



MINIMALLY INVASIVE DEVICES PRODUCT SOLUTIONS



INNOVATING TOGETHER

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

Our comprehensive technical capabilities range from the design and manufacture of minimally invasive, catheter-based, 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 175

years ago, Freudenberg develops innovative products and services in 40 market segments worldwide. Financial stability and long-term orientation form the basis for longstanding partnerships with our customers. With more than 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 expertise and experience to ensure your success. We prove it every day, across the healthcare industry, all around the world.

“INNOVATION, CUSTOMER ORIENTATION, DIVERSITY AND TEAM SPIRIT ARE THE CORNERSTONES OF FREUDENBERG”

FREUDENBERG MEDICAL PRODUCT SOLUTIONS

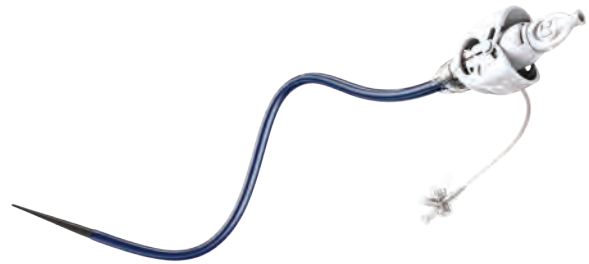
Proactively Developed Solutions for Accelerating Your Time to Market

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 Platform



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

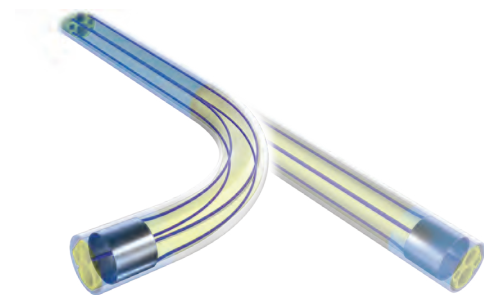
- Composer® Handle Platform
- Composer® XL Handle Platform
- Composer® EP Handle Platform
- Composer® Mini Handle Platform
- FlexSeal® Hemostasis Valve
- HyperSeal® Hemostasis Valve
- HyperSeal® XL Hemostasis Valve
- HyperSeal® Mini Hemostasis Valve
- CertuSeal® Hemostasis Valve



PROCESS

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

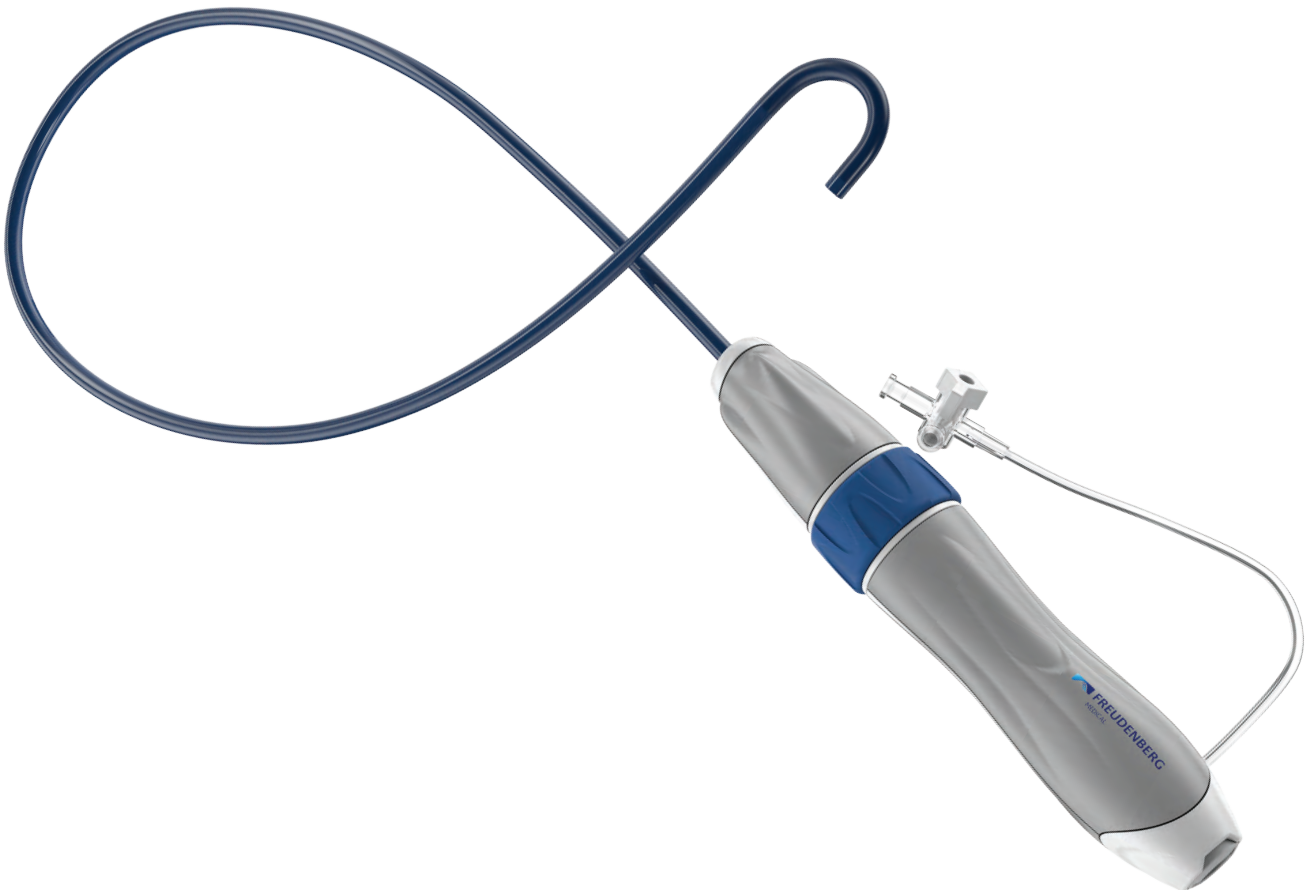
- Composite Catheter Shafts
- E-Pro™ Hypotubes
- Mμ-Coat & Rho-Coat™ Lubricious Coatings
- Advanced Extrusions



