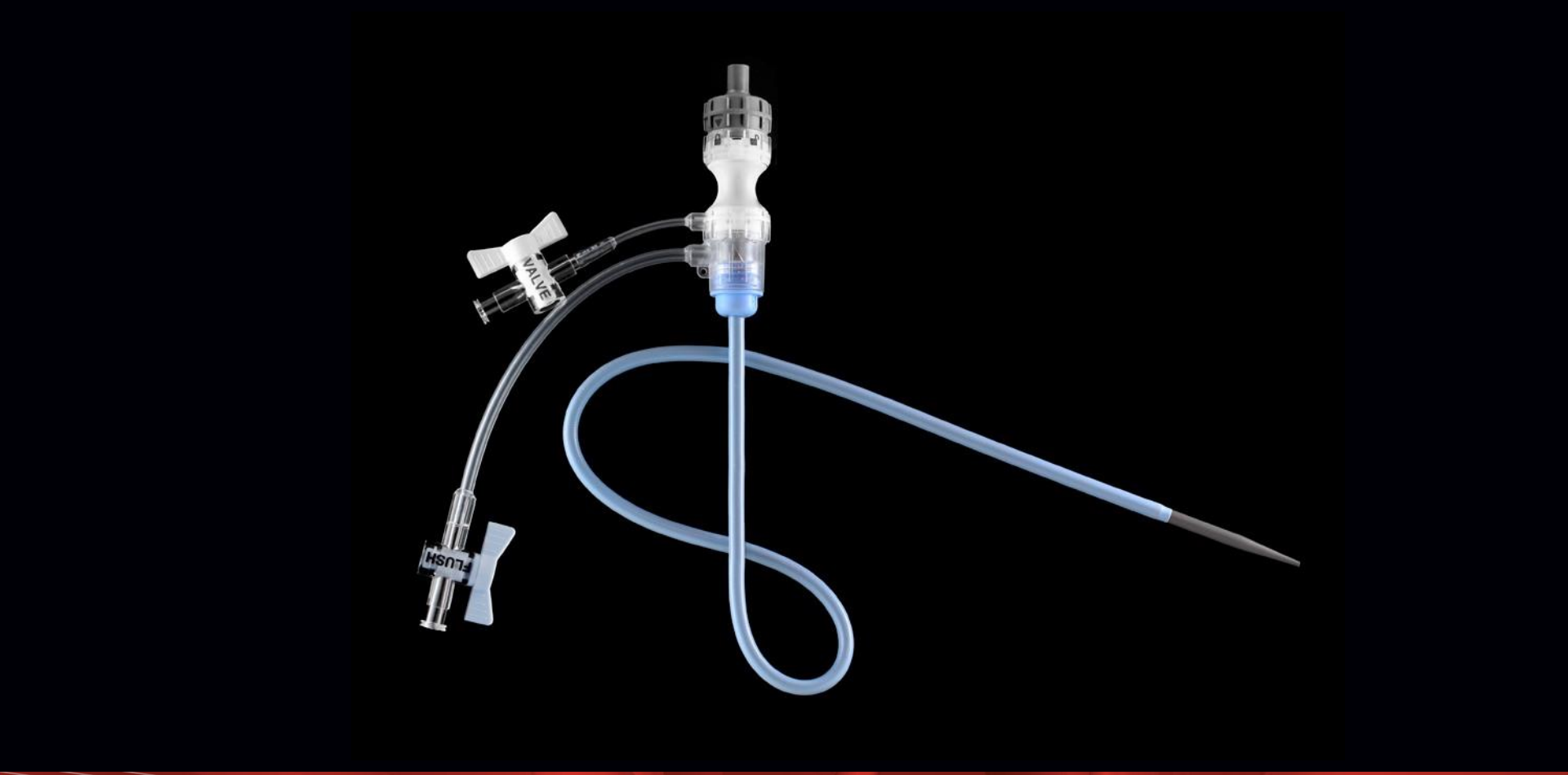


PERFORMANCE by design

GORE® DrySeal Flex Introducer Sheath

Design Updates

GORE DRYSEAL FLEX INTRODUCER SHEATH

Design Benefits

Sheath offers:

