*Together, improving life*

# TIPS PROCEDURE GUIDE

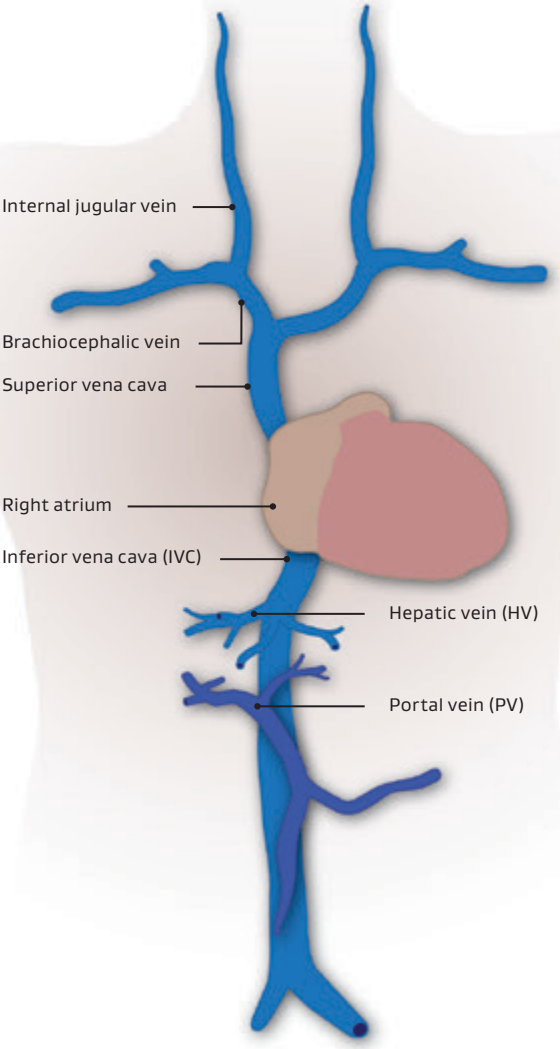
## GORE® VIATORR® TIPS

Endoprosthesis with Controlled Expansion
and the

## GORE TIPS Set

To be used in conjunction with the
GORE® VIATORR® TIPS Endoprosthesis
with Controlled Expansion and
GORE TIPS Set *Instructions for Use*.

# ANATOMY


Internal jugular vein
Brachiocephalic vein
Superior vena cava
Right atrium
Inferior vena cava (IVC)
Hepatic vein (HV)
Portal vein (PV)

## REQUIRED ACCESSORIES

- Micro-puncture kit
- Saline or heparinized saline
- Contrast media
- Syringe
- 0.035" (0.89 mm) or smaller guidewire
- 0.035" (0.89 mm) or smaller stiff guidewire, 180 cm or longer
- Appropriate angioplasty balloons (non-compliant recommended) and accessories
- Appropriate diagnostic catheters and accessories
- Sizing catheter (1 cm interval markings recommended)
- GORE TIPS Set
- GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion

## OPTIONAL ACCESSORIES

- Carbon dioxide gas
- Occlusion balloon catheter for wedged venograms
- Hydrophilic guidewire

# *GORE* TIPS SET

| GORE TIPS Set component | Size | Effective length (cm) | Accepts guidewire diameter (in) |
|---|---|---|---|
| Needle | 16 ga | 56 | ≤ 0.035 |
| Guiding catheter | 10 Fr | 49 | ≤ 0.035 |
| Introducer sheath | 10 Fr | 40 | ≤ 0.035 |
| Dilator | 10 Fr | 47 | ≤ 0.035 |

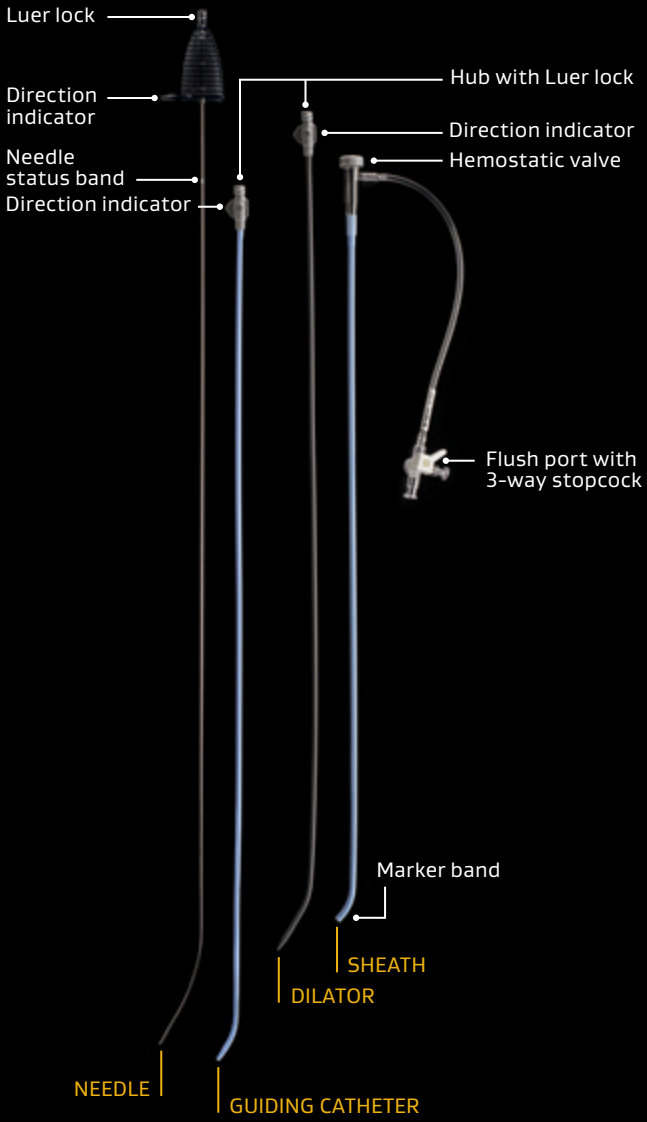
# *GORE® VIATORR®* TIPS ENDOPROSTHESIS WITH CONTROLLED EXPANSION

| Endoprosthesis internal diameter (mm)* | Graft-lined length (cm) | Unlined length (cm) | Maximum guidewire diameter (in) | Introducer sheath size (Fr) | Maximum dilatation balloon diameter (mm)* |
|---|---|---|---|---|---|
| 8–10 | 4 | 2 | ≤ 0.035 | 10 | 10 |
| 8–10 | 5 | 2 | ≤ 0.035 | 10 | 10 |
| 8–10 | 6 | 2 | ≤ 0.035 | 10 | 10 |
| 8–10 | 7 | 2 | ≤ 0.035 | 10 | 10 |
| 8–10 | 8 | 2 | ≤ 0.035 | 10 | 10 |

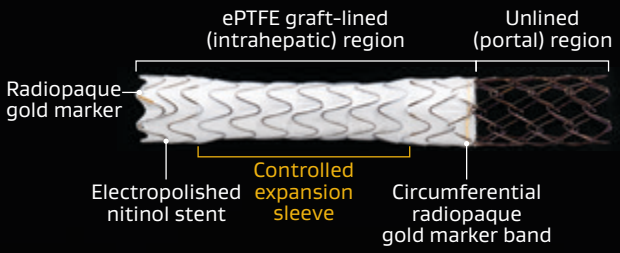
* The selected balloon diameter may be 8, 9, or 10 mm and should not exceed 10 mm. A balloon which can reach an inflation pressure of 10 ATM must be selected and should be inflated to a minimum of 10 ATM.

