INSTRUCTIONS FOR USE FOR:

GORE VIATORR®

TIPS ENDOPROSTHESIS

en
English

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INSTRUCTIONS FOR USE

GORE® VIATORR® TIPS ENDOPROSTHESIS

NOTICE FOR USE WITHIN THE UNITED STATES

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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

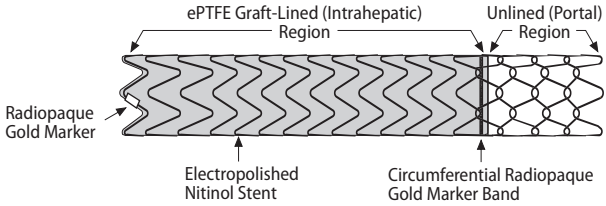
DESCRIPTION

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 containment plastic access sleeve. The access sleeve constrains the unlined, chain-link portion of the endoprosthesis and facilitates insertion of the delivery catheter through the hemostatic 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 for large valve assemblies. 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 removable, stainless steel shipping mandrel inserted into the leading edge of the guidewire lumen that must be removed prior to flushing or use.

Figure 2: Dual-Lumen Delivery Catheter

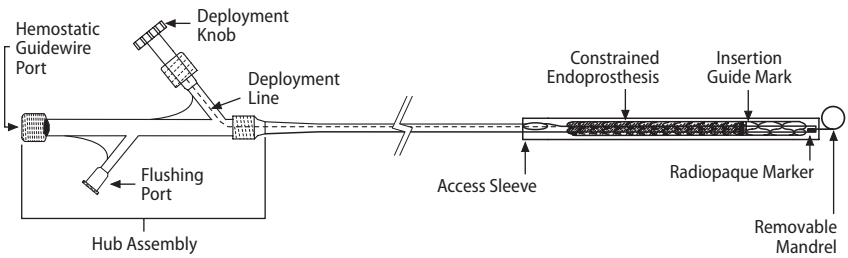


Table 1: GORE® VIATORR® TIPS Endoprosthesis Dimensions and Recommended Accessories

Endoprosthesis Dimensions						Recommended Accessory Equipment		
Internal Diameter (mm)	Graft-Lined Length / Unlined Length[1] (cm / cm)					Maximum Guidewire Diameter[2] (inches)	Hemostatic Introducer Sheath[3] (Fr)	Maximum Dilatation Balloon Diameter[4] (mm)
Labeled	4 / 2	5 / 2	6 / 2	7 / 2	8 / 2			
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

[1] Lengths may vary by ± 0.5 cm.

[2] 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.

[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., COOK® FLEXOR® CHECK-FLO® II).

[4] The same balloon dilatation device can be used for TIPS dilatation and dilatation of the endoprosthesis following implantation.

INTENDED USE/INDICATIONS FOR USE

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.

CONTRAINDICATIONS

There are no known contraindications for this device.

WARNINGS

The risks and potential adverse effects of creating a TIPS in patients with pre-existing conditions (such as those listed below) must be considered relative to the potential benefits of this procedure:

1. Patients with known allergies or sensitivity to nitinol (nickel titanium).
2. Patients with severe hepatic encephalopathy which is not controlled by medical therapy.
3. Increased cardiac output, increased central venous system pressure, increased pulmonary wedge pressure and a fall in systemic vascular resistance may occur immediately after the procedure. Patients with heart failure, pulmonary hypertension or elevated central venous pressure should be carefully evaluated prior to the procedure and monitored closely afterwards.
4. Patients should be monitored closely following the procedure for worsening hepatic encephalopathy. Those patients who develop hepatic encephalopathy that is not responsive to medical therapy may require reduction or occlusion of the TIPS tract to control the symptoms.
5. Stents that extend too far into the portal vein or inferior vena cava at the time of the TIPS procedure may cause difficulties with the formation of vascular anastomoses during liver transplant surgery.
6. Any reversible coagulopathy or bleeding diathesis should be corrected prior to the creation of the TIPS tract.
7. Successful TIPS placement may not be feasible in patients with cavernous portal vein occlusion, non-cavernous portal vein obstruction, or splenic vein thrombosis.
8. The safety and effectiveness of the device have not been evaluated in subjects with the following conditions:
    a. Primary or extensive metastatic hepatic malignancy.
    b. Polycystic liver disease.
    c. Budd-Chiari syndrome.
    d. Severe or rapidly progressive hepatic failure.
    e. Unrelieved biliary obstruction.

Inadvertent, partial, or failed deployment of the device or device migration may require surgical intervention.

PRECAUTIONS

- The GORE® VIATORR® TIPS Endoprosthesis should only be used by physicians trained in its use and familiar with hepatic interventional radiological procedures including TIPS. The implantation procedure should be performed only at facilities where surgical expertise is available if necessary.
- Safety and effectiveness in children under the age of 18 has not been established.
- The GORE® VIATORR® TIPS Endoprosthesis is intended for single use only and should not be resterilized.
- 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.
- Follow the Instructions for Use supplied with all accessories used in conjunction with the GORE® VIATORR® TIPS Endoprosthesis.
- The device should only be delivered and deployed using the supplied delivery system.
- 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.
- If any evidence of sheath kinking has occurred, it must be removed and replaced with a new one or GORE® VIATORR® TIPS Endoprosthesis advancement and / or delivery will be compromised.
- 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.
- Do not attempt to deploy the device or manipulate the delivery system without a guidewire or fluoroscopic guidance.
- 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 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.
- The graft-lined portion of the GORE® VIATORR® TIPS Endoprosthesis should completely cover the intrahepatic tract 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.
- 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.
- Prophylactic antibiotic treatment is recommended for patients undergoing periodontal procedures following implantation.
- Ultrasonic visualization of the lumen of the graft-lined region may be difficult immediately following implantation, and through five days post-implantation.