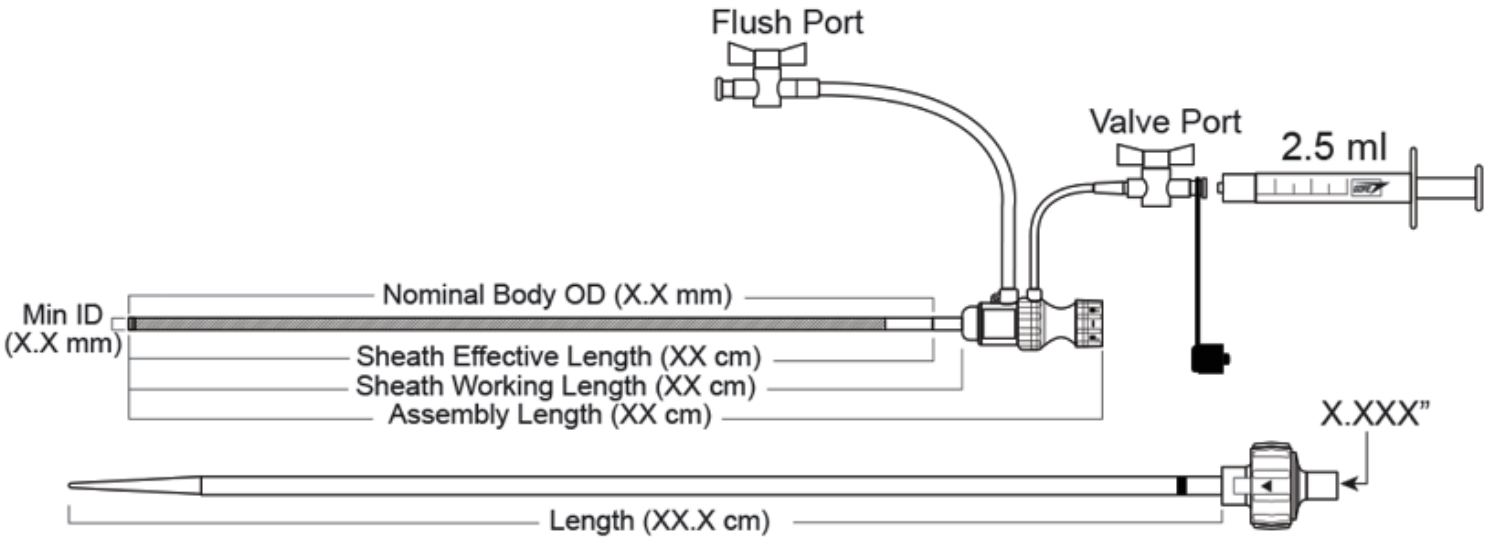
- Distinct combination of enhanced flexibility and kink resistance.
- Optimized profile with decreased sheath wall thickness for larger inner diameter and decreased outer diameter.
- Smooth guidewire to dilator transition.
- Locking dilator for ease of insertion.
- Excellent sheath lubricity.

Exclusive GORE® DrySeal Flex Introducer Sheath Valve offers:

- Simple management of hemostasis.
- Minimal blood loss.
- Simultaneous insertion and passage of multiple guidewires and catheters.

Configurations

The GORE® DrySeal Flex Sheath offers additional working lengths of 33, 45, and 65 cm for a broader range of patient anatomy.

