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.

At Freudenberg Medical, we empower our customers with the confidence to innovate, design, and manufacture premier medical devices that revolutionize and grow their business.

Our comprehensive technical capabilities range from the design and manufacture of minimally invasive, catheter, and handheld devices and subassemblies 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 hypotube and coating technologies.

Freudenberg Medical is part of the Freudenberg Group. Founded over

“CONFIDENCE TO INNOVATE, DESIGN, AND MANUFACTURE PREMIER MEDICAL DEVICES”
FREUDENBERG MEDICAL

Your Global Partner for Innovative Medical Device Solutions

Freudenberg Medical proactively develops innovative and cost effective solutions that can help your organization accelerate time to market. Whether you’re 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, white label medical devices that can be readily incorporated into commercial product portfolios
• FlexSeal® Introducer Sheath with Hydrophilic Coating
• HyperSeal® Introducer Sheath with Hydrophilic Coating

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
• FlexSeal® Hemostasis Valve
• HyperSeal® Hemostasis Valve
• CertuSeal® Hemostasis Valve
• E-Pro™ Hypotubes

PROCESS SOLUTIONS

Manufacturing process solutions that expand design options, enhance material/device performance and decrease production costs
• Composite Catheter Shafts
• Cambus Coat™
• Mµ-Coat & Rho-Coat™ Lubricious Coatings
• Advanced Extrusions
INTRODUCER SHEATHS WITH HYDROPHILIC COATING

FlexSeal® and HyperSeal® Introducer Sheaths offer state of the art product design and robust clinical solutions to help your organization quickly meet increasing market demands in large bore procedures.

FLEXSEAL® INTRODUCER SHEATH
Adjustable and easy to use valve designed to
• Improve procedural workflow
• Increase tactile feel and control
Robust hemostasis and valve durability
• Maintains hemostasis after multiple, large catheter insertions
• Supports complex procedures requiring multiple devices or a wide range of device sizes
Exceptional kink resistance
• Composite shaft that balances flexibility and pushability
• Inserts through challenging anatomies while maintaining lumen patency
Superior trackability
• Hydrophilic coating provides improved insertion and tracking
• Shaft and dilator profile enables smooth insertion performance

HYPERSEAL® INTRODUCER SHEATH
Incorporates an automatically adjusting hemostasis valve that constantly adapts to minimize drag and maintain hemostasis. Uses the same high performance shaft and dilator as the FlexSeal® Introducer Sheath.
0.035" Guidewire Compatible

Fully Adjustable Hemostasis Valve

1/4-Turn Locking Dilator

Hydrophilic Coating Shaft OD

Lubricious PTFE Liner Shaft ID

Kink Resistant, Coil Reinforced Shaft

Flexible, Radiopaque Dilator Shaft and Tip

Radiopaque Marker Band

Low Profile / Aspect Ratio Sheath ID:OD

Smooth, Continuous Tip to Sheath Transition
HEMOSTASIS VALVE FAMILY

**FlexSeal® Hemostasis Valve**
- Continuously operator adjustable
- Seals around a full range of devices, sizes and shapes
- Maintains hemostasis after multiple large catheter insertions
- ¼ turn locking dilator hub
- 12Fr to 26Fr applications

**HyperSeal® Hemostasis Valve**
- Automatically and constantly adjusts to seal around a full range of devices, sizes and shapes
- Maintains hemostasis after multiple large catheter insertions
- ¼ turn locking dilator hub
- 12Fr to 20Fr+ applications
- 3-way stopcock
- Composer® integration

**CertiSeal® Hemostasis Valve**
- Robust cross-slit design
- ¼ turn locking dilator hub
- ≤12Fr applications
- 3-way stopcock
- Composer® integration

E-PRO™ HYPOTUBES

E-Pro™ is an advanced metallurgical solution offering superior kink resistance over traditional ‘304 stainless steel’, making navigation through tortuous anatomies safer. In thin walled tube applications, E-Pro’s high kink resistance allows for larger internal diameters thus delivering reduced deflation times and improved product performance.
COMPOSER® DEFLECTABLE CATHETER HANDLE PLATFORM

The Composer’s commercialization ready, modularized “plug and play” versatility can help companies cut down project lead times and costs when adding next generation features into their product lines.

