



MEDICAL DESIGN | DEVELOPMENT | MANUFACTURING



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FROM CONCEPT TO COMMERCIALIZATION

From concept to commercialization, Oscor designs, develops, manufactures and markets a wide-range of life enhancing medical devices as well as medical implantable grade components and delivery systems. As your manufacturing partner, Oscor can offer you product solutions with maximum quality, control and cost efficiency. Oscor delivers complete contract manufacturing solutions from R&D, design, engineering, design verification and validation, regulatory services, clean-room manufacturing, packaging, sterilization, supply chain management, global distribution and post-market surveillance support.

We provide our customers with state-of-the-art facilities and operations located in the US, Germany and the Dominican Republic dedicated to product development, prototyping and engineering, low cost manufacturing and sterilization capabilities.



USA — FLORIDA

4 facilities with over 100,000 sq ft of engineering and cleanroom manufacturing space

GERMANY — DÜSSELDORF

Sales and Warehouse facilities – EU Representative

DOMINICAN REPUBLIC — SANTO DOMINGO

2 facilities with over 120,000 sq ft of cleanroom manufacturing space

GLOBAL

Global distribution partners in over 100 countries!





IMPLANTABLE DEVICE DEVELOPMENT

As the first manufacturer of an implantable active fixation cardiac pacing lead in the US, Oscor's team has over 40 years experience manufacturing Class III implantable devices. Leading supplier to medical device companies with the commercialization of implantable devices including but not limited to:

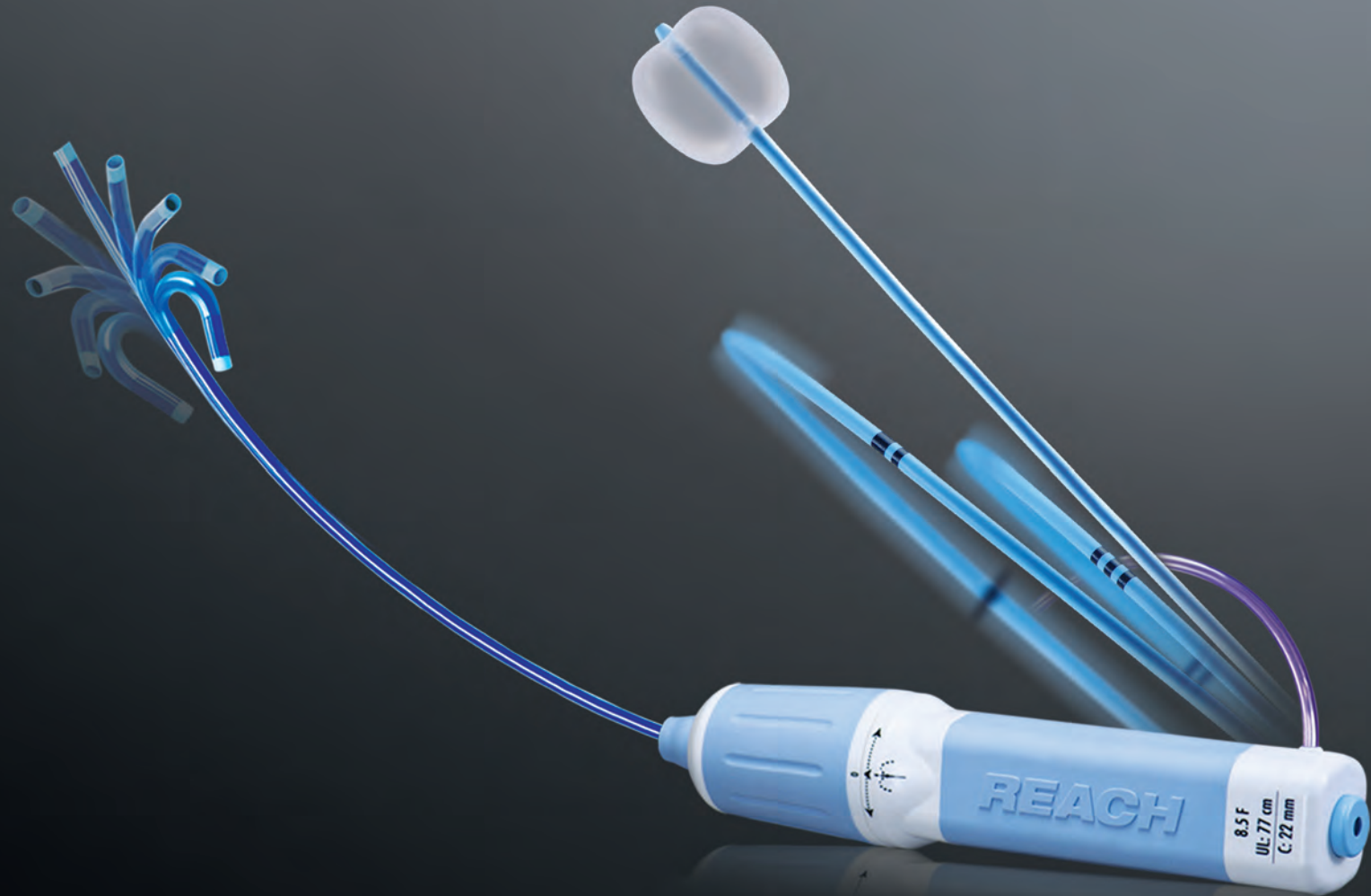
- Cardiac pacing and defibrillation leads
- Neurostimulation devices
- Pain management device lead and lead extension systems
- Vagal nerve stimulation leads
- Custom cuff stimulation leads
- Incontinence stimulation system
- Deep brain stimulation leads
- Implantable urology leads
- Implantable lead extensions and adaptors
- Various introducer, tunneling tools and kits
- Other Class III implantable systems and pumps