*GORE* TIPS NEEDLE

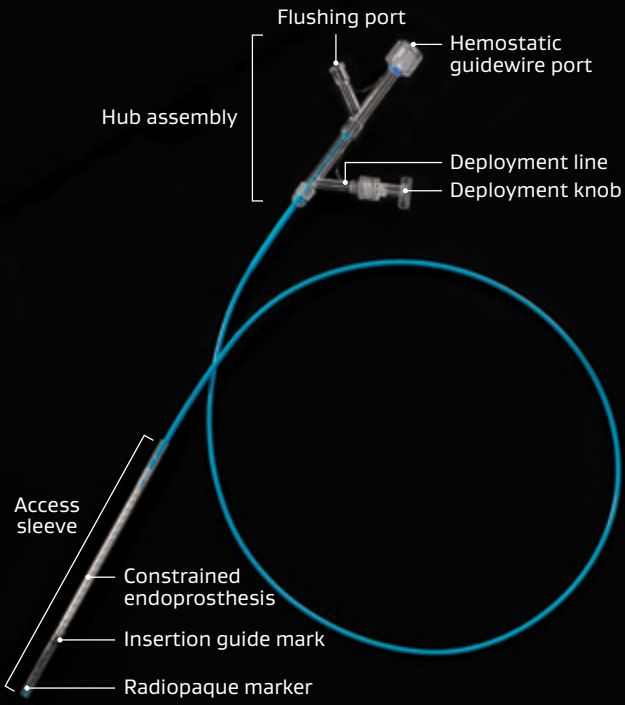
*GORE®* TIPS SHEATH



## *GORE® VIATORR®* TIPS ENDOPROSTHESIS WITH CONTROLLED EXPANSION




## *GORE® VIATORR®* TIPS ENDOPROSTHESIS WITH CONTROLLED EXPANSION DELIVERY SYSTEM

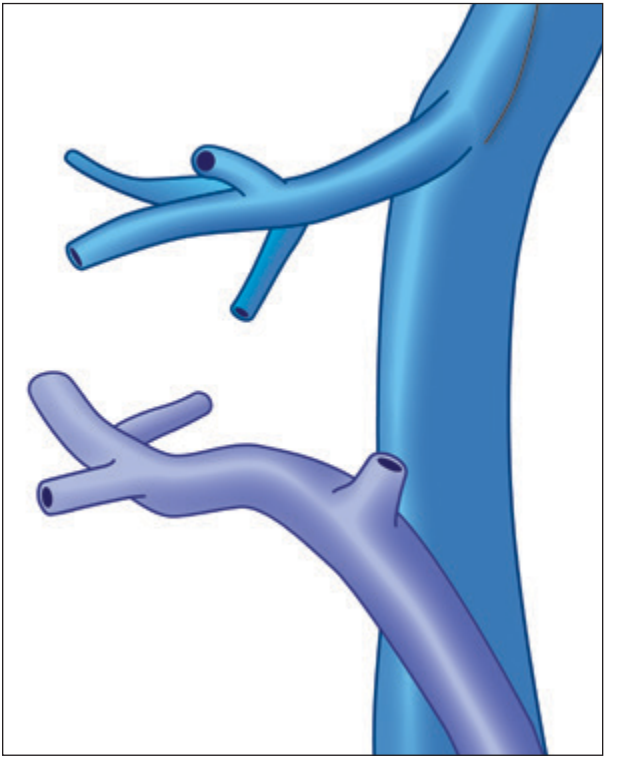


# PHASE 1: VASCULAR ACCESS

## 1.1

Access the internal jugular vein with a micro-puncture set. Ultrasound imaging guidance may be used.

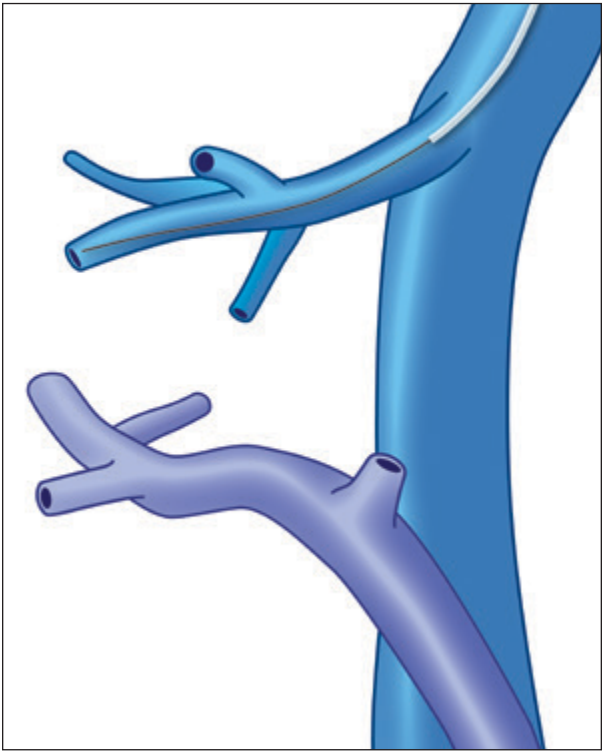
Advance a soft tip 0.035" guidewire in the inferior vena cava down to the hepatic vein confluence.



# PHASE 2: HV CATHETERIZATION

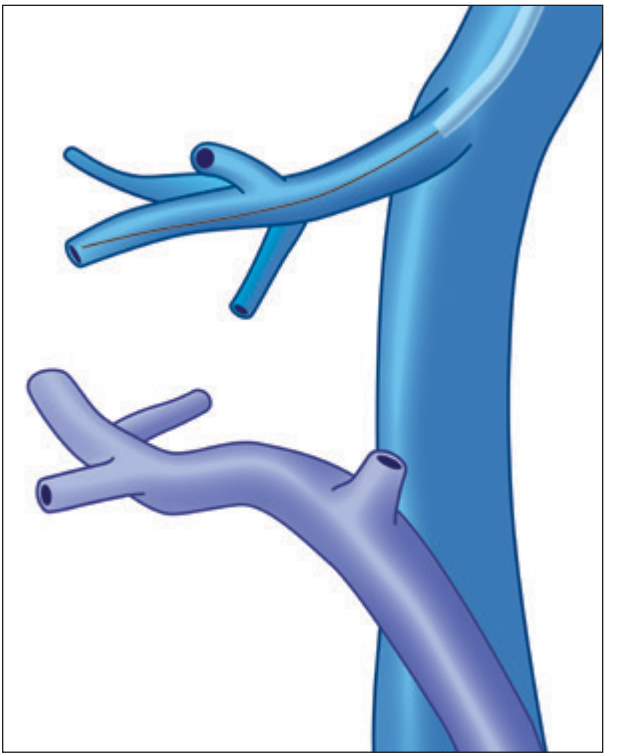
## 2.1

Direct the wire into the appropriate hepatic vein until it bottoms out.



