

INSTRUCTIONS FOR USE FOR:



WITH SILICONE PINCH VALVE

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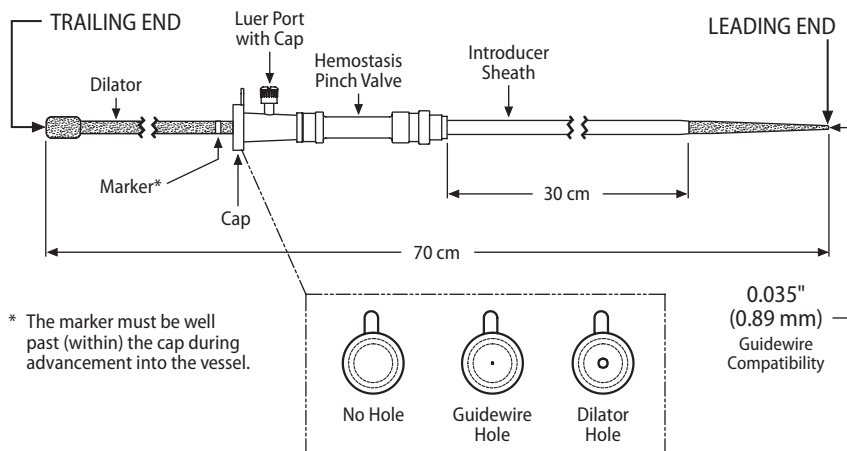
INSTRUCTIONS FOR USE

GORE Introducer Sheath With Silicone Pinch Valve

NOTICE FOR USE WITHIN THE US

Caution: Federal law restricts this device to sale by or on the order of a physician. Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in serious complications.

DESCRIPTION



The GORE Introducer Sheath with Silicone Pinch Valve consists of an introducer sheath, dilator, and interchangeable caps. The introducer sheath incorporates a hemostasis pinch valve near the trailing end. The hemostasis pinch valve is designed to be clamped to prevent blood leakage when a catheter or dilator is not in place within the introducer. A luer port near the trailing end of the introducer sheath allows a heparinized flush to be attached. The dilator has a tapered leading end to facilitate introduction into vessels and a marker on the trailing end to ensure correct positioning of the dilator. Interchangeable caps of varying hole sizes can be attached to the trailing end of the introducer sheath to fit the dilator, guidewires, or catheters, as appropriate.

SIZING GUIDE

Size (Fr)	ID (mm)	OD (mm)
18	6.0	6.9
20	6.7	7.6
22	7.3	8.3
24	8.1	9.1

PACKAGE CONTENTS

- GORE Introducer Sheath with Silicone Pinch Valve
- Dilator
- Three (3) caps

INTENDED USE

The GORE Introducer Sheath with Silicone Pinch Valve is intended to be inserted in the peripheral vasculature to provide a conduit for the insertion of endovascular devices.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The GORE Introducer Sheath with Silicone Pinch Valve should only be advanced or retracted under fluoroscopic guidance.
- Do not alter this device. Alterations may impair device function.
- Do not attempt to use a guidewire with a maximum diameter greater than 0.035" (0.89 mm).
- Do not advance the introducer sheath without a dilator inside. Major bleeding, vessel rupture/perforation, and serious injury to the patient including death may result.
- Ensure the vessel is of adequate size and appropriate tortuosity for the insertion of the introducer sheath. If vessel is too small, major bleeding, vessel rupture/perforation, and serious injury to the patient including death may result.

- Do not advance the introducer sheath if the marker on the dilator can be seen outside of the cap. When the marker on the dilator is outside of the cap, the tip of the introducer sheath may not be fully supported by the cylindrical section of the dilator. Therefore, the unsupported tip of the introducer sheath may cause major bleeding, vessel rupture/perforation, and serious injury to the patient, including death.
- Do not attempt to advance or withdraw guidewire, catheter, or other device through the introducer sheath and/or dilator if resistance is felt. Use fluoroscopy to determine the cause. Continued advancement or retraction against resistance may result in serious injury to the patient, damage to or breakage of the guidewire, catheter, or other device.
- Do not allow the hemostasis pinch valve to bend or twist around the catheter or other device during introduction or withdrawal; resistance to movement or damage to the catheter or other device may result.
- Advance dilator/sheath assembly together with a twisting motion to avoid damage to the sheath or vessel.
- Do not attempt to insert a catheter or other device having a diameter larger than the introducer sheath size indicated. Device damage or breakage may occur.
- This device should only be used by physicians thoroughly trained in the use of catheter delivery systems.