COMPOSER® STEERABLE PLATFORM

Composer® Steerable Platform provides innovative ergonomic and clinical solutions for a wide range of electrophysiology, structural heart and vascular applications.

- Next generation composite shaft designed for torque, deflection response, kink resistance, bi-directional deflection durability and stability
- Smooth, continuous transition between dilator and sheath tip
- 8.5Fr and 12Fr applications ready for private label and regulatory development
- Custom sizes, lengths and configurations are also available for development



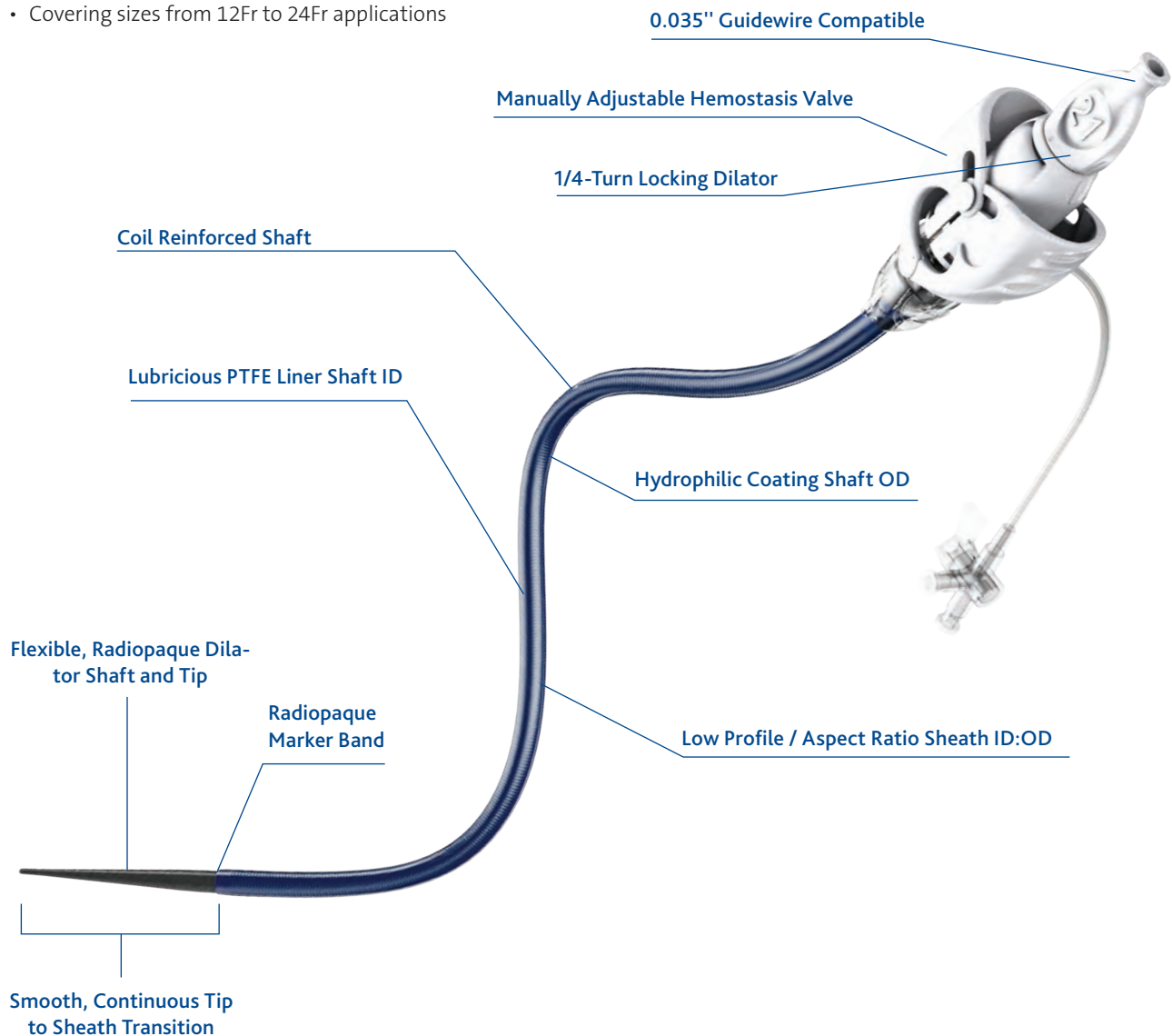
LARGE BORE INTRODUCER SHEATHS WITH HYDROPHILIC COATING