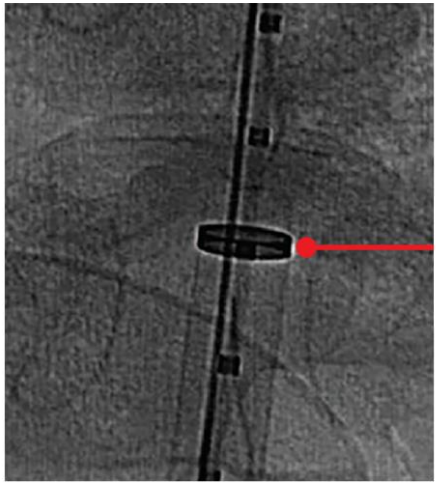


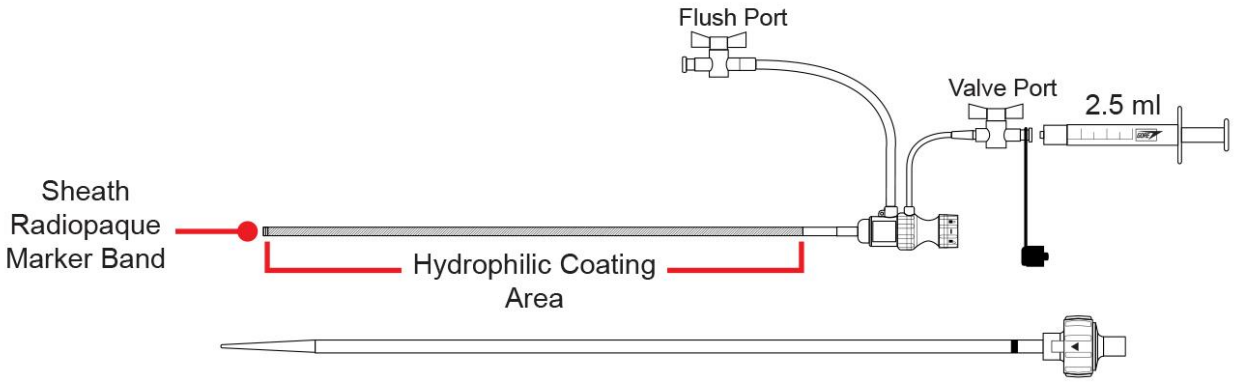
Configurations

Catalogue Number	Configuration		Minimum Sheath ID (mm)	Nominal Body OD (mm)	Sheath Effective Length (cm)	Sheath Working Length (cm)	Assembly Length (cm)	Dilator Length (cm)
	Sheath Size (Fr)	Length (cm)						
DSF1233	12	33	4.0	4.7	32	33	39	42.9
DSF1245	12	45	4.0	4.7	44	45	51	55.1
DSF1433	14	33	4.7	5.3	32	33	39	43.7
DSF1533	15	33	5.0	5.6	32	33	39	43.9
DSF1633	16	33	5.3	6.1	32	33	39	44.2
DSF1833	18	33	6.0	6.7	32	33	39	45.0
DSF2033	20	33	6.7	7.5	32	33	39	45.5
DSF2065	20	65	6.7	7.5	64	65	71	77.5
DSF2233	22	33	7.3	8.2	32	33	39	46.2
DSF2265	22	65	7.3	8.2	64	65	71	78.0
DSF2433	24	33	8.0	8.8	32	33	39	46.7
DSF2465	24	65	8.0	8.8	64	65	71	78.7
DSF2633	26	33	8.7	9.5	32	33	39	47.5
DSF2665	26	65	8.7	9.5	64	65	71	79.5

New Design Feature — Sheath

- **New:** Thin wall stainless steel reinforced flexible tube with durable tip across all sizes.
- Radiopaque marker band allows fluoroscopic identification of the leading end of the sheath.
- Hydrophilic coating covers the sheath effective length as shown in the diagram below.
- The GORE® DrySeal Flex Introducer Sheath offers a hydrophilic coating which optimizes lubricity for ease of insertion while reducing potential for particulation.





