

CATHETER AND FINISHED DEVICE MANUFACTURING SOLUTIONS





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.”

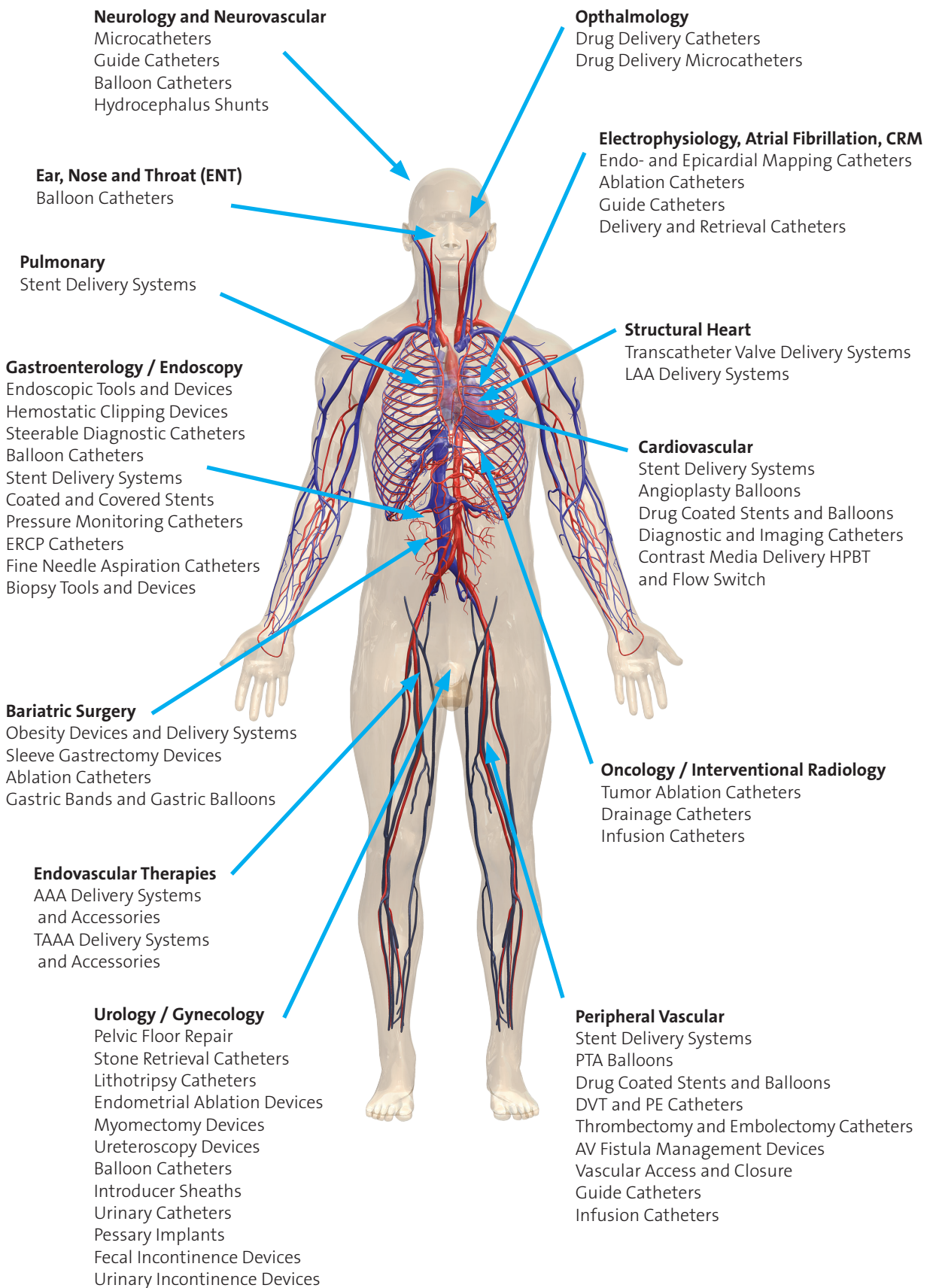
Freudenberg Medical combines over 35 years of global manufacturing experience in finished medical devices, complex subassemblies, components, and materials with a robust culture of quality, innovation and continuous improvement to deliver cost effective, long-term, and reliable outsourced manufacturing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

MARKET SEGMENT EXPERIENCE

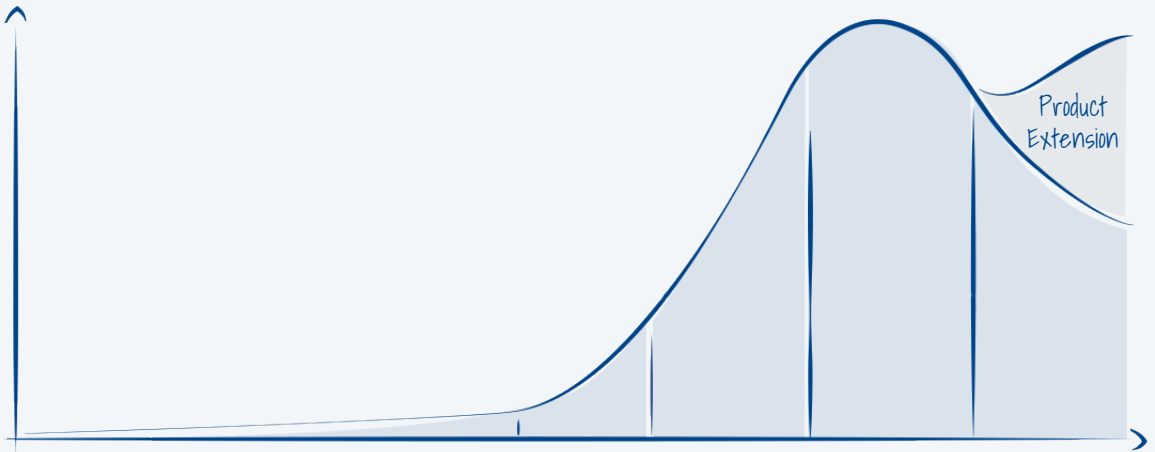
Freudenberg Medical brings extensive development and manufacturing experience across a broad range of clinical applications.