MAGNETIC RESONANCE IMAGING (MRI)

MR Conditional

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 3.0W/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 1.9ºC at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 3.0W/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 1.9ºC at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 2.8W/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

Two clinical studies were conducted in the United States (US) to evaluate the GORE® VIATORR® TIPS Endoprosthesis (also referred to as the "VIATORR® Device") for use in *de novo* TIPS and TIPS revision. These studies are referred to as the "Primary *De Novo* Study" and the "TIPS Revision Cohort." This Instructions for Use contains the results of both of these clinical studies.

A US multicenter, randomized, controlled study was conducted at 14 centers and enrolled 253 subjects (125 test subjects and 128 control subjects) and provides the basis of the observed adverse event rates for the VIATORR® Device *de novo* TIPS group (i.e., > 2%) (**Table 2**). Subjects were also eligible for TIPS revision with the VIATORR® Device, and the observed adverse event rates from the cohort whose TIPS was revised with the VIATORR® Device (i.e., > 5%) are summarized in **Table 3**.

Table 2: Primary *De Novo* Study: Adverse Events

Adverse Event	VIATORR® Device Group (N = 125)	WALLSTENT® Device Group (N = 128)
Encephalopathy	47 (37.6%)	54 (42.2%)
Ascites	26 (20.8%)	25 (19.5%)
Hydrothorax	11 (8.8%)	6 (4.7%)
Anemia	11 (8.8%)	10 (7.8%)
GI Other/Bile Duct	11 (8.8%)	3 (2.3%)
PSG > 12 mmHg	10 (8.0%)	26 (20.3%)
Fever	10 (8.0%)	5 (3.9%)
Lower Extremity Edema	8 (6.4%)	8 (6.3%)
Pulmonary Failure	7 (5.6%)	4 (3.1%)
Hypotension	7 (5.6%)	1 (0.8%)
Renal Dysfunction	6 (4.8%)	8 (6.3%)
Pneumonia	6 (4.8%)	4 (3.1%)
Urinary Tract Infection	6 (4.8%)	2 (1.6%)
Myocardial Infarction	6 (4.8%)	2 (1.6%)
Cardiac Other	6 (4.8%)	6 (4.7%)
Sepsis	5 (4.0%)	4 (3.1%)
Liver Failure	5 (4.0%)	10 (7.8%)
Coagulopathy	5 (4.0%)	2 (1.6%)
Other Infection	5 (4.0%)	9 (7.0%)
Bowel Other	5 (4.0%)	8 (6.3%)
Upper GI Bleed	4 (3.2%)	0 (0.0%)
Liver Other	4 (3.2%)	2 (1.6%)
Congestive Heart Failure	4 (3.2%)	4 (3.1%)
Electrolyte Imbalance	4 (3.2%)	3 (2.3%)
Spontaneous Bacterial Peritonitis	3 (2.4%)	2 (1.6%)
Stenosis	3 (2.4%)	33 (25.8%)
Hepatic Vein Stenosis	3 (2.4%)	3 (2.3%)
Pulmonary Edema	3 (2.4%)	1 (0.8%)

Table 3: TIPS Revision Cohort: Adverse Events

Adverse Event	Number of Subjects (%)
Ascites	5 (17.9%)
Encephalopathy	2 (7.1%)
Anemia	2 (7.1%)
Prosthesis Malposition	2 (7.1%)
Non-Variceal Bleeding	2 (7.1%)
Electrolyte Imbalance	2 (7.1%)
Bowel Other	2 (7.1%)

Post-TIPS Hepatic Encephalopathy

Reported adverse events for encephalopathy post-*de novo* TIPS were 37.56% and 42.2% in the VIATORR® Device and WALLSTENT® Device groups, respectively, during the course of the six-month follow-up period. Twenty-nine (23.2%) VIATORR® Device and 33 (25.8%) WALLSTENT® Device subjects had an early (≤ 30 days) adverse event of encephalopathy reported (p = 0.663). Late (> 30 days) adverse events for encephalopathy were reported for 22 (18.8%) VIATORR® Device and 24 (22.0%) WALLSTENT® Device subjects (p = 0.621).

Death

Forty (40) subjects died while enrolled in the *de novo* study, 18 in the VIATORR® Device group and 22 in the WALLSTENT® Device group (p = 0.607). Most (82.5%) occurred > 30 days after the procedure. No death was believed to be device-related. Of the subjects who died prior to the six-month follow-up, 17 had symptoms of hepatic encephalopathy at the time of death (6 VIATORR® Device subjects and 11 WALLSTENT® Device subjects).

Thrombosis

Thrombus formation in the TIPS usually occurs early and may be caused by hypercoaguable syndromes, inadequate coverage of the TIPS tract, leakage of bile into the tract, or technical complications during the procedure. During the clinical trial, thrombosis of the TIPS during the procedure was identified in 12.8% (16/125) VIATORR® Device subjects and the majority (63%) of these cases had thrombus formation within the splenic and / or portal veins (not within the device). Nine subjects needed no reintervention, six had the thrombus successfully removed during the procedure with angioplasty or thrombectomy, and one subject had an additional device placed. Only two cases of post-procedure thrombus formation with VIATORR® Device subjects were observed, and both required a reintervention to re-establish patency.