ACCESS INTRODUCER DEVELOPMENT

We specialize in intricate product designs requiring reinforced multi-layer and multi-lumen shafts with integration of various materials, connector hubs, control mechanisms and coatings. Our core capabilities in introducer design and development include:

- Introducers for vascular access
- Multi-lumen and multi-layer shafts
- Hydrophilic and hydrophobic coatings
- Soft, atraumatic tips
- Hemostatic valve system
- Luer connectors and ports
- Peel Away Introducers
- Expandable Introducers
- Dilators and accessories
- Micro Access Introducers
- Custom Delivery Systems

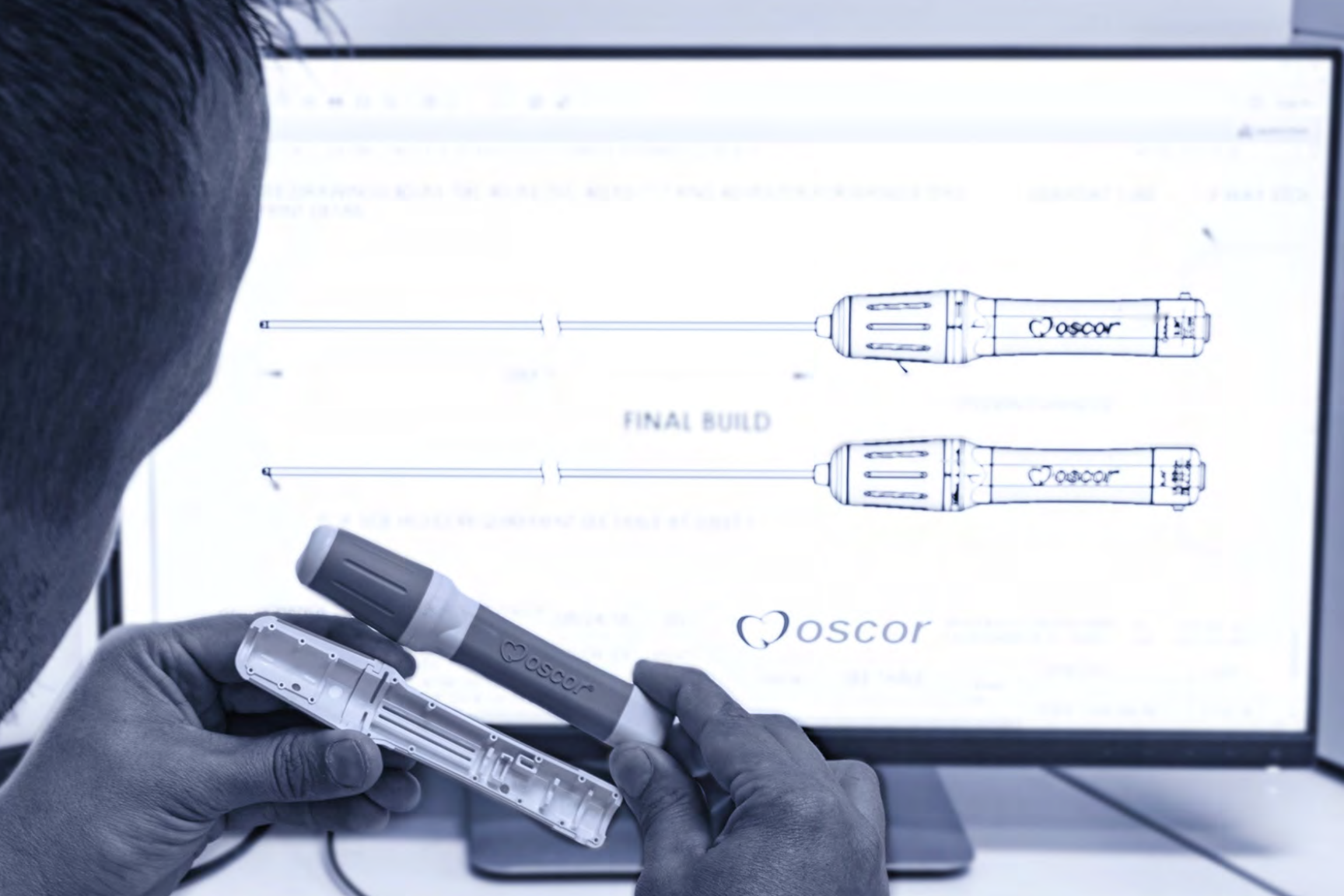


CUSTOM CATHETER DEVELOPMENT

Our innovation center offers technologies and equipment to form, shape, attach, reflow, package and test catheters with extensive geometric features and requirements. We offer turnkey solutions for vascular access, transeptal access, EP diagnostic and ablation catheters. Our portfolio of product and core capabilities in catheter development and component design include:

- Guiding sheaths and diagnostic catheters
- EP Ablation, Pacing, Diagnostic and Basket Catheters
- Balloon Catheters
- Multi-lumen and multi-layer shafts
- Braid and coil reinforced shafts
- Encapsulated electronic sensors and antennas
- Steerable design and handles
- Hydrophilic and hydrophobic coatings
- Soft, atraumatic tips
- Laser welding, cutting, marking and ablating
- Luer connectors and ports





DESIGN & DEVELOPMENT

- Product Design
- Design Feasibility
- Prototype Build (Proto-Prime Center)
- Pilot Line for Limited Clinical Build
- FMEA
- Test Method Development and Validation
- Design Verification Testing
- Packaging Design and Validation
- UDI / MDR Labeling
- OEM Branding

With over 40 years experience and with product certifications in over 100 countries, Oscor is the industry leader in the design and development of minimally invasive and implantable medical devices. Our wide range of approved devices, validated components and processes allows us to offer customized turnkey prototyping and product development services, with shortest lead times, maximum control and minimum project risk.

