INSTRUCTIONS FOR USE

GORE® VIATORR® TIPS ENDOPROSTHESIS

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DESCRIPTION

The GORE® VIATORR® Transjugular Intrahepatic Portosystemic Shunt (TIPS) Endoprosthesis is comprised of an implantable endoprosthesis and percutaneous delivery catheter.

**Endoprosthesis** (refer to Figure 1)

The endoprosthesis consists of an electropolished, self-expanding nitinol (nickel titanium) stent that supports a reduced permeability expanded polytetrafluoroethylene (ePTFE) graft. The endoprosthesis is divided into two functional regions: a graft-lined intrahepatic region, and an unlined portal region. The interface between the lined and unlined regions is indicated by a circumferential radiopaque gold marker band. An additional radiopaque gold marker is located on the trailing edge of the device. Endoprosthesis diameters and lengths are provided in Table 1.

**FIGURE 1: GORE® VIATORR® TIPS ENDOPROSTHESIS**

Percutaneous Delivery Catheter (refer to Figure 2)

The endoprosthesis is secured to the leading end of a dual-lumen delivery catheter beneath a protective plastic access sleeve. The access sleeve facilitates insertion of the delivery catheter through the hemostasis valve of an introducer sheath, and should not be removed prior to use.

A mark on the access sleeve serves as a guide to confirm correct insertion depth. The delivery catheter is compatible with a ≤ 0.038" (0.97 mm) diameter guidewire, and has a working length of 75 cm. A radiopaque marker is located beneath the leading tip of the delivery catheter. A removable ePTFE constraining sleeve is used to constrain and subsequently deploy the graft-lined region of the GORE® VIATORR® TIPS Endoprosthesis. An extension of the constraining sleeve becomes the deployment line, which is routed through the catheter shaft and allows for deployment of the device. The trailing end of the delivery catheter is attached to a hub assembly that includes a central hemostatic guidewire port, a flushing port, and a port for the deployment line/deployment knob. The delivery catheter is packaged with a stainless steel mandrel inserted into the leading edge of the guidewire lumen that must be removed prior to use.

**FIGURE 2: DUAL-LUMEN DELIVERY CATHETER**
TABLE 1: GORE® VIATORR® TIPS ENDOPROSTHESIS DIMENSIONS AND RECOMMENDED ACCESSORIES

<table>
<thead>
<tr>
<th>Internal Diameter (mm)</th>
<th>Endoprosthesis Dimensions</th>
<th>Recommended Accessory Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Labeled</td>
<td>Guidewire Diameter (inches)</td>
</tr>
<tr>
<td></td>
<td>4 / 2</td>
<td>5 / 2</td>
</tr>
<tr>
<td>8</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>10</td>
<td>X</td>
<td>X</td>
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<tr>
<td>12</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

1. Lengths may vary by ± 0.5 cm.
2. A stiff guidewire, having a length of at least 180 cm and diameter ≤ 0.038” (0.97 mm), 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. It is recommended that a Cook Check-Flo II Introducer Set (Cook, Bloomington, IN) with an integral radiopaque marker band and a length of approximately 40-45 cm be used.
4. The same balloon dilatation device can be used for TIPS dilatation and dilatation of the endoprosthesis following implantation.

INTENDED USE/INDICATIONS

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.

CONTRAINDICATIONS
- Congestive heart failure
- Polycystic liver disease or hepatic malignancy
- Severe hepatic failure
- Severe hepatic encephalopathy
- Cavernous portal vein occlusion or splenic vein thrombosis
- Presence or suspicion of active systemic infection, hepatobiliary infection, ascitic fluid infection, or bacterial peritonitis

