INNOVATION STRENGTH, STRONG CUSTOMER ORIENTATION, DIVERSITY AND TEAM SPIRIT ARE THE CORNERSTONES OF FREUDENBERG.

“Empowering our customers with the confidence to innovate, design, and manufacture premier medical devices that revolutionize and grow their business.”

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 your product life cycle.

With 11 manufacturing operations and more than 1,500 associates worldwide, Freudenberg Medical offers a wide range of capabilities from high precision silicone and thermoplastic components, extrusions, and drug coatings to finished medical devices and subassemblies for minimally invasive, handheld, and catheter-based applications.

Our parent company, Freudenberg, is a global technology group that strengthens its customers and society through forward-looking and long term innovations. For more than 167 years, our company has been committed to excellence, reliability, sustainability and proactive, responsible action. Together with our partners, customers and the world of science, we develop leading-edge technologies and high value products, solutions and services for thousands of applications in more than 30 market segments.
Freudenberg Medical brings extensive development and manufacturing experience across a broad range of clinical applications.

**Neurology and Neurovascular**
- Microcatheters
- Guide Catheters
- Balloon Catheters
- Hydrocephalus Shunts

**Ear, Nose and Throat (ENT)**
- Balloon Catheters

**Pulmonary**
- Stent Delivery Systems

**Gastroenterology / Endoscopy**
- Endoscopic Tools and Devices
- Hemostatic Clipping Devices
- Steerable Diagnostic Catheters
- Balloon Catheters
- Stent Delivery Systems
- Coated and Covered Stents
- Pressure Monitoring Catheters
- ERCP Catheters
- Fine Needle Aspiration Catheters
- Biopsy Tools and Devices

**Bariatric Surgery**
- Obesity Devices and Delivery Systems
- Sleeve Gastrectomy Devices
- Ablation Catheters
- Gastric Bands and Gastric Balloons

**Endovascular Therapies**
- AAA Delivery Systems and Accessories
- TAAA Delivery Systems and Accessories

**Urology / Gynecology**
- Pelvic Floor Repair
- Stone Retrieval Catheters
- Lithotripsy Catheters
- Endometrial Ablation Devices
- Myomectomy Devices
- Ureteroscopy Devices
- Balloon Catheters
- Introducer Sheaths
- Urinary Catheters
- Pessary Implants
- Fecal Incontinence Devices
- Urinary Incontinence Devices

**Ophthalmology**
- Drug Delivery Catheters
- Drug Delivery Microcatheters

**Electrophysiology, Atrial Fibrillation, CRM**
- Endo- and Epicardial Mapping Catheters
- Ablation Catheters
- Guide Catheters
- Delivery and Retrieval Catheters

**Structural Heart**
- Transcatheter Valve Delivery Systems
- LAA Delivery Systems

**Cardiovascular**
- Stent Delivery Systems
- Angioplasty Balloons
- Drug Coated Stents and Balloons
- Diagnostic and Imaging Catheters
- Contrast Media Delivery HPBT and Flow Switch

**Oncology / Interventional Radiology**
- Tumor Ablation Catheters
- Drainage Catheters
- Infusion Catheters

**Peripheral Vascular**
- Stent Delivery Systems
- PTA Balloons
- Drug Coated Stents and Balloons
- DVT and PE Catheters
- Thrombectomy and Embolectomy Catheters
- AV Fistula Management Devices
- Vascular Access and Closure
- Guide Catheters
- Infusion Catheters
DELIVERING MANUFACTURING EXCELLENCE THROUGHOUT YOUR PRODUCT LIFE CYCLE

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, improve quality and value throughout the product life cycle and across the value chain.