Revision

Revision of an existing TIPS may be considered if shunt failure is suspected and confirmed by venography or elevated portosystemic gradients. The **Precautions**, **Directions for Use**, and **Post-placement Management of the TIPS** sections provide further information that should be followed regarding TIPS revision.

Other adverse events that may occur and / or require intervention due to the TIPS procedure or underlying liver disease include, but are not limited to the following adverse events:

- Cerebrovascular accident
- Myocardial infarction
- Disseminated intravascular coagulopathy
- ARDS
- Pulmonary embolism
- Shock
- Congestive heart failure
- Pulmonary hypertension
- Renal failure
- Hepatic infarction
- Liver failure
- Vessel rupture
- Gall bladder puncture
- Hemoperitoneum
- Hemobilia
- Hepatic artery injury
- Sepsis
- Hemolysis
- Variceal hemorrhage
- Bile duct injury
- Hyperbilirubinemia secondary to bile duct puncture
- Portal vein injury
- Subcapsular hematoma
- Transient contrast-induced renal failure
- Transient pulmonary edema
- Stent malposition/migration
- Deployment failure
- Radiation injury
- Pneumonia
- Fever
- Entry site hematoma
- Arteriovenous fistula formation
- Pseudoaneurysm formation
- Hepatic artery thrombosis
- Shunt stenosis or occlusion
- Hepatic or portal vein occlusion or stenosis
- Recurrence of ascites
- Recurrence of varices

DEVICE RELATED ADVERSE EVENT REPORTING

Any adverse event involving the GORE® VIATORR® TIPS Endoprosthesis should be reported to W. L. Gore & Associates immediately. To report an event in the US, call 800.437.8181. Outside the US, contact your local technical representative.

SUMMARY OF US CLINICAL STUDIES

Two clinical studies were conducted with the GORE® VIATORR® TIPS Endoprosthesis: a multicenter, randomized, controlled study of the device for *de novo* TIPS, and a prospective, multicenter, single-arm study of the device for TIPS revision.

PRIMARY *DE NOVO* STUDY

Primary *De Novo* Study: Objectives

The primary objective of the *de novo* TIPS clinical study was to evaluate the safety and effectiveness of the GORE® VIATORR® TIPS Endoprosthesis for treating portal hypertension and its associated complications. Safety was determined by evaluating whether the proportion of VIATORR® Device subjects with adverse events was comparable to that of the control WALLSTENT® Device subjects. Effectiveness was based on primary effectiveness endpoint of primary patency at six months. Primary patency was a composite endpoint of the portosystemic gradient or PSG and percent diameter stenosis or % DS (PSG ≤ 12 mmHg and % DS ≤ 50) without reintervention. Secondary effectiveness endpoints included technical success, hemodynamic success and venographic success post-procedure, and primary-assisted patency, and secondary patency through the study period.

Primary *De Novo* Study: Study Design

This multicenter, randomized, controlled study was designed to compare subjects treated with the GORE® VIATORR® TIPS Endoprosthesis to those treated with the WALLSTENT® Endoprosthesis. A total of 253 subjects (125 VIATORR® Device subjects and 128 WALLSTENT® Device subjects) were enrolled at 14 investigational sites in the US. Study follow-up evaluations were scheduled for pre-discharge, one month, three months, and six months. An independent Core Laboratory reviewed venographic films to determine device patency. Please refer to **Table 4** for subject follow-up and disposition.

Table 4: Primary *De Novo* Study: Subject Follow-up and Disposition[1]

Treatment	VIATORR® TIPS Endoprosthesis (N = 125)			WALLSTENT® Endoprosthesis (N = 128)		
	1 Month	3 Months	6 Months	1 Month	3 Months	6 Months
Number of Subjects Available[2]	125 (100.0%)	120 (96.0%)	108 (86.4%)	128 (100.0%)	105 (86.4%)	90 (70.3%)
Number with Exam	112 (89.6%)	100 (83.3%)	80 (74.1%)	97 (75.8%)	82 (78.1%)	65 (72.2%)
Number with Exam Outside of Window	2 (1.6%)	1 (0.8%)	5 (4.6%)	3 (2.3%)	1 (1.0%)	5 (5.6%)
Number Without Exam	11 (8.8%)	19 (15.8%)	23 (21.3%)	28 (21.9%)	22 (21.0%)	20 (22.2%)
Reason for Withdrawal:						
Death	1 (0.8%)	8 (6.7%)	9 (8.3%)	9 (7.0%)	4 (3.8%)	9 (10.0%)
Liver Transplant	2 (1.6%)	4 (3.3%)	7 (6.5%)	2 (1.6%)	8 (7.6%)	6 (6.7%)
Lost to Follow-up	0 (0.0%)	0 (0.0%)	6 (5.6%)	0 (0.0%)	0 (0.0%)	1 (1.1%)
Subject Choice / Other	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)	2 (1.9%)	1 (1.1%)
Revision[3]	2 (1.6%)	0 (0.0%)	1 (0.9%)	10 (7.8%)	1 (1.0%)	3 (3.3%)
Number of Subjects with Primary Patency Assessment (6 Months Only)			77[4] (61.6%)			57[4] (44.5%)
Number of Subjects with No or Incomplete Primary Patency Assessment (6 Months Only)			11 (8.8%)			18 (14.1%)

1 Subjects who withdrew in the same interval as a completed visit are reported as a withdrawal in the next interval.

2 The denominators for the Number of Subjects Available, Number of Subjects with Primary Patency Assessment, and Number of Subjects with No or Incomplete Primary Patency Assessment are the number of subjects in each treatment group. The denominators for all other percentage calculations (with the exception of primary patency assessments) are the Number of Subjects Available in each treatment group at each interval.