WARNINGS
- The risks and potential adverse effects of creating a TIPS in patients with biliary obstruction, pneumonia, adult respiratory distress syndrome, pulmonary hypertension, non-cavernous portal vein obstruction, cholangitis, or bacteremia must be considered relative to the potential benefits of this procedure.
- Do not remove the access sleeve from the delivery system prior to use. Do not attempt to re-sleeve the GORE® VIATORR® TIPS Endoprosthesis if the access sleeve is inadvertently removed prior to use.
- Do not cut the GORE® VIATORR® TIPS Endoprosthesis. The device should only be delivered and deployed using the supplied delivery system.
- Do not use the GORE® VIATORR® TIPS Endoprosthesis if the hemostatic introducer sheath cannot negotiate the entire pathway from the transjugular access site into the portal vein without kinks.
- Do not attempt to re-capture or re-sheath the GORE® VIATORR® TIPS Endoprosthesis after initiation of deployment of the unlined region.
- Do not attempt to dislodge or displace the GORE®VIATORR® TIPS Endoprosthesis once deployment of the graft-lined region has commenced.
- Do not attempt to deploy the device or manipulate the delivery system without a guidewire or fluoroscopic guidance.
- Inadvertent, partial, or failed deployment of the device or device migration may require surgical intervention.

PRECAUTIONS
- The GORE® Medical Device is designed for single use only; do not reuse device. Gore does not have data regarding reuse of this device. Gore does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility and device contamination. Reuse may result in infection, serious injury, or patient death. Do not resterilize.
- Do not use if the device has been damaged or if the sterile packaging has been compromised.
- Do not use the GORE® VIATORR® TIPS Endoprosthesis after the labeled “use-by” (expiration) date.
- The GORE® VIATORR® TIPS Endoprosthesis should only be used by physicians trained in its use and familiar with interventional radiological procedures including TIPS. The implantation procedure should be performed only at facilities where surgical expertise is available if necessary.
- Follow the Instructions for Use supplied with all accessories used in conjunction with the GORE® VIATORR® TIPS Endoprosthesis.
- Deployment of the GORE®VIATORR® TIPS Endoprosthesis should only follow successful balloon dilatation. If the GORE®VIATORR® TIPS Endoprosthesis is to be deployed within an existing stent residing in the TIPS, ensure ≤ 30% residual stenosis prior to implantation.
- Do not dilate the endoprosthesis with a balloon having a diameter greater than the labeled diameter of the device (refer to Table 1).
- Do not attempt to withdraw or re-position a balloon dilatation catheter within the lumen of a GORE® VIATORR® TIPS Endoprosthesis if the balloon is not completely deflated.
The graft-lined portion of the GORE® VIATORR® TIPS Endoprosthesis should completely cover the intrahepatic tract, preferably to the ostium of the hepatic vein at the inferior vena cava. Discretion must be exercised during implantation of the device in order to minimize deleterious effects of obstructing portal perfusion, venous return, and potential anastomotic sites for subsequent liver transplantation.

Caution should be exercised while advancing instruments, including the delivery system, through the right atrium. The patient’s heart should be monitored for possible arrhythmia.

Prophylactic antibiotic treatment is recommended for patients undergoing perioperative procedures following implantation.

Ultrasonic visualization of the lumen of the graft-lined region may be difficult immediately following implantation.

**MR CONDITIONAL**

**Magnetic Resonance Imaging (MRI)**

Non-clinical testing has demonstrated that the GORE® VIATORR® TIPS Endoprosthesis is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Spatial gradient field of ≤ 720 Gauss/cm
- Maximum scanner displayed whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning.

**3.0 Tesla Temperature Rise:**

In non-clinical testing, the GORE® VIATORR® TIPS Endoprosthesis produced a temperature rise of 1.9°C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR scanner using G3.0-052B Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 2.8 W/kg.

**1.5 Tesla Temperature Rise:**

In non-clinical testing, the GORE® VIATORR® TIPS Endoprosthesis produced a temperature rise of 1.9°C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 2.8 W/kg for 15 minutes of MR scanning in a 1.5 Tesla, Magnetom, Siemens Medical Solutions, active-shield, horizontal field MR scanner using Numaris/4 Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 1.5 W/kg.

**Image Artifact:**

The image artifact extends approximately 1 – 2 mm from the device, both inside and outside the device lumen when scanned in non-clinical testing using sequence: T1 – weighted, spin echo and gradient echo pulse sequences in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR system with a send-receive RF body coil.

For each vascular device and assembly, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were minor in size relative to the size and shape of these implants. The gradient echo pulse sequence produced larger artifacts than the T1 – weighted, spin echo pulse sequence for the GORE® VIATORR® TIPS Endoprosthesis. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE® VIATORR® TIPS Endoprosthesis. Therefore, it may be necessary to optimize the MR imaging parameters to compensate for the presence of this implant.

