



MANUFACTURING SOLUTIONS FOR MEDICAL DEVICE, IVD, BIOPHARMA

INNOVATING TOGETHER WITH FREUDENBERG MEDICAL

Freudenberg Medical is a global partner for the design, development, and manufacture of medical devices and components, pharmaceutical tubing, and minimally invasive product 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 and pharmaceutical components utilizing advanced materials and processes. We are an industry leader in the manufacture of high precision silicone and thermoplastic molded 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 50,000 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, ISO 14001 environmental management
- FDA registered sites in North America, Central America, Europe, and Asia
- Unrivaled lean manufacturing expertise



PIONEERING INNOVATION

THE LATEST PROCESS AND PRODUCT INNOVATIONS



Extrusion Measurement Technology

Helix iMC™, a groundbreaking new technology to continuously measure the inner geometry of silicone tubes. Unique to the industry, it increases product quality for critical applications and dramatically reduces material waste and process time.



Twisted Lumen Tubing

A unique multi-lumen silicone tubing technology designed to prevent lumen kinks and blockage by providing an equal balance of stress across the inner and outer lumens as the tube bends. HelixTwist™ tubing is optimal for pacemakers, breathing tubes, neurostimulation and other applications that require navigation through tortuous pathways within the human body.

Composer® Handle Platform and Hemostasis Valves

Freudenberg Medical holds patents for minimally invasive technologies, these include the Composer® Catheter Handle Platform, hemostasis valves with variable diameter seals, and expandable introducer sheaths. Three next generation Product Solutions were recently added to the portfolio – Composer® EP and Composer® Mini Catheter Handle Platforms, and the HyperSeal® Mini hemostasis valve. Designed for medical device companies looking to accelerate time to market with commercialization-ready solutions.



Advanced Material Solutions

As a materials specialist, Freudenberg Medical has developed a proprietary conductive silicone compound used for smart therapeutic devices that deliver electrical currents also used to shield sensitive electronics.

PRODUCT SOLUTIONS FOR CATHETERS AND DELIVERY SYSTEMS

Proactively Developed Solutions for Accelerating Time to Market

Whether you're looking to private 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.

FINISHED DEVICE

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

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

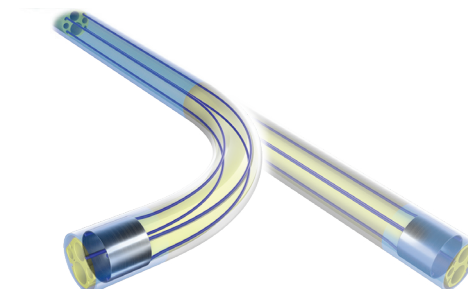
- Composer® Handle Platform
- Composer® XL Handle Platform
- Composer® EP Handle Platform
- Composer® Mini Handle Platform
- FlexSeal® Hemostasis Valve
- HyperSeal® Hemostasis Valve
- HyperSeal® XL Hemostasis Valve
- HyperSeal® Mini Hemostasis Valve
- CertuSeal® Hemostasis Valve

