

**SPECIALTY COATING SYSTEMS™**  
A KISCO Company

# Conformal Coatings and Medical Devices

Dick Molin, Medical Market Segment Manager - August 2024

**ETHICON** North American Medical Grade  
Consortium Group

# Agenda

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- ▶ Introductions
- ▶ Conformal Coatings
- ▶ Medical Applications
- ▶ Biocompatibility
- ▶ Conclusion

SCS

# SCS Sales and Engineering Contacts

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▶ Jay Beddow – Territory Sales Manager

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▶ Nick Motsay – Sales Support Engineer

- Former SCS Applications Engineer
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# Overview of Conformal Coatings

- ▶ Thin, nonconductive, protective layers
- ▶ Electrical insulation, barrier protection to enhance performance or service life
- ▶ Common types of conformal coatings:
  - Parylenes
  - Plasma polymerized
  - Liquids: Silicones, Acrylics, Epoxies, Polyurethanes
  - Ultra-thins
  - Styrene rubber co-polymers
  - Multilayer coatings
  - ...and more

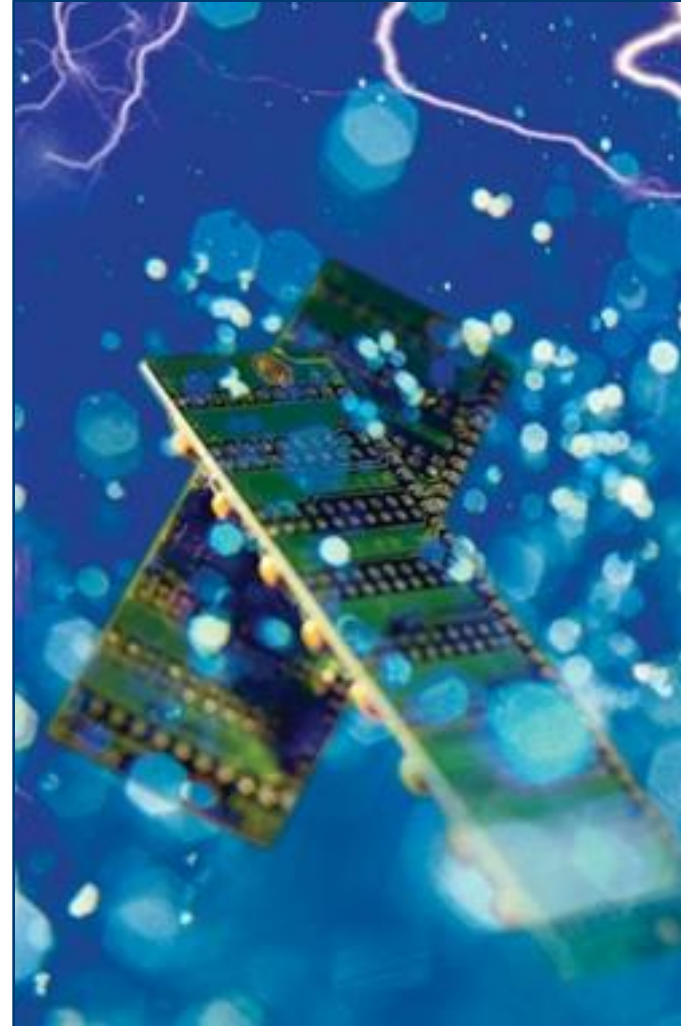




# Conformal Coatings: Objectives

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- ▶ 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