PRECAUTIONS

- Examine packaging and device before use. Do not use if either the packaging or device is damaged or if the sterile barrier has been compromised.
- The GORE Introducer Sheath with Silicone Pinch Valve is supplied sterile and non-pyrogenic. Do not use after the "use by" (expiration) date printed on the label.
- Do not resterilize; for single use only.
- To prevent or reduce the risk of clot formation, consider 1) using systemic anticoagulation, and 2) keeping the introducer sheath filled with an appropriate heparinized flushing solution when it is in the vessel.
- Store in a cool, dry place.
- Verify sheath, device catheter and accessory components size compatibility prior to use. Advance and remove sheath only under fluoroscopic guidance.
- Do not continue advancement or retraction of the catheter or other interventional medical device into and out of the introducer if there is resistance. Determine the cause of resistance before proceeding.

RECOMMENDED ACCESSORIES

- Hemostatic vascular clamp with soft jaws
- 0.035" (0.89 mm) guidewire
- 3-way stopcock
- Heparinized saline solution

DIRECTIONS FOR USE

Sheath Preparation

1. Verify the proper size introducer sheath is selected for the device to be introduced.
2. Verify the vessel is of adequate diameter and tortuosity to accommodate the introducer sheath.
3. Remove the introducer sheath from its packaging and examine for possible damage or defects. Caution: Do not use if damaged or defective.
4. Attach an appropriate 3-way stopcock (not included) to the luer port.
5. Remove the dilator from the introducer sheath.
6. Flush the dilator, introducer sheath, and luer port with heparinized intravenous fluid.

Sheath Use

1. Follow accepted clinical practice for vessel puncture or incision and guidewire insertion.
2. Attach the dilator hole cap (largest hole) to the trailing end of the introducer sheath.
3. Insert the dilator tip through the cap and into the sheath until the mark on the dilator is well past (within) the cap. This ensures that the tapered portion of the dilator is beyond the leading end of the introducer sheath. You may advance the dilator even further beyond the end of the sheath to optimize the flexibility of the leading end before advancing into the vessel.
4. Advance the dilator with sheath as a unit over the guidewire; do not allow dilator to back out of sheath while advancing. Stop advancement of the assembly if there is resistance. Investigate the cause of resistance before proceeding. Carefully advance the assembly until it is at the desired location.
 - Caution: Do not attempt advancement without a guidewire. Severe vascular damage and/or injury may occur.
5. Hold the sheath steady and withdraw the dilator over the guidewire. Before the dilator has been completely retracted from the cap, clamp the hemostasis pinch valve with the appropriate clamp to prevent blood leakage.


6. Remove the cap at the end of the sheath and carefully slide it off the length of the guidewire. Select a cap with the proper size hole for the catheter or other device to be introduced. A cap has been provided with no hole to be custom fitted for use with catheters or devices that do not fit the provided caps. Carefully slide the cap over the length of the guidewire and attach to the end of the sheath.
7. Advance the selected catheter or other device over the guidewire into the sheath. Keep the sheath assembly as straight as possible outside the body to prevent kinking of the introducer sheath. Unclamp the hemostasis pinch valve after the initial insertion of the catheter into the cap to continue advancement of the catheter.
 - Caution: Do not continue advancement or retraction of the catheter or other device into and out of the introducer if there is resistance. Determine the cause of resistance before proceeding.
8. When exchanging catheters, repeat Steps 5 and 6 for retraction and repeat Step 7 for advancement of the catheter. Exchange the cap only if necessary for Steps 5 and 6.
9. Keep the hemostasis pinch valve clamped at all times when a catheter or dilator is not inside the sheath. Failure to do so may result in significant blood loss. When the introducer sheath will remain in a vessel for an extended period, follow normal practice of using a continuous drip of heparinized intravenous fluid under pressure through the luer port.

DEFINITIONS

 Use By

 Caution

 Consult Instructions for Use

 Do Not Re-Use

 Catalogue Number

 Batch Code

 European Authorized Representative

 STERILE


Contents sterile unless package has been opened or damaged.


 STERILE|EO

Contents sterile unless enclosed package has been opened or damaged. Sterilized by ethylene oxide.

 Do Not Re-Sterilize

 Guidewire Compatibility

 **Rx Only** CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.

 Store in a cool dry place



AG4806-ML2



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