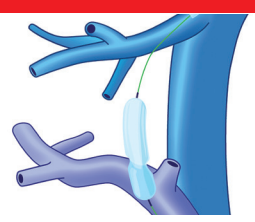
GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion

Implantation guide

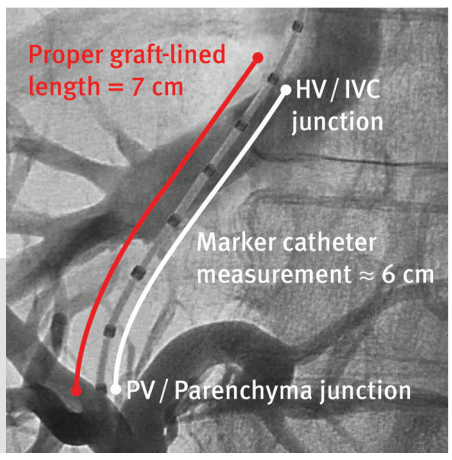
1 Tract pre-dilatation

Pre-dilate tract. An undersized balloon may be used to pre-dilate de novo tract to enhance tactile feel.



2 Tract measurement

Measure tract length from portal vein (PV) / parenchyma junction to hepatic vein (HV) / inferior vena cava (IVC) junction using marker catheter. **Add 1 cm to measurement for proper graft-lined length selection.**

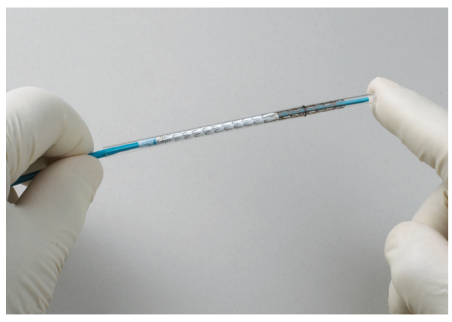


3 Device selection

Select the appropriate device (diameter and length) from the sizing table below.

4 Delivery system preparation

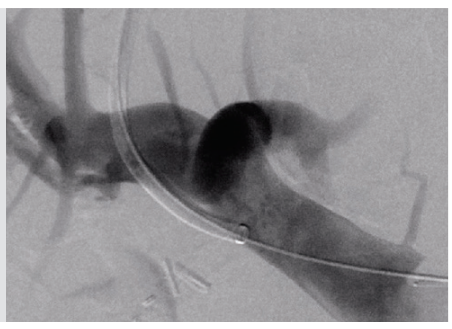
Do not remove access sleeve.
Thoroughly flush delivery system, including guidewire port, delivery catheter lumen and device. To ensure full device flush, place finger over distal end of access sleeve and flush until saline emerges from proximal end of access sleeve.



5 Sheath placement prior to device insertion

De novo procedures
Advance sheath ≥ 3 cm into portal vein.

Revision procedures
Advance sheath to distal end of stent being revised or desired final position.

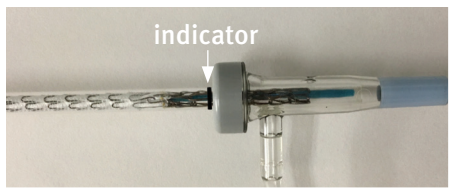


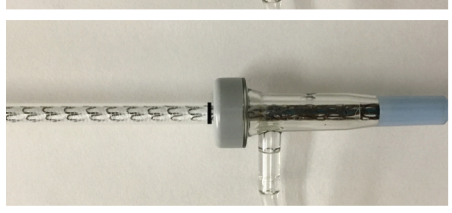
6 Device insertion

Advance the access sleeve together with the delivery catheter completely through the hemostatic valve of the introducer sheath and into the bottom of the valve body.

Confirm that the indicator on the access sleeve aligns with the edge of the hemostatic valve.

While maintaining forward pressure on the access sleeve, advance the delivery catheter in small increments until the radiopaque marker on the leading tip of the delivery catheter aligns with the leading end of the introducer sheath.



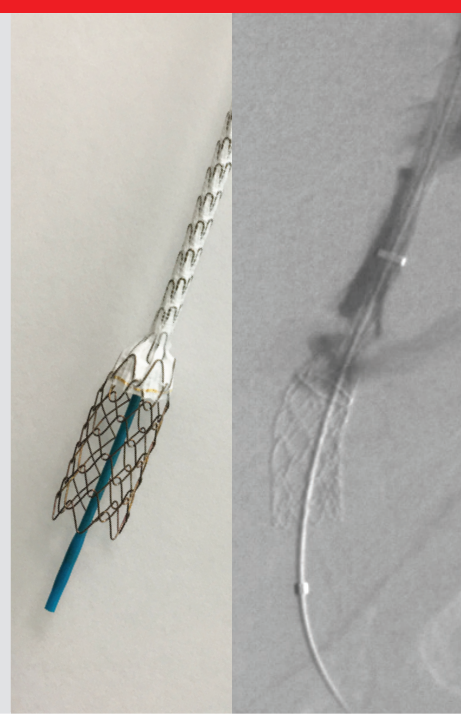


7 Device positioning

De novo procedures: Withdraw sheath so that it does not cover any portion of constrained implant. Gently pull endoprosthesis back until circumferential radiopaque marker band is just distal to the PV / parenchyma junction.