3 Subjects withdrawn from the primary *de novo* study and enrolled in the subsidiary TIPS revision study.

4 Subjects with an assessment of primary patency at six months and subjects who had failed primary patency by having a reintervention prior to the six-month evaluation but were not enrolled in the subsidiary TIPS revision study.

Primary *De Novo* Study: Subject Demographics

Table 5 compares the subject characteristics, including etiology of underlying liver disease, indication for TIPS, and comorbidities.

Table 5: Comparison of Subject Characteristics

Parameter	Primary *De Novo* Study		
	VIATORR® Device Group (N = 125)	WALLSTENT® Device Group (N = 128)	p-value
Gender			0.002*
Male	93 (74.4%)	71 (55.5%)	
Female	32 (25.6%)	57 (44.5%)	
Age			0.971‡
Mean (years)	53	54	
Ethnicity			0.778†
White or Caucasian	96 (76.8%)	98 (76.6%)	
Hispanic or Latino	18 (14.4%)	22 (17.2%)	
Black or African American	4 (3.2%)	2 (1.6%)	
American Indian or Alaska Native	0 (0.0%)	1 (0.8%)	
Asian	1 (0.8%)	0 (0.0%)	
Pacific Islander or Hawaii Native	0 (0.0%)	1 (0.8%)	
Other	1 (0.8%)	0 (0.0%)	
Unknown	5 (4.0%)	4 (3.1%)	
Primary Indication			0.467†
Variceal Bleeding	45 (36.0%)	45 (35.2%)	
Ascites	72 (57.6%)	76 (59.4%)	
Gastropathy	3 (2.4%)	0 (0.0%)	
Hepatic Hydrothorax	4 (3.2%)	4 (3.1%)	
Other	1 (0.8%)	3 (2.3%)	
Liver Disease Etiology			
Hepatitis B	11 (8.8%)	7 (5.5%)	0.337*
Hepatitis C	59 (47.2%)	56 (43.8%)	0.615*
Alcoholic Cirrhosis	79 (63.2%)	60 (46.9%)	0.011*
Cryptogenic	13 (10.4%)	23 (18.0%)	0.105*
Other	17 (13.6%)	21 (16.4%)	0.599*
Comorbidities			
Hepatic Failure	20 (16.0%)	21 (16.4%)	1.000*
Pulmonary Hypertension	0 (0.0%)	3 (2.3%)	0.247*
Renal Failure	0 (0.0%)	3 (2.3%)	0.247*
Pulmonary Edema	1 (0.8%)	1 (0.8%)	1.000*
Child-Pugh Class			0.611‡
A	14 (11.2%)	15 (11.7%)	
B	85 (68.0%)	91 (71.1%)	
C	23 (18.4%)	20 (15.6%)	
Unable to Calculate	3 (2.4%)	2 (1.6%)	
Mental Status Score			0.191‡
0	100 (80.0%)	110 (85.9%)	
1	20 (16.0%)	16 (12.5%)	
2	3 (2.4%)	2 (1.6%)	
3	1 (0.8%)	0 (0.0%)	
4	1 (0.8%)	0 (0.0%)	
MELD Score			0.737‡
6 - 10	47 (37.6%)	42 (32.8%)	
11 - 15	61 (48.8%)	64 (50.0%)	
16 - 20	13 (10.4%)	18 (14.1%)	
21 - 24	2 (1.6%)	1 (0.8%)	
Unable to Calculate	2 (1.6%)	3 (2.3%)	

* p-values based on 2 by 2 Fisher's Exact Test to compare percentages between treatment groups.

‡ p-values based on Wilcoxon Rank Sum Test to compare the two treatment groups.

† p-values based on Fisher's Exact Test to compare distribution across categories between the two treatment groups.

Primary *De Novo* Study: Efficacy Results

Primary Patency At Six-Months

The primary effectiveness endpoint for the *de novo* TIPS study was primary patency at six months. Primary patency was a composite endpoint (i.e., PSG ≤ 12 mmHg and % DS ≤ 50). The primary efficacy (alternative) hypothesis of this study was that the proportion of subjects successful with regard to primary patency is greater for subjects treated with the VIATORR® Device than for subjects treated with the WALLSTENT® Device. Three analyses are presented: Intent-to-treat (ITT), modified intent-to-treat (MITT) and as treated/evaluable per protocol (AT). All subjects enrolled in the study were included in the ITT analysis. In the MITT analysis, subjects who died or were withdrawn from the study due to liver transplant were censored from the analysis. The AT analysis included those subjects with an assessment of primary patency at six months and subjects who had failed primary patency by having a reintervention prior to the six-month evaluation (e.g., reintervention, enrollment in the subsidiary revision study). In the three analyses, primary patency of the VIATORR® Device group was superior to that of the WALLSTENT® Device group ($p < 0.001$). Therefore, the primary efficacy endpoint was met. See **Table 6**.