PROJECT DEVELOPMENT FLOW



- PROTOTYPING**
- Manufactured to Customer Requirements
 - Leverage on Existing Validated Components
 - Matured Processes
 - Material Traceability
 - CAD Design
 - 3D Modeling
 - Functional, Non-Validated

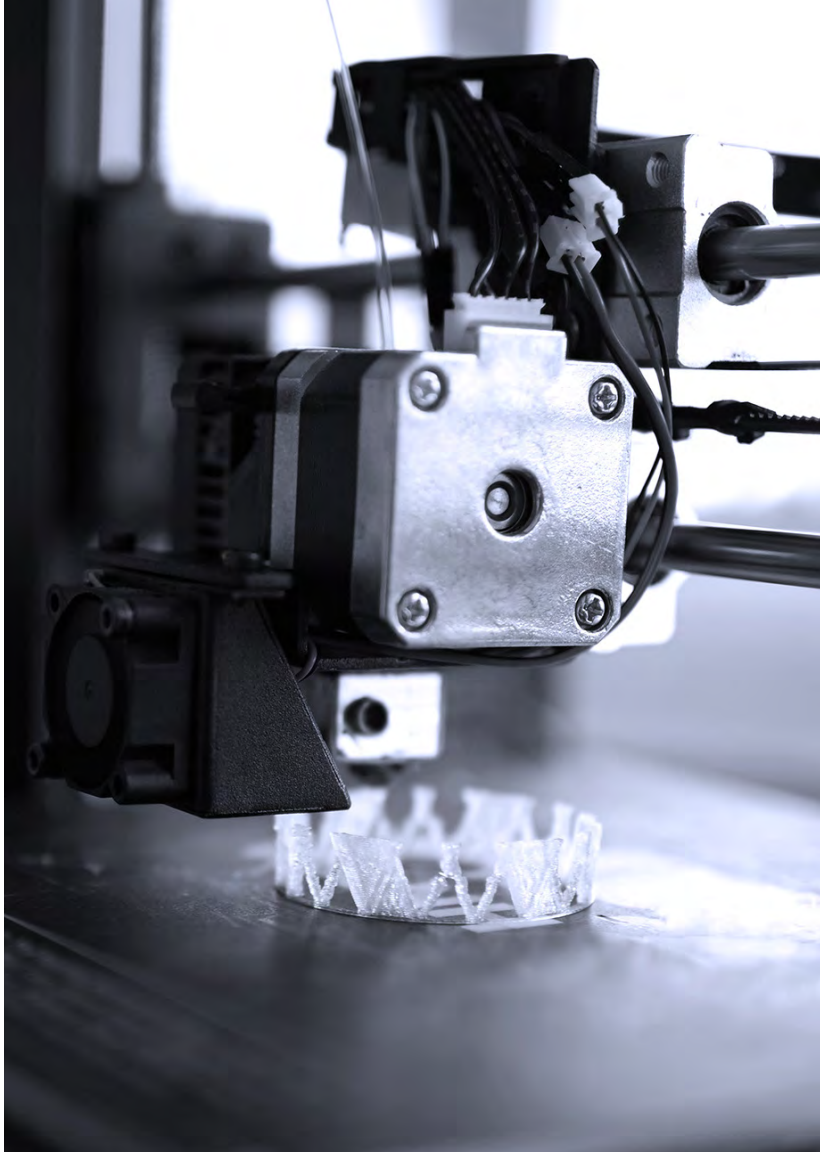
- CONCEPT/FEASIBILITY ASSESSMENT**
- Design Assessment
 - Design Risk Analysis
 - Material Selection & Characterization
 - Process Assessment
 - Biological & Toxicology Hazard
 - Sterilization
 - Labeling
 - Packaging

- PILOT LINES FOR LIMITED CLINICAL USE**
- Define Abbreviated Requirements USA & OUS
 - Design and Development Plan
 - Risk Hazard Assessment
 - Manufacturing & Quality Control Plan
 - Labeling of Investigational Devices
 - Import/Export Requirements
 - Post Market Activities
 - Sponsor Responsibilities
 - Quality System Audit



RAPID PROTOTYPING

- Manufactured to Customer Requirements
- Leverage on Existing Validated Components
- Matured Processes
- Material Traceability
- Off the shelf product and component offering for rapid project start
- Rapid Product Prototype Built (Proto-Prime Center)
- CNC Prototype Machining
- CAD Design
- 3D Printing



DEDICATED PROTO-PRIME CENTER

- Rapid prototyping team of experts
- Wide range of technologies
- First-class equipment
- Ready to use components
- Fast turn around

From Prototype to Proto-Prime Oscor is dedicated to the realization of your project. Oscor's Proto-Prime Center consist of a team of experts that create highly specialized medical grade prototypes, allowing you to get customer feedback faster. Our dedicated center also combines a wide range of technologies and first-class equipment to develop innovative and complex prototypes. Additionally, we offer a ready to use supply of validated components and processes, allowing us to accelerate your project with maximum control and minimal project risk.