**Ergonomic, versatile and efficient handle design**
- Improves grip, comfort and control
- Supports single handed operation

**Broad range of therapeutic and device delivery applications**
- Single or multi-knob configuration on a modular platform provides multiple catheter modalities
- Open shaft architecture supports a wide range of custom shaft configurations

**Flexible, modular design with patented control platform**
- In-line steering for direct catheter response and accurate distal tip positioning
- Integrated hemostasis valve and electrical connector options
- Low count and standardized parts across all catheter sizes

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**Novel Strain Relief**

**Ergonomic Handle Design**
- Soft Grip Control Knob
- Dual knob configurations for additional functionality

**Integrated Connector**

- HyperSeal® Hemostasis Valve with ¼-Turn Locking Dilator Hub for 12-20Fr Applications
- CertuSeal® Hemostasis Valve with ¼-Turn Locking Dilator Hub for ≤12Fr Applications
COMPOSITE CATHETER SHAFTS

High performance, low profile, kink resistant, braid and/or coil reinforced catheter shafts. Adaptable for custom applications and specifications.

CAMBUS COAT™

The Cambus Coat™ applicator system was created by Cambus Medical engineers to provide substantial competitive advantages over traditional coating methods such as dipping and spraying of hypotube and guidewire based products.

MJ-COAT

High performance PTFE enhanced coating material is applied using state-of-the-art Cambus Coat™ proprietary application technology. Cured on the substrate it forms a lubricious and non-stick matrix, ideal for guidewires and hypotube-based devices.

RHO-COAT™

PTFE-free coating material for guidewires and hypotube-based catheters. It is applied using our state of the art proprietary application technology – Cambus Coat™. Rho-Coat™ provides an ultra smooth coating with high lubricity for easy insertion and removal of the wire or catheter with a finish similar in performance to a polymer jacket.
ADVANCED EXTRUSIONS

Continuous investment and development combined with extensive expertise in tubing and catheter manufacturing, ensures best in class capabilities and provides innovative product and material performance solutions.

EXTRUSION CAPABILITIES

- Single-Lumen
- Multi-Lumen
- Co-Extrusion
- Multi-Layer
- Profiles (lumens or outer profile)
- Thin Wall Tubing
- Balloon Tubing
- Braided and Coil Reinforced Tubing
- Bump or Taper Tubing
- Striped Tubing (radiopaque or colored)
- Wire Coating

EXTRUSION MATERIALS

- Polyurethane
- PEEK
- PET
- Pebax
- Nylon (polyamide)
- Polyolefin
- Polyethylene
- Polycarbonate
- FEP
- PVC
- PFA
- PVA
Product Specifications:

FlexSeal® Introducer Sheath is available in 12Fr to 26Fr inner diameters and 20cm, 28cm, and 35cm lengths. Custom lengths and configurations are available.

HyperSeal® Introducer Sheath is available in 12Fr to 20Fr inner diameters and 20cm, 28cm, and 35cm lengths. Custom lengths and configurations are available.

FlexSeal® Hemostasis Valve is available for integration into 12Fr to 26Fr catheter and delivery system applications.

HyperSeal® Hemostasis Valve is available for integration into 12Fr to 20Fr catheter and delivery system applications. Larger 22Fr to 40Fr applications are available as a custom development project.

CertuSeal® Hemostasis Valve is available for integration into 12Fr and smaller catheter and delivery system applications. Larger sizes are available as a custom development project.

Composer® Deflectable Catheter Handle Platform is designed for single to multiple modality catheter, guiding catheter and delivery system applications up to 20Fr. Larger applications available as a custom development project.

Trademarks:

FlexSeal®, HyperSeal®, CertuSeal®, and Composer® are all registered trademarks of Freudenberg Medical Minimally Invasive Solutions, Inc.

Cambus Coat™, Rho-Coat™ and E-Pro™ are all trademarks of Cambus Medical.

This brochure is intended for a medical device manufacturing audience.

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