



SPECIALTY COATING SYSTEMS™

A KISCO Company

Comprehensive Coating Solutions for Medical Technologies

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ETHICON North American Medical Grade
Consortium Group

Agenda

- ▶ Conformal Coatings Overview
- ▶ Parylene Coatings
- ▶ Comparison of Coating Types
- ▶ Suitability for Medical Devices
- ▶ Common Applications
- ▶ SCS Overview

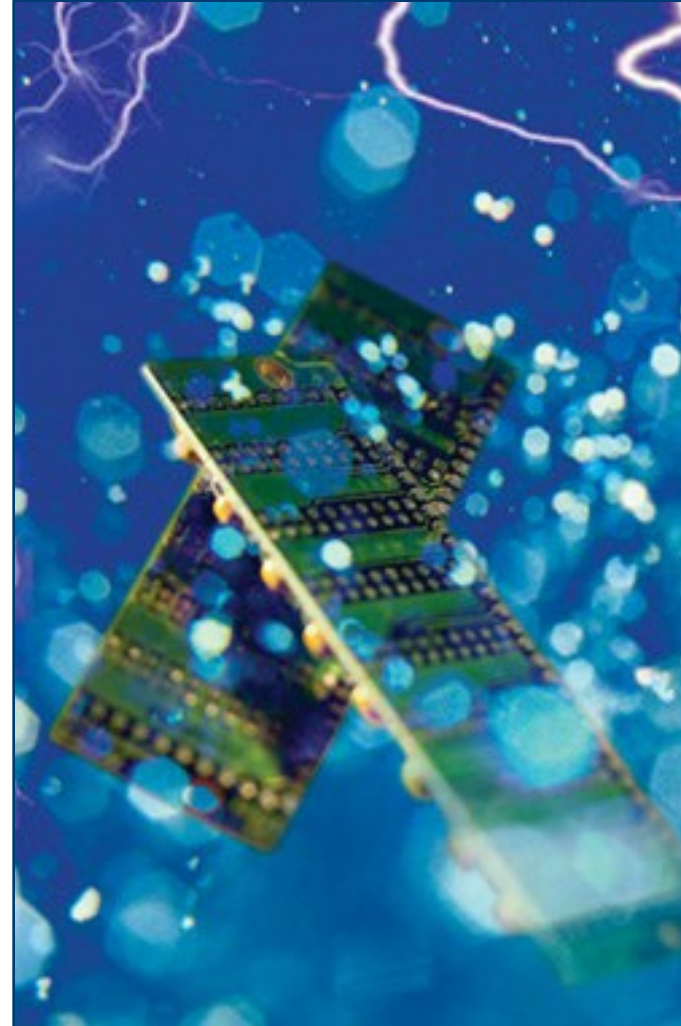
SCS

Conformal Coatings: Industry Overview

- ▶ By nature, conformal coatings conform to the shape of the underlying substrate, following the contours and features of objects and surfaces
- ▶ Introduced in the 1960's
 - First applications were high reliability electronics
 - First military specification was written in 1968
- ▶ Manual or automated application methods: Brush, spray, dip, vacuum deposition
- ▶ Industry trends: Cost reduction, waste minimization, repeatability, environmental friendliness, cure technologies, etc.
- ▶ Typical conformal coatings thicknesses: 3 to 8 mil (0.075 to 0.2mm)
 - Range from 0.1 mil (2.5 microns) for vapor-deposited films to 10 mils for elastomeric silicones