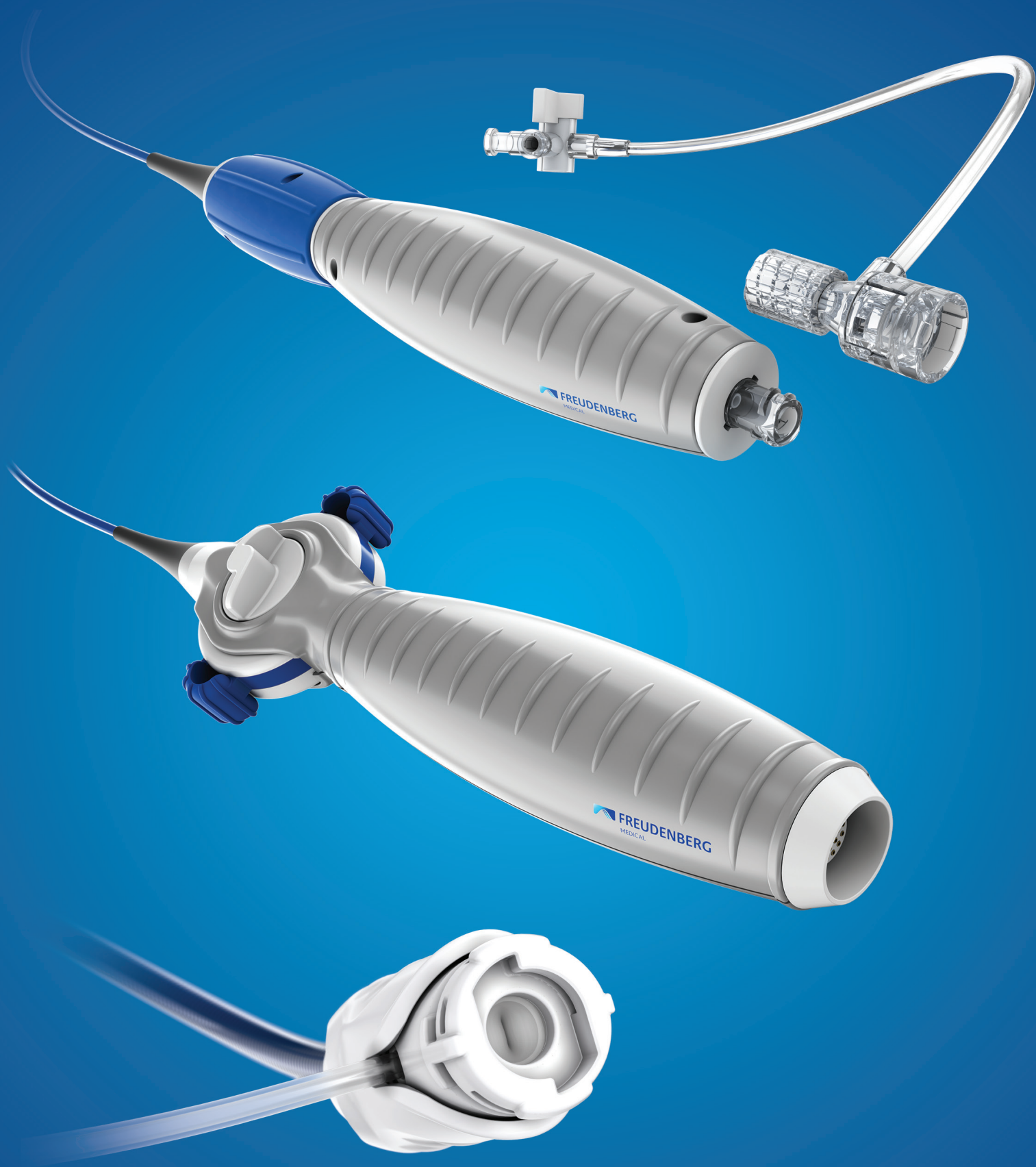


PROCESS

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

- Composite Catheter Shafts
- E-Pro™ Hypotubes
- M μ -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
- 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



HYPOTUBES & MICRO COMPONENTS

Freudenberg Medical is a leading supplier of advanced hypotube components, pullwires, 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. Freudenberg 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.



SPECIALTY NEEDLES

Velona Custom & Specialty Needles are engineered, minimally invasive, needle-based devices used in diagnostic and therapeutic interventions for internal medicine. Freudenberg provides design and product development support, manufacturing services and assembly for needle devices in the clinical areas of fine needle aspiration, fine needle biopsy, minimally invasive delivery systems, and structural heart applications.

SPECIALTY COMPONENTS

PRECISION EXTRUSION & MOLDING

Freudenberg Medical has the experience and expertise to SIMPLIFY YOUR SUPPLY CHAIN and get products to market faster. Our global network of R&D and manufacturing facilities supports customers from material selection and design optimization to prototyping and mass production of components and finished devices.