Table 6: Primary *De Novo* Study: Primary Patency at Six-Months

Analysis	Primary *De Novo* Study		
	VIATORR® Device Group (N = 125)	WALLSTENT® Device Group (N = 128)	p-value
Intent-to-Treat			
Number of Subjects†	126	127	
Success	57 (45.2%)	28 (22.0%)	< 0.001*
Failure	69 (54.8%)	99 (78.0%)	
Modified Intent-to-Treat			
Number of Subjects†	98	94	
Success	57 (58.2%)	28 (29.8%)	< 0.001*
Failure	41 (41.8%)	66 (70.2%)	
As Treated / Evaluable Per Protocol			
Number of Subjects	80	71	
Success	57 (71.3%)	28 (39.4%)	< 0.001*
Failure	23 (28.8%)	43 (60.6%)	

* p-value based on one-sided Fisher's Exact Test of the null hypothesis that the proportion of successes for the VIATORR® Device group is less than or equal to that for the WALLSTENT® Device group versus the alternative hypothesis that the proportion of successes of primary patency is greater for the VIATORR® Device group than for the WALLSTENT® Device group.

† Number of subjects is based on device received.

Effectiveness Post-Procedure

More procedures with the VIATORR® Device were accomplished with only one device as compared to the WALLSTENT® Device procedures, and there was a statistically significant difference between treatment groups for the distribution of the number of devices required per subject to perform the TIPS procedure ($p < 0.001$). See **Table 7**.

Table 7: Primary *De Novo* Study: Comparison Between VIATORR® Device Group and WALLSTENT® Device Group in the Number of Devices Implanted

Number of Devices	VIATORR® Device Group	WALLSTENT® Device Group	
Number of Subjects	**125**	**128**	**p-value**
One Device	91 (72.8%)	59 (46.1%)	< 0.001*
Two Devices	33 (26.4%)	54 (42.2%)	
Three Devices	1 (0.8%)	14 (10.9%)	
Four Devices	0 (0.0%)	1 (0.8%)	

* p-values base on Kruskal-Wallis (Wilcoxon Rank Sum) test comparing the number of devices per subject between the two treatment groups.

Technical success, hemodynamic success, and venographic success were assessed post-*de novo* TIPS procedure. All procedures in both treatment arms were a technical success. There were higher percentages of hemodynamic and venographic successes in the VIATORR® Device treatment group. See **Table 8**.

Table 8: Primary *De Novo* Study: Technical Success, Hemodynamic Success, and Venographic Success Post-Procedure

Secondary Endpoint	Primary *De Novo* Study		
	VIATORR® Device Group (N = 125)	WALLSTENT® Device Group (N = 128)	95% CI*
Technical Success[a]			
Success	125 (100.0%)	128 (100.0%)	(-0.8%, 0.8%)
Failure	0 (0.0%)	0 (0.0%)	
Hemodynamic Success[b] (n)†	110	119	
Success	104 (94.5%)	110 (92.4%)	(-5.2%, 9.4%)
Failure	6 (5.5%)	9 (7.6%)	
Venographic Success[c] (n)‡	125	125	
Success	120 (96.0%)	114 (91.2%)	(-2.0%, 1.6%)
Failure	5 (4.0%)	11 (8.8%)	

† Subjects with PSG ≤ 12 mmHg pre-procedure were excluded from the analysis. The denominator for percentage is based on subjects with pre-procedure PSG > 12 mmHg.

‡ Number of subjects with nonmissing values of % Diameter Stenosis. These are the denominators for the percentages.

* 95% confidence interval for the difference between treatment groups in the proportion of successes.

a Technical success was defined as the successful delivery and deployment of the device to create (or revise) an intrahepatic shunt connection between the portal and hepatic circulation.

b Hemodynamic success was defined as the reduction of PSG to ≤ 12 mmHg.

c Venographic success was defined as post-implant residual DS ≤ 30%.

Additional Effectiveness Analyses Throughout the Study Period

Kaplan-Meier survival estimates were calculated for the time to loss of patency and time to reintervention or revision by treatment group (**Figures 3** and **4**, respectively). The differences in time to loss of patency ($p < 0.001$) and time to reintervention ($p = 0.007$) through six months were statistically significant between the two treatment groups, with the VIATORR® Device group exhibiting a consistently higher proportion of subjects without loss of patency and a higher proportion of subjects remaining free from reintervention than the WALLSTENT® Device group.

Figure 3: Primary *De Novo* Study: Kaplan-Meier Estimate of Time to Loss of Patency by Treatment Group

