



# MEDICAL DEVICE & MANUFACTURING SOLUTIONS

# INNOVATING TOGETHER WITH FREUDENBERG MEDICAL

Freudenberg Medical is a global partner for the design, development and manufacture of medical devices, components, and minimally invasive solutions.

Our comprehensive technical capabilities range from the design and manufacture of minimally invasive, catheter, and handheld technology to the development and production of medical components utilizing advanced materials and processes. We are an industry leader in the manufacture of high precision silicone and thermoplastic components and tubing as well as metal hypotubes and coating technology.

Financial stability and long-term orientation form the basis for our longstanding partnerships with customers. With over 48,000 Freudenberg associates around the globe, Freudenberg Medical has access to a unique pool of expertise as well as a global network of R&D facilities. This allows us to support customers from material and design optimization to mass production of finished medical devices.

Freudenberg Medical has the experience and expertise to ensure your success. As a global partner, we offer unique advantages:

- Exclusive focus on medical device and pharmaceutical markets
- Full range of services from development to final assembly
- Material and process expertise across a wide range of applications
- Large pool of expertise and creativity with over 200 engineers in 11 locations around the globe
- Long-term orientation and financial stability, backed by the Freudenberg Group
- ISO 13485 certified quality systems and FDA registered sites in North America, Central America, Europe, and Asia
- Unrivaled lean manufacturing expertise





## MANUFACTURING REDEFINED

Freudenberg Medical combines over 35 years of global manufacturing experience in finished medical devices, complex subassemblies, components, and materials with a robust culture of quality, innovation and continuous improvement to deliver cost effective, long-term, and reliable outsourced manufacturing throughout the product lifecycle.

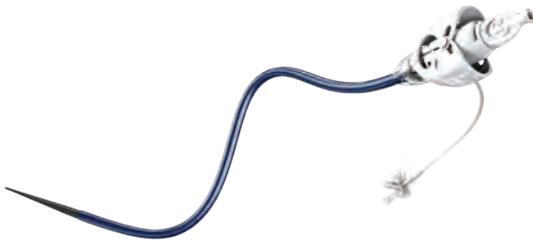
### Our Manufacturing Process

We define total success as a collaborative and integrated partnership with our customers. Our customer-focused process ensures that needs and expectations are explicitly documented, translated into requirements, and that manufacturing project plans are executed on-time and within budget, from a single component to a full facility transfer.

FROM NAPKIN SKETCHED IDEAS TO VOLUME MANUFACTURING AND PRODUCT LINE EXTENSIONS WITH NEXT GENERATION DEVICES, FREUDENBERG MEDICAL POSSESSES THE EXPERTISE AND INNOVATIVE SOLUTIONS TO HELP YOU GROW YOUR BUSINESS, AND IMPROVE QUALITY AND VALUE THROUGHOUT THE PRODUCT LIFE CYCLE

# MEDICAL DEVICE SOLUTIONS FOR CATHETERS AND DELIVERY SYSTEMS

Freudenberg Medical proactively develops innovative and cost-effective solutions that can help organizations accelerate time to market. Whether you are looking to white label a new and innovative device, improve your next generation catheter and delivery system, or reduce time when building new feature sets into your products, Freudenberg Medical's growing portfolio of finished device, design and process solutions can meet your needs.



## DEVICE SOLUTIONS

Finished, medical devices that can be readily developed with a private label and incorporated into commercial product portfolios.

- FlexSeal® Introducer Sheath with Hydrophilic Coating
- HyperSeal® Introducer Sheath with Hydrophilic Coating
- Composer® Steerable Introducers



## DESIGN SOLUTIONS

Component and subassembly solutions that can be directly incorporated into new and next gen product development projects to facilitate shorter development times and lower development costs.

- Composer® Deflectable Catheter Handle Platform
- Composer® XL Deflectable Catheter Handle Platform
- FlexSeal® Hemostasis Valve
- HyperSeal® Hemostasis Valve
- CertuSeal® Hemostasis Valve



## PROCESS SOLUTIONS

Manufacturing process solutions that expand design options, enhance material/device performance and decrease production costs.