## 2.2

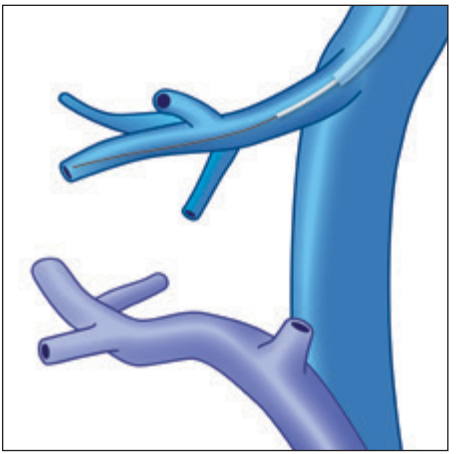
Advance the introducer sheath dilator assembly over the wire. Remove the dilator.

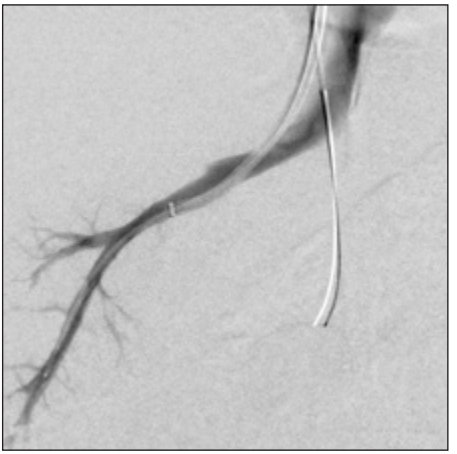


# PHASE 3: IMAGING

## 3.1

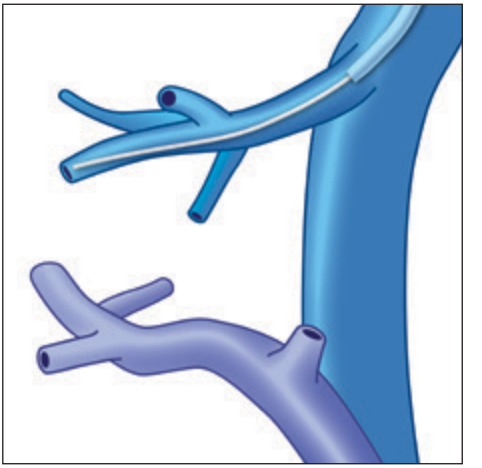
Advance a diagnostic catheter over the wire and perform a venogram for hepatic vein and inferior vena cava imaging.

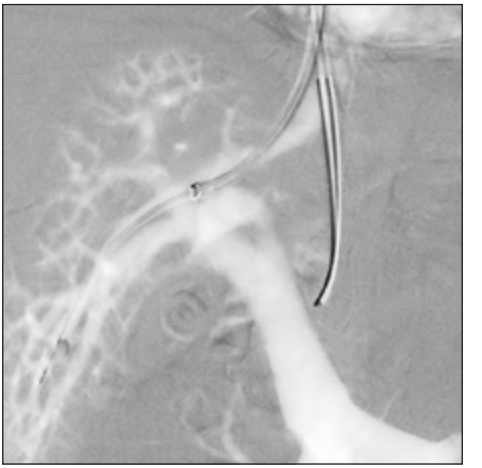




## 3.2

Optional: Perform a wedged $CO_2$ venogram for portal vein imaging. Ultrasound imaging may also be used.

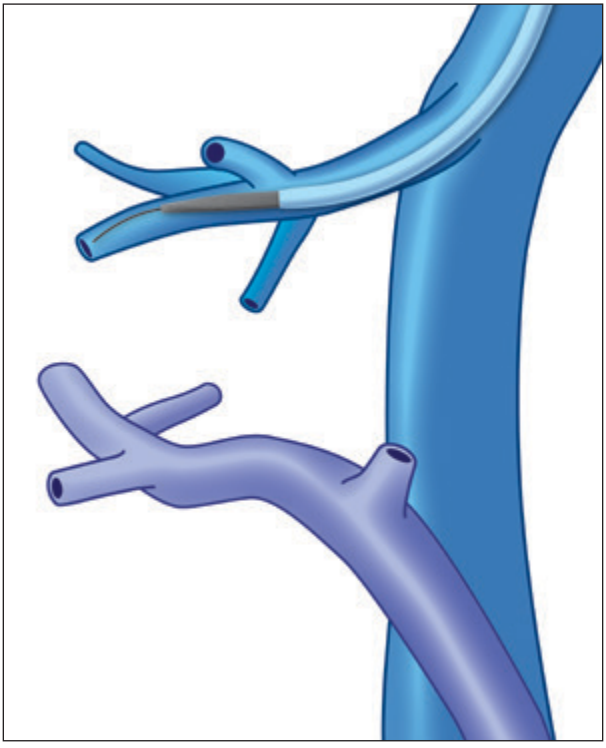




## 3.3

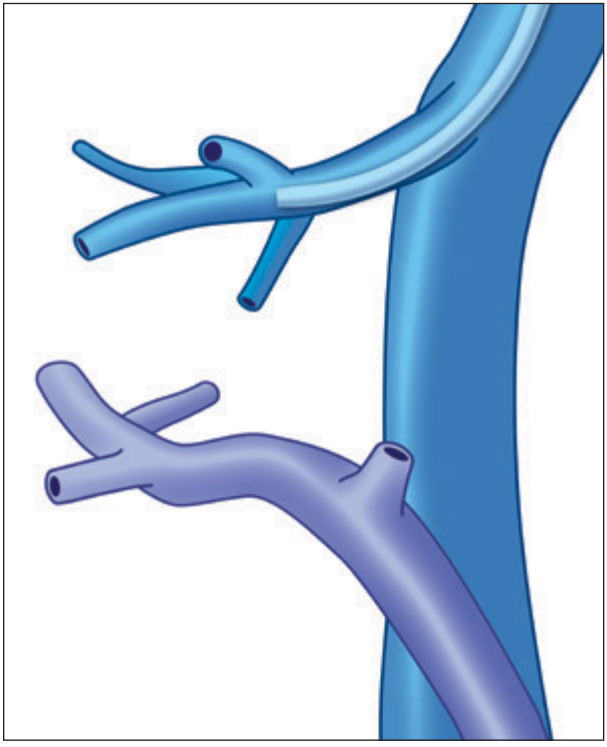
Remove diagnostic catheter and reinsert dilator.

Advance the introducer sheath dilator assembly over the 0.035" wire as distal as possible in the hepatic vein in anticipation of needle insertion.



## 3.4

Remove both dilator and guidewire.

