

# Implantation

*Tips for Success*



**PERFORMANCE** by design

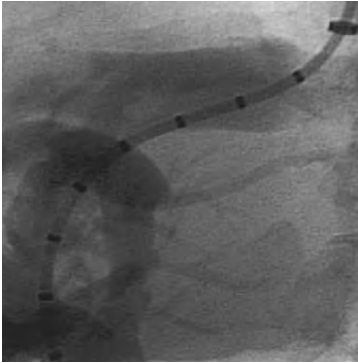


**VIATORR<sup>®</sup>**

TIPS ENDOPROTHESIS

# Implantation Tips for Success

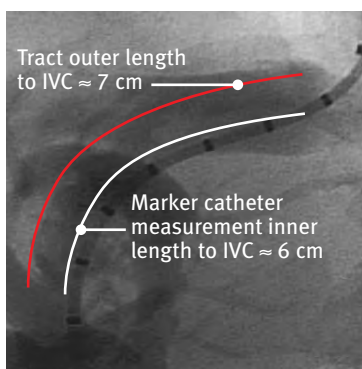
## STEP 1



### Pre-dilate Parenchymal Tract

- All balloon-dilated segments should be covered by the device post-deployment.
- The entire *de novo* tract from the liver parenchyma / portal vein junction to hepatic vein / IVC ostium should be covered by the lined portion of the GORE® VIATORR® TIPS Endoprosthesis.
- To enhance tactile feel and to minimize the potential for pulling the bare chain-link portion of the device into the liver parenchyma, use an undersized balloon from the selected device diameter to pre-dilate the *de novo* parenchymal tract.

## STEP 2



### Measure

- Using a graduated sizing catheter, take the following measurements:
- Proximal and distal native diameter.
- Length to be lined by graft-lined region of the endoprosthesis (liver parenchyma / portal vein junction to hepatic vein / IVC ostium). Add 1 cm when using a graduated sizing catheter.
- When using digital measurements, measure the length of the outside of the *de novo* tract after pre-dilatation

## STEP 3

### Device Selection

- Select the appropriate device (diameter and length) from the sizing table.
- Select the appropriate accessory equipment.

Table 1: Dimensions and Recommended Accessories (12 mm device is not available in all countries)

Endoprosthesis Dimensions					
Internal Diameter (mm)	Graft-Lined Length / Unlined Length <sup>1</sup> (cm / cm)				
Labeled	4 / 2	5 / 2	6 / 2	7 / 2	8 / 2
8	X	X	X	X	X
10	X	X	X	X	X
12	X		X		X

Recommended Accessory Equipment			
Internal Diameter (mm)	Maximum Guidewire Diameter <sup>2</sup> (inches)	Hemostatic Introducer Sheath <sup>3</sup> (Fr)	Maximum Dilatation Balloon Diameter <sup>4</sup> (mm)
8	≤ 0.038	10	8
10	≤ 0.038	10	10
12	≤ 0.038	10	12

<sup>1</sup> Lengths may vary by ± 0.5 cm.

<sup>2</sup> A stiff guidewire, having a length of at least 180 cm and a maximum diameter ≤ 0.038" (0.97 mm), is required. Delivery catheter working length is 75 cm for all endoprosthesis configurations.

<sup>3</sup> Introducer sheath length must be sufficient to be delivered into the portal circulation by ≥ 3 cm. It is recommended that a wall-reinforced TIPS introducer sheath (such as Cook CHECK-FLO®, FLEXOR® or equivalent) with an integral radiopaque marker band and a length of approximately 40-45 cm be used.

<sup>4</sup> The same balloon dilatation device can be used for TIPS dilatation and dilatation of the endoprosthesis following implantation.

## STEP 4



### Prepare the Delivery System

- Do not displace or remove the access sleeve.
- Inspect for damage.

- Flush guidewire lumen and flushing port. To ensure complete endoprosthesis flush, place finger over end of access sleeve and flush until liquid emerges from proximal end of access sleeve.

## STEP 5



### Insert the Device into Introducer Sheath

#### Insertion of Access Sleeve:

- Recommended accessories: 0.035" x 180 cm stiff guidewire; 10 Fr x 40 cm reinforced wall introducer sheath (Table 1).
- Hold access sleeve in center and push straight through hemostatic valve in introducer sheath.
- Advance to the stop bottom of hemostatic valve body and maintain access sleeve position during process of device transfer into introducer sheath tube.
- Once device transfer is complete, access sleeve may be retracted from hemostatic valve loading.

#### Insertion of Delivery Catheter

- For *de novo* cases: advance distal end of introducer sheath ≥ 3 cm into portal vein.
- For revision cases: align distal end of introducer sheath to distal end of stent being revised.
- Hold access sleeve within bottom of introducer sheath to prevent 'backing out'.
- Hold delivery catheter near the end of the access sleeve.
- Advance delivery catheter through access sleeve in small (approximately 5 mm) increments until entire device has cleared the hemostatic valve body and has advanced at least 5 cm into the introducer sheath tube.

#### NOTE:

If sheath kinks, discard and replace with new one. Do not attempt to deliver the GORE® VIATORR® TIPS Endoprosthesis through a sheath that has been kinked and re-straightened.