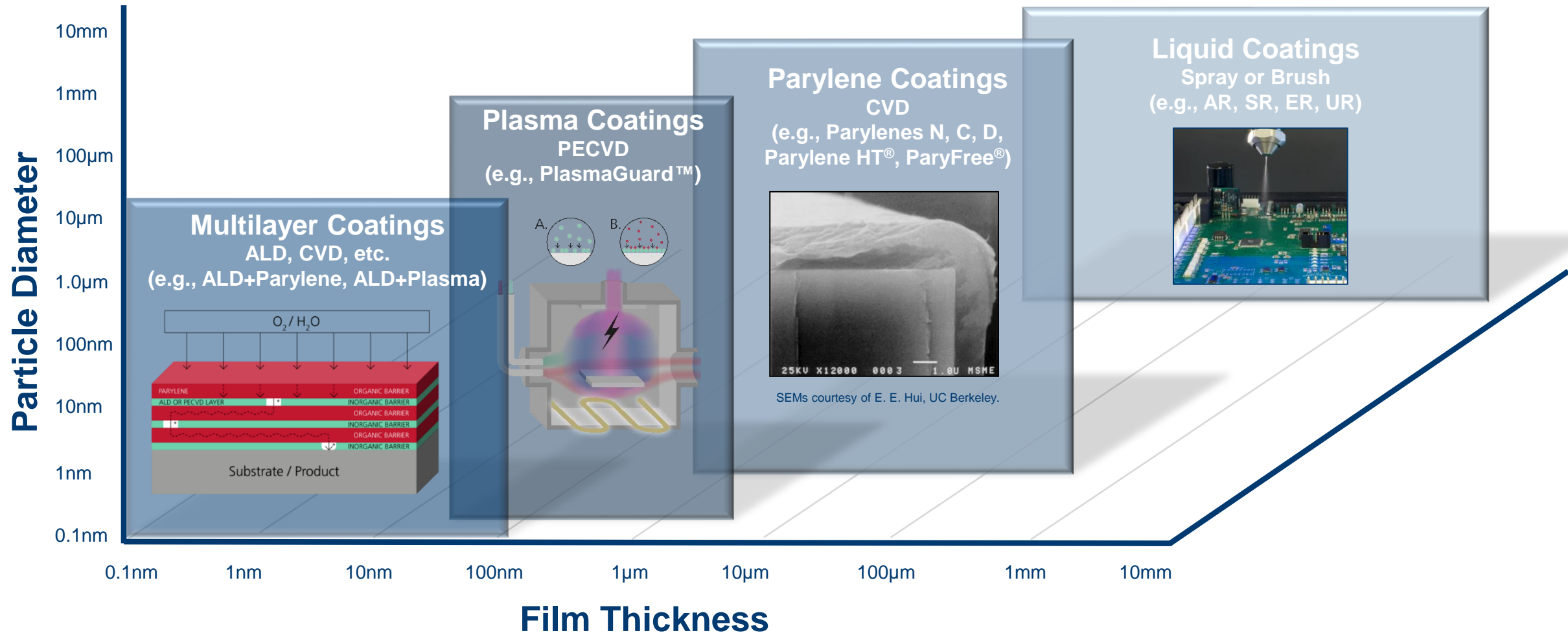


# Conformal Coatings: Industry Drivers

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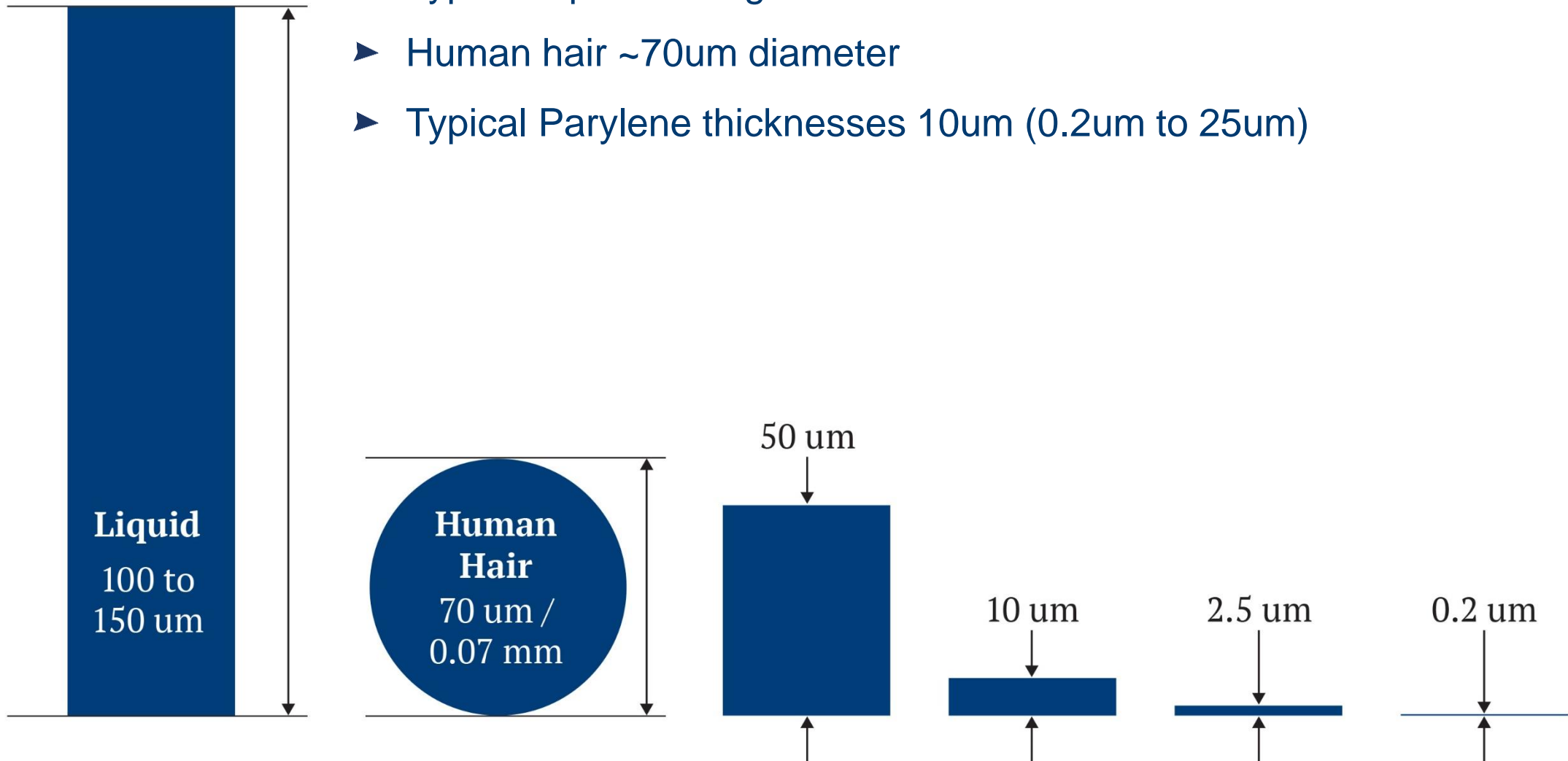
- ▶ Performance
- ▶ Cost reduction
- ▶ Waste minimization/environmental friendliness
  - PFAS minimization/elimination
- ▶ Repeatability
- ▶ Volume capacity