Silicones & Thermoplastics

EXTRUSION

- From complex single-lumen to multi-lumen tubing
- Silicones, thermoplastics including TPEs, and more
- Specialty tubing for catheters and delivery systems
- HelixMark® off-the-shelf silicone tubing for medical device and lab applications
- HelixTwist™ multi-lumen silicone tubing designed to prevent kinks or blocked lumens
- Innovative Helix iMC™ in-line measurement technology for critical tubing made of silicone
- All extrusion processed in ISO Class 8 cleanrooms; most facilities FDA registered

MOLDING

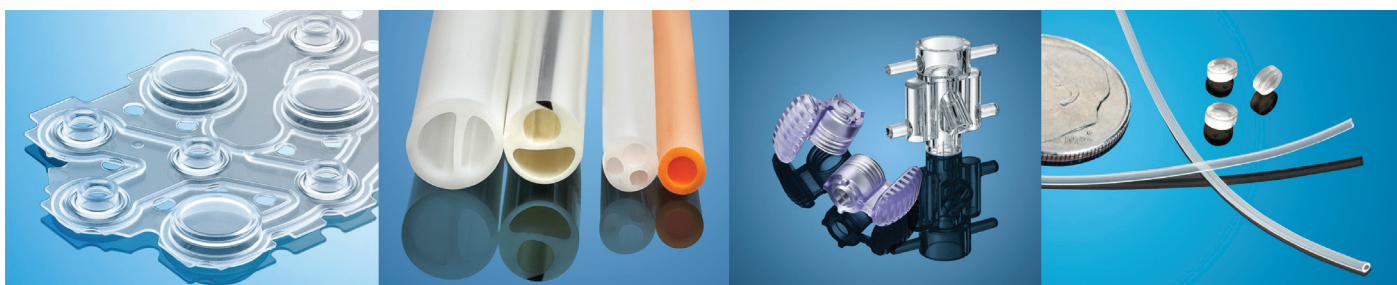
- Silicone and thermoplastics component processing in the Americas, Europe and Asia
- Partner with all raw material suppliers to source the highest quality medical grade material
- Low to high volume liquid injection molding (LIM) with valve gate cold runner systems
- Low to high volume thermoplastic injection molding with advanced hot runner systems
- Two-shot molding and micro molding in both silicones and thermoplastics
- Molding and assembly performed in ISO Class 7 & 8 cleanrooms
- Validated processes including Scientific Injection Molding
- High engineer-to-customer ratio and Six Sigma, lean manufacturing

IMPLANTABLE

- Solutions in long-term implantable silicone and implant-grade PEEK
- Molding and extrusion of implantable silicone devices since 1984
- Specific facilities in compliance with FDA, European MDR, and Health Canada
- Devices range from peritoneal dialysis shunts, gastric bands, and joints to lip implants, heart pump components and tear duct plug
- Extruded silicone as insulation for pacemaker leads and drainage devices

FINISHED DEVICE

- Integrated development and assembly manufacturing
- Supplement and accelerates product development while protecting and enhancing IP
- Finished devices can be private labeled and incorporated into commercial product portfolios





TUBING FOR BIOPHARMACEUTICAL, MEDICAL DEVICE, AND LAB APPLICATIONS

Freudenberg Medical manufactures several proprietary brands of fluid transfer tubing, molded components, and single-use assemblies for pharmaceutical, lab and bioprocessing applications. Products are manufactured in certified cleanrooms in the United States, Germany, and Ireland within ISO 13485 certified medical device facilities.

FLUID TRANSFER PRODUCTS

PHARMAFOCUS®
PREMIUM

SILICONE TUBING FOR BIOPHARMA

High purity tubing fabricated using a premium silicone raw material formulated for demanding biopharma applications.

