# BIOMEDICAL PARYLENE COATING TECHNOLOGIES

## BIOSTABILITY AND BIOCOMPATIBILITY

An effective coating is essential for many medical devices to protect their surfaces from degradation while isolating body tissues from incompatible materials. Such a coating must meet performance requirements, exhibit stability in the presence of biofluids, and be biocompatible in the intended application. Vacuum-deposited Parylenes meet these needs and are often the coating of choice for such applications.

Medical device manufacturers that use Parylene coatings are required to confirm the biological compatibility of their devices and coatings during pre-market regulatory approval processes. Common biological evaluation considerations include:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatibility
- Implantation

Categories of medical devices that may require coating to resolve pertinent issues include:

- Surface Devices
  - Skin
  - Mucosal membrane
  - Breached or compromised surfaces
- Externally Communicating Devices
  - Blood path, indirect
  - Tissue/bone/dentin communicating
  - Circulating blood
- Implant Devices
  - Tissue/bone
  - Blood

### SCS PARYLENES BIOLOGICAL PERFORMANCE

SCS Parylenes N, C, Parylene HT® and ParyFree® have been tested according to the biological evaluation requirements of ISO-10993 for those tests indicated in the table. Further, the biocompatibility and biostability of SCS Parylenes have been demonstrated in a wide range of medical coating applications over the past four decades.[1,2]

- SCS Parylenes N, C, Parylene HT and ParyFree are certified to comply with USP biological testing requirements for Class VI Plastics[3,4] in the categories of Acute Systemic Toxicity, Irritation/Intracutaneous Reactivity and Implantation.
- In vitro tissue culture studies show that human cell types readily proliferate on Parylene C-coated surfaces to produce thin, adherent layers of morphologically normal tissue.[5,6,7,8]
- Parylene C is a preferred candidate for electrodes for neural interfacing applications.[9]
- Parylenes have been demonstrated as superior dielectric coatings on probes and needles used in neurostimulating technologies as well as in neurosensory needles used in surgical and nerve block/anesthetic procedures.
- A drug-containing copolymer is applied to a Parylene C-coated metal coronary stent for human implantation.[10]
- ParyFree offers a new, halogen-free option.

### ISO–10993 BIOLOGICAL EVALUATIONS

| | SCS Parylene Variant | | | |
|---|---|---|---|---|
| **Tests** | **N** | **ParyFree** | **C** | **Parylene HT** |
| Cytotoxicity | ✓ | ✓ | ✓ | ✓ |
| Sensitization | ✓ | ✓ | ✓ | ✓ |
| Intracutaneous Reactivity | ✓ | ✓ | ✓ | ✓ |
| Acute Systemic Toxicity | ✓ | ✓ | ✓ | ✓ |
| Implantation (2 weeks) | ✓ | ✓ | ✓ | ✓ |
| Implantation (12 weeks) | ✓ | ✓ | ✓ | ✓ |
| Implantation (26 weeks) | ✓ | ✓ | ✓ | ✓ |
| Hemolysis | ✓ | ✓ | ✓ | ✓ |
| Lee–White Clotting Time | ✓ | ✓ | ✓ | ✓ |
| Pyrogenicity | ✓ | ✓ | ✓ | ✓ |

50 YEARS SCS 1971 - 2021

## STERILIZATION

Parylene coatings are used to protect a wide variety of medical devices and substrates, including objects that must be sterilized on a one-time basis and those requiring repeated sterilization. SCS contracted with independent laboratories to test several sterilization methods to determine the impact of these procedures on the coatings. This proprietary research serves as a useful resource in the continuing development of SCS Parylenes for medical coating technologies.

Tested sterilization methods include steam autoclave, gamma and e-beam irradiation, hydrogen peroxide plasma and ethylene oxide, with post-sterilization analysis indicating minimal impact of these sterilizing agents on Parylenes N, C and Parylene HT samples when compared to unsterilized control samples.

### GENERAL OBSERVATIONS

Electrical, barrier and mechanical properties were evaluated post-sterilization with results indicating these properties remained unchanged for the vast majority of the tests across all Parylene variants. For example, the tensile strength of Parylene film was not significantly affected, although steam sterilization did cause a very slight but measurable change, and sterilization impact on the coefficient of friction of Parylene was mixed by variant. In the case of irradiation, the sterilization process impact on Parylene film may be cumulative. In this case, device manufacturers considering repeated e-beam or gamma sterilization should conduct tests to determine the effect of radiation sterilization in the intended application.

### IMPLEMENTING A STERILIZATION OPTION

Sterilization test results are generally instructive for medical device manufacturers. It is important that each Parylene coating application be studied to determine the most appropriate sterilization method. A more detailed discussion of SCS Parylenes N, C and Parylene HT sterilization tests is available to SCS customers. SCS also offers engineering consultation and application assistance to customers in this and other aspects of Parylene coating implementation. Interested companies should contact SCS for further information on the selection of an appropriate sterilization method for SCS Parylene coated medical devices.

## MEDICAL REGULATORY SUPPORT

Specialty Coating Systems proactively supports medical device manufacturers through the creation and maintenance of Device and Drug Master Files at the U.S. FDA. These FDA files contain confidential information on the formulations and process conditions under which the Parylene coatings are applied. In addition, all certificates relating to biocompatibility of SCS Parylenes N, C, Parylene HT and ParyFree are contained therein. With permission from Specialty Coating Systems, FDA examiners can review these documents on behalf of 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 of the world.

## IMPLEMENTING SCS PARYLENE COATINGS

The suitability of Parylene coatings for a given medical device application must be determined by testing and process confirmation and supported by established resources in experience, laboratory testing and regulatory body documentation. SCS customers benefit from proven Parylene quality and consistency as well as extensive application engineering resources, process integrity, quality control and coating service resources at multiple sites around the world. Contact SCS for further information on the development and implementation of custom Parylene coating services.

## REFERENCES


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