- Composite Catheter Shafts
- E-Pro™ Hypotubes
- Cambus Coat™
- M $\mu$ -Coat & Rho-Coat™ Lubricious Coatings
- Advanced Extrusions



## CATHETER MANUFACTURING

Freudenberg Medical offers unsurpassed expertise in the design, development, and manufacture of minimally invasive surgical and catheter-based devices. Our product development and manufacturing teams collaborate to ensure design for manufacturability, decreased development time, and increased speed to market for finished goods.

Our solutions meet a diverse set of market needs across a variety of categories including neurology and neurovascular, ophthalmology, ENT, cosmetic surgery, pulmonary, structural heart, cardiovascular, gastroenterology and endoscopy, bariatric surgery, endovascular therapies, electrophysiology/CRM/A-Fib, urology/gynecology, in vitro diagnostics, orthopedics, peripheral vascular, oncology/interventional radiology, and drug delivery.



## EXTRUSION, BALLOONS AND CATHETER FINISHING

To meet the ever-evolving requirements of our client's complex catheter and delivery systems, Freudenberg Medical and VistaMed continue to innovate and invest in key technologies and capabilities. Offering design and development services, we collaborate with our clients to deliver customer specific solutions to the toughest challenges facing engineering and operations teams. Working with a wide range of materials, we offer diverse tubing solutions as well as balloon design and forming for complex catheters, delivery systems, and a wide variety of specialized applications.



### CATHETER ASSEMBLY

- Design and development
- Prototyping
- Material and component selection
- Single- and multi-lumen extrusion
- Balloon forming
- Hypotubes and micro-components
- Validation and qualification
- Sterilization
- Packaging and labeling

### CATHETER FINISHING

- Insert and over molding
- Annealing
- Tip forming
- Fusing
- Adhesive bonding
- Precision hole drilling
- Punching
- Hydrophilic coating
- Laser cutting & drilling
- Multi-durometer transition
- Catheter reinforcing

### BALLOON CAPABILITIES

- Materials-Pebax, Polyamides, PET, Polyurethanes
- Non-compliant, semi-compliant, and compliant
- Diameters 2.0 mm to 35 mm+
- Lengths 5 mm to 300 mm
- Speciality design



## HYPOTUBES AND MICRO-COMPONENTS

Cambus Medical, a Freudenberg Medical joint venture company, is a world-leading supplier of advanced hypotube components, assemblies and products for minimally invasive surgical devices used in diagnostic and therapeutic interventions. PTFE coating applied using proprietary Cambus Coat™ application technology is PFOA-free and offers the highest levels of adhesion thus ensuring peak performance and safety. Cambus Medical also develops and manufactures stylets, cannulas, and high-precision specialty needles used in vascular and endovascular access, biopsy, and drug delivery procedures.

Capabilities include Navigate™ product development, laser cutting and welding, laser marking/ablation, EDM, ECM, centerless grinding, needle-tip grinding, passivation, electro-polishing, PTFE coating, bead blasting, injection molding, pad printing and assembly.



## COATINGS

**Hemoteq, a Freudenberg Medical company,** is a leading contract development and contract manufacturing organization (CDMO) for device drug combination products (DDCP) and specialty coated medical devices and components. With a proven track record backed by two decades of 360° expertise, Hemoteq provides advanced coating design, product and process development, regulatory strategy, and volume production of DDCP and specialty coated components.

