INNOVATING TOGETHER

FREUDENBERG
MEDICAL

INNOVATIVE SOLUTIONS. SUPERB SERVICE.

Freudenberg Medical is a global partner for the design, development and manufacture of innovative medical device technologies.

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 lead the way in the manufacture of high precision silicone and thermoplastic components and tubing as well as metal hypotubes and coating technology.

Freudenberg Medical is part of the Freudenberg Group. Founded over 165 years ago, Freudenberg develops innovative products and services for more than 30 market segments worldwide. Financial stability and long-term orientation form the basis for longstanding partnerships with our customers. With over 40,000 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. We prove it every day, across the healthcare industry, all around the world. As your global partner, we offer critical 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 and Europe
- Unrivaled lean manufacturing expertise

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

MINIMALLY INVASIVE SOLUTIONS

SURGICAL, HANDHELD, AND CATHETER-BASED DEVICES

Freudenberg Medical offers unparalleled expertise in the design, development, and manufacture of minimally invasive devices. We offer years of experience developing and manufacturing complex catheter systems for very demanding applications. Freudenberg Medical also develops integrated solutions for the endoscopy, interventional cardiology, electrophysiology, cardiovascular surgery, endovascular, neurovascular, urology, oncology, and gynecology markets, among others.

Freudenberg Medical provides integrated development and assembly manufacturing that supplements and accelerates our customers' projects in order to quickly deliver quality products to market. We use a multi-phase design process to deliver the best products possible; this proven approach helps structure the flow of product development and ensures maximum collaboration at every step. We co-develop break-through medical device designs using the latest design tools and techniques to create products that are robust, safe, effective, and within budget.

EXTRUSION AND CATHETER INNOVATIONS

To meet the ever-evolving requirements of our client's complex catheter and delivery systems, Freudenberg Medical and our joint venture partner, VistaMed, continue to invest and innovate in key technologies and capabilities. Offering design and development services we collaborate with clients to identify manufacturable designs and deliver customer-specific solutions to the toughest challenges facing their 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 variety of specialized applications.

Catheter assembly manufacturing services include design and development, prototyping, material and component selection, single- and multi-lumen extrusions, medical balloons, hypotubes and micro-components, validation and qualification, sterilization, packaging and labeling.

Catheter finishing services consist of insert and over-molding, annealing, tip forming, fusing, adhesive bonding, precision hole drilling, punching, hydrophilic coating, laser cutting, and catheter reinforcing.

HYPOTUBES

Cambus Medical, a Freudenberg Medical joint venture company, designs, develops, and manufactures technically advanced hypotubes for minimally invasive surgical devices used in diagnostic and therapeutic interventions.

PTFE coating applied using our proprietary Cambus Coat™ technology is PFOA-free and offers the highest levels of adhesion. Cambus Medical also produces high precision specialty needles used in vascular and endovascular access and drug delivery procedures, as well as stylets and cannula products.

COATINGS

Freudenberg Medical is a leading provider of surface coating technologies and related development, regulatory and serial production services for medical devices.

Hemoteq, a Freudenberg Medical company, develops innovative coating solutions for combination products like drug eluting stents and is a leading manufacturer for drug-coated balloon catheters. Hemoteq holds over 100 technology patents in surface modification and drug delivery technologies.

FROM SPECIALTY COMPONENTS TO FINISHED DEVICES

SILICONE AND THERMOPLASTIC MOLDING

Freudenberg Medical is an industry leader in medical silicone and thermoplastic injection molding. We provide low- to high-volume cleanroom thermoplastic injection molding, liquid silicone injection molding (LIM), transfer/compression molding, micro-molding, insert molding, over-molding, and two-shot molding services.

Additional specialties include advanced hot runner systems for both valve gate and open tip thermoplastics to reduce scrap and the molding of implantable components using PEEK, thermoplastics, and short- and long-term implantable silicones.

SILICONE EXTRUSION

Our capabilities encompass a wide variety of tubing types, including single- and multi-lumen, micro extrusion, braided reinforced, cord, color stripe, close tolerance, profiles and tapes, as well as co-extrusion, pigmenting, and radiopacity. We also offer an unsurpassed selection of implant, medical, and pharmaceutical-grade silicones.

THERMOPLASTIC EXTRUSION

The Freudenberg Medical joint venture company, VistaMed, offers comprehensive design and engineering expertise to deliver high-quality, tight-tolerance tubing for unique medical device applications. Working with a wide range of materials, including PEEK, polyurethane, polycarbonate, nylon and many other thermoplastics, VistaMed provides single, multi-lumen, co-extrusion, bump, and wire reinforced solutions incorporating braid and coil configurations to produce thin walled stent delivery systems.

TUBING FOR PHARMACEUTICAL AND MEDICAL APPLICATIONS

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

PharmaFocus® Premium is a new line of high purity silicone tubing fabricated using a premium silicone raw material specifically formulated to meet the demanding requirements of pharmaceutical and bioprocessing applications.

For the past 10 years pharmaceutical and medical device companies have relied on HelixMark® to deliver an extensive selection of high-quality silicone tubing and fluid handling components. Manufactured globally HelixMark® products are available off-the-shelf and in a wide array of product types and sizes.

QUALITY AND LEAN MANUFACTURING

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.

- Five FDA registered manufacturing facilities in the United States, Costa Rica, and Ireland
- cGMP and QSR compliant globally
- ISO 13485 certification
- European MDD 93/42–ECC
- CMDCAS Health Canada
- Regulatory 510(k) and CE submittal process
- CDPH licensed medical device manufacturer
- Class 7 and 8 cleanrooms
- Electronic record keeping

Freudenberg Medical and the Freudenberg Group are recognized as world leaders in Lean Manufacturing with more than 30 years of experience. Using Lean Manufacturing and Six Sigma methodology, we deliver solutions that reduce lead times, maximize efficiency, and ensure superior product quality.

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