# Conformal Coatings: Options



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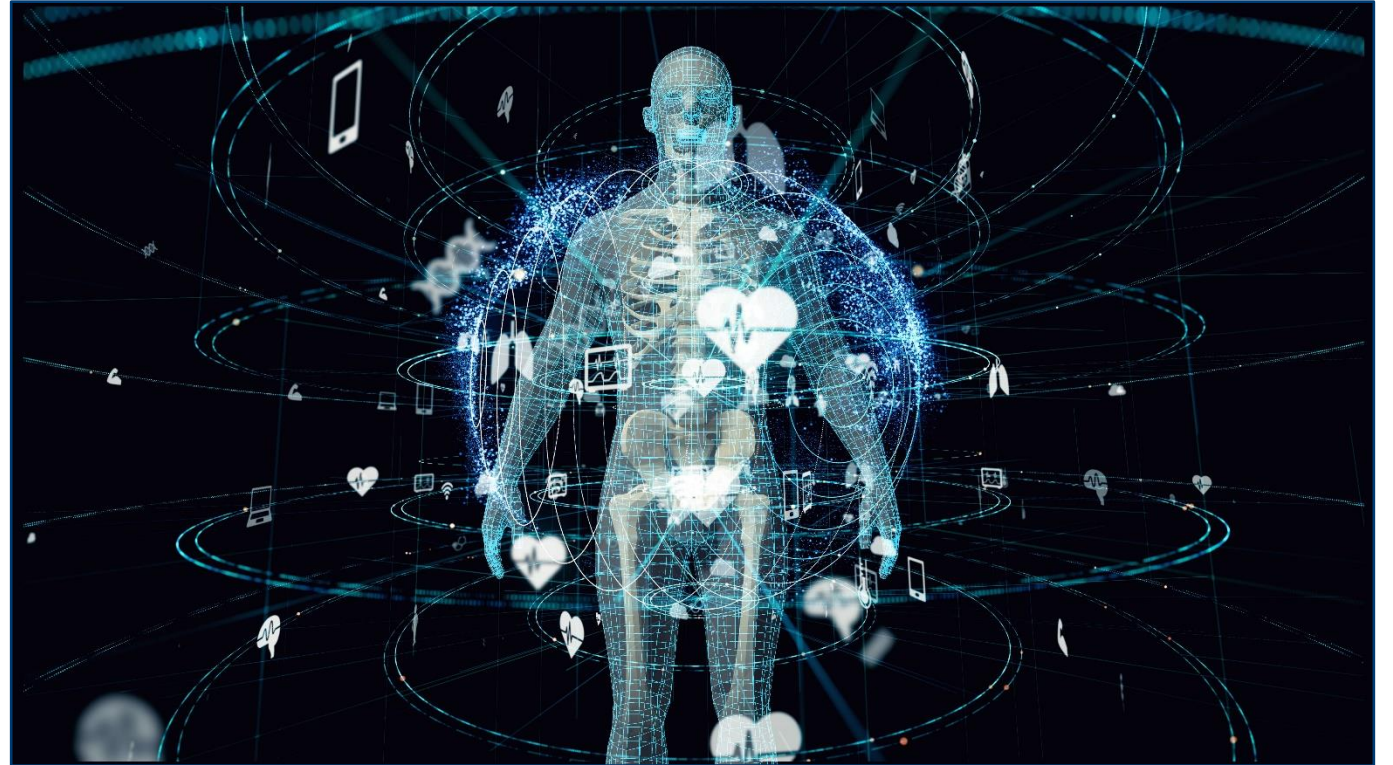
- ▶ Typical liquid coatings ~100 to 150um
- ▶ Human hair ~70um diameter
- ▶ Typical Parylene thicknesses 10um (0.2um to 25um)