- Coating design
- Design for manufacturability
- Coating process development & scale-up
- Iterative prototyping, pilot production
- Design and process verifications & validation
- Interface services for external testing
- Interface services for preclinical & clinical studies
- Regulatory submission services
- Legal manufacturer services (CE Mark)
- Post market surveillance and vigilance support
- Volume coating production
- Coating technology transfer, in- and outsourcing

### **Device Drug Combination Products**

Our coatings reliably and precisely deliver a wide range of active pharmaceutical ingredients with a specified release profile that ensures optimal clinical performance. We have extensive experience in customization and volume production of DDCP for the following applications:

- Drug-eluting stents
- Drug-coated balloons
- Drug delivery coatings of non-vascular implants

**THE CLINICAL EFFECTIVENESS AND SAFETY OF DEVICE DRUG COMBINATION PRODUCTS DEVELOPED BY HEMOTEQ HAVE BEEN CONFIRMED IN NUMEROUS CLINICAL STUDIES**



## DESIGN AND DEVELOPMENT

We co-develop breakthrough medical device designs using the latest design tools and techniques to create products that are robust, safe, effective, and within budget. We develop manufacturing processes that ensure effectiveness all the way through product launch. And we validate processes across the entire spectrum of product development, from bottom-up creation to parallel line-transfer.

Rely on Freudenberg Medical from the very beginning. We provide comprehensive medical device and component design and development services:

- Industrial design and prototyping
- Design for manufacturability support
- Computer-aided engineering and simulation
- Complete solutions for minimally invasive surgical, handheld, and catheter-based devices



## SILICONE TUBING FOR PHARMACEUTICAL AND MEDICAL

Freudenberg Medical manufactures two proprietary brands of platinum-cured silicone tubing and fluid handling products for pharmaceutical and bioprocessing applications.

PharmaFocus® Premium is a high purity silicone tubing fabricated using a premium silicone raw material specifically formulated to meet the demanding requirements of pharmaceutical and bioprocessing applications. Manufactured globally the HelixMark® product line offers a wide array of product types and sizes, available ready to ship.

# SPECIALTY COMPONENTS TO FINISHED DEVICES

Freudenberg Medical partners with customers to offer end to end contract medical device manufacturing services. As an organization, we pride ourselves on having no limits to what we can do with complex materials, technologies and processes and our experienced team of engineers will assist you through the entire process.

## **Precision Molding & Extrusion**

Freudenberg Medical brings deep engineering expertise in the molding and extrusion of thermoplastic and silicone components. With manufacturing facilities in North America, Central America, Europe and Asia we deliver world class products to our medical device and pharmaceutical clients around the world. Freudenberg Medical partners with all raw material suppliers to source only the highest quality medical grade raw materials. We operate only in cleanrooms, using state of the art equipment, and stay competitive by combining a high engineer-to-customer ratio, lean manufacturing principles, and validated processes including Scientific Injection Molding.

## **Implantable Solutions**

Freudenberg Medical offers implantable product solutions in long-term implantable silicone material as well as implantable-grade PEEK polymers. Our implantable product solutions are manufactured in ISO 13485 certified facilities within ISO certified cleanrooms. If your product requires compliance with stringent regulatory requirements, specific facilities are in compliance with FDA, European MDD, and Health Canada requirements as well as equipped with ISO Class 7 & 8 cleanrooms.

## **Finished Devices**

Freudenberg Medical is the perfect match for companies seeking development partnerships for finished devices. We provide integrated development and assembly manufacturing that supplements and accelerates an OEM's ability to quickly deliver quality products to market while protecting and enhancing their IP.

# QUALITY AND LEAN MANUFACTURING

Freudenberg Medical and the Freudenberg Group are recognized as world leaders in Lean Manufacturing with more than 35 years of experience. Using Lean Manufacturing and Six Sigma methodology, we deliver solutions that reduce lead times, maximize efficiency, and ensure superior product quality.

Quality is always our focus at Freudenberg Medical. We work closely with our clients to implement customized validation and quality assurance systems. Our objectives are to ensure compliance with all FDA, ISO, MDD, and customer requirements.

- Six FDA registered manufacturing facilities in the United States, Costa Rica, Ireland, and China
- cGMP and QSR compliant globally
- ISO 13485 certification
- ISO 14001 environmental management system in multiple locations
- European MDD 93/42/EEC as amended by Directive 2007/47/EC
- FDA QSR 21 CFR part 820
- CMDCAS Health Canada
- Regulatory 510(k) and CE submittal process
- CDPH licensed medical device manufacturer
- Class 7 and 8 cleanrooms
- Electronic record keeping

Editorial Information

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