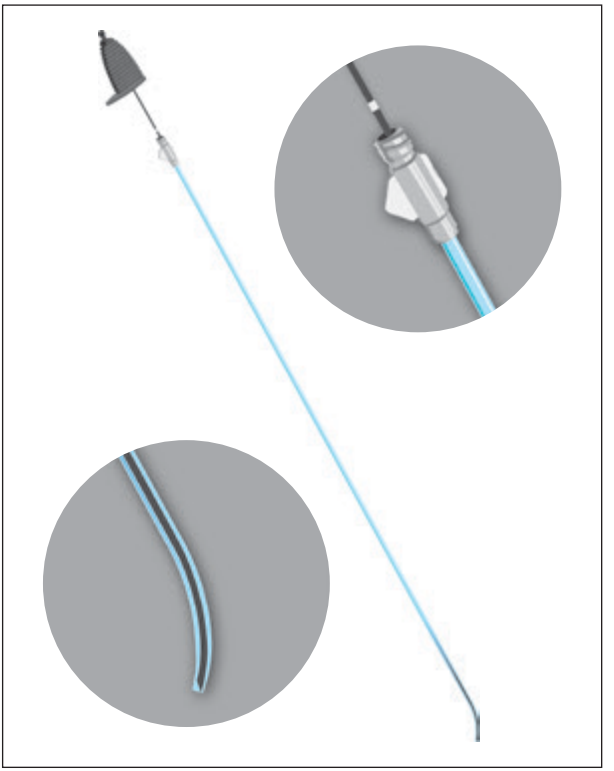


# PHASE 4: LIVER PUNCTURE

## 4.1

Assemble needle-guiding catheter unit by inserting needle into guiding catheter until needle status band at the trailing end of the needle lines up with the guiding catheter hub.

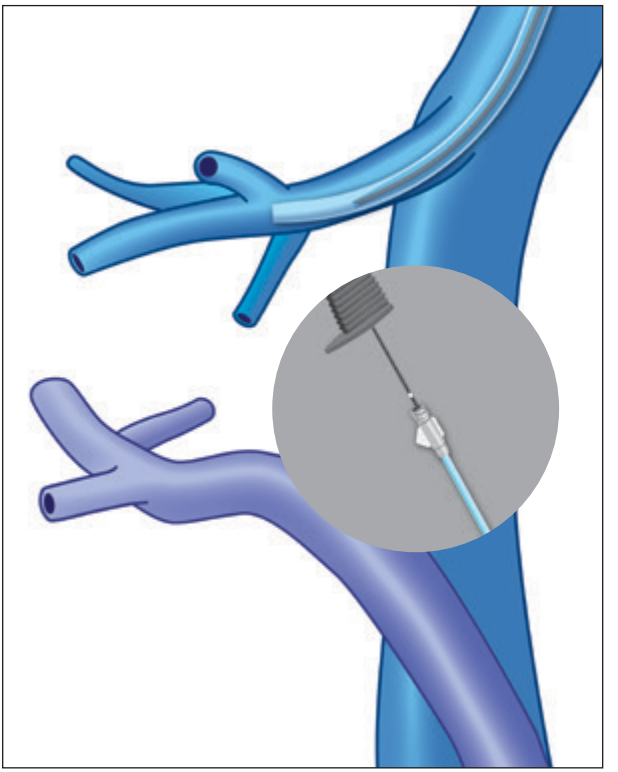
Ensure the status band is visible, which indicates that the needle tip is covered.



## 4.2

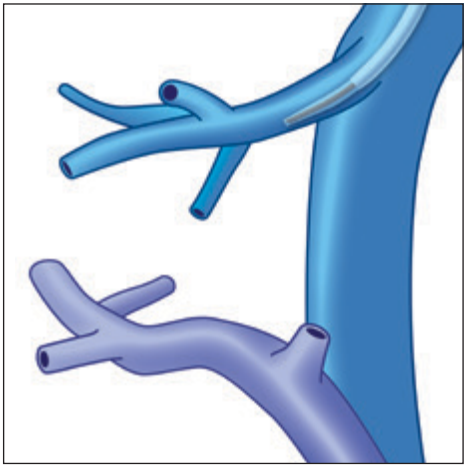
Do not allow the needle tip to protrude from the guiding catheter while inserting the needle-guiding catheter assembly through the hemostatic valve and into the introducer sheath.

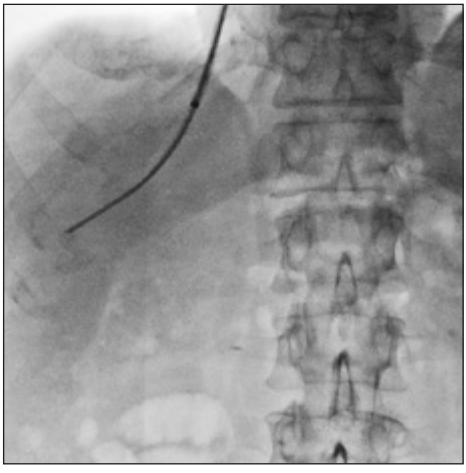
Advance the leading end of the needle-guiding catheter assembly into the hepatic vein.



## 4.3

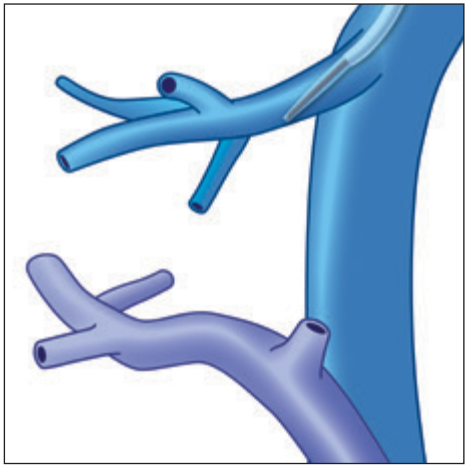
Retract the introducer sheath to expose the leading end of the needle-guiding catheter assembly.

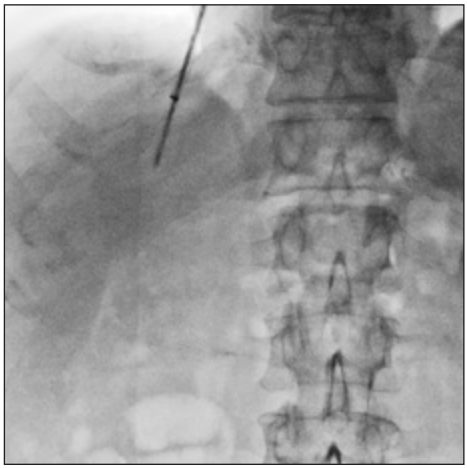




## 4.4

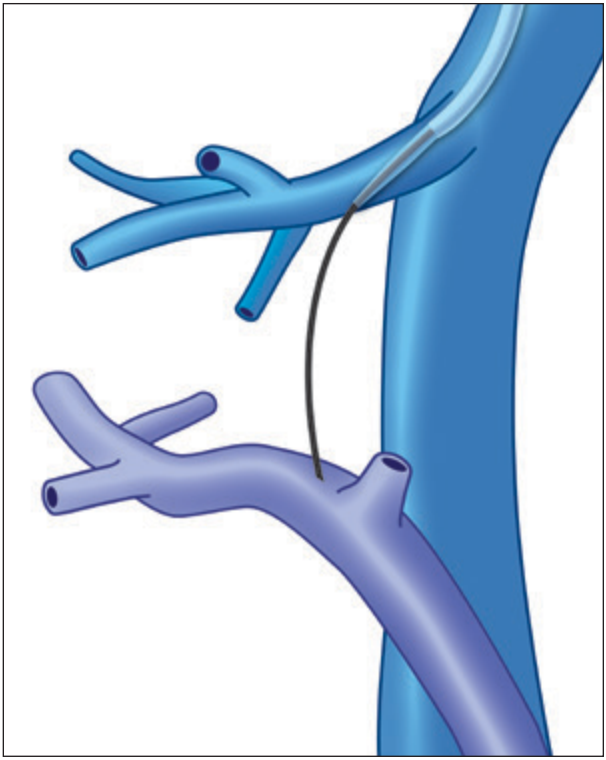
Orient and wedge the needle-guiding catheter assembly against the hepatic vein wall.