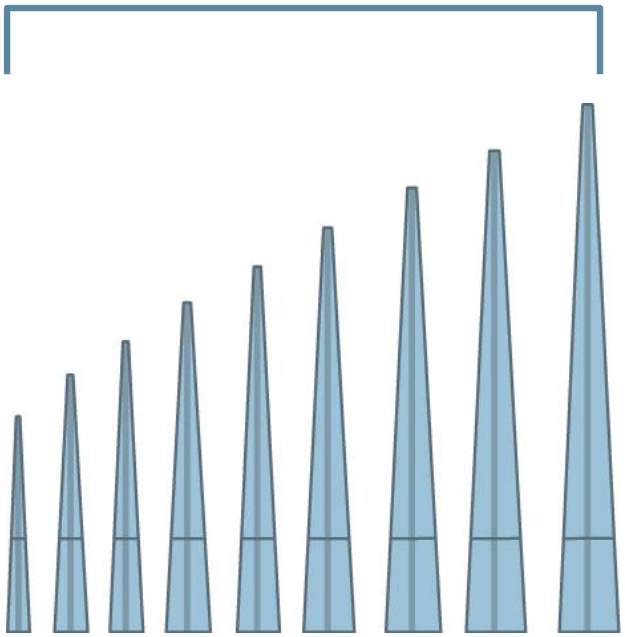
New Design Feature — Locking Dilator

- The GORE® DrySeal Flex Introducer Sheath locking dilator eliminates the potential of dilator slip back during insertion into the patient.
- Twist Lock. The entrance to the valve has two lock keys that mate to the locking fingers on the dilator locking cap.
- Lock and unlock logos are incorporated into the design.
- Dilator French size marking has been added.

New Design Feature — Smooth Dilator Tip Transition

- Constant taper tip across all diameters equals enhanced tip flexibility as sheath French size diameter increases.
- Small dilator tip outer diameter enhances passage of dilator through trunk leg gates.

GORE® DrySeal Flex Introducer Sheath constant taper tips



Small tip outer diameter on
GORE® DrySeal Flex Introducer Sheath
12–26 French dilators

New Design Feature — Smooth Dilator Tip Transition

- Constant taper tip provides a minimum of 1 cm full diameter dilator extension beyond sheath tip (when dilator locked in place).

Design Feature — Valve

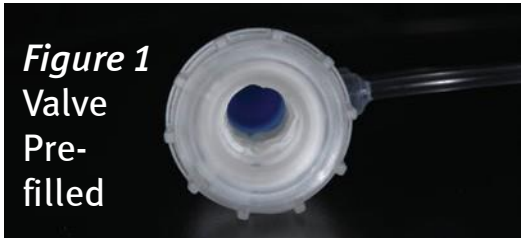


Figure 1
Valve
Pre-
filled

Figure 2
Valve
Filled

- The valve is comprised of an outer silicone tube and an inner film tube. Injecting saline using the valve port, between these two tubes, pressurizes the valve.
- *Figure 1* shows the valve before it is pressurized.

  Enhanced flush port diameter reduces injection pressure.
- *Figure 2* shows the valve after it is pressurized.
- *Figure 3* shows the location of the suture tab used to secure sheath position.

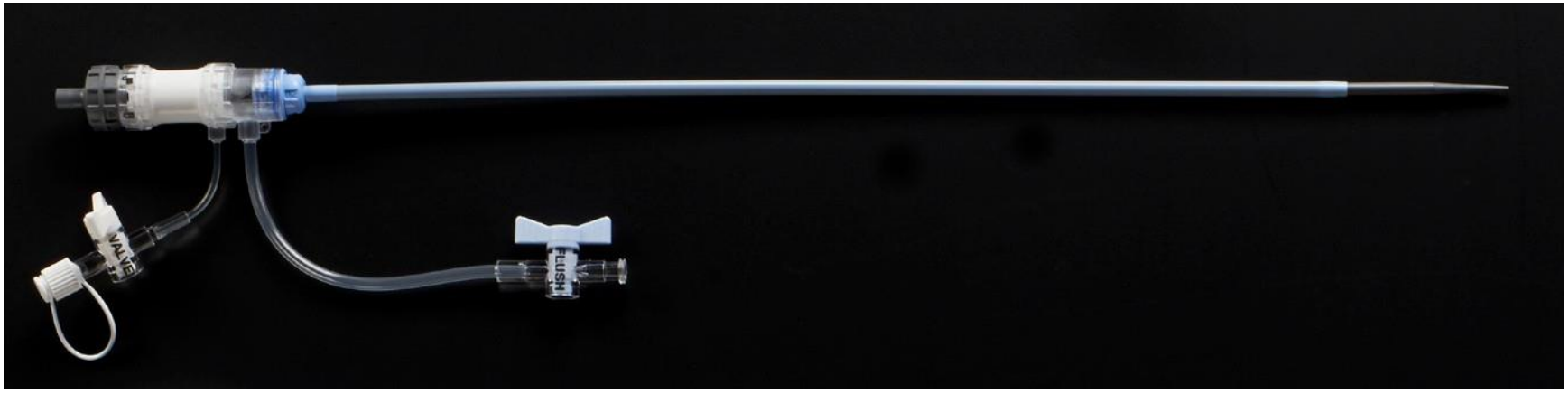
Figure 3
Suture Tab

Sheath Preparation

- Aspirate air from valve through white stopcock labeled “VALVE”.
- Using supplied syringe, inject 2.5 ml saline through the white stopcock labeled “VALVE” to pressurize the valve.
- Close the white stopcock and attach white cap (tethered to white stopcock).
- Caution: If saline leaks from valve or valve junctions, do not use sheath.