**ADVERSE EVENTS**

Adverse events may include, but are not limited to: arteriovenous fistula formation, embolism, fever, hemoperitoneum, entry site bleeding and/or hematoma, vessel trauma, hepatic artery injury, hepatic vein occlusion, gall bladder puncture, bile duct injury, hemobilia, hemolysis, hepatic infarction, portal vein injury, portal vein occlusion, pulmonary edema or infarction, pseudoaneurysm formation, transient or permanent contrast induced renal failure, renal toxicity, recurrent variceal hemorrhage, recurrent ascites, sepsis, shock, subcapsular hematoma, new onset or worsened encephalopathy, liver failure, radiation injury, deployment failure, prosthesis malposition, prosthesis migration, prosthesis/device failure, implant infection, thrombosis, stenosis, occlusion, exacerbation of respiratory complications, congestive heart failure, impaired venous return, myocardial infarction, cerebrovascular accident, and/or death.

**HOW SUPPLIED**

The GORE® VIATORR® TIPS Endoprosthesis is supplied sterile in a protective tray sealed within one or more pouches.

**STORAGE AND HANDLING**

Handle the device with care, and avoid exposure to extreme temperatures and humidity. Store under ambient conditions.

**REQUIRED MATERIALS** (refer to Table 1 for GORE® VIATORR® TIPS Endoprosthesis and accessory sizing)

- GORE® VIATORR® TIPS Endoprosthesis selected for the appropriate diameter and length
- 10 cc syringe, or similar
- Heparinized saline
- Cook Check-Flo II Introducer Set (Cook, Bloomington, IN) of appropriate diameter (10 Fr) and length (approximately 40-45 cm). Note that a hemostatic introducer sheath with an integral radiopaque band on its leading tip is recommended.
- ≤ 0.038” (0.97 mm) diameter stiff guidewire, at least 180 cm long
- Appropriate angioplasty balloon catheters and accessories
- Appropriate diagnostic catheters and accessories
- Radiopaque contrast media
- Graduated sizing catheter
DIRECTIONS FOR USE

A. Selection of the GORE® VIATORR® TIPS Endoprosthesis
1. Inflate an appropriately sized angioplasty balloon within the transjugular intrahepatic portosystemic shunt (TIPS) according to the manufacturer’s instructions.
2. Evaluate the TIPS fluoroscopically noting the shunt’s dimensions.
3. Using Table 1, select an appropriately sized GORE® VIATORR® TIPS Endoprosthesis for implantation based on the shunt’s length and diameter. The graft-lined length of this device should be selected to completely line the TIPS, preferably to the ostium of the hepatic vein at the inferior vena cava. The diameter of the device should be selected to correspond to the diameter of the largest balloon used to dilate the TIPS, or to provide an adequate interference fit for anchoring. If the GORE® VIATORR® TIPS Endoprosthesis is to be deployed within an existing stent residing in the TIPS, ensure ≤ 30% residual stenosis prior to implantation.