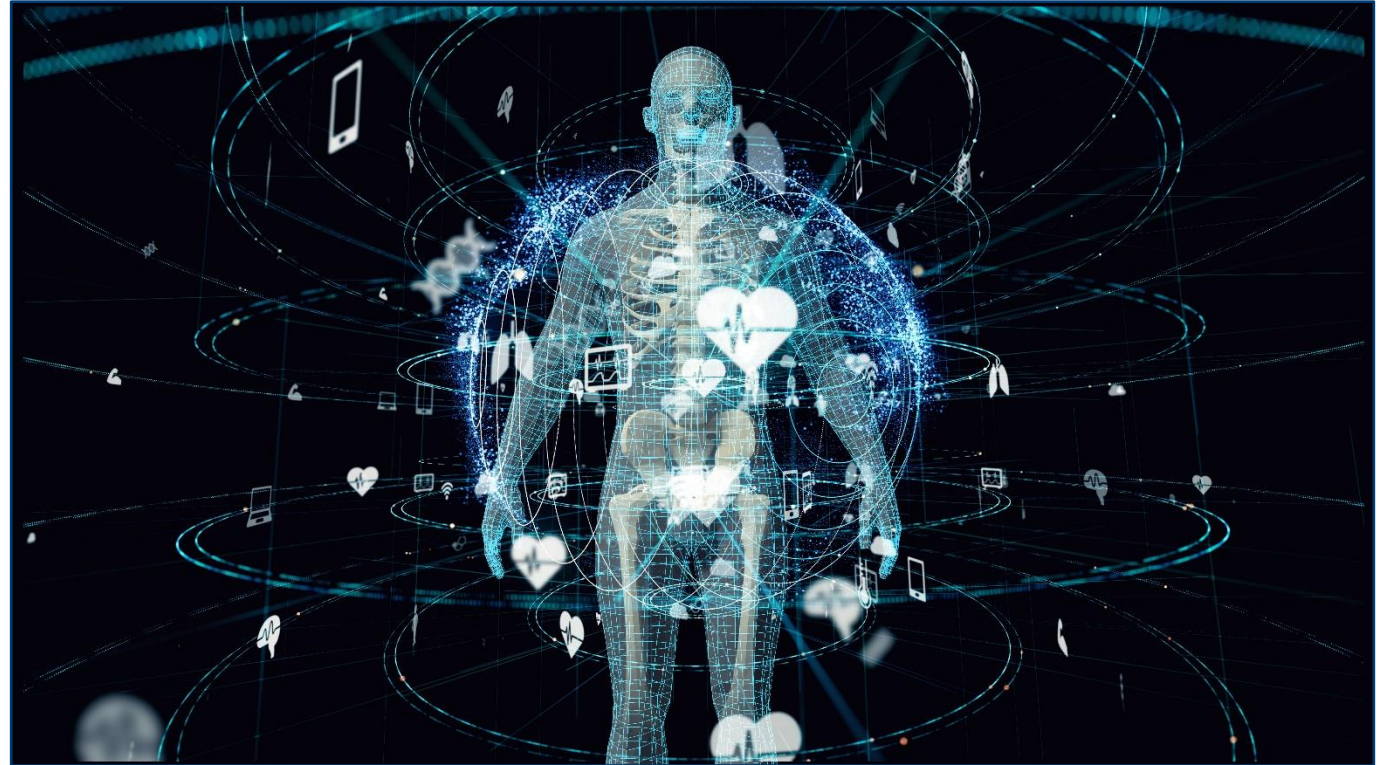
# Medical Applications: Examples

- ▶ Electrosurgical
- ▶ Powered surgical
- ▶ Electronics, printed circuit boards, flex circuits
- ▶ Infusion
- ▶ Elastomers
- ▶ Electronics in imaging
- ▶ Cardio
- ▶ Neurostimulation
- ▶ Neuro sensing



# Medical Applications: Examples

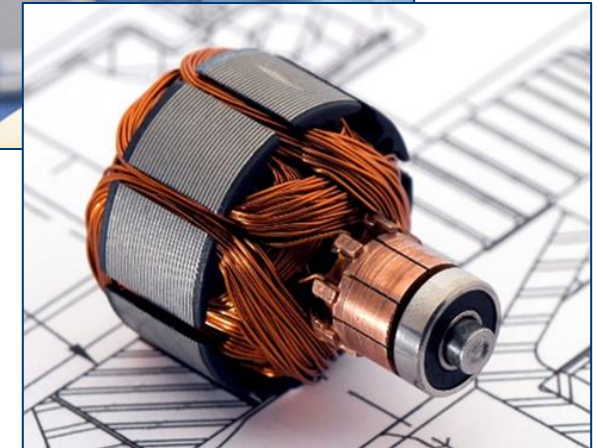
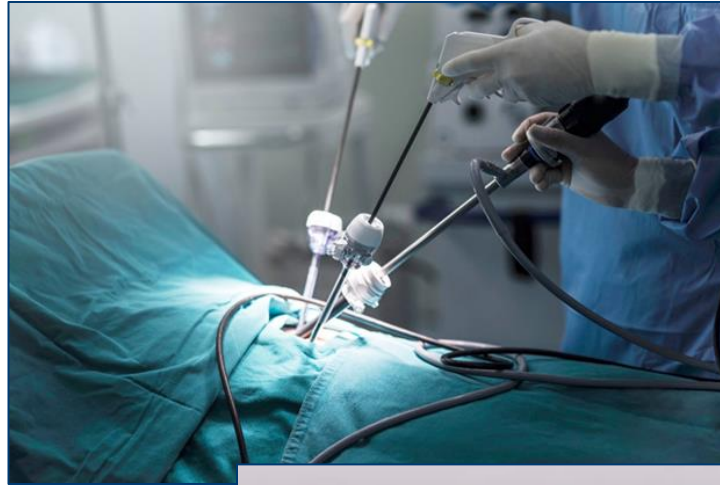
- ▶ Electrosurgical
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# Medical Applications: Electrosurgical/Power Surgical Devices

- ▶ Coating properties
  - Electrical insulation
  - Barrier
  - Lubricity
- ▶ Applications
  - End Effectors
  - Flex and rigid PCBs
  - Rotors/Stators
  - Introducers
  - Cables