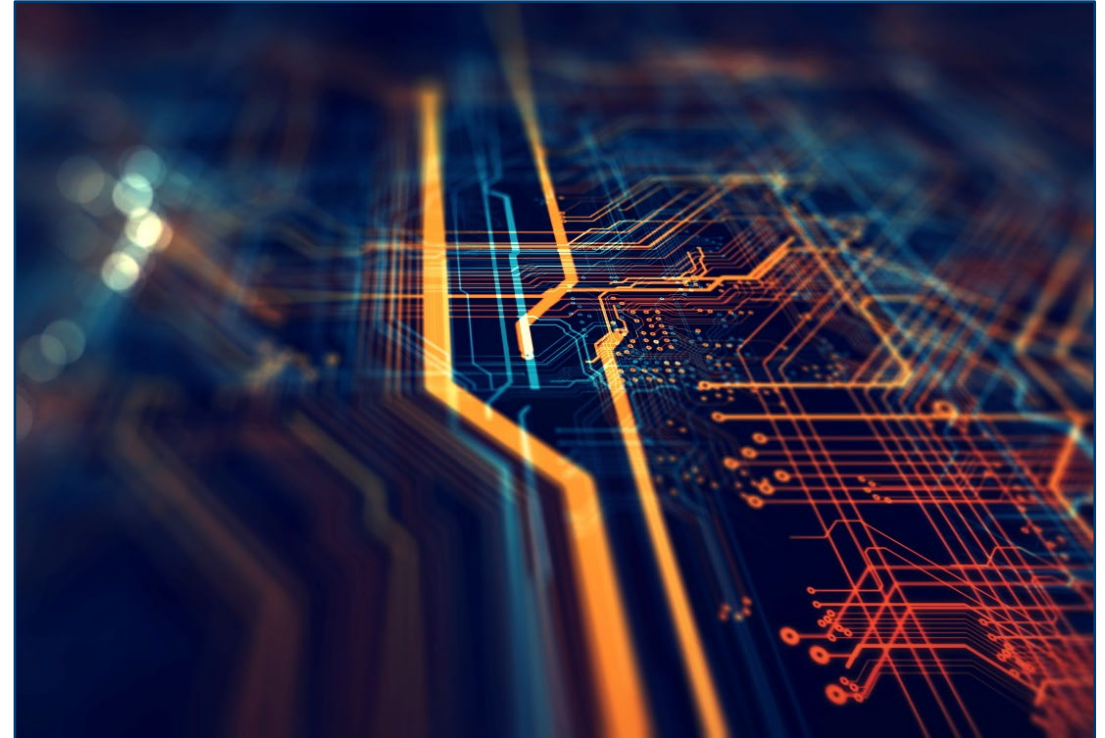
Conformal Coatings: Industry Overview

- ▶ Dielectric strength
- ▶ Moisture, chemical, fluid barrier
- ▶ Biocompatibility and biostability
- ▶ Anti-stiction, low friction
- ▶ Seal or reduce micro porosity
- ▶ Antistatic
- ▶ Thermal insulation
- ▶ Heat dissipating
- ▶ Radiation shielding
- ▶ Abrasion resistance
- ▶ Stabilizes components and structures



Conformal Coatings: Industry Overview

- ▶ Generally thin, nonconductive, dielectric layers
- ▶ Provide electrical insulation properties and barrier protection, prolonging service life of the coated application
- ▶ Several types of conformal coatings:
 - Parylenes
 - Plasma polymerized
 - Liquids
 - Acrylics
 - Epoxies
 - Silicones
 - Polyurethanes
 - Ultra-thins
 - Styrene rubber co-polymers
 - Multilayer coatings
 - ...and more



Comparison of Conformal Coatings

Coating Properties	Acrylics	Urethanes	Epoxies	Silicones	Plasma Coatings	Parylenes	Multilayer Coatings (ALD+Parylene)
Chemical Resistance	Good	Excellent	Excellent	Good	Good	Excellent	Excellent
Dielectric Properties	Good	Excellent	Excellent	Fair	Good	Excellent	Good
Adhesion	Good	Good	Excellent	Excellent	Excellent	Excellent	Excellent
Thermal Cycling	Fair	Good	Good	Excellent	Good-Excellent	Excellent	Good-Excellent
Abrasion Resistance	Fair	Excellent	Excellent	Fair	N/A	Fair	Fair
Component Stress	High	High	High	Low	Low	Low	Low
Cure	Easy	2-Part	2-Part	Easy	None	None	None

SCS Coating Solutions

Liquid Coatings	Parylene Coatings	Plasma Coatings	ALD+Parylene Multilayer Coating
25 - 200 microns	0.2 - 50 microns	50 nm – 3 microns	1 - 200 nanometers
<ul style="list-style-type: none"> • Dielectric strength • Fair moisture & chemical barrier • Abrasion resistance 	<ul style="list-style-type: none"> • Moisture & chemical barrier • Biocompatible • High dielectric strength • Chemically inert 	<ul style="list-style-type: none"> • Moisture barrier • High water contact angle >120° • Biocompatible • Abrasion resistant 	<ul style="list-style-type: none"> • Dense • Smooth • Dielectric and insulating • Inorganic nanocoating
Application Method: Robotic, spray, dip, brush	Application Method: Vacuum deposition	Application Method: Vacuum deposition	Application Method: Complex vacuum deposition
<ul style="list-style-type: none"> • Inexpensive • Easy to apply & rework • Good electrical and physical properties 	<ul style="list-style-type: none"> • Unique combination of performance, protection & durability characteristics 	<ul style="list-style-type: none"> • Splash proof and waterproof barrier protection in extremely thin coatings 	<ul style="list-style-type: none"> • Improved corrosion resistance / barrier performance against water vapor and gases
Applications: Electronics, medical and other substrates for moderate protection	Applications: Electronics, medical and other substrates for high reliability & protection	Applications: consumer electronics, wearables and medical devices	Applications: Consumer products (electronics, medical devices, flexible devices)