B. Preparation of the GORE® VIATORR® TIPS Endoprosthesis
1. Prior to Opening the Sterile Package
   a) Ensure that the diameter and length of the selected implant are correctly matched to the patient anatomy and TIPS configuration.
2. Opening the Sterile Package and Inspection Prior to Use
   a) Carefully inspect the packaging for damage to the outer pouch. If the packaging is damaged, do not use.
   b) Open the packaging. Remove and inspect the sterile GORE® VIATORR® TIPS Endoprosthesis. Do not use any damaged product.
3. Preparation of the GORE® VIATORR® TIPS Endoprosthesis Delivery System
   a) Carefully remove only the packaging mandrel from the leading edge of the delivery system and discard. Do not displace or remove the access sleeve.
   b) Thoroughly flush the delivery system by connecting a 10 cc syringe of heparinized saline to the flush port on the catheter adapter (see Figure 2). Tighten the hemostatic guidewire port while flushing to prevent air entrapment or back-flushing.
   c) After flushing the delivery system, remove the syringe, and loosen the hemostatic guidewire port.
4. Ensure that a stiff guidewire having a diameter ≤ 0.038” (0.97 mm), and a length of at least 180 cm, extends into the portal circulation.
5. If necessary, exchange the indwelling transjugular hemostatic introducer sheath for one that has an appropriate diameter and length for device delivery (refer to Table 1).
6. Using fluoroscopic guidance and inserted dilator, carefully position the leading edge of the hemostatic introducer sheath well into the central portal circulation (≥ 3.0 cm). Note: This is a pre-requisite for implantation.
7. Carefully remove the dilator. Note: Ensure that all significant kinks are removed from the hemostatic introducer sheath prior to insertion of the delivery catheter.
8. With the delivery system held as straight as possible, insert the trailing end of the guidewire into the access sleeve, together with the delivery catheter, completely through the hemostasis valve until significant resistance to further insertion is detected. Do not force the access sleeve past this point. Confirm that the indicator on the access sleeve aligns with the edge of the hemostasis valve.
9. Use the access sleeve to penetrate the hemostasis valve of the hemostatic introducer sheath. Advance the access sleeve, together with the delivery catheter, completely through the hemostasis valve until significant resistance to further insertion is detected. Do not force the access sleeve past this point. Confirm that the indicator on the access sleeve aligns with the edge of the hemostasis valve.
   a) While supporting the delivery catheter and access sleeve, carefully advance the endoprosthesis in small increments (approximately 5 mm) over the guidewire, until the entire device is advanced out of the access sleeve and into the hemostatic introducer sheath. If excessive resistance is felt upon attempting to insert the delivery catheter into the hemostatic introducer sheath, remove and inspect for damage and proper sizing. Do not reuse the device if damaged. If the device is partially deployed outside the access sleeve, do not attempt to recapture or reuse.
10. While the delivery catheter is fully constrained within the hemostatic introducer sheath, confirm that the leading edge of the graft-lined region of the GORE® VIATORR® TIPS Endoprosthesis is located distal to the TIPS, and is within the portal vein. This can be achieved via fluoroscopic visualization of the circumferential radiopaque marker band that indicates the leading edge of the graft-lined region.
11. Confirm that the length of the implant is appropriately sized relative to the intrahepatic tract. Minimal shortening of the graft-lined portion of the device can be anticipated.
12. Withdraw the hemostatic introducer sheath proximally so that it does not cover any portion of the constrained implant. Withdrawal of the hemostatic introducer sheath allows for spontaneous deployment of the distal portion of the implant including the entire unlined region and part of the graft-lined region containing the circumferential radiopaque marker. Note: Do not attempt to re-capture or re-sheath the deployed portion of the implant.
13. Using fluoroscopic guidance, adjust the delivery catheter position so that the deployed region including the deployed circumferential radiopaque marker is aligned just distal to the TIPS.