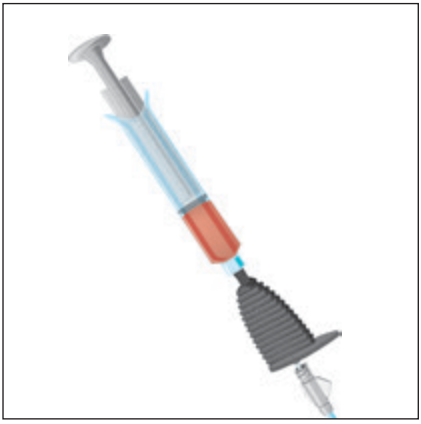
## 4.5

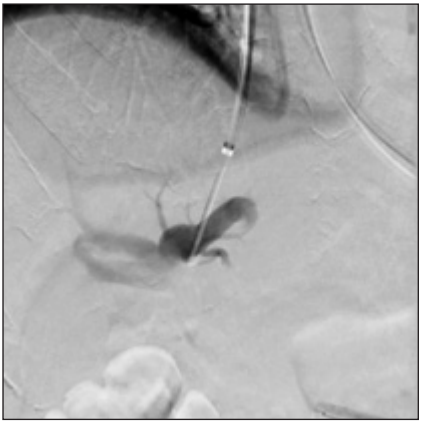
Thrust the needle in one movement forward through the hepatic vein wall and hepatic parenchyma towards and into the portal vein.



## 4.6

Confirm portal vein access by connecting a syringe with contrast medium to the luer lock of the needle handle. Apply suction and withdraw the needle until blood return is seen. Confirm access by injecting a small volume of contrast medium.

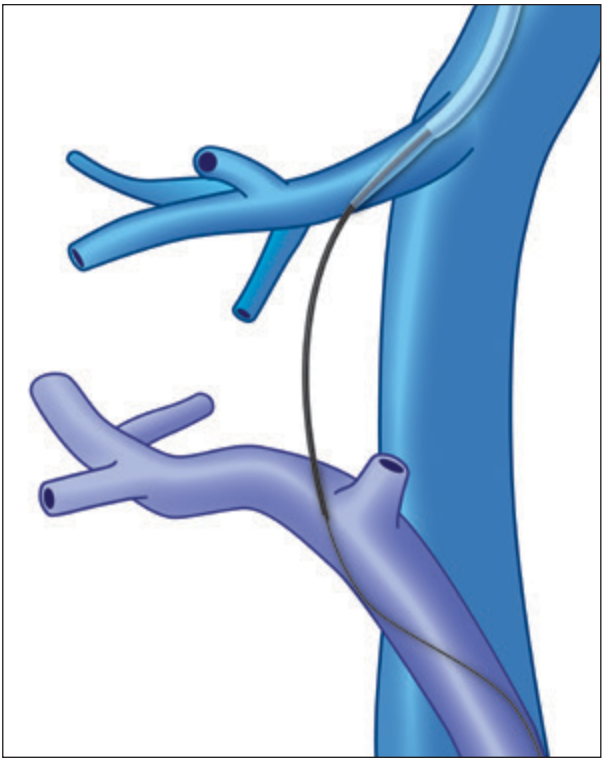




# PHASE 5: PV CATHETERIZATION

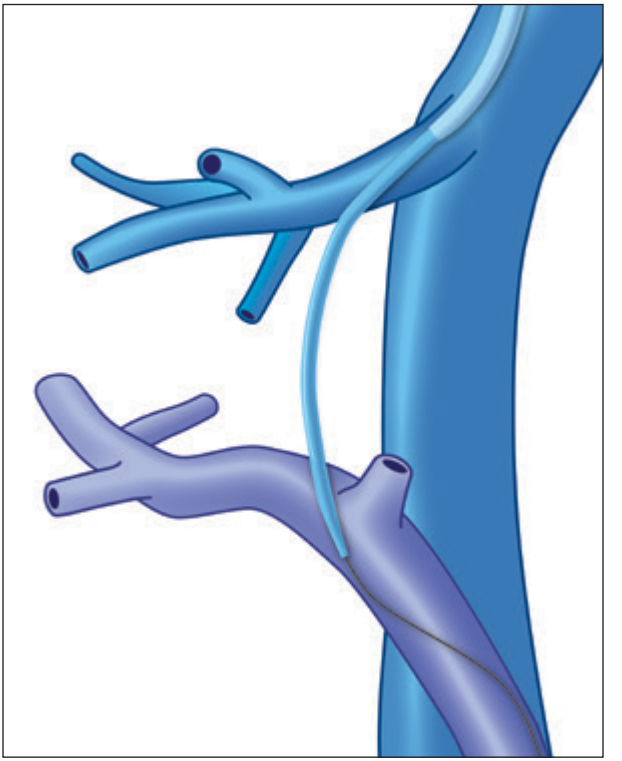
## 5.1

Advance a 0.035" guidewire through the needle to gain secure position within the portal vein.



## 5.2

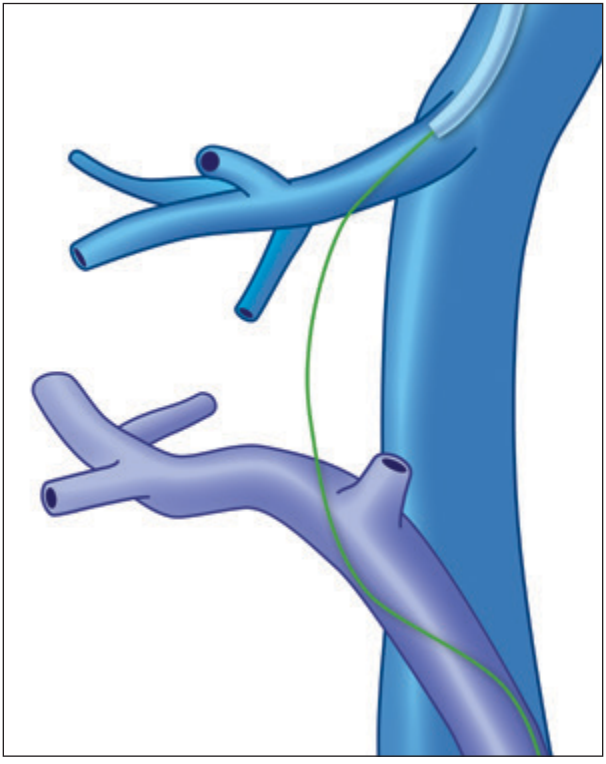
Advance the guiding catheter over the needle and guidewire deep in the portal vein. Remove the needle.