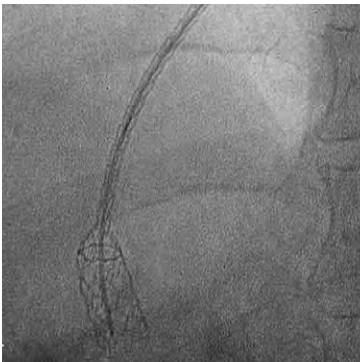
## STEP 6



### Positioning

- Position the device using fluoroscopic visualization.
- Position device across TIPS tract using delivery catheter and endoprosthesis markers:
  - For *de novo* cases: Advance distal end of introducer sheath 3 cm into portal vein.
  - For revision cases: Align distal end of introducer sheath to distal end of stent being revised and align stent gold ring to liver parenchyma / portal vein junction.

## STEP 7



### Deployment

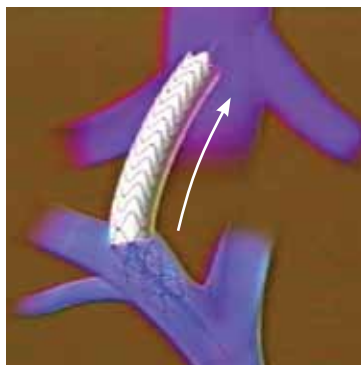
- Consider utilizing a two-operator approach to device deployment.
- Fluoroscopic guidance is required.
- While maintaining the delivery system position, retract the sheath and deploy the chain-link segment of the device into the portal vein. Completely retract the hemostatic introducer sheath beyond the trailing end of the endoprosthesis and into the IVC:

- For *de novo* procedures, once the chain-link portion is deployed (3 cm) into the portal vein, gently pull back on the delivery catheter until resistance is felt. This will seal the distal end of the covered device portion to the liver parenchyma/portal vein junction.
- While maintaining delivery system traction and the delivery system position relative to the sheath, keep the delivery system straight and loosen the GORE SIM-PULL Deployment system knob.
  - Pull the deployment knob with smooth, controlled tension.
  - Do not attempt repositioning during deployment.

### NOTE:

- Do not attempt to recapture once deployment is initiated.
- Device cannot be repositioned once deployment is complete.
- For *de novo* cases: Advance distal end of introducer sheath 3 cm into portal vein.
- For revision cases: Align distal end of introducer sheath to distal end of stent being revised. Do not advance chain-link beyond end of bare stent as pulling back the GORE® VIATORR® TIPS Endoprosthesis may result in device or deployment line entanglement on the distal end of bare stent. Exercise care when positioning device while patient is breathing.

## STEP 8



### Remove Delivery Catheter

- Gently remove the spent delivery catheter. Stop if resistance is felt when removing the catheter.
- Maintain guidewire access.

## STEP 9



### Post-dilate the Device

- Select the appropriate balloon size for the endoprosthesis implanted (Table 1).
- Dilate the entire length of the graft-lined region per the balloon manufacturer's *Instructions for Use*.
- Do not use a balloon larger than the device implanted.
- Ballooning device to full labeled diameter is not mandatory.

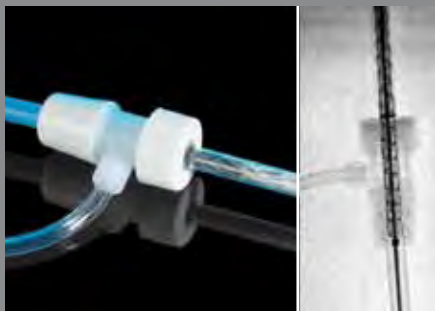
## STEP 10



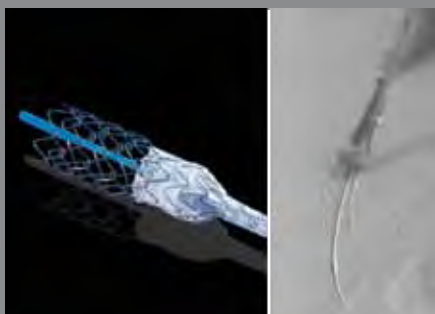
### Completion Imaging

- Confirm positioning and patency of device.
- NOTE: If placing a second endoprosthesis to provide adequate length coverage, ensure  $\geq 2$  cm of lined graft-to-lined graft overlap of the telescoping devices.
- Take final PSG measurement and re-balloon as necessary.
- Use caution to not displace a deployed GORE® VIATORR® TIPS Endoprosthesis by re-introduction of an introducer sheath or working catheter back through the endoprosthesis.

## Summary of Delivery Steps



Transfer of the delivery catheter with endoprosthesis chain-link through the hemostatic valve body and into the introducer sheath tube.



Ejection of the lined and chain-link portion from the introducer sheath into the portal vein.



Release of the covered device portion from the delivery catheter thereby lining the entire tract from the liver parenchyma / portal vein junction to the hepatic vein / IVC ostium.



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**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](http://goremedical.com) for a complete description of all contraindications, warnings, precautions and adverse events. <sup>Rx Only</sup>

 Consult Instructions for Use

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