- Platinum-cured silicone tubing for critical fluid transfer
- Extractables tested, full validation package available
- Cleanroom manufactured in the US & Germany
- Available braided, non-reinforced, and peristaltic pump
- Off-the-shelf tubing, ready to ship



TPE TUBING FOR BIOPROCESSING

Ideal choice for demanding fluid transfer, bioprocess lines, filling and sampling, and peristaltic pump applications.

- TPE tubing is heat sealable & weldable
- Sterilizable by autoclave, gamma irradiation, x-ray, e-beam
- Safe material solution for bioprocessing
- Off-the-shelf tubing, ready to ship



SILICONE TUBING FOR LAB / MEDICAL

HelixMark® platinum-cured silicone tubing has been manufactured in the U.S. and Germany for over 20 years.

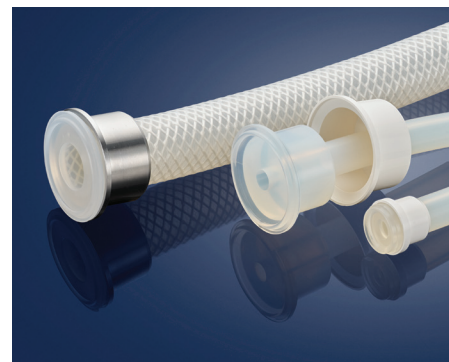
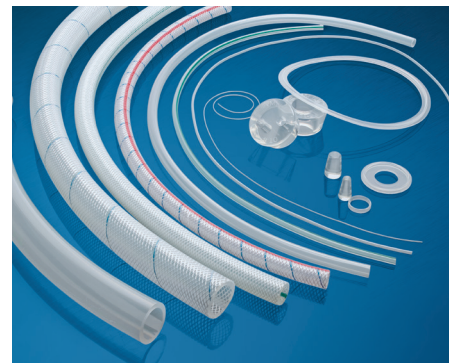
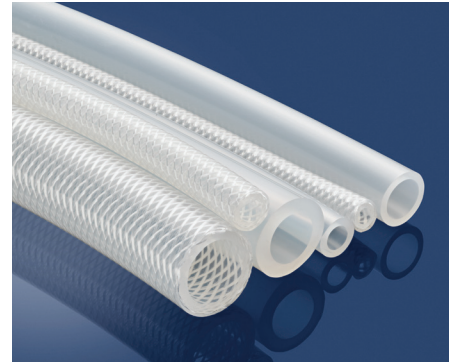
- Choice of silicone material
- Braided, color stripe, pump, close tolerance, stoppers & gaskets
- Meets USP Class VI biocompatibility
- Off-the-shelf tubing, ready to ship



SANITARY ENDS FOR SINGLE-USE SYSTEMS

Overmolded sanitary ends integrate with PharmaFocus® Premium silicone tubing to produce a final assembly for aseptic manufacturing.

- Available in standard and mini
- Stainless steel or polysulfone back-up cups
- Custom sizes or assemblies made to order





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 verification & process validation
- Interface services for external testing
- Interface services for preclinical & clinical studies
- Regulatory submission services
- Post market surveillance and vigilance support
- Volume coating production
- Coating technology transfer