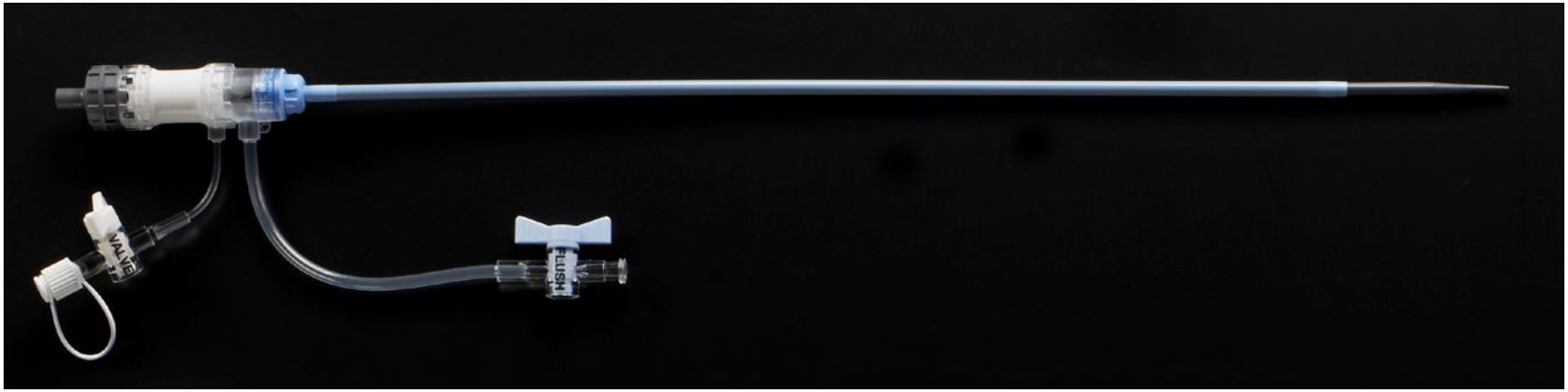
Sheath Preparation

- Flush dilator through luer port on the trailing end of the dilator.
- Flush sheath through the blue stopcock labeled “FLUSH”. Close blue stopcock.
- **New:** Insert the dilator tip through the valve and into the sheath until the dilator locking cap engages the sheath valve.
- **New:** Rotate the dilator lock cap until locked into the GORE® DrySeal Flex Introducer Sheath Valve. Dilator arrow and valve lock / unlock icons are provided.



Sheath Preparation — Hydrophilic Coating

- Coating Activation: Wet the outer surface of the sheath with either sterile saline or water to activate the hydrophilic coating.
- **Note:** It is important to keep the sheath tube outer surface wet / slippery throughout the procedure. For procedures of extended duration, it may be necessary to reactivate the hydrophilic coating. This can be achieved through minor rotational or axial movement of the sheath to allow blood to reactivate the coating.



Warnings and Precautions

- Do not advance sharp objects / instruments through the valve. This could cause damage and result in blood loss.
- In the event of valve failure (rupture of the inner film tube), clamping of the valve, twisting of the valve, or inserting the dilator, will minimize blood loss. These actions are shown in *Figures 1–3* below.