CNC MACHINING

- Quick Prototyping
- Multi-axis CNC Swiss Turning
- High Speed Multi-Axis Machining
- CNC EDM Sinker and EDM Wire
- Laser Welding, Marking, Cutting, Ablating
- Centerless Grinding
- CAD/CAM Simulation
- Automation
- Inline Inspections / SPC Controls



MOLD MAKING

- Mold Design and Development
- Material Selection and Compounding Solutions
- Mold Flow Analysis
- Fully Automated Mold Making



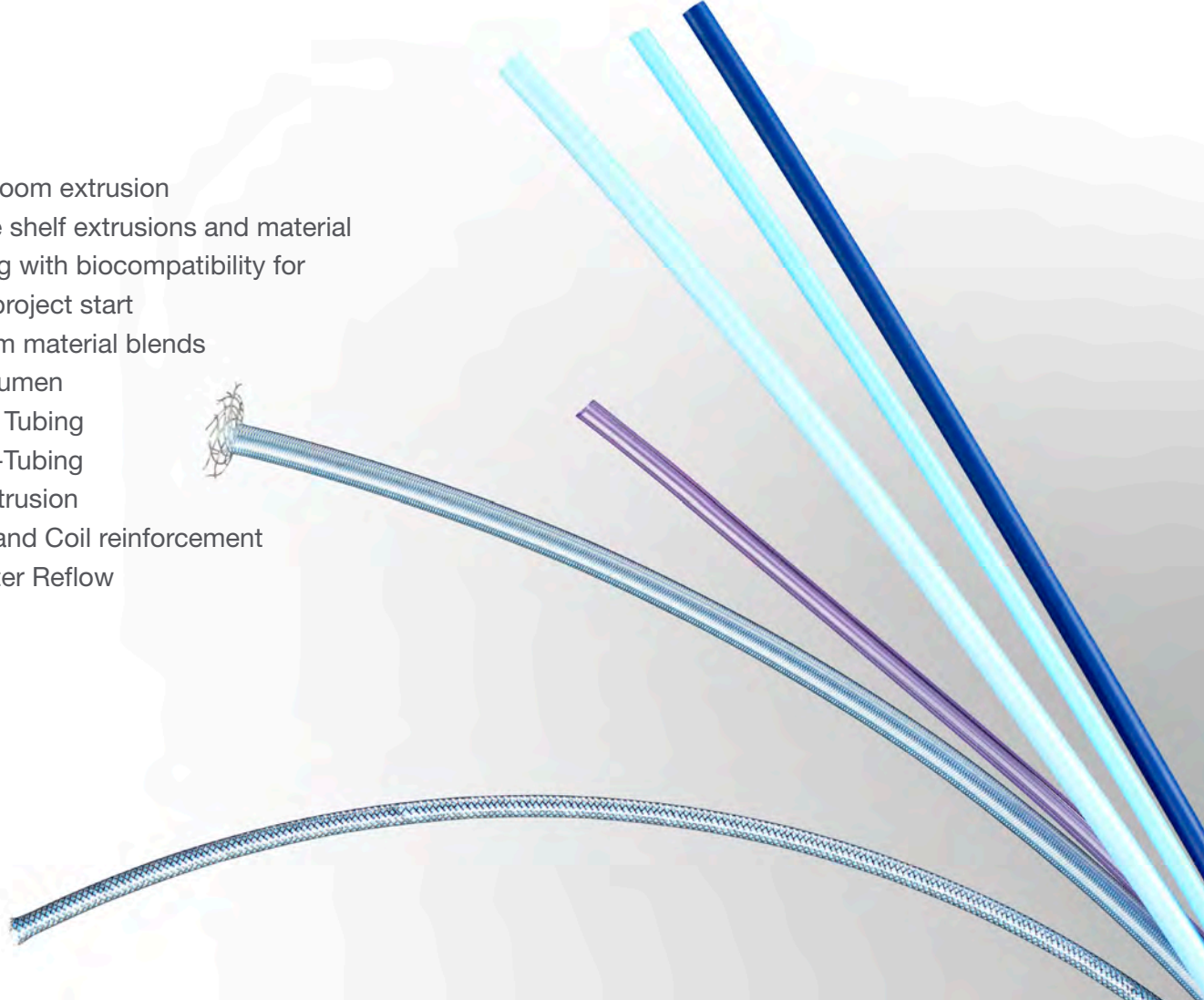
INJECTION MOLDING