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

Incorporates a novel hemostasis valve that allows operators to manually adjust insertion forces and drag. Designed for robust hemostasis, valve durability, kink resistance and trackability.

- Covering sizes from 12Fr to 24Fr applications



HYPERSEAL® INTRODUCER SHEATH

Incorporates an automatically adjusting hemostasis valve that continuously adapts to minimize drag and maintain hemostasis. Uses the same high performance shaft and dilator as the FlexSeal® Introducer Sheath.

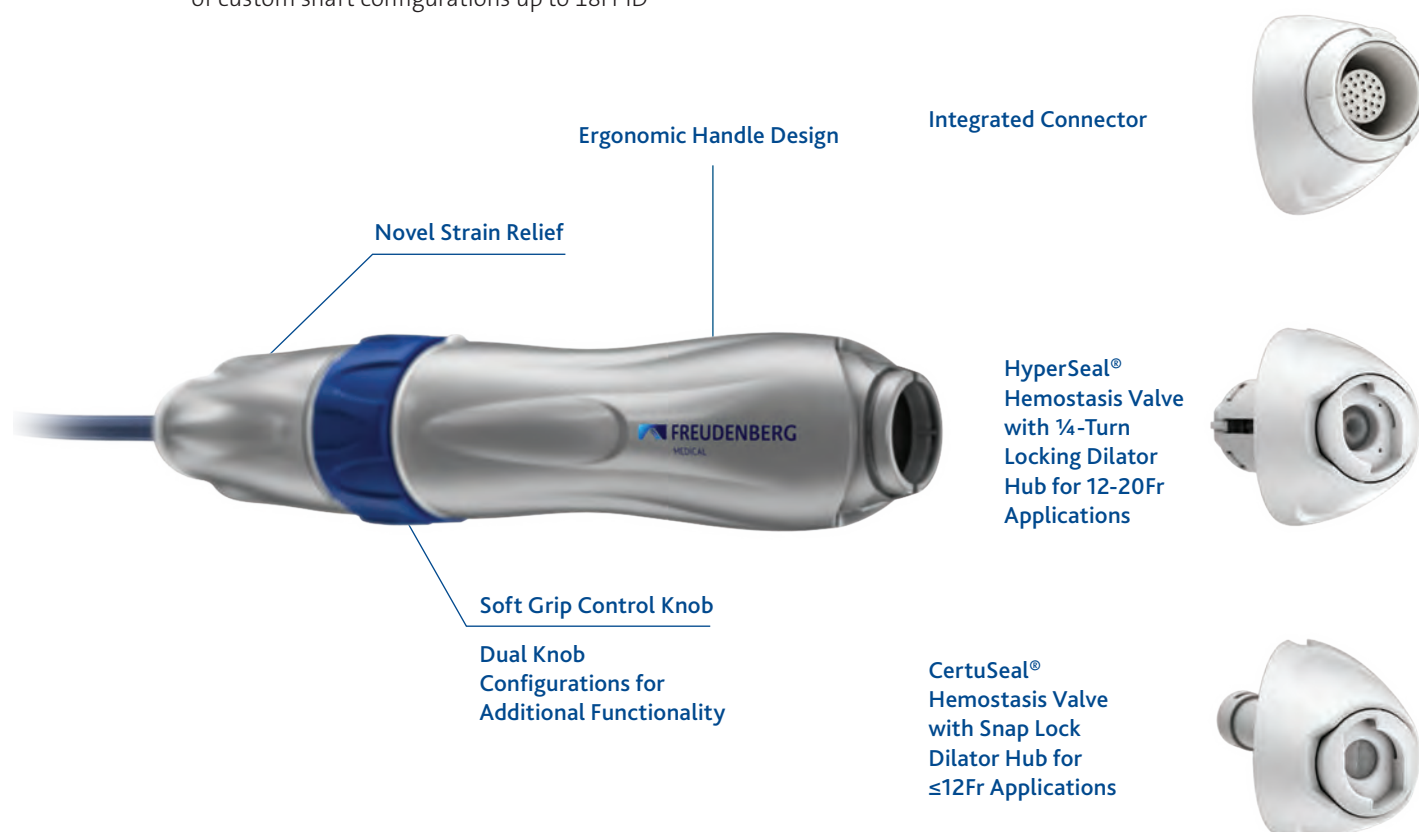
- Covering sizes from 12Fr to 18Fr applications



