

COMPANY PROFILE: SPECIALTY COATING SYSTEMS



SPECIALTY COATING SYSTEMS™

Nowhere are leadership, experience and proven technology more crucial than in the medical and pharmaceutical industries. Specialty Coating Systems (SCS) has been developing and applying ultra-thin, pinhole-free Parylene conformal coatings to essential devices and components for more than 40 years.

As the global leader in delivering innovative Parylene coating solutions for advanced medical technologies, manufacturers have continually turned to SCS for planning, development, engineering and application of thin-film Parylene polymer coatings to their critical components.

Our team consists of the world's foremost Parylene specialists working in state-of-the-art laboratory facilities. Our strict quality control systems across eleven coating facilities worldwide ensure that all SCS customers experience the most innovative, precise and consistent coating processes.

OUR HERITAGE

SCS dates back to the 1970s when Parylene conformal coatings were first commercialised due to William F. Gorham's work at Union Carbide Corporation (UCC), now a subsidiary of Dow. In 1971, Nova Tran Corporation was established in Clear Lake, WI, US, having purchased a license agreement from UCC to be one of the world's first Parylene service providers. Union Carbide Corporation purchased Nova Tran in 1984 and in 1991, Nova Tran, along with several other companies, were combined into a new company called Specialty Coating Systems (SCS). Union Carbide transferred all of the original information and patents regarding the development of Parylene to SCS. With our global headquarters now located in Indianapolis, IN, US (see photo), we are proud of our herit-

age, which has afforded us unprecedented coating and applications expertise.

INNOVATIVE PRODUCTS FOR THE MEDICAL & PHARMA INDUSTRIES

Ultra-thin and pinhole-free, SCS Parylenes offer exceptional properties for medical device protection. We couple the properties of Parylene with our years of experience, vast technology and worldwide

These files, which include the results of biological studies on SCS Parylenes, are available for reference by SCS commercial coating service customers.

HOW WE CAN HELP YOU MAKE SAFER AND BETTER DEVICES

SCS can apply Parylene coatings to virtually any surface material, including metal, elastomer, plastic, glass, ceramic and paper.



Specialty Coating Systems' worldwide headquarters in Indianapolis, IN, US.

resources to provide the industry with reliable coatings and services. 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
- Dry-film lubricity
- Superior chemical, moisture and electrical barrier.

SCS Parylenes N, C and Parylene HT® comply with biological testing requirements for ISO-10993 and USP Class VI Plastics. Specialty Coating Systems maintains Device and Drug Master Files with the US FDA.

The thickness of a Parylene coating can range from a few hundred angstroms to several mils. Parylene polymerises as a uniform, thin-film coating that conforms to all surfaces, edges and crevices of a substrate, including the interior of tubing, without blocking orifices, adding dimension or weight. 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 very little dimension or mass to critical, weight-sensitive components.

Numerous medical devices and device components benefit from Parylene coatings, including syringe components, needles, stents, electrosurgical tools, cochlear and

ocular implants, ingestible devices, pace-makers, and elastomeric components.

PHARMACEUTICAL APPLICATIONS: WHY PARYLENE STANDS OUT

Shelf-life is important for all medications, for prefilled syringes as well as pharmaceuticals in vials and bottles. For these, the more aggressive chemicals tend to attack not only the containers, but can cause unwanted chemicals to be extracted from the container material into the drug itself. Parylene can prevent this. It is an excellent barrier coating, protecting the container, including caps and seals, and also protecting the drug from any unwanted leaching or extractions.

Some prefilled syringes have sealing mechanisms to ensure needle sterility and to prevent premature drug dispensing. These seals can occasionally form a very tight bond as it sits on the shelf. The self-seal can be difficult to break. Coating these components with Parylene before assembly helps prevent seal bonding. In this case, Parylene acts as a release agent allowing the sealing material to release easily when needed.

AT SCS, EVERY CUSTOMER MATTERS

Our worldwide resources include highly experienced sales engineers and expert manufacturing personnel working in eleven state-of-the-art coating facilities around the globe.

The following is an overview of the activities, standards and certifications to which SCS and/or SCS Parylene coatings comply:

- AS9100C certification
- US FDA Device and Drug Master Files
- Notified Bodies and Accredited Third Parties co-ordination
- ISO 10993 biological evaluations and certifications
- USP Class VI certification
- ISO 14644 cleanrooms.

Every customer has unique product and performance specifications that must be met. Our experience and expertise are leveraged on every project in order to meet the most challenging specifications and quality requirements.

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When it comes to reliability, nothing protects like Parylene.

Parylene is an ideal conformal coating for medical and pharmaceutical delivery devices and components. SCS Parylenes can be applied to virtually any material to provide ultra-thin, pinhole-free coatings with superior extractables/leachables barrier properties and excellent non-liquid, low friction/stiction characteristics. Biocompatible Parylene coatings are USP Class VI certified and ISO 10993 tested.

With 11 locations around the world (6 in the Americas, 3 in Europe, 2 in Asia), Specialty Coating Systems is the leader in Parylene coatings and maintains comprehensive FDA Drug and Device Master Files for customer reference.

Contact SCS today for more information about the ways Parylene coatings can enhance the performance and reliability of your medical or pharmaceutical applications.

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