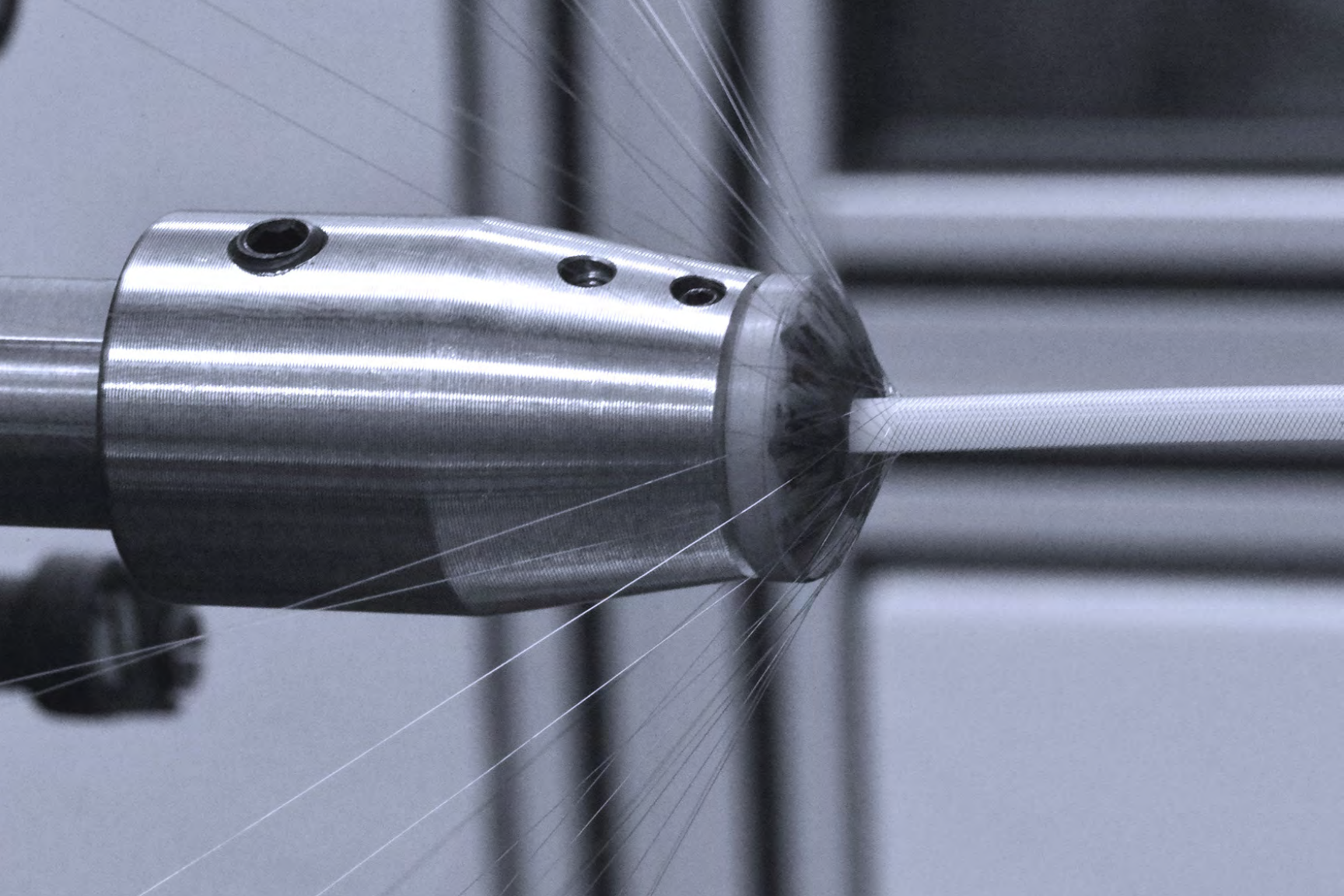
- Cleanroom Injection Molding (Thermoplastic, PEEK, LIM)
- Insert Molding
- Component Qualification
- Mold Validation



EXTRUSION

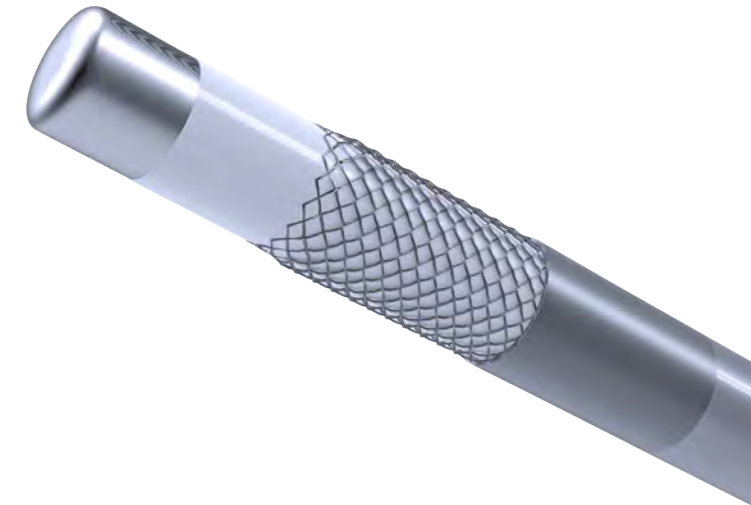
- Cleanroom extrusion
- Off the shelf extrusions and material offering with biocompatibility for rapid project start
- Custom material blends
- Multi-lumen
- Profile Tubing
- Bump-Tubing
- Co-Extrusion
- Braid and Coil reinforcement
- Catheter Reflow

