

# Implantation Guide



*GORE® VIATORR® TIPS Endoprosthesis*



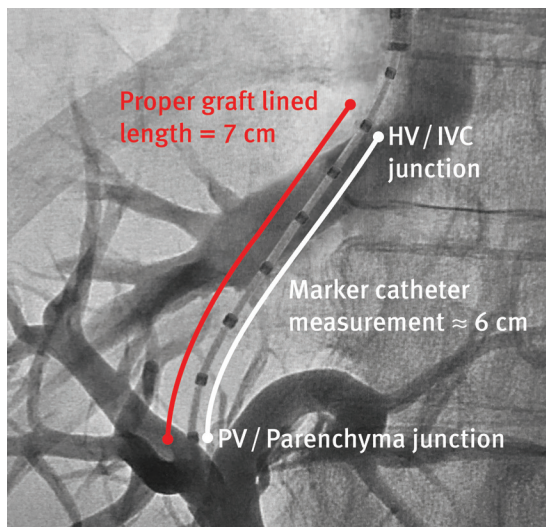
*GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion*

# 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 PV /parenchyma junction to HV / IVC junction using marker catheter. **Add 1 cm to measurement for proper graft-lined length selection.**

## 3. Device selection

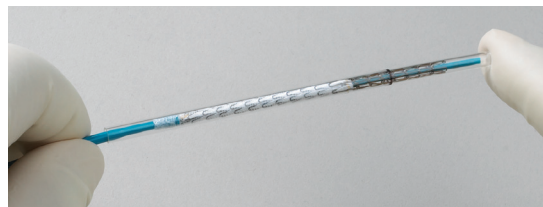
Select the appropriate device (diameter and length) from the sizing table (Table 1).

**Table 1**

| Labeled Internal Diameter (mm)                                      | ENDOPROSTHESIS DIMENSIONS                                  |       |       |       |       | RECOMMENDED ACCESSORY EQUIPMENT                  |  |   |
|---|--|-------|-------|-------|-------|--|--|---|
|   | GRAFT-LINED LENGTH / UNLINED LENGTH <sup>1</sup> (cm / cm) |       |       |       |       | MAXIMUM GUIDEWIRE DIAMETER <sup>2</sup> (inches) | HEMOSTATIC INTRODUCER SHEATH <sup>3</sup> (Fr) | MAXIMUM DILATATION BALLOON DIAMETER <sup>4</sup> (mm) |
|   | 4 / 2  | 5 / 2 | 6 / 2 | 7 / 2 | 8 / 2 |  |  |   |
| <b>GORE® VIATORR® TIPS Endoprosthesis</b>                           |  |       |       |       |       |  |  |   |
| 8   | X  | X     | X     | X     | X     | ≤ 0.038  | 10   | 8   |
| 10  | X  | X     | X     | X     | X     | ≤ 0.038  | 10   | 10  |
| 12  | X  |       | X     |       | X     | ≤ 0.038  | 10   | 12  |
| <b>GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion</b> |  |       |       |       |       |  |  |   |
| 8–10  | X  | X     | X     | X     | X     | ≤ 0.035  | 10   | 10 <sup>5</sup>                                       |

- Lengths may vary by ± 0.5 cm.
- A stiff guidewire, having a length of at least 180 cm and a maximum diameter as listed in **Table 1**, is required. Delivery catheter working length is 75 cm for all endoprosthesis configurations.
- 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® II).
- The same balloon dilatation device can be used for TIPS dilatation and dilatation of the endoprosthesis following implantation.
- For devices with controlled expansion, a balloon which can reach ≥ 10 ATM must be selected.

