SCS MEDICAL COATINGS

Protection for life’s most critical devices.
INNOVATIVE SOLUTIONS FROM THE LEADER IN PARYLENE

With over 45 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 in 12 countries worldwide. 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.

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
SCS PARYLENE COATING PROPERTIES

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 PTT) and pyrogenicity. In vitro tissue culture studies have shown that human cell types readily proliferate on Parylene C coated surfaces. Additionally, SCS Parylenes N, C and Parylene HT 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.

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. 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 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, Parylene N at 0.25 and 0.25, and Parylene C at 0.29 and 0.29, respectively. Additionally, Figure 2 provides an indication of improved dry film lubricity on rubber specimens.
SCS PARYLENE PROPERTIES

<table>
<thead>
<tr>
<th>Water Absorption (%)</th>
<th>Parylene N</th>
<th>Parylene C</th>
<th>Parylene HT</th>
<th>Silicone (SR)</th>
<th>Polyurethane (UR)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;0.1</td>
<td>&lt;0.1</td>
<td>&lt;0.01</td>
<td>0.1</td>
<td>0.6–0.8</td>
</tr>
<tr>
<td>Gas Permeability @ 25°C (\text{cc} \cdot \text{mm}^2 \cdot \text{day} \cdot \text{atm})</td>
<td>N₂</td>
<td>3.0</td>
<td>0.4</td>
<td>4.8</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>O₂</td>
<td>15.4</td>
<td>2.8</td>
<td>23.5</td>
<td>19,685</td>
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<tr>
<td></td>
<td>CO₂</td>
<td>84.3</td>
<td>3.0</td>
<td>95.4</td>
<td>118,110</td>
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<tr>
<td></td>
<td>H₂</td>
<td>212.6</td>
<td>45.3</td>
<td>—</td>
<td>17,717</td>
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<tr>
<td>Coefficient of Friction</td>
<td>Static</td>
<td>0.25</td>
<td>0.29</td>
<td>0.15</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Dynamic</td>
<td>0.25</td>
<td>0.29</td>
<td>0.13</td>
<td>—</td>
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<tr>
<td>Rockwell Hardness</td>
<td>R85</td>
<td>R80</td>
<td>R122</td>
<td>40A–45A (Shore)</td>
<td>68A – 80D (Shore)</td>
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<tr>
<td>Tensile Strength</td>
<td>7,000 psi</td>
<td>10,000 psi</td>
<td>7,500 psi</td>
<td>350 – 1,000 psi</td>
<td>175 – 10,000 psi</td>
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<tr>
<td>Thermal Usage w/o Breakdown</td>
<td>Continuous</td>
<td>60°C</td>
<td>80°C</td>
<td>350°C</td>
<td>260°C</td>
</tr>
<tr>
<td></td>
<td>Short-Term</td>
<td>80°C</td>
<td>100°C</td>
<td>450°C</td>
<td>—</td>
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<tr>
<td>Penetration Ability*</td>
<td>40 x dia.</td>
<td>5 x dia.</td>
<td>50 x dia.</td>
<td>Dip or Brush</td>
<td>Dip or Brush</td>
</tr>
<tr>
<td>Dielectric Strength @ 1 mil</td>
<td>7.0KV</td>
<td>5.6KV</td>
<td>5.4KV</td>
<td>2.0KV</td>
<td>5.5KV</td>
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<tr>
<td>USP Class VI Polymer</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Not All</td>
<td>Not All</td>
</tr>
</tbody>
</table>

*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.

Parylene also serves 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, Parylene can benefit both prefilled syringes and pharmaceutical containers. Applied in micron-level thicknesses, Parylene can prevent extractables and leachables when substrates are in contact with drug formulations. Additionally, the inert coating eliminates break-out force due to similar static and dynamic coefficients of friction.

MEDICAL ELECTRONICS
SCS Parylenes protect 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 of Hazardous Substances (RoHS) in Electrical and Electronic Equipment Directive.

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.
REFERENCES


6. Summary Certificates of Biological Evaluation of Medical Devices. NAMSA Inc., Norwood, OH.