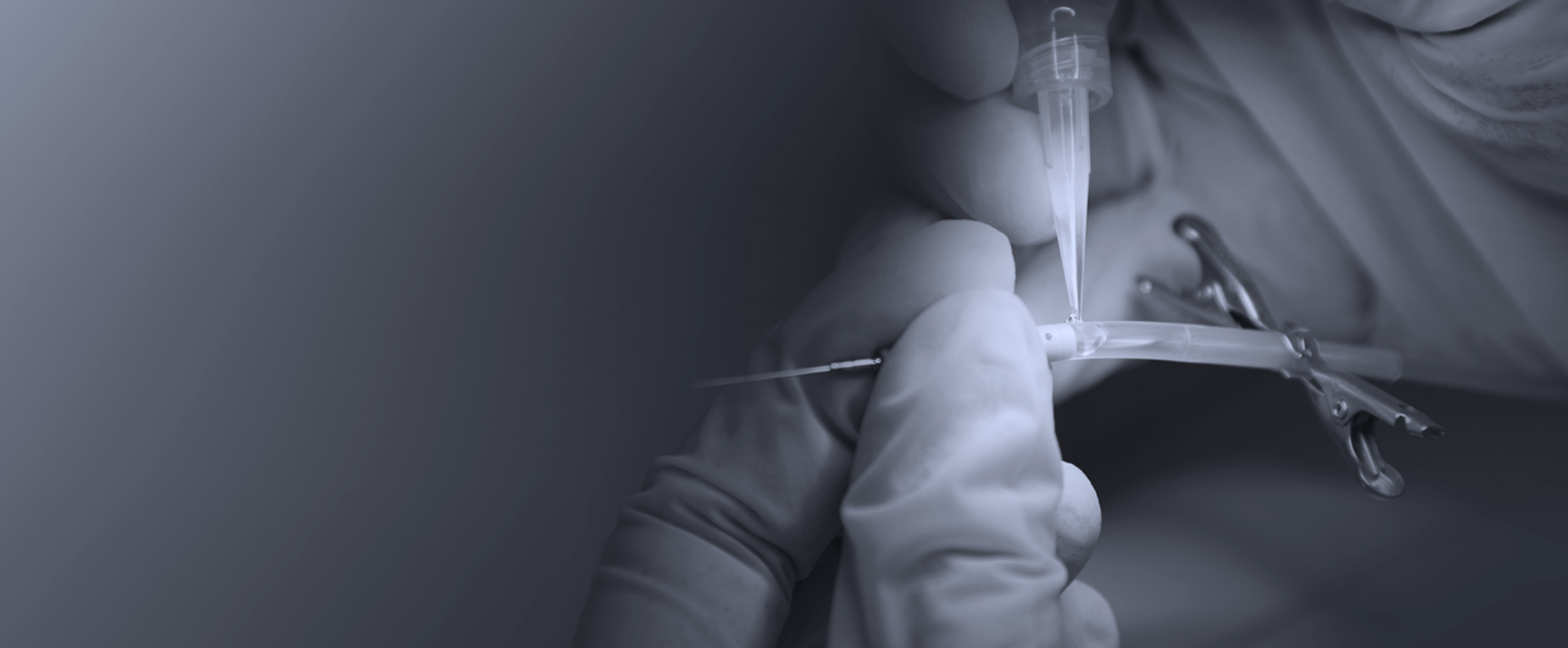
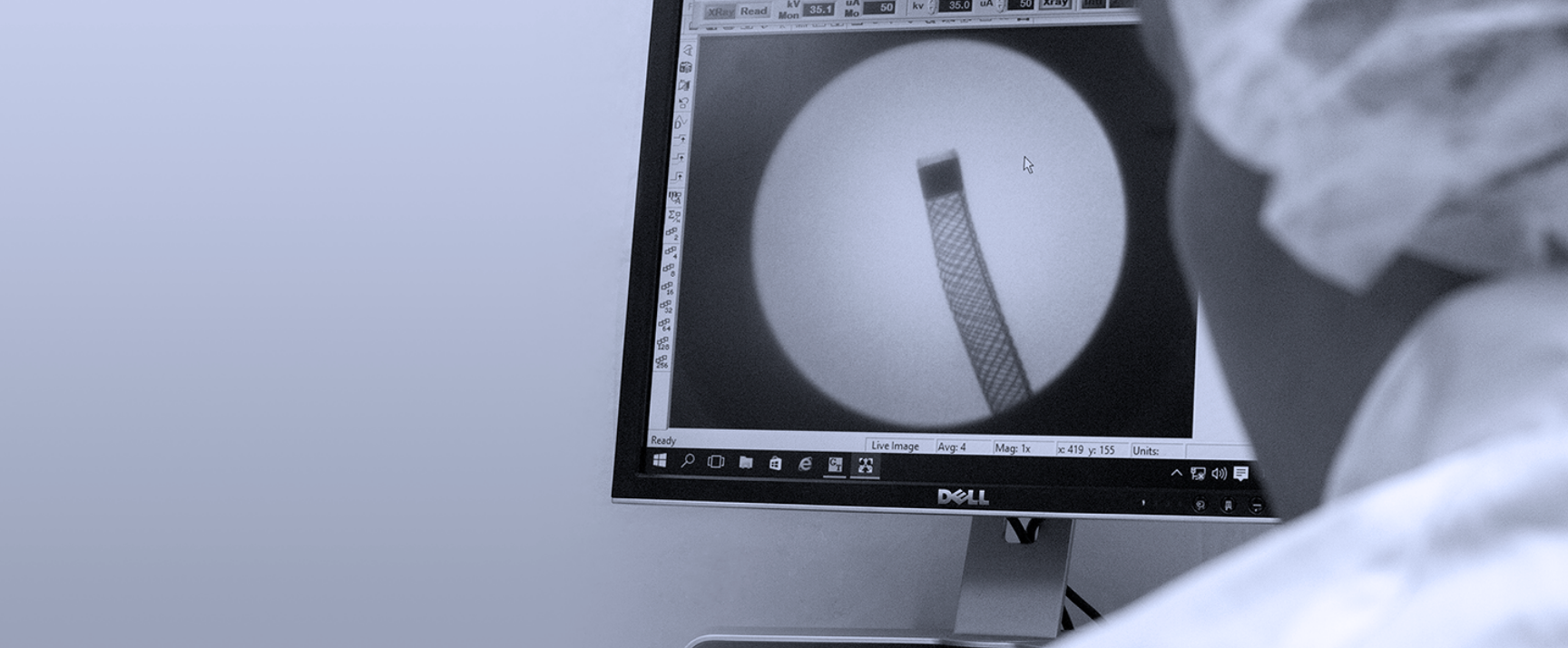