COMPOSER® 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.

- Single or multi-knob configuration on a modular platform
- Open shaft architecture supports a wide range of custom shaft configurations up to 18Fr ID*
- Patented control platform for direct catheter response and accurate distal tip positioning



COMPOSER® XL

Deflectable handle platform designed to integrate with large bore Endovascular and Structural Heart devices including Transcatheter Tricuspid and Mitral Valve delivery systems.

- Open shaft architecture supports a wide range of custom shaft configurations up to 28Fr ID*
- Integrated HyperSeal® XL Hemostasis Valve with valve actuator and snap lock dilator
- Flexible, modular design with patented control platform and in-line steering for direct catheter response and accurate distal tip positioning

*Custom shaft development required



COMPOSER® EP

Handle platform designed for controlling Electrophysiology guide, diagnostic and therapeutic catheters.

- Open shaft architecture supports a wide range of custom shaft configurations up to 8.5Fr ID*
- Handle designed to support a through lumen
- Bidirectional deflection capable of >270 degrees
- Modular distal end accommodates a range of electrical connectors or hemostasis valves
- Adjustable tension control knob



COMPOSER® MINI

Compact handle platform designed for a wide range of catheter applications.

- Open shaft architecture supports a wide range of custom shaft configurations up to 8.5Fr ID*
 - Soft touch control knob
 - Precision tip deflection capable of >270 degrees
 - Luer connection provides options for multiple flushport or hemostasis valve configurations
 - Adjustable tensioning system allows for fine tuning of deflection wire tension
- *Custom shaft development required

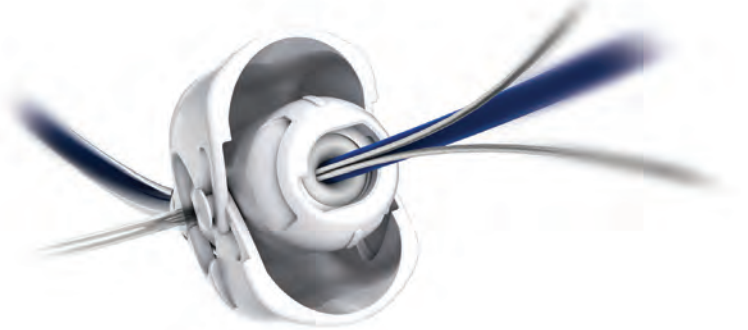


HEMOSTASIS VALVE FAMILY

Our innovative family of hemostasis valves provide a wide range of options for integration and facilitation of vascular access including large bore and complex procedures.