**Product Life Cycle**

**Design and Development**
- Rapid Prototyping and Concept Development
- Device, Design, and Process Solutions
- Test Method Development
- Material Selection
- Industrial Design

**Manufacturing Solutions**
- Single Source Manufacturing
- Global Vertical Integration
- Volume / Capacity Ramp Up
- Low Cost Manufacturing
- Nearshore Manufacturing

**Core Functions**
- Lean Systems
- Supply Chain Optimization
- Quality Management Systems
- Regulatory Support
- Customer Focus and Communication
OUR MANUFACTURING PROCESS

Freudenberg Medical customer-centric manufacturing process ensures that needs and expectations are explicitly documented, translated into requirements, and manufacturing project plans are executed on time and within budget, from a single product line to a full facility transfer.

1. **Design and Process Changes**
   - Perform and Document Testing to Support
   - Run Prototype and Evaluate Changes
   - Implement Design and Process Improvements
   - Assess Design for Manufacturability (DFM)
   - Establish Tooling and Fixture Strategy
   - Optimize Supply Chain
   - Implement a Risk Management Strategy
   - Establish Quality System Plan
   - Customer Review of Project Proposal and Costs

2. **Operational Excellence**
   - Preventative Action Plans (CAPA)
   - Statistical Process Control (SPC)
   - Design Control and Documentation
   - Customer Review of Project Proposal and Costs
   - Pre-Approval of Test Methods and Validations
   - Customer Support and Communication
   - Customer Focus and Communication
   - Customer Review of Project Proposal and Costs
   - Implement Design and Process Improvements

3. **Operational Excellence**
   - Design and Process Changes
   - Product Development
   - Process Validation
   - Manufacturing Line Install
   - Design and Process Improvements
   - Process Validation
   - Manufacturing Line Install
   - Design and Process Improvements

DELIVERING MANUFACTURING EXCELLENCE THROUGHOUT YOUR PRODUCT LIFE CYCLE

Freudenberg Medical’s proprietary GROWTH® process ensures that your business needs are met and expectations are exceeded. Freudenberg Medical provides expertise and innovative solutions to help you grow your business, improve quality and value throughout the product life cycle and across the value chain.

1. **Product Life Cycle**
   - Build and Manage Safety and Close Out Stock
   - Confirm Capacity Kup-Up Plan and Metrics
   - Monitor Line Metrics
   - Test and Verify Fielded Device

2. **Design and Development**
   - New Product Development
   - Product Line Audit for Manufacturing Kick Off

3. **Manufacturing Solutions**
   - Single Source Manufacturing
   - Global Vertical Integration
   - Volume / Capacity Kup-Up
   - Low Cost Manufacturing
   - Vertical Manufacturing

4. **Operational Excellence**
   - Gap Analyses
   - Rapid Improvement Events (Kaizen)
   - Value Stream Mapping
   - Value Analysis / Value Engineering (VA/VE)

5. **Process Validation**
   - Single Source Manufacturing
   - Global Vertical Integration
   - Volume / Capacity Kup-Up
   - Low Cost Manufacturing
   - Vertical Manufacturing

6. **Transfer Opportunity Analysis**
   - Confirm Project Charter
   - Develop Detailed Project Schedule
   - Assist with Functional Manufacturing Transfer Team
   - Establish a Communication Plan Between Project Teams
   - Establish Quality System Plan
   - Identify Regulatory Needs and Support
   - Implement a Risk Management Strategy
   - Optimize Supply Chain
   - Establish Costing and Forecasting Strategy
   - Assess Design for Manufacturability (DFM)
   - Customer Review of Project Proposals and Improvements

7. **Process Validation**
   - Gap Analyses
   - Rapid Improvement Events (Kaizen)
   - Value Stream Mapping
   - Value Analysis / Value Engineering (VA/VE)

8. **Transfer Planning**
   - Establish a Communication Plan Between Project Teams
   - Establish Quality System Plan
   - Identify Regulatory Needs and Support
   - Implement a Risk Management Strategy
   - Optimize Supply Chain
   - Establish Costing and Forecasting Strategy
   - Assess Design for Manufacturability (DFM)
   - Customer Review of Project Proposals and Improvements