BRAIDING & SURFACE TREATMENTS

- Braided and coiled shafts
- Full range of braid material, sizes and shapes
- Reflow processing
- Coating
- Surface Treatment
- Tipping
- Nitinol forming and processing
- Bonding
- Pad Printing
- Laser marking





DEVICE TESTING

- Mechanical
- Electrical
- Design Verification and Validation
- Analysis
- Engineering Usability
- Biological and Toxicology

CLEANROOM MANUFACTURING

Oscor offers over 150,000 sq ft of ISO 14644-1 Class 7 and 8 certified cleanroom environment, dedicated for the manufacturing of minimal invasive and long term medical implantable devices.

Oscor provides functional, sustainable and innovative packaging systems for critical applications, under controlled environments that maintain the highest regulation standards. From single batch to automated high volume, we offer protective trays, pouches, blister packs, custom kit configurations and label design services that meet your brand requirements.

Oscor's packaging capabilities include:

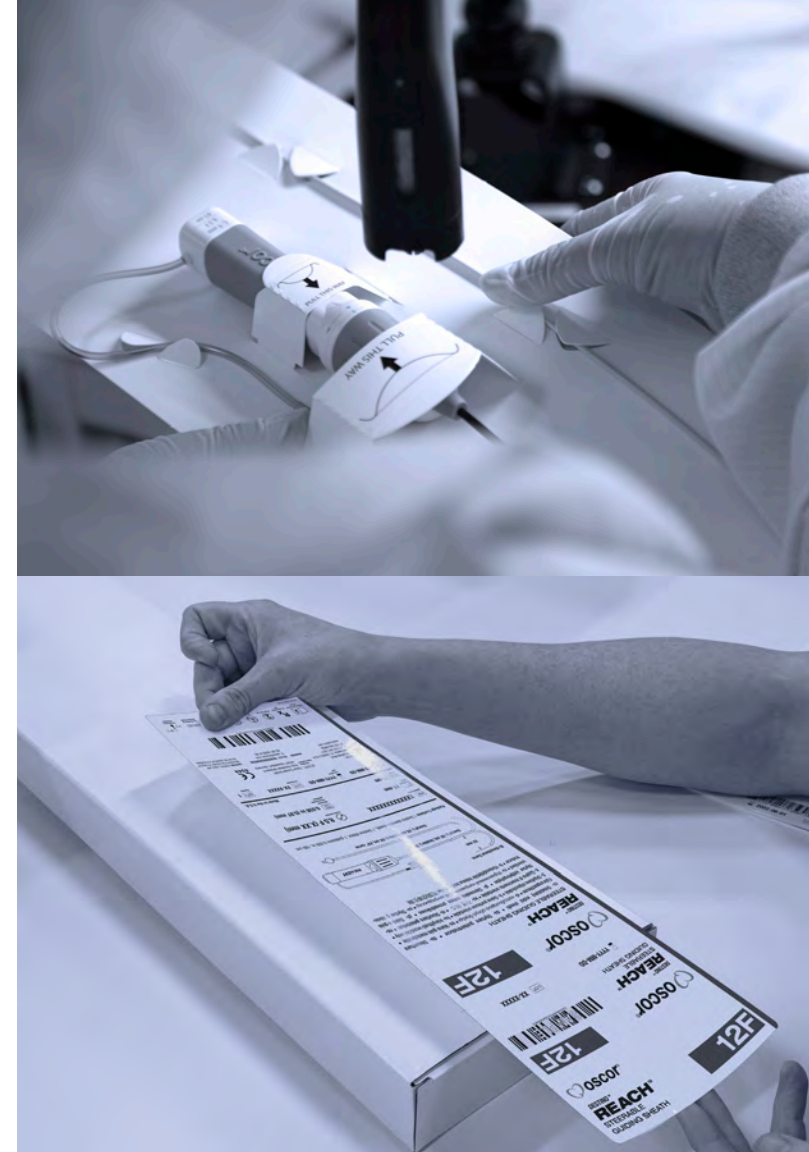
- Packaging Design
- Packaging Validation
- Packaging Shelf Life Testing
- Cleanroom Packaging
- Packaging in certified ISO 14644-1, Class 7 and Class 8 cleanrooms
- US and offshore locations
- Low and high volume
- Single and complex kit packaging
- Pouch and blister tray thermosealing
- Packaging design and validation
- Automated packaging inspection systems
- Automated label inspection systems
- UDI Labeling Capabilities

CLEANROOM PACKAGING

- Kit Assembly
- Pouch Sealing
- Tray Sealing

FINAL PACKAGING

- EU and USA UDI labeling
- OEM branding
- Country specific packaging requirements





STERILIZATION

Oscor's state-of-the-art facilities are dedicated to sterilize even the most complex medical devices. Our team of experts will work with you to ensure maximum protection of your device, sterilization compatibility, cost-effectiveness and fast turnaround, to get your product to market.