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

QUALITY AND LEAN MANUFACTURING

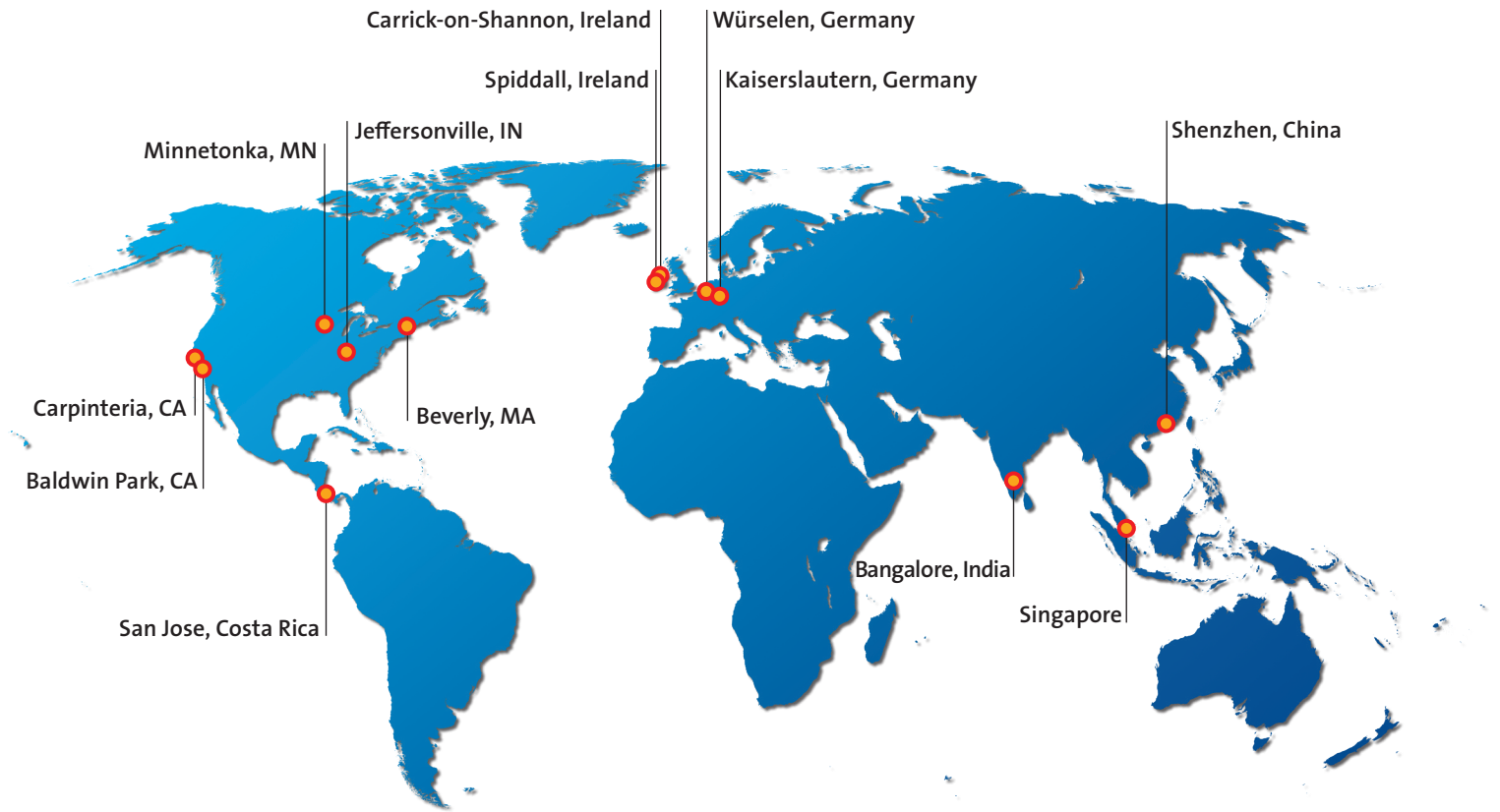
Freudenberg Medical and the Freudenberg Group are recognized as world leaders in Lean Manufacturing with more than 35 years of experience. Using Lean Manufacturing and Six Sigma methodology, we deliver solutions that reduce lead times, maximize efficiency, and ensure superior product quality.

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, MDR and customer requirements.

- Eight FDA registered manufacturing facilities in the United States, Costa Rica, Germany, Ireland, and China
- GMP and QSR compliant globally
- ISO 13485 certification
- ISO 14001:2015 for environmental management system
- European MDR 2017/745
- MDSAP Health Canada
- Regulatory 510(k) and CE submittal process
- CDPH licensed medical device manufacturer
- Class 7 and 8 controlled cleanrooms



GLOBAL RESOURCES, LOCAL SOLUTIONS



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