# Medical Applications: Electronics

## ► Coating properties

- Electrical insulation
- Barrier

## ► Applications

- Rigid and flex PCBs
- Blood/fluid heating technology
- Endoscopy
- Sensors
- Ultrasonic transducers

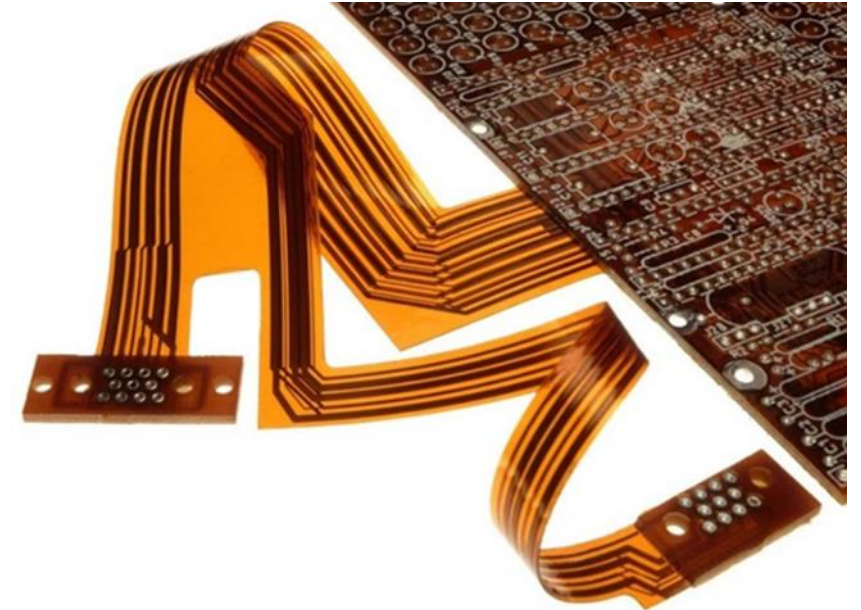
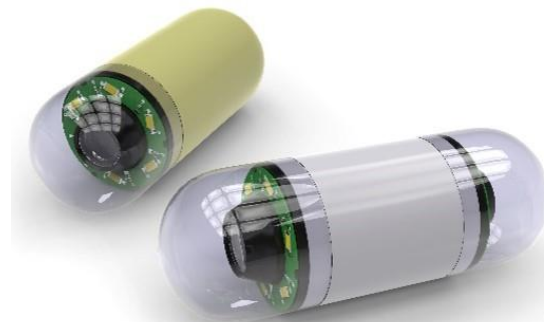


Image courtesy of DuPont



# Medical Applications: Infusion

- ▶ Coating properties
  - Barrier
  - Lubricity
- ▶ Applications
  - Needles and syringe technology
  - Closures, IV components, catheters, connectors
  - Blood glucose monitors and insulin pumps
  - Pharma ampoules and containers (USP VI)
  - Inhalers: Metered dose, dry powder, nasal
  - Pre-filled syringes





# Medical Applications: Elastomers

## ► Coating properties

- Lubricity
- Barrier

## ► Applications

- Mandrels and guidewires
- O-Rings
- Seals/gaskets
- Cable sheaths/tubing
- Therapy masks
- Nasal and IV cannula
- Endotracheal tubes
- Gastric balloons and cuffs



# Biocompatibility

- ▶ Liquids – vary by type and manufacturer
- ▶ SCS Parylenes
  - Approved devices (e.g., FDA, CE, PMDA, etc.)
    - Surface
    - Externally communicating
    - Implants
  - Compatible with all common sterilization methods
  - Comprehensive range of ISO 10993 biocompatibility
  - SCS maintains FDA Drug and Device Master Files with biocompatibility test results for reference by commercial coating customers



## 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	✓	✓	✓	✓

# Conclusion

- ▶ Conformal coatings provide:
  - Electrical insulation
  - Barrier protection
  - Dry film lubricity
  - Additional benefits
- ▶ SCS offers an expansive coating portfolio, enabling support for a wide range of customer applications
- ▶ Long, successful history of supporting J&J
  - Ethicon, DePuy, Abiomed, Biosense Webster, Cerenovous, J&J Vision, etc.
- ▶ Decades of sales and applications expertise throughout the SCS global team



# Thank You!

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