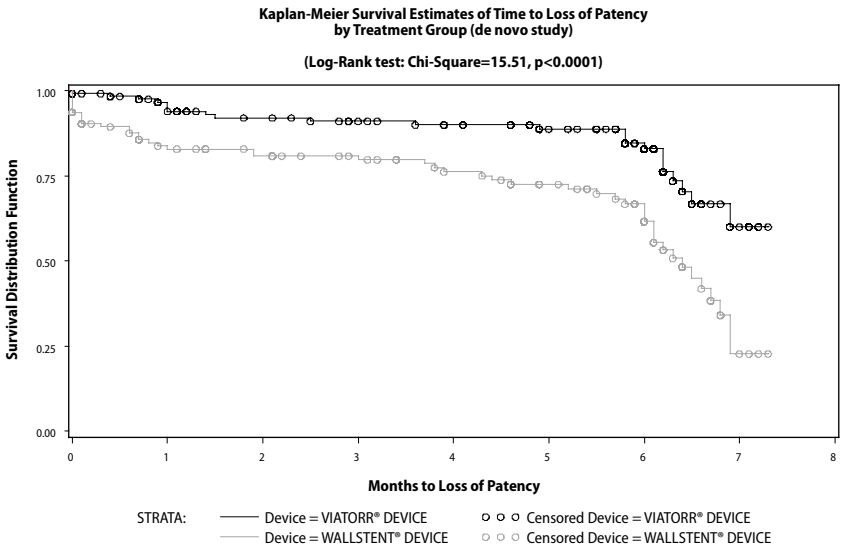
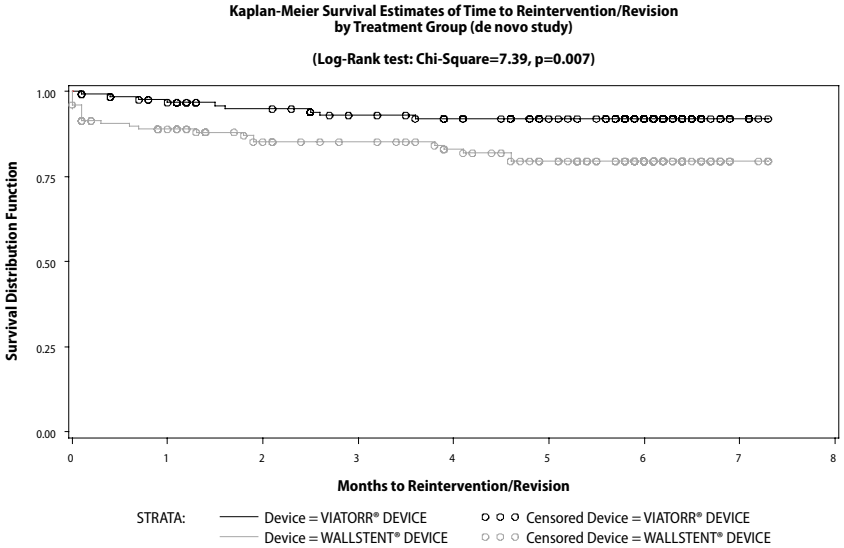


Figure 4: Primary *De Novo* Study: Kaplan-Meier Survival Estimates of Time to Reintervention/Revision



The proportion of VIATORR® Device subjects requiring a reintervention to maintain or re-establish patency was statistically significantly lower than for WALLSTENT® Device subjects ($p < 0.001$). The ratio of VIATORR® Device to WALLSTENT® Device subjects requiring an intervention to maintain or re-establish patency was 1 : 2.5. On an intervention level, the resulting ratio of VIATORR® Device to WALLSTENT® Device interventions was 1 : 2.4. Please refer to **Table 9**.

Table 9: Primary *De Novo* Study: Reinterventions to Maintain or Re-Establish Patency[1]

	VIATORR® Device Group	**WALLSTENT® Device Group**	**Reintervention Rate (VIATORR® Device: WALLSTENT® Device Group)**
PSG > 12 Only	11	12	
% DS > 50 Only	1	3	
PSG > 12 and % DS > 50	1	19	
PSG > 12 and % DS Unknown	1	2	
Neither (Primary Assisted Patency)	2	3	
Total Reinterventions	16 (15 Subjects)	39 (37 Subjects)	Number of Reinterventions **1 : 2.4** Number of subjects requiring a reintervention **1 : 2.5 ($p < 0.001$[1])**

[1] p-value associated with the chi-square test of the difference between treatment groups in the proportions of subjects with reinterventions or revisions. VIATORR® Device subjects required significantly fewer reinterventions.

The change in the mean % DS at the time of the completion of the procedure compared to the time of the evaluation of primary patency was statistically significantly different between treatment groups ($p < 0.001$). The mean % DS for VIATORR® Device subjects at the time of evaluation of primary patency compared to the completion of the procedure was 2.3 as compared to 23.5 for WALLSTENT® Device subjects. See **Table 10**.

Table 10: Primary *De Novo* Study: Change in Percent Diameter Stenosis (% DS) from Completion of Procedure to Time of Evaluation of Primary Patency

	VIATORR® Device Group (N = 125)	WALLSTENT® Device Group (N = 128)	p-value
Number of Subjects	**79**	**70**	
	Change in % DS	**Change in % DS**	
At six months or time of evaluation of primary patency			
n*	78	70	
Mean	2.3	23.5	< 0.001
Std Dev	18.48	25.71	
Range	(-25.0, 100.0)	(-36.0, 92.0)	

* n = Number of observations for each variable.

In addition, VIATORR® Device subjects had a significantly higher proportion of hemodynamic successes (PSG ≤ 12 mmHg) at the time of the primary patency evaluation. The percentage of VIATORR® Device successes was 27.6% higher than that of the WALLSTENT® Device successes with a 95% CI around this difference of 10.7% to 44.5%. See **Table 11**.

Table 11: Primary *De Novo* Study: Hemodynamic Success at Time of Evaluation of Primary Patency

	VIATORR® Device Group (N = 125)		WALLSTENT® Device Group (N = 128)		95% CI*
	n = 71		n = 68		
	Success	**Failure**	**Success**	**Failure**	
Hemodynamic Success	54 (76.1%)	17 (23.9%)	33 (48.5%)	35 (51.5%)	(10.7%, 44.5%)

* 95% confidence interval for the difference between treatment groups in the percentage of successes.