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

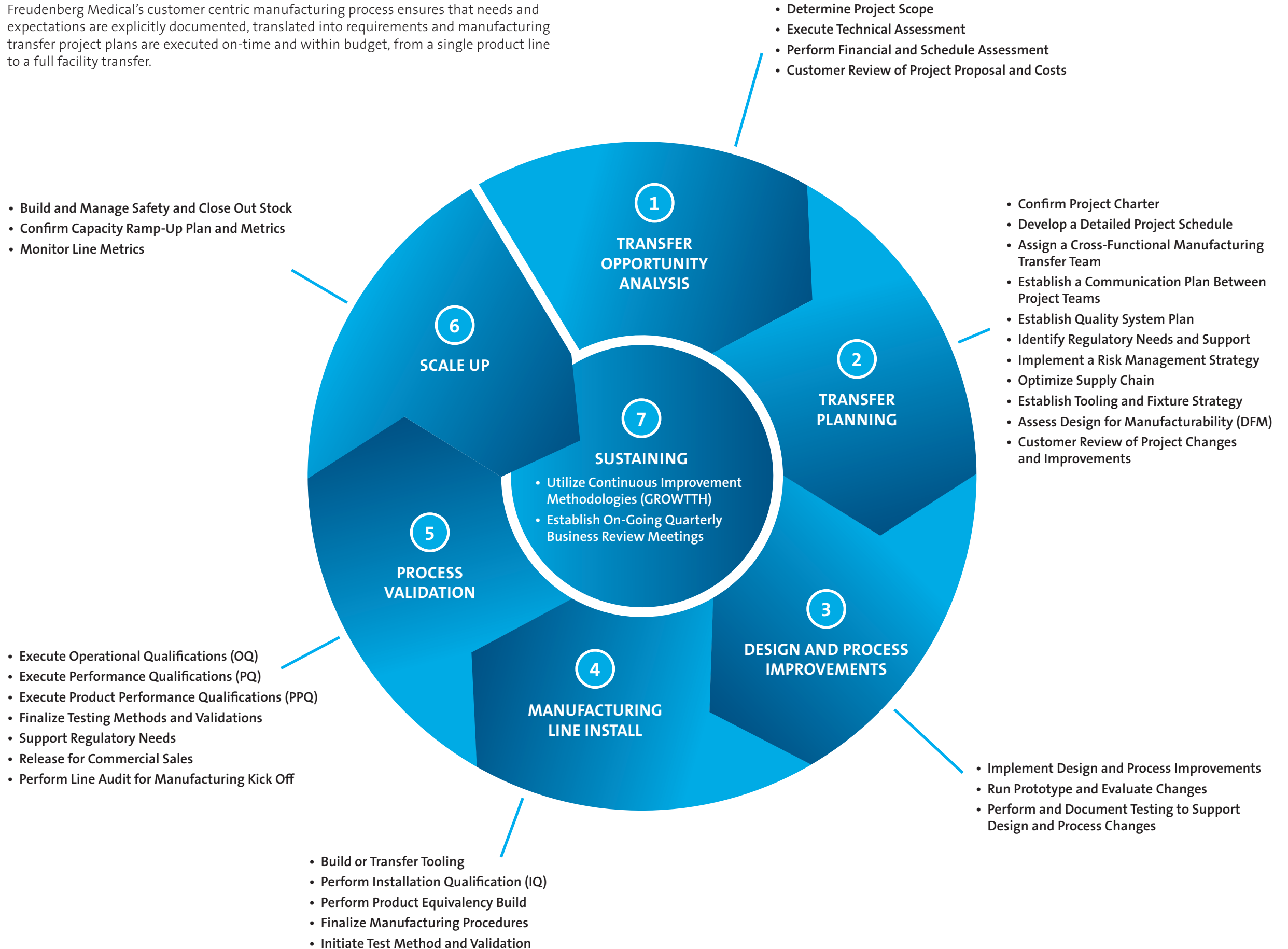
- Single Source Manufacturing
- Global Vertical Integration
- Volume / Capacity Ramp Up
- Low Cost Manufacturing
- Nearshore Manufacturing

Core Functions

- Lean Systems
- Supply Chain Optimization
- Quality Management Systems
- Regulatory Support
- Customer Focus and Communication

OUR MANUFACTURING PROCESS

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



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



Supply Chain Optimization

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

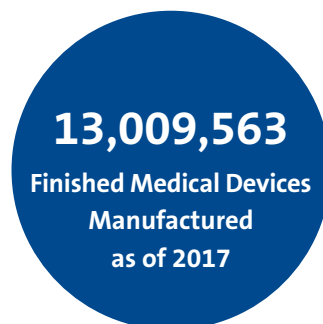
The objective is improved visibility with less waste, overhead and a more stable, balanced supply chain, responsive to constantly changing market demands.

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

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



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