FLEXSEAL[®]

- 12Fr to 24Fr inner diameter applications
- 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



HYPERSEAL[®]

- 12Fr to 18Fr inner diameter applications
- Automatically and continuously adjusts to seal around a full range of devices, sizes and shapes
- Maintains hemostasis after multiple large catheter insertions
- ¼ turn locking dilator hub
- Composer[®] integration



CERTUSEAL[®]

- ≤12Fr inner diameter applications
- Robust cross-slit design for standard venous and arterial applications
- ¼ turn locking or snap lock dilator hub
- Composer[®] integration



HYPERSEAL® MINI

- Up to 12Fr inner diameter applications
- Automatically and continuously adjusts to seal around a full range of devices, sizes and shapes
- Maintains hemostasis after multiple device insertions
- Snap lock dilator hub
- Composer® EP and Composer® Mini integration



HYPERSEAL® XL 30FR & 40FR

- 30Fr and 40Fr inner diameter applications from 20-40Fr and 30Fr+, respectively
- Automatically and continuously adjusts to seal around a full range of devices, sizes and shapes
- Valve actuator to decrease insertion force for blunt and delicate catheter tips
- ¼ turn locking dilator hub 40Fr



30Fr



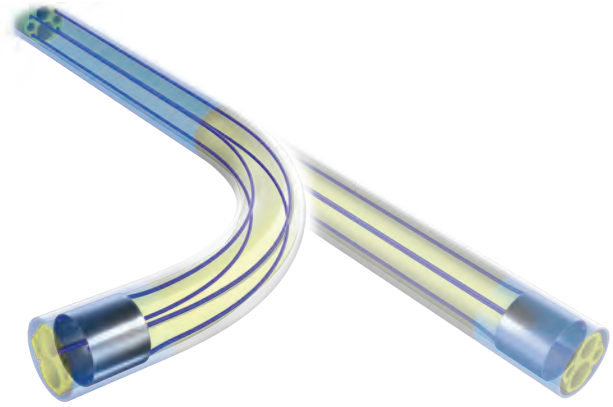
40Fr

COMPOSITE CATHETER SHAFTS

Composite catheter shaft, hypotube, and advanced extrusion solutions expand design options, enhance material and device performance with established manufacturing processes that can speed development of advanced features.

COMPOSITE CATHETER SHAFTS

- Multi modal, steerable, coaxial and triaxial catheter shaft designs for enhanced functionality, control and delivery
- Smart Catheters with integrated sensors and electrodes
- Full range of sizes from microcatheters up to 33Fr steerable and 40Fr introducer sheaths
- Rapid Response Prototyping options with Composer® and Hemostasis Valve technologies
- Engineering and application expertise provides innovative approach, optimized design and material selection into early iterations
- Vertically integrated complex catheter shaft design, development and manufacturing



HYPOTUBES

E-PRO™ HYPOTUBES

E-Pro™ is an advanced metallurgical solution offering superior kink resistance over traditional '304 stainless steel', improving navigation through tortuous anatomies. 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.

MU-COAT

High performance PTFE enhanced coating material is applied using Freudenberg Medical's state-of-the-art 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. 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
- Jacketing
- 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
- TPE
- Polyimide
- Filled Material
- Blends
- Customized Material



Product Specifications:

FlexSeal® Introducer Sheath application size range 12Fr to 24Fr inner diameter. Requires private labeling and regulatory development effort. Custom shaft development is available.

HyperSeal® Introducer Sheath application size range 12Fr to 18Fr inner diameter. Requires private labeling and regulatory development effort. Custom shaft development is available.

Composer® Steerable Introducers standard configuration includes 8.5Fr x 72cm and 12 Fr x 65cm. Requires private labeling and regulatory development effort. Custom sizes, lengths, and configurations are available for development.

FlexSeal® Hemostasis Valve is designed for integration into 12Fr to 24Fr inner diameter catheter and delivery system applications.

HyperSeal® Hemostasis Valve is designed for integration into 12Fr to 18Fr inner diameter catheter and delivery system applications.

HyperSeal® XL 30Fr & 40Fr Hemostasis Valve is designed for integration into catheter and delivery system applications from 20-40Fr and 30Fr+ inner diameters, respectively.

HyperSeal® Mini Hemostasis Valve is designed for integration into catheter and delivery system applications up to 12Fr inner diameter.

CertuSeal® Hemostasis Valve is designed for integration into 12Fr and smaller catheter and delivery system applications.

Composer® Handle Platform is designed for single to multiple modality catheter, guiding catheter and delivery system applications up to 18Fr OD.

Composer® XL Handle Platform is designed for guiding catheter and delivery system applications up to 28Fr ID.

Composer® EP Handle Platform is designed for guide, diagnostic and therapeutic catheter applications up to 8.5Fr ID.

Composer® Mini Handle Platform is designed for guide, diagnostic and therapeutic catheter applications up to 8.5Fr ID.

Trademarks:

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This brochure is intended for a medical device manufacturing audience.

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