TIPS REVISION COHORT

TIPS Revision: Objectives

The primary objective was to evaluate the safety and effectiveness of the GORE® VIATORR® TIPS Endoprosthesis when used to revise malfunctioning TIPS. The effectiveness and safety endpoints were hemodynamic success (PSG ≤ 12 mmHg at completion of procedure) of the TIPS revision and subject incidence of adverse events. Secondary effectiveness endpoints included technical success.

TIPS Revision: Study Design

This was a prospective, multicenter, single-arm study with the VIATORR® Device. The TIPS revision cohort consisted of 36 subjects enrolled at the same investigational sites as in the primary *de novo* study. Study follow-up evaluations were scheduled for pre-discharge, one month, and six months. Please refer to **Table 12** for subject follow-up and disposition.

Table 12: TIPS Revision: Subject Follow-up and Disposition[1]

Disposition	TIPS Revision Cohort (N = 36)	
	1 Month	6 Months
Number of Subjects Available[2]	35 (97.2%)	33 (91.7%)
Number with Exam	31 (88.6%)	29 (87.9%)
Number with Exam Outside of Window	3 (8.6%)	3 (9.1%)
Number without Exam	1 (2.9%)	1 (3.0%)
Death	0 (0.0%)	1 (3.0%)
Liver Transplant	1 (2.9%)	2 (6.1%)

[1] Subjects who withdrew in the same interval as a completed visit are reported as a withdrawal in the next interval.

[2] The denominators for the Number of Subjects Available are the number of subjects in the TIPS Revision Cohort. The denominators for all other percentage calculations are the Number of Subjects Available at each interval.

TIPS Revision: Subject Demographics

Table 13 provides the subject characteristics, including etiology of underlying liver disease, indication for *de novo* TIPS, and comorbidities.

Table 13: TIPS Revision: Subject Characteristics

Parameter	VIATORR® TIPS Device Revision (N = 36)
Gender	
Male	30 (83.3%)
Female	6 (16.7%)
Age	
Mean (years)	52.9
Ethnicity	
White or Caucasian	29 (80.6%)
Hispanic or Latino	3 (8.3%)
Black or African American	2 (5.6%)
American Indian	1 (2.8%)
Unknown	2 (5.6%)
Primary Indication	
Variceal Bleeding	14 (38.9%)
Ascites	22 (61.1%)
Liver Disease Etiology	
Hepatitis B	2 (5.6%)
Hepatitis C	14 (38.9%)
Alcoholic Cirrhosis	21 (58.3%)
Cryptogenic	2 (5.6%)
Other	5 (13.9%)
Comorbidities	
Hepatic Failure	4 (11.1%)
Pulmonary Edema	1 (2.8%)
Child-Pugh Class	
A	7 (19.4%)
B	20 (55.6%)
C	7 (19.4%)
Unable to Calculate	2 (5.6%)
Mental Status Score	
0	30 (83.3%)
1	6 (16.7%)
2	0 (0.0%)
3	0 (0.0%)
4	0 (0.0%)
MELD Score	
6 - 10	15 (41.7%)
11 - 15	13 (36.1%)
16 - 20	4 (11.1%)
21 - 24	2 (5.6%)
Unable to Calculate	2 (5.6%)

TIPS Revision: Results

The primary effectiveness endpoint for the TIPS revision cohort was hemodynamic success post-revision procedure (i.e., PSG ≤ 12 mmHg).

Thirty-two revision subjects had PSG ≤ 12 mmHg post-procedure (88.9%). Thus, a hemodynamic success proportion of 0.89 (32/36) was observed. The exact binomial probability associated with the test of the alternative hypothesis, Ha: $P_R > 0.75$, was 0.03. Therefore, the efficacy endpoint was met.

As a supplemental analysis for looking at hemodynamic success or PSG post-procedure, the mean PSG post-procedure was compared against 12 mmHg. A one-tailed t-test was used to test the null hypothesis that the mean post-procedure PSG is ≥ 12, against the alternative hypothesis that the mean PSG post-procedure is < 12. The mean post-procedure PSG was 8.8 mmHg. Results of the statistical test were $t = 3.92$ with $p < 0.001$, demonstrating that the mean PSG of the revision cohort was significantly less than 12 mmHg post-revision procedure.

Conclusions Drawn from the Clinical Studies

The clinical investigations of the GORE® VIATORR® TIPS Endoprosthesis provide valid scientific evidence and demonstrate with a reasonable assurance that the device is safe and effective for *de novo* and revision TIPS.

In the primary *de novo* study, the primary effectiveness endpoint was met ($p < 0.001$), demonstrating that there was a greater proportion of VIATORR® Device subjects with primary patency at six-months than WALLSTENT® Device subjects. In addition, there was less need for reintervention or TIPS revision to maintain patency. More procedures with the VIATORR® Device were accomplished with only one device as compared to the WALLSTENT® Device procedures, and there was a statistically significant difference between treatment groups in the number of devices required to perform the TIPS procedure ($p < 0.001$).

In the primary *de novo* study, the proportions of subjects with at least one adverse event were comparable between the two treatment groups, and the endpoint was met. The adverse events in the study were consistent with those expected and previously reported for the disease population, and no new adverse events were identified for the GORE® VIATORR® TIPS Endoprosthesis.

For the revision cohort, a hemodynamic success proportion of 0.89 (32/36) was observed and the endpoint was met.