Coating Suitability for Medical Devices

- ▶ Parylene coatings have a long history of use
 - Approved devices (e.g., FDA, CE, PMDA, etc.), including surface devices, externally communicating devices and implants
 - Compatible with all common sterilization methods
 - Demonstrated biocompatibility based on a comprehensive range of ISO 10993 tests, including long-term implantation
 - SCS maintains FDA Drug and Device Master Files with biocompatibility test results for reference by commercial coating customers
- ▶ PlasmaGuard™ coatings
 - Biocompatible per ISO 10993-5
 - Not hypersensitive per ISO 10993-10

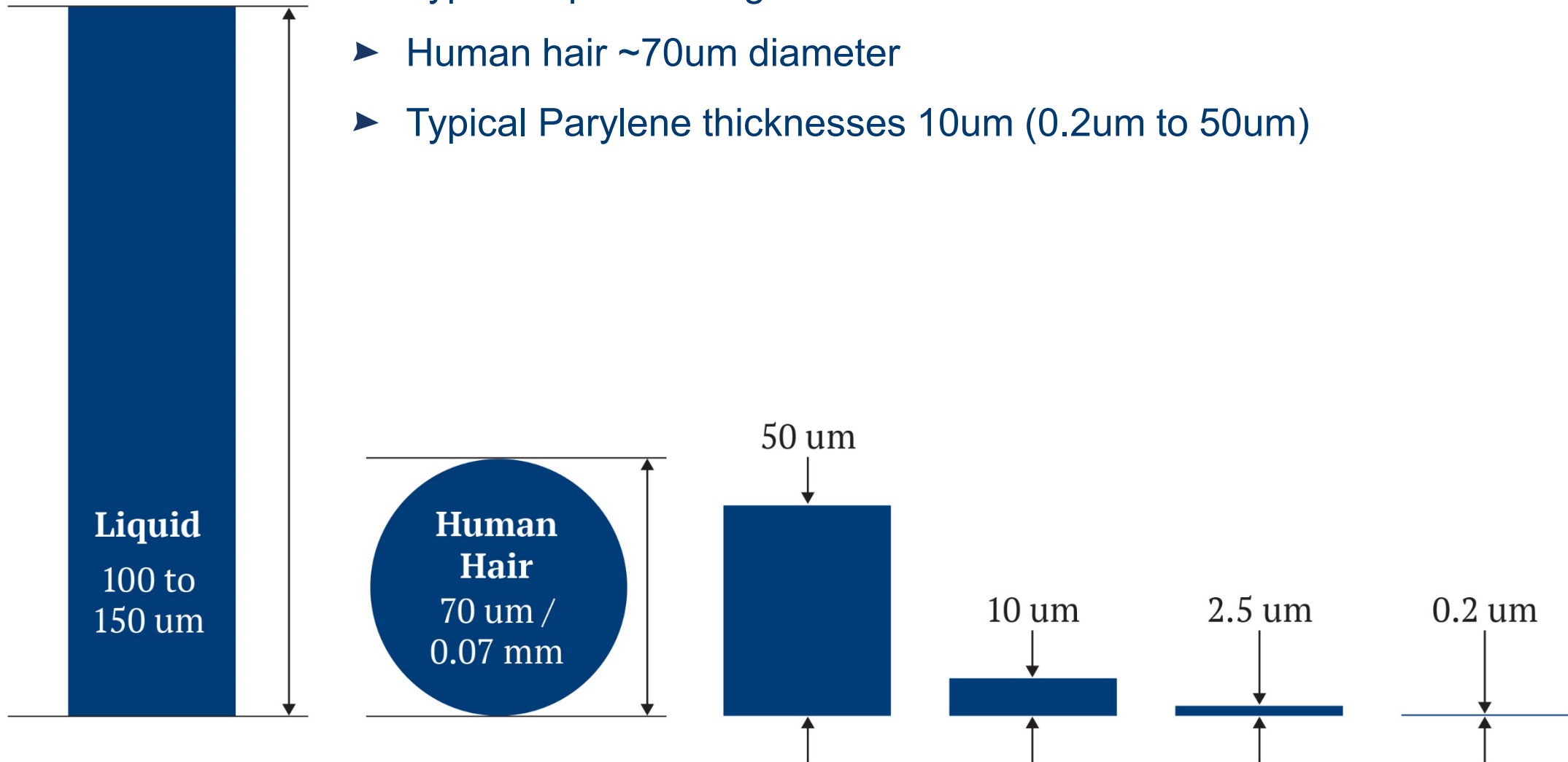
ISO-10993 BIOLOGICAL EVALUATIONS



Tests	SCS Parylene Variant			
	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	✓	✓	✓	✓

Conformal Coatings: Industry Overview

- ▶ Typical liquid coatings ~100 to 150um
- ▶ Human hair ~70um diameter
- ▶ Typical Parylene thicknesses 10um (0.2um to 50um)



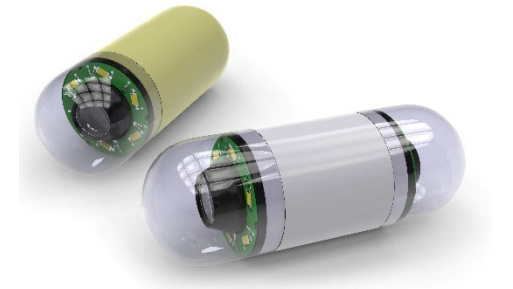
Medical Coating Applications: Short-Term

- ▶ Surgical tools
 - Electrocautery devices (flex and rigid circuits, jaws)
 - Energized surgical tools (motors, stators)
 - Endoscopic technologies (electronics, lens tech, introducers)
- ▶ Needles: Hypodermic, acupuncture, epidural/nerve block
- ▶ Mandrels, molds, core pins
- ▶ Seals: O-rings, endoscopic port seals, valves
- ▶ Ultrasonic transducers and sensors
- ▶ Gastric balloons and cuffs
- ▶ Catheters: CV, IV, urology, biliary, etc.
- ▶ Guide wires
- ▶ Pharmaceutical containers
 - Syringe components, stoppers, caps, capsules, containers



Medical Applications: Long-term

- ▶ Cardiac assist devices and components