9. **Operational Excellence**
   - Gap Analyses
   - Rapid Improvement Events (Kaizen)
   - Value Stream Mapping
   - Value Analysis / Value Engineering (VA/VE)

10. **MANUFACTURING LINE INSTALL**
    - Build and Test New Line
    - Perform Installation Qualification (IQ)
    - Build or Transfer Tooling
    - Perform Installation Qualification (IQ)
    - Ongoing Line Metrics
    - Perform Installation Qualification (IQ)

11. **Transfer Planning**
    - Establish a Communication Plan Between Project Teams
    - Establish Quality System Plan
    - Identify Regulatory Needs and Support
    - Implement a Risk Management Strategy
    - Optimize Supply Chain
    - Establish Costing and Forecasting Strategy
    - Assess Design for Manufacturability (DFM)
    - Customer Review of Project Proposals and Improvements

Supply Chain Optimization

Freudenberg Medical provides an optimized end-to-end supply chain that reduces lead time, creates a balanced supply chain, responsive to constantly changing market demands.

- Global ERP System (SAP)
- Kanban Managed Inventory
- Pooled Supplier Database (RIS)
- Vertically Integrated Global Partnerships
- Disaster Recovery Plan

Operational Excellence is not an end, it is an approach and a philosophy to continuously improve the quality of your products and the efficiency of your processes and services.

GROWTH®

“The Lean Enterprise” is a principal that Freudenberg Medical applies to every business practice across all its business worldwide. For over 40 years our focus was a proprietary system called “Last Unit/Fastest Through Time/Zero waste”.

Our philosophy permeates the entire organization. From the development of customer requirements to the completion of a finished product. We work side by side with customers to define processes and procedures that reduce lead time, create a balanced supply chain, responsive to constantly changing market demands.

Freudenberg’s GROWTH® Manufacturing Process includes:

- Value Stream Mapping
- Value Analysis / Value Engineering (VA/VE)
- Production Preparation Process (3P)
- Rapid Improvement Events (Kaizen)
- Gap Analyses

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OPERATIONAL EXCELLENCE

Operational Excellence is a mind set, an approach and a philosophy, to continuously optimize the quality of your products and the efficiency of our processes and services.

GROWTTH®

“The Lean Enterprise” is a principal that Freudenberg Medical applies to every business practice across all 11 facilities worldwide. For over 30 years we have utilized a proprietary process called GROWTTH® which stands for “Get Rid of Waste Through Team Harmony.”

Our philosophy permeates the entire organization from the development of customer requirements to the completion of a finished product. We work side by side with customers to define processes and procedures that reduce lead-time, create a balanced workflow, and meet demand while achieving exceptional quality.

Freudenberg’s GROWTTH® Manufacturing Process includes:
- Value Analysis / Value Engineering (VA/VE)
- Value Stream Mapping
- Production Preparation Process (3P)
- Rapid Improvement Events (Kaizen)
- Gap Analyses

Quality Management System and Regulatory Support

Freudenberg Medical has established, documented, and implemented a quality and environmental management system that is reviewed continuously for effectiveness in accordance with ISO 13485, MDD EC Directive 2007/47/EC, FDA QSR 21 CFR Part 820, and Canadian Regulations. We also offer regulatory services to support a broad range of regulatory requirements and needs.

- Design Control and Documentation
- Statistical Process Control (SPC)
- Formal Corrective Action and Preventative Action Plans (CAPA)
- Design History File Management
- Process Capability Measurements and Validations FDA
- 510k and CE Mark Submissions

Supply Chain Optimization

Freudenberg Medical provides an optimized end to end supply chain that includes upstream suppliers and downstream customers.

The objective is improved visibility with less waste, overhead and a more stable, balanced supply chain, responsive to constantly changing market demands.

- Global ERP System (SAP)
- Kanban Managed Inventory
- Proven Supplier Database (ASL)
- Vertically Integrated Global Partnerships
- Disaster Recovery Plan