Revision procedures: Withdraw sheath to uncover constrained device. Device position cannot be adjusted once chain-link is deployed.

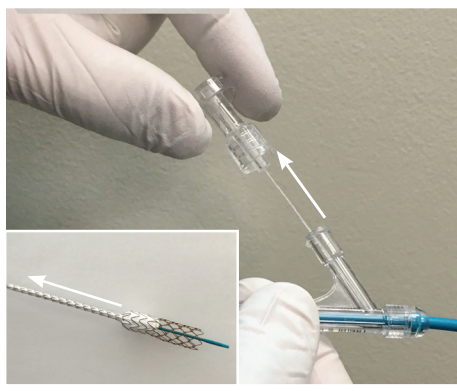
NOTE: Do not attempt to re-capture or re-sheath the deployed portion of the device. If placing a second device to provide adequate length coverage to HV / IVC junction, ensure ≥ 2 cm of lined graft overlap of the devices.



8 Device deployment

Untwist deployment knob while maintaining light tension on the catheter, smoothly pull the deployment knob and line, until the graft-lined region is fully deployed.

NOTE: Deployment line remains attached to delivery catheter. Do not attempt to reposition the device during deployment.



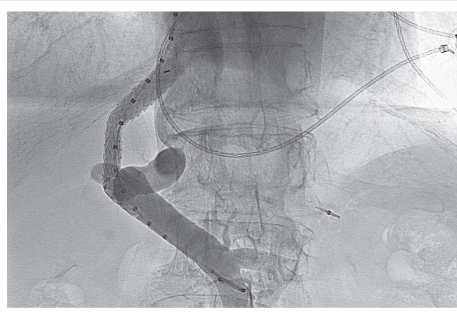
9 Post-dilatation

Dilate entire length of graft-lined region per balloon manufacturer instructions. **Dilate with a balloon at a pressure ≥ 10 ATM** and according to balloon manufacturer instructions.

NOTE: Depending on balloon selection, balloon may need to be inflated up to labeled rated burst pressure.

10 Completion imaging

Evaluate the TIPS prior to completion. Further balloon dilations may be necessary if residual device folds, kinks, compression or incomplete expansion are visualized.



11 Ultrasound follow-up

Ultrasonic visualization of the lumen of the graft-lined region may be difficult through seven days or greater post-implantation.

Sizing table

Endoprosthesis dimensions						Recommended accessory equipment		
Labeled internal diameter (mm)	Graft-lined length / unlined length[1] (cm / cm) 4 / 2	5 / 2	6 / 2	7 / 2	8 / 2	Maximum guidewire diameter[2] (in)	Hemostatic introducer sheath[3] (Fr)	Maximum dilatation balloon diameter[4] (mm)
8-10	x	x	x	x	x	≤ 0.035	10	10[5]

INDICATIONS FOR USE IN THE US: The GORE® VIATORR® TIPS Endoprosthesis is indicated for use in the de novo and revision treatment of portal hypertension and its complications such as variceal bleeding, gastropathy, refractory ascites, and / or hepatic hydrothorax. **INDICATIONS FOR USE UNDER CE MARK:** The GORE® VIATORR® TIPS Endoprosthesis is indicated for use in the treatment of portal hypertension and its complications such as: variceal bleeding refractory to, or intolerant of, conventional therapies, inaccessible varices, gastropathy, refractory ascites, and / or hepatic hydrothorax. Refer to *Instructions for Use* at goremedical.com for a complete description of all contraindications, warnings, precautions and adverse events. ℞ Only

1. Lengths may vary by ± 0.5 cm.
2. A stiff guidewire, having a length of at least 180 cm and a maximum diameter as listed in the **Sizing table**, is required. Delivery catheter working length is 75 cm for all endoprosthesis configurations.
3. Introducer sheath length must be sufficient to be delivered into the portal circulation by ≥ 3 cm. It is recommended that a wall-reinforced 10 Fr TIPS introducer sheath with an integral radiopaque marker band, a hemostatic valve large enough to accept the 13 Fr access sleeve, and a length of approximately 40–45 cm be used (e.g., GORE® TIPS Sheath or COOK® FLEXOR® CHECK-FLO® Introducer).
4. The same balloon dilatation device can be used for TIPS dilatation and dilatation of the endoprosthesis following implantation.
5. For devices with controlled expansion, a balloon which can reach ≥ 10 ATM must be selected.

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Consult Instructions for Use

Products listed may not be available in all markets.

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