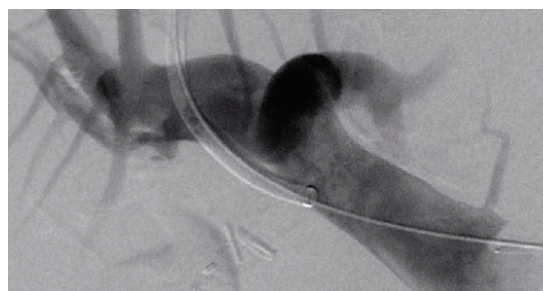
## 4. Delivery system preparation



**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



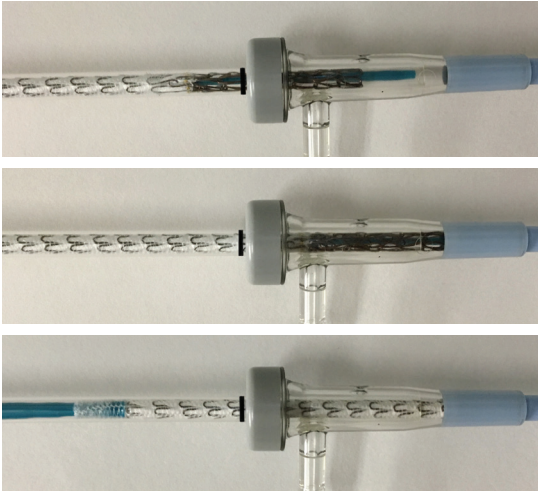
**De Novo Procedures**

Advance sheath ≥ 3 cm into portal vein.

**Revision Procedures**

Advance sheath to distal end of stent being revised.

## 6. Device insertion

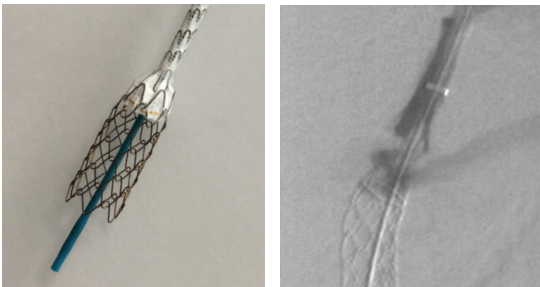


Advance the access sleeve together with the delivery catheter completely through the hemostatic valve of the introducer sheath and into the bottom of the valve body.

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

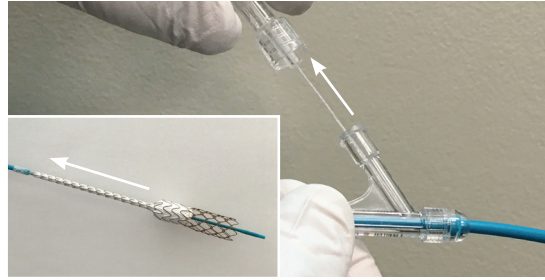
Withdraw sheath so that it does not cover any portion of constrained implant. Gently pull endoprosthesis back until circumferential radiopaque marker band is just distal to the PV /parenchyma junction.

### Revision Procedures

Align circumferential radiopaque marker band with PV / parenchyma junction prior to deployment of bare stent portion. Withdraw sheath to uncover constrained device.

**NOTE:** Do not attempt to re-capture or re-sheath the deployed portion of the device.

## 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.

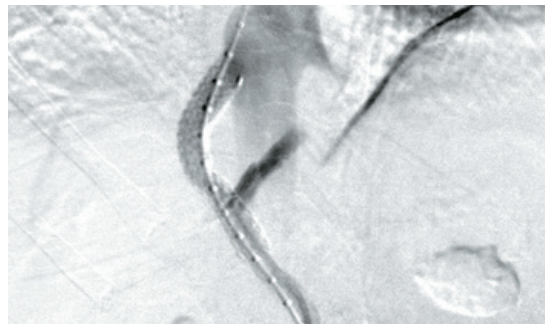
## 9. Post-dilatation

Dilate entire length of graft-lined region per balloon manufacturer instructions.

For devices with controlled expansion, **dilate with a balloon at a pressure  $\geq 10$  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.

**NOTE:** If placing a second device to provide adequate length coverage to HV / IVC junction, ensure  $\geq 2$  cm of lined graft overlap of the devices.

## 11. Ultrasound follow-up

Ultrasonic visualization of the lumen of the graft-lined region may be difficult:

- immediately following implantation
- through five days post-implantation
- or in devices with controlled expansion, through seven days or greater post-implantation



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 Consult Instructions for Use

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