## 5.3

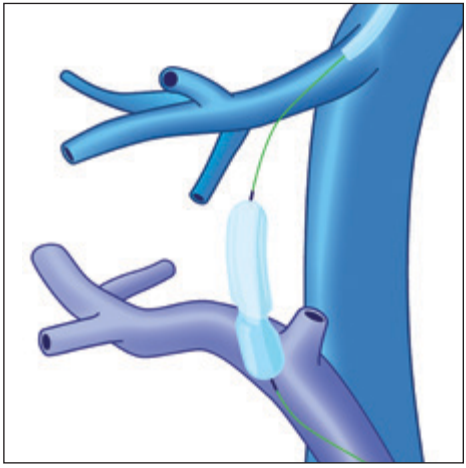
Exchange the guidewire through the guiding catheter for a stiff guidewire.

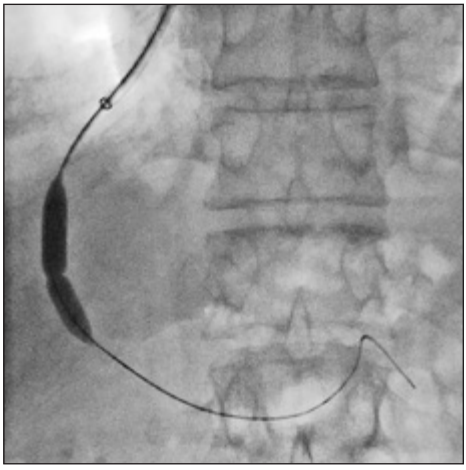
Remove the guiding catheter.



## 5.4

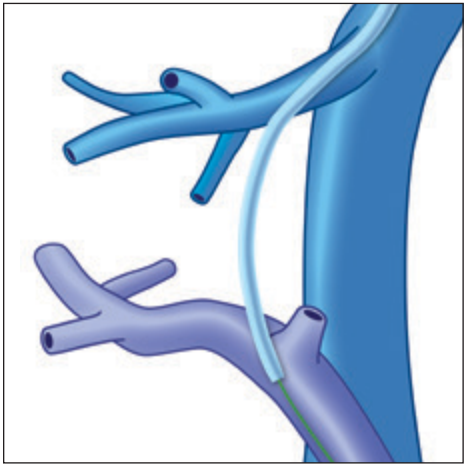
Perform balloon dilatation of the liver tract as desired. Remove balloon and reinsert dilator.

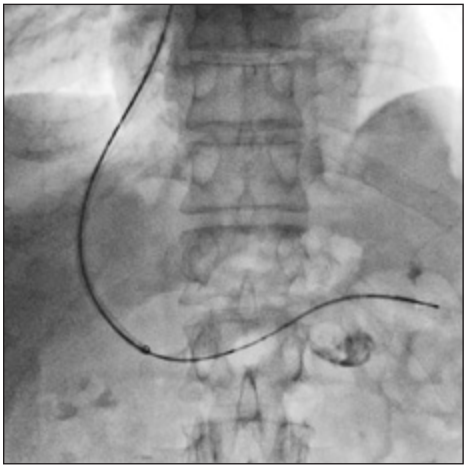




## 5.5

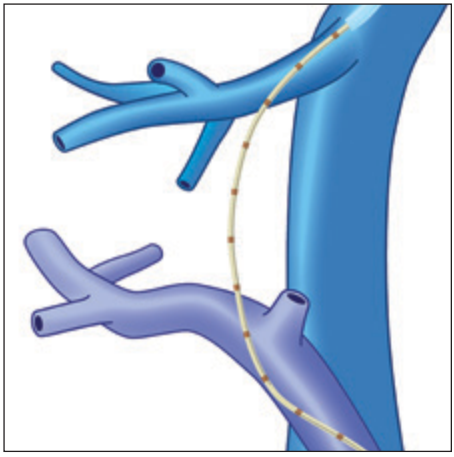
Advance the introducer sheath dilator assembly into the portal vein. Remove the dilator.

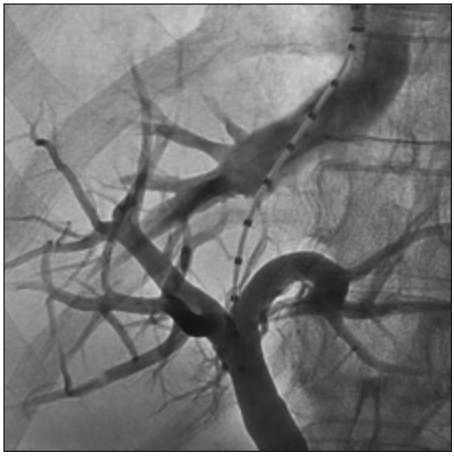




## 5.6

Advance sizing catheter into portal system.
Withdraw sheath for pressure measurements.
Perform portal venography.



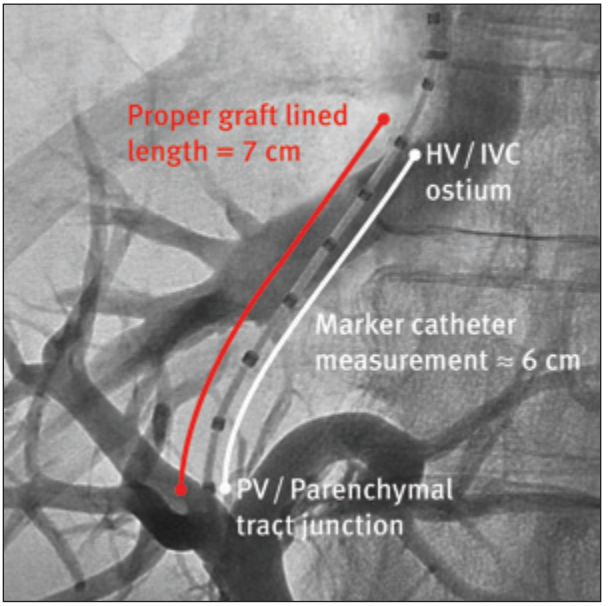


# PHASE 6: DEVICE SELECTION

## 6.1

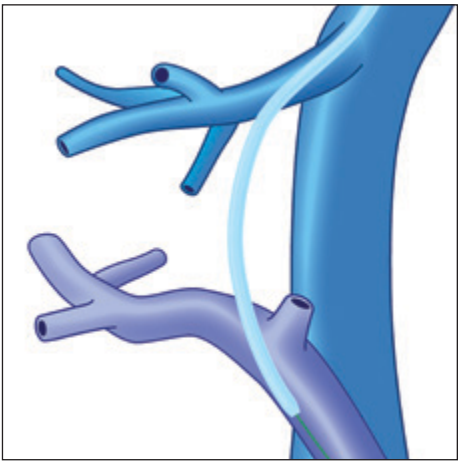
Determine appropriate graft-lined length as the tract length (distance between the portal vein / parenchymal tract junction and the hepatic vein / IVC ostium) plus one additional centimeter.