C. Introduction of the Delivery Catheter and Deployment of the Implant
1. Ensure that a stiff guidewire having a diameter ≤ 0.038” (0.97 mm), and a length of at least 180 cm, extends into the portal circulation.
2. Using fluoroscopic guidance and inserted dilator, carefully position the leading end of the hemostatic introducer sheath well into the central portal circulation (≥ 3.0 cm). Note: This is a pre-requisite for implantation.
3. Carefully remove only the packaging mandrel from the leading end of the delivery system and discard. Do not displace or remove the access sleeve.
4. If necessary, exchange the indwelling transjugular hemostatic introducer sheath for one that has an appropriate diameter and length for device delivery (refer to Table 1).
5. Using fluoroscopic guidance and inserted dilator, carefully position the leading edge of the hemostatic introducer sheath well into the central portal circulation (≥ 3.0 cm). Note: This is a pre-requisite for implantation.
6. Carefully remove the dilator. Note: Ensure that all significant kinks are removed from the hemostatic introducer sheath prior to insertion of the delivery catheter.
7. With the delivery system held as straight as possible, insert the trailing end of the guidewire into the access sleeve, together with the delivery catheter, completely through the hemostasis valve until significant resistance to further insertion is detected. Do not force the access sleeve past this point. Confirm that the indicator on the access sleeve aligns with the edge of the hemostasis valve.
8. Use the access sleeve to penetrate the hemostasis valve of the hemostatic introducer sheath. Advance the access sleeve, together with the delivery catheter, completely through the hemostasis valve until significant resistance to further insertion is detected. Do not force the access sleeve past this point. Confirm that the indicator on the access sleeve aligns with the edge of the hemostasis valve.
9. While supporting the delivery catheter and access sleeve, carefully advance the endoprosthesis in small increments (approximately 5 mm) over the guidewire, until the entire device is advanced out of the access sleeve and into the hemostatic introducer sheath. If excessive resistance is felt upon attempting to insert the delivery catheter into the hemostatic introducer sheath, remove and inspect for damage and proper sizing. Do not reuse the device if damaged. If the device is partially deployed outside the access sleeve, do not attempt to recapture or reuse.
10. While the delivery catheter is fully constrained within the hemostatic introducer sheath, confirm that the leading edge of the graft-lined region of the GORE® VIATORR® TIPS Endoprosthesis is located distal to the TIPS, and is within the portal vein. This can be achieved via fluoroscopic visualization of the circumferential radiopaque marker band that indicates the leading edge of the graft-lined region.
11. Confirm that the length of the implant is appropriately sized relative to the intrahepatic tract. Minimal shortening of the graft-lined portion of the device can be anticipated.
12. Withdraw the hemostatic introducer sheath proximally so that it does not cover any portion of the constrained implant. Withdrawal of the hemostatic introducer sheath allows for spontaneous deployment of the distal portion of the implant including the entire unlined region and part of the graft-lined region containing the circumferential radiopaque marker. Note: Do not attempt to re-capture or re-sheath the deployed portion of the implant.
13. Using fluoroscopic guidance, adjust the delivery catheter position so that the deployed region including the deployed circumferential radiopaque marker is aligned just distal to the TIPS.
14. Once the optimal device position is verified and the hemostatic introducer sheath is fully withdrawn, deploy the remainder of the GORE® VIATORR® TIPS Endoprosthesis. To initiate deployment, stabilize the position of the delivery catheter relative to the hemostatic introducer sheath. While keeping the catheter straight, untwist the screw-connector at the base of the deployment knob. Smoothly pull the deployment knob, attached to the deployment line, away from the hub assembly until the graft-lined portion of the implant is fully deployed. Deployment of the implant will occur from the leading end toward the trailing end of the delivery catheter. Following deployment, the deployment line will remain attached to the delivery catheter. Once the deployment has started, displacement of the endoprosthesis should not be attempted.

15. While maintaining the guidewire across the TIPS, withdraw the delivery catheter through the hemostatic introducer sheath. Excessive force should not be used to remove the delivery catheter. If unable to withdraw the delivery catheter, remove the hemostatic introducer sheath and delivery catheter together, and inspect for damage.

16. Following delivery catheter removal, the endoprosthesis must be secured within the TIPS by balloon dilatation. The balloon selected for this purpose should be the same diameter as the implanted GORE® VIATORR® TIPS Endoprosthesis (refer to Table 1). Do not attempt to dilate the GORE® VIATORR® TIPS Endoprosthesis with a balloon having a diameter greater than the labeled diameter of the device. The balloon should be inflated along the entire length of the implant. To avoid trauma to the vasculature, care should be taken to keep the inflated balloon within the implant. Dilatation of the unlined region of the endoprosthesis may be omitted to reduce the likelihood of portal venous trauma. Ensure complete deflation of the balloon prior to removal.

17. Using multi-view contrast venography, evaluate the TIPS prior to completion. Further balloon dilatations may be necessary if residual device folds, compression, or kinks are visualized.

**DEFINITIONS**

- **Use By**
- **Caution**
- **Consult Instructions for Use**
- **Do Not Re sterilize**
- **Do Not Reuse**
- **Catalogue Number**
- **Batch Code**
- **Authorised Representative in the European Community**
- **MR Conditional**
- **Only CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.**
- **STERILE**
- **Sterilized using Ethylene Oxide**
- **Do Not Use if Package is Damaged**
- **Keep Dry**
- **Store in a Cool Place**
- **Catheter Working Length**
- **Delivery Profile**
- **Do Not Remove Access Sleeve**
- **Guidewire Compatibility**
- **Manufacturer**