Figure 1 Clamp

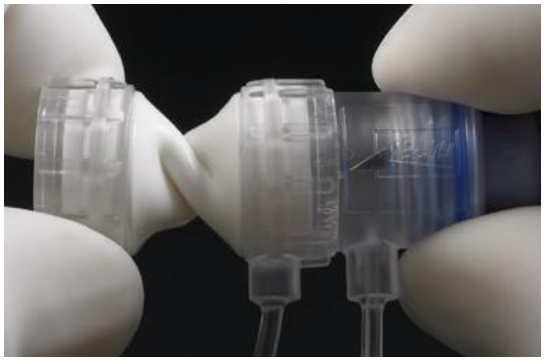


Figure 2 Twist

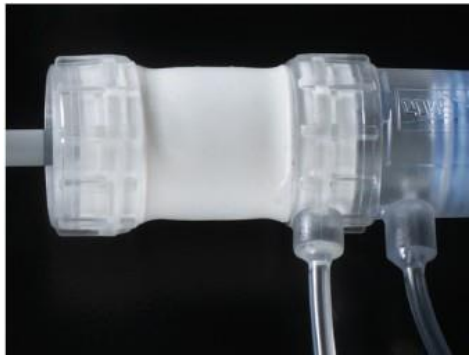


Figure 3 Dilator

Warnings and Precautions

- Use an appropriate wire guide to introduce additional guidewires through the GORE® DrySeal Flex Introducer Sheath Valve alongside the previously placed guidewire, catheter, or other interventional device. Advancement of guidewires without the appropriate wire guide through the GORE® DrySeal Flex Introducer Sheath Valve may result in damage to the guidewire or the GORE® DrySeal Flex Introducer Sheath Valve. Damage to the GORE® DrySeal Flex Introducer Sheath Valve could result in major blood loss.
- Do not attempt to advance or withdraw guidewire, catheter, or other device through the introducer sheath or dilator if resistance is felt. Use fluoroscopy to determine the cause. Continued advancement or retraction against resistance may result in major bleeding, vessel damage, serious injury to the patient, or damage / breakage of the guidewire, catheter, or other device.
- See *Instructions For Use* on www.goremedical.com for more information.

Advancing Care Through Access

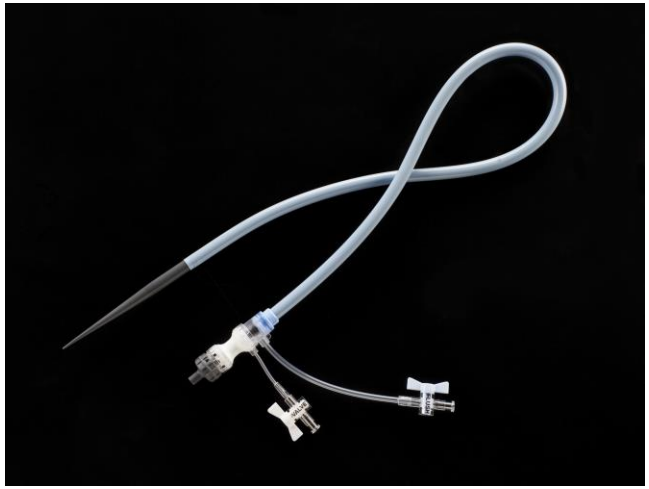
A new standard of flexibility to treat more challenging anatomies.

Deliver with Ease: Hydrophilic coating and enhanced flexibility provide exceptional access to challenging anatomies and branch vessels.

Minimize Blood Loss: Exclusive DrySeal valve enables introduction of multiple devices with proven hemostasis control.

Care for More Patients: Optimized profile and new configurations provide tailored delivery options for a broader range of patient anatomy.

Complete Confidence: Engineered for use with our endovascular portfolio.



Adverse Events

- If an adverse event occurs with the GORE® DrySeal Flex Introducer Sheath, it must be reported to the Product Surveillance Coordinators at Gore or your Sales Associate.

- If possible, send the GORE® DrySeal Flex Introducer Sheath back to Gore for analysis. Ship the sheath in a histology kit, which can be obtained through your Sales Associate.

  Report any adverse event associated with the GORE® DrySeal Flex Introducer Sheath to Gore's Product Surveillance office.

  Phone: 1.928.779.2771 ext. 44922
  or email: medcomplaints@wlgore.com

- Histology kits can be ordered through the Gore Product Surveillance office in the U.S. or Customer Service in other regions.

Packaging

- Packaged on backer board in single TYVEK® Film Pouch protected in paperboard box
- Package contents:
  - GORE® DrySeal Flex Introducer Sheath with
  - GORE® DrySeal Flex Introducer Sheath Valve attached
  - Locking dilator
  - 2.5 ml syringe

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goremedical.com

Products listed may not be available in all markets.