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
- 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 (e.g., COOK® FLEXOR® CHECK-FLO® II).
- ≤ 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 (i.e., no greater than the labeled diameter of the device to be implanted) within the transjugular intrahepatic portosystemic shunt (TIPS) utilizing nominal pressure according to the manufacturer's instructions. Note: to enhance tactile feel and to minimize the potential for pulling the unlined, chain-link portion of the device into the liver parenchyma, an undersized balloon from the selected device labeled diameter may be used to pre-dilate the *de novo* parenchymal/TIPS tract.
2. Evaluate the TIPS fluoroscopically noting the shunt's dimensions.
3. Measurements: when utilizing a pig-tailed marker catheter, add 1 cm to the total length measurement of the TIPS tract (i.e., parenchymal tract/portal vein junction to hepatic vein/inferior vena cava ostium). When utilizing digital measurements, if the measurement is of the outside curvature of the TIPS tract, an additional 1 cm to the total length measurement is not necessary.
4. 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 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 shipping mandrel from the leading end 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 flushing port on the catheter adapter (see **Figure 2**). Tighten the hemostatic guidewire port while flushing to prevent air entrapment or back-flushing. To ensure full device flush, place finger over distal end of access sleeve and flush side-port until saline emerges from the proximal end of the access sleeve.
   c) After flushing the delivery system, remove the syringe, and loosen the hemostatic guidewire port.

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. 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**).
3. Using fluoroscopic guidance and inserted dilator, for *de novo* procedures, carefully position the leading end of the hemostatic introducer sheath well into the central portal circulation (≥ 3.0 cm). For TIPS revision procedures, align the distal end of the introducer sheath to the distal end of the stent being revised. Note: This is a pre-requisite for implantation. Care must be taken not to damage the internal lumen of the 10 Fr introducer sheath when passing the Colapinto needle for tract creation. Damage to the internal lumen of the 10 Fr introducer sheath may prevent passage of the GORE® VIATORR® TIPS Endoprosthesis into the sheath.
4. Carefully remove the dilator. Note: Ensure that there are no kinks in the hemostatic introducer sheath prior to insertion of the delivery catheter.
5. With the delivery system held as straight as possible, insert the trailing end of the guidewire into the leading tip of the delivery system.
6. Use the access sleeve to penetrate the hemostatic valve of the hemostatic introducer sheath. Advance the access sleeve, together with the delivery catheter, completely through the hemostatic valve and into the bottom of the valve body 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 hemostatic valve (this indicator is calibrated for large valve assemblies and may not align for small valve assemblies).
7. 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 tube. 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 of the sheath (see **Table 1**). Do not reuse the device if damaged. If the device is partially deployed outside the access sleeve, do not attempt to recapture or reuse.
8. Withdraw the access sleeve from the hemostatic valve of the introducer sheath.
9. Advance the delivery catheter through the hemostatic introducer sheath until the radiopaque marker on the leading tip of the delivery catheter aligns with the leading end of the hemostatic introducer sheath in the portal vein or at the end of the device being revised. If advancement of the device is difficult, verify that there are no kinks in the hemostatic introducer sheath. If kinks are noted, remove and replace the hemostatic introducer sheath. Do not attempt to re-straighten a kinked introducer sheath.
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 *de novo* TIPS, and is within the portal vein. For TIPS revision procedures, the circumferential radiopaque marker band is located at the portal vein/parenchymal tract junction to prevent entrapment of the unlined, chain-link portion with the wire ends of the stent being revised. 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. Please refer to Measurements in Section A.3.
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 unlined, chain-link portion of the implant including the entire unlined region and part of the graft-lined region (approximately 5 mm) 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 at the portal vein/parenchymal tract junction.

14. Once the optimal device position is verified and the hemostatic introducer sheath is fully withdrawn, deploy the remaining graft-lined region 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 and maintaining light tension on the catheter, untwist the screw-connector at the base of the GORE® SIM-PULL Deployment System knob. Note: maintaining light tension on the catheter during deployment of the graft-lined region of the endoprosthesis will facilitate seal of the lined region to the portal vein/parenchymal tract junction and prevents sliding of the graft-lined region back into the portal vein. Smoothly pull the deployment knob, attached to the deployment line, straight out from the hub assembly until the graft-lined region of the implant is fully deployed and released from the delivery catheter. 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. Once the stent is released from the delivery catheter, excessive force should not be used to remove the delivery catheter from the GORE® VIATORR® TIPS Endoprosthesis. If unable to remove the delivery catheter through the GORE® VIATORR® TIPS Endoprosthesis, readvance the delivery catheter, rotate 90°, and reattempt removal.
16. 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. Note: if placing a second GORE® VIATORR® TIPS Endoprosthesis to provide adequate length coverage of the TIPS tract (portal vein/parenchymal tract junction to hepatic vein/inferior vena cava ostium), ensure ≥ 2 cm of lined graft to lined graft overlap of the devices.
17. Care should be taken to not displace a deployed GORE® VIATORR® TIPS Endoprosthesis by re-introduction of an introducer sheath or working catheter back through the endoprosthesis.
18. Following delivery catheter removal, the portal systemic pressure gradient should be measured and the endoprosthesis must be secured within the TIPS by balloon dilatation. The balloon selected for this purpose should be no greater than the diameter of 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.
19. 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.

POST-PLACEMENT MANAGEMENT OF THE TIPS

Institutions performing TIPS should have an established program for TIPS surveillance