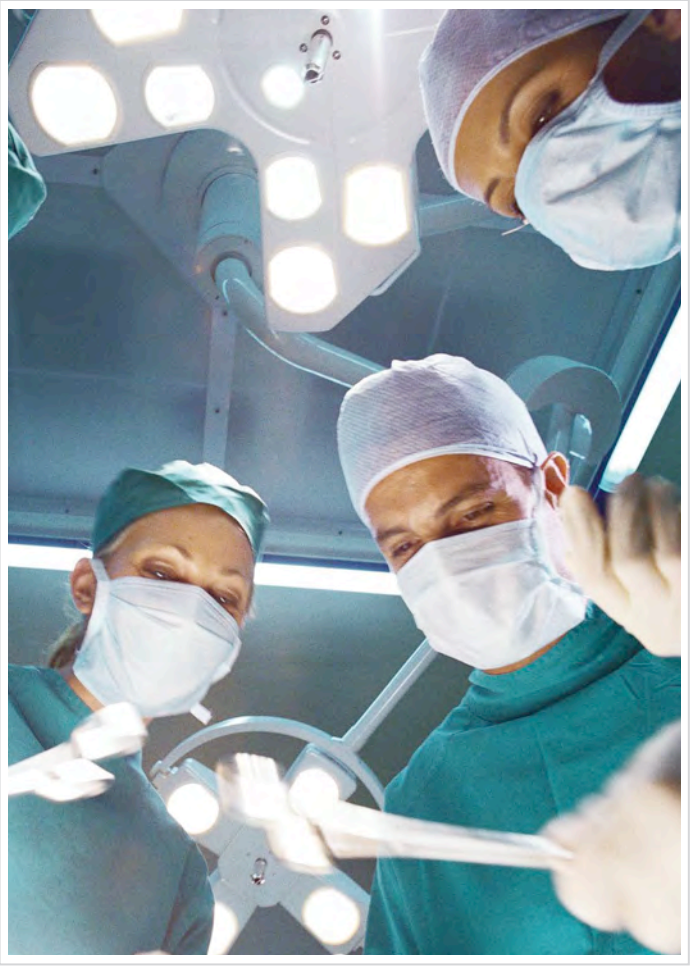
devices such as wire mandrels. The film significantly improves the safety and utility of such components by eliminating flaking and delamination. Because Parylene is solid and inert, there is no residue to contaminate molded products.

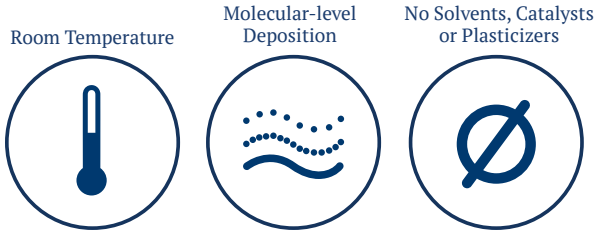
PHARMACEUTICAL CONTAINERS

Whether an application requires barrier capabilities or dry film lubricity, Parylenes can benefit both prefilled syringes and pharmaceutical containers. Applied in micron-level thicknesses, Parylene coatings can prevent extractables and leachables when substrates are in contact with drug formulations. Additionally, the inert coatings eliminate break-out force due to similar static and dynamic coefficients of friction.

MEDICAL ELECTRONICS

SCS Parylenes protect medical electronic components from moisture, biofluids, biogases and sterilization processes 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. This can apply to 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. SCS Parylenes comply with stringent regulatory requirements including California Proposition 65 and the European Union's Restriction of Hazardous Substrates (RoHS) Directive, REACH regulations and Medical Device Regulation (MDR).





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, cross-linking, elevated temperatures or UV cure cycles to improve coating properties.

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