 - ICDs, VADs, pacemakers
 - Stents: coronary, cerebral, ocular
- ▶ Neurostimulators
- ▶ Blood and fluid heating technology
- ▶ Sensors
- ▶ Cochlear and ocular implants
- ▶ Drug delivery devices
 - Inhalers (metered dose, dry powder, nasal)
 - Needles, and other infusion devices
 - Blood glucose monitors and insulin pumps
 - Pharma ampoules and containers



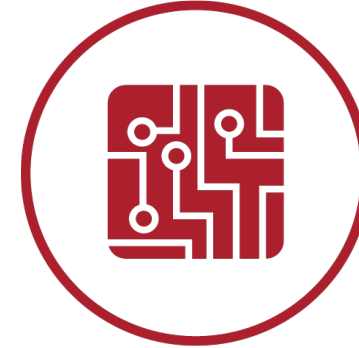
SCS Overview

- ▶ Primary business model – contract coating services
 - Customers send products to one of SCS' global coating center locations; products are coated and returned
- ▶ Reliable partner to Ethicon/J&J for decades
- ▶ Extensive coatings portfolio
 - Parylene coatings
 - Plasma coatings
 - Liquid coatings
 - ALD coatings
 - Multilayer coatings
- ▶ Highly-experienced R&D and applications engineering teams
 - Development of new coating variants and technologies
 - Experts in the art and science of conformal coating applications
- ▶ Only vertically-integrated Parylene company in the industry
 - SCS-owned raw material production facilities
 - Internal design and manufacture of conformal coating systems
 - 21 coating service locations globally



Conclusion

- ▶ Conformal coatings provide added value and increased reliability to medical devices
 - Electrical insulation
 - Barrier protection
 - Dry film lubricity
 - Component stabilization
 - Additional select benefits
- ▶ SCS offers expansive coating portfolio, enabling support for a wide range of customer applications
- ▶ Decades of sales and applications experience and expertise throughout the SCS global team



Thank You!

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