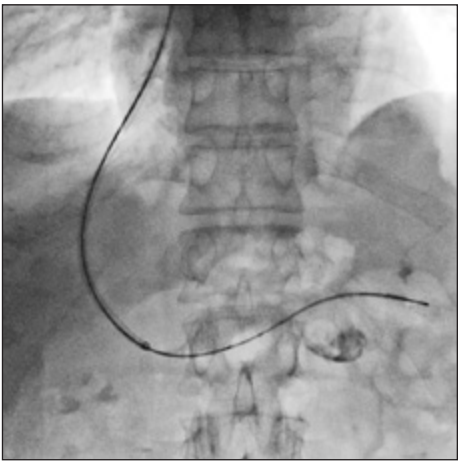
Prep the delivery system of the selected device by thoroughly flushing the delivery catheter and device.



## 6.2

Remove sizing catheter and reinsert dilator. Advance the sheath at least 3 cm into the portal system. Remove the dilator.



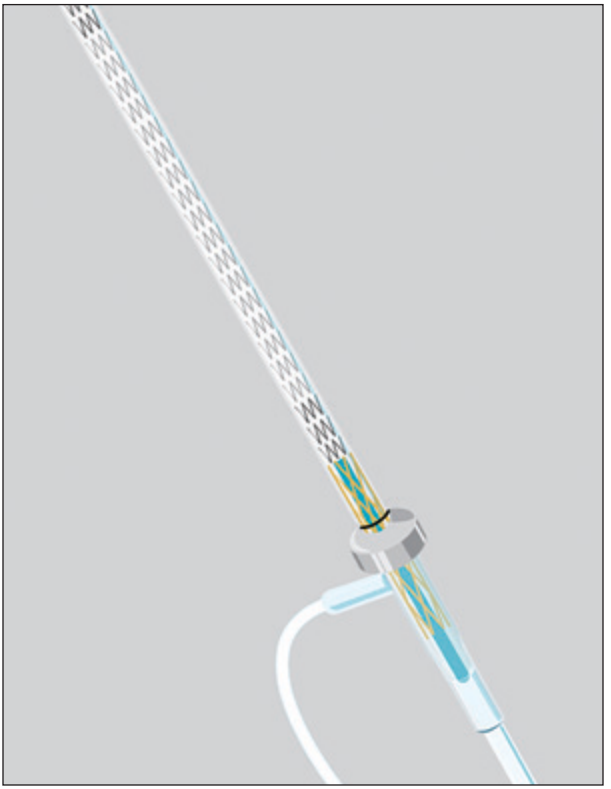


# PHASE 7: DEVICE IMPLANTATION

## 7.1

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.

Alignment of the black indicator on the access sleeve with the edge of the hemostatic valve confirms proper insertion.



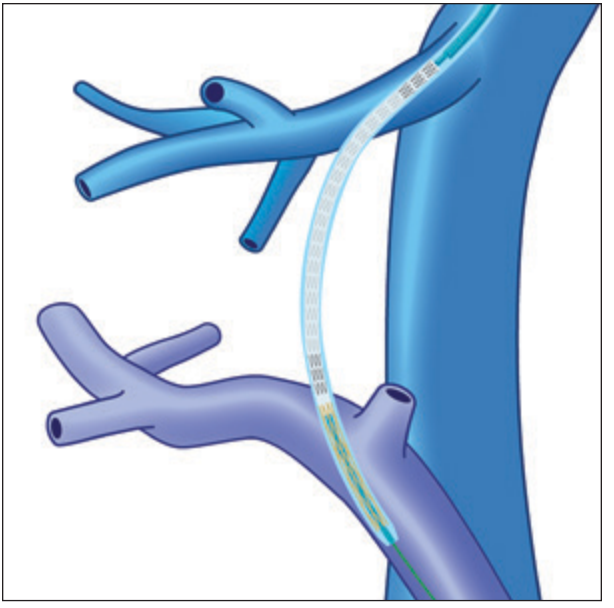
## 7.2

While maintaining forward pressure on the access sleeve, advance the delivery catheter in small increments until the entire device is advanced out of the access sleeve.

Withdraw access sleeve from the sheath valve.

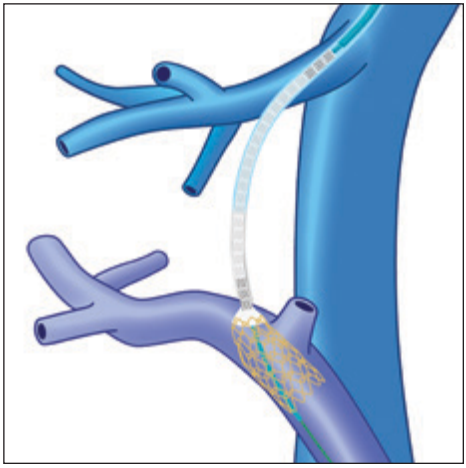
## 7.3

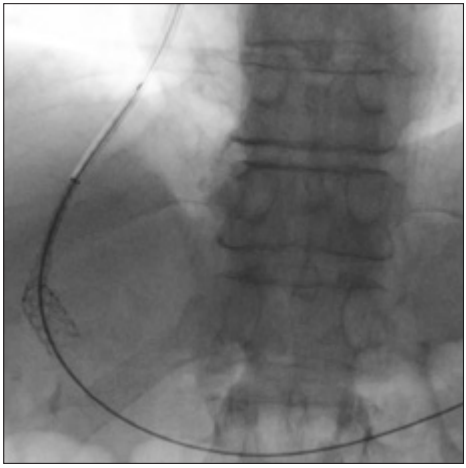
Continue to advance the device until the radiopaque marker on the leading tip of the delivery catheter aligns with the leading end of the introducer sheath in the portal system.



## 7.4

Withdraw sheath to deploy unlined portal region.

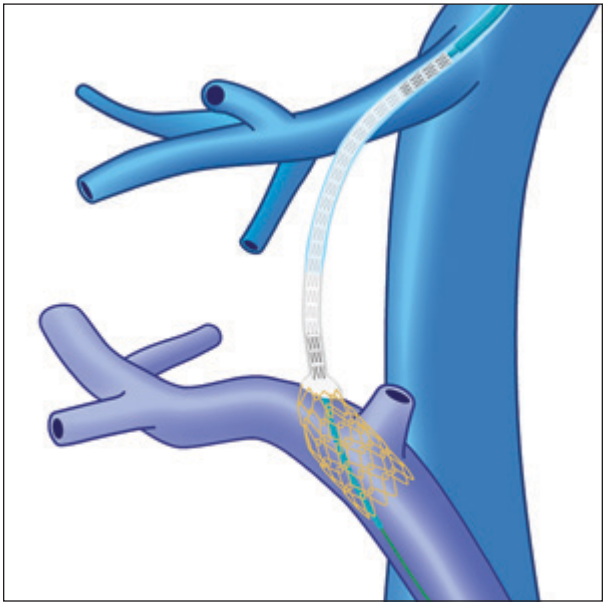




## 7.5

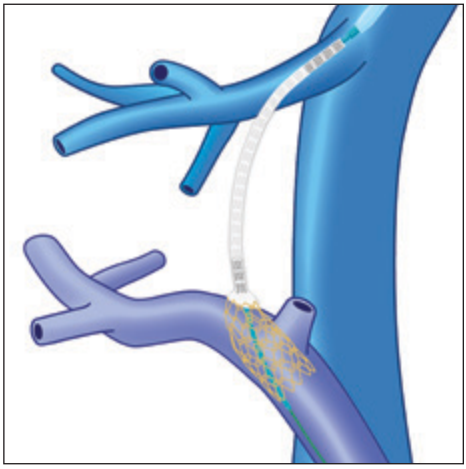
Gently pull delivery catheter and endoprosthesis back until circumferential radiopaque marker band is just distal to the PV / parenchyma tract junction and the graft-lined region is “seated” against the portal vein entry.