Sterilization Capabilities Include:

- State of the art EO sterilizers utilizing 8% EO
- 12 hour turnaround times
- Various EO technologies and cycles available: from 8% EO to 100% EO
- Low volume and high volume chamber sizes available
- Sterilization facilities located in US and Dominican Republic
- Experienced sterilization and validation team
- ISO 13485 and ISO 11135 certified

GLOBAL REGULATORY

Offering comprehensive support and regulatory services to bring your product to global market approval:

- Global Regulatory Consulting
- Device Registration
- Post Market Surveillance
- Global Medical Device Reporting
- US and EU Representative
- FDA Registered
- 510(k) and PMA device experience
- ISO 13485:2016 certified
- CMDCAS (Canada) certified
- JAPAN Accreditation
- Australia Accreditation
- Anvisa (Brazil)
- Oscor Quality System is approved by the best industry leading medical device companies and most notified bodies



GLOBAL DISTRIBUTION

- Global Supply Chain Management
- Global Distribution
- After Hour Technical Support
- Warehousing
- Customer Support
- Global partners



SUPPLY CHAIN MANAGEMENT



PRODUCT
MANAGEMENT



ANALYSIS



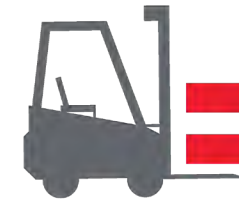
PLAN



PROCUREMENT



PRODUCT



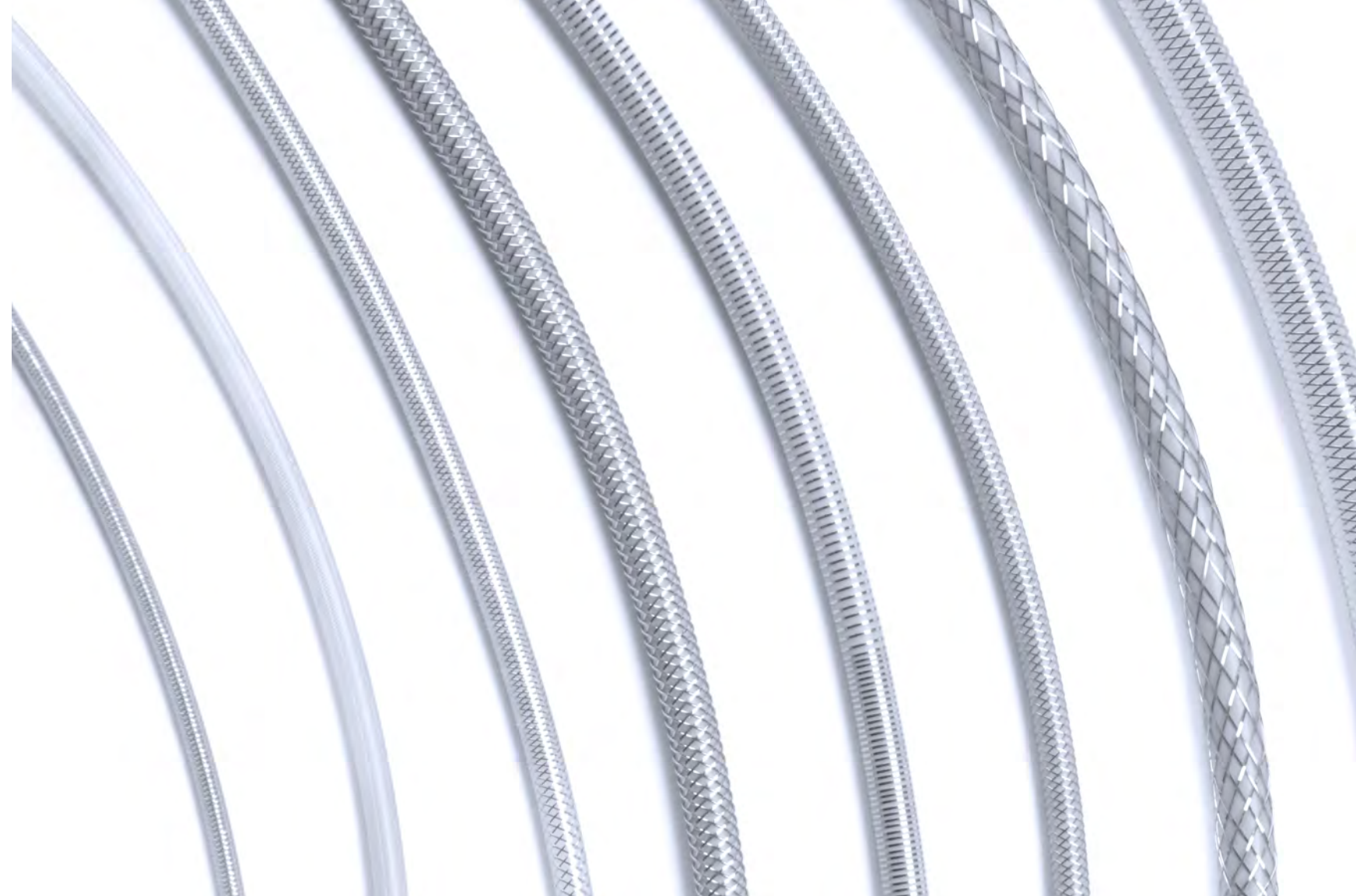
LOGISTICS



DISTRIBUTION



24/7 CUSTOMER
SUPPORT



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YOUR SUCCESS ACCELERATOR!



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