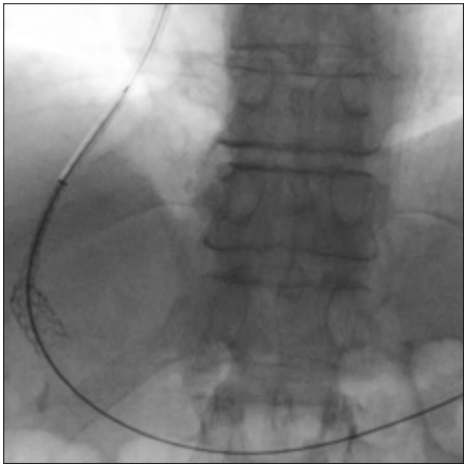
Contrast injection and tactile feedback can confirm proper positioning of device.



## 7.6

Withdraw sheath so that it does not cover any portion of the endoprosthesis.

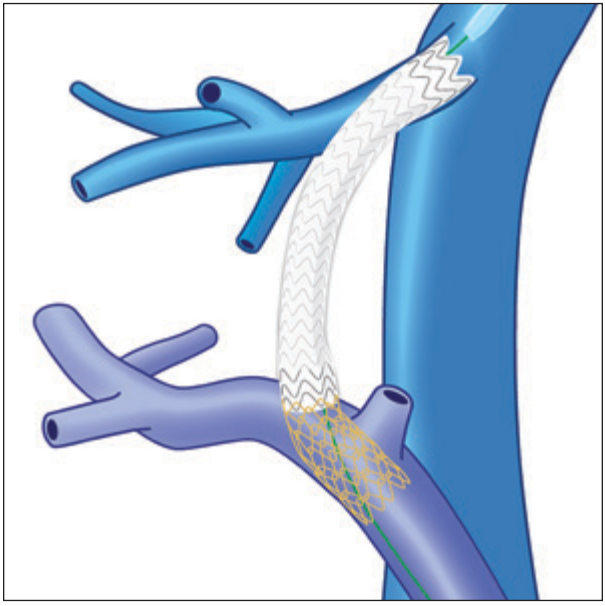




## 7.7

Unscrew deployment knob and pull deployment line until the device releases from the catheter and the line stops.

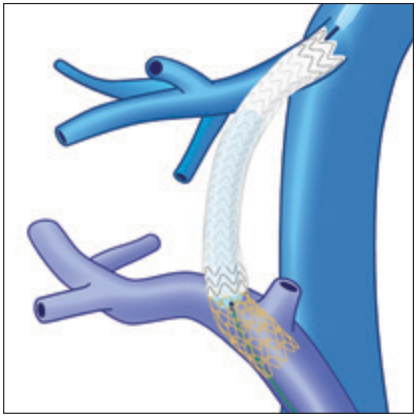
Remove delivery catheter.

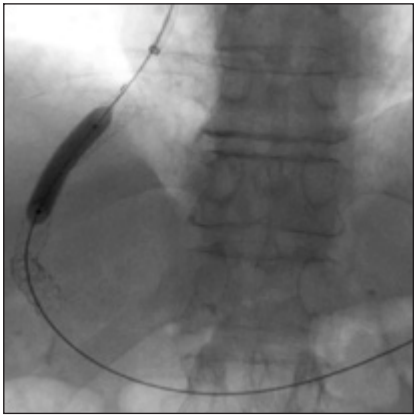


## 7.8

Secure the endoprosthesis within the TIPS by balloon dilatation.

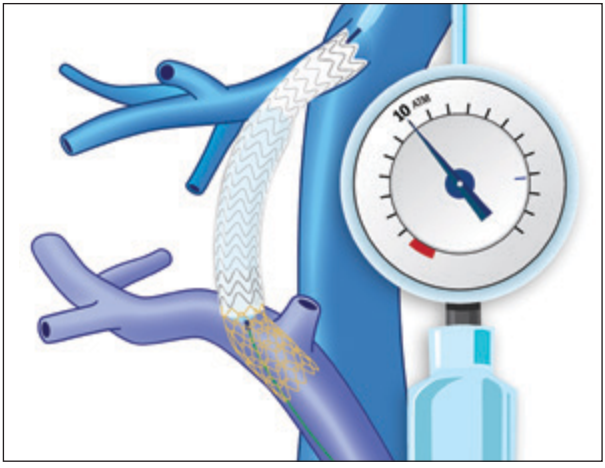
Note: The controlled expansion feature will limit self-expansion of the device to a diameter of 8 mm unless dilated beyond 8 mm.





## 7.9

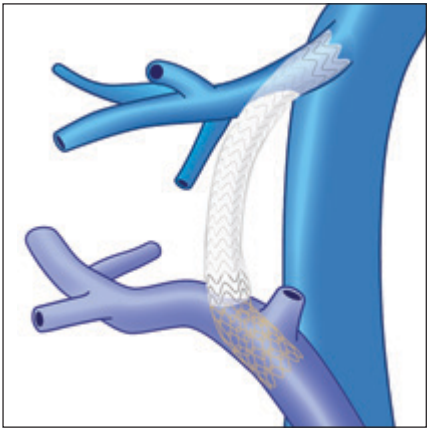
To increase device diameter above 8 mm, use a non-compliant balloon of desired diameter and inflate with a pressure of at least 10 ATM. Maximum dilatation balloon diameter is 10 mm.

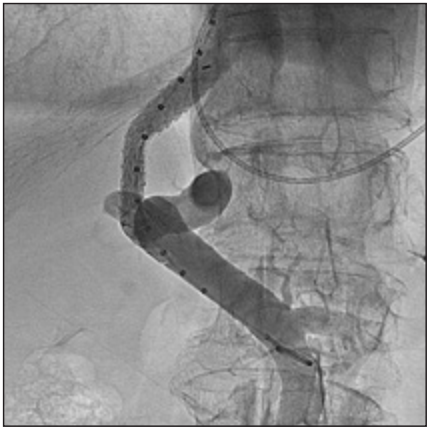


## 7.10

Evaluate the TIPS prior to completion.

Further balloon dilatations may be necessary if residual folds, kinks, compression, or incomplete expansion are visualized.





**INTENDED USE:** The GORE TIPS Set, GORE® TIPS Sheath and GORE TIPS Needle, are intended to be used together for percutaneous transjugular liver access during diagnostic and interventional procedures in patients undergoing a Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure.
**FDA Approved indication:** The GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion 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

Consult Instructions for Use
**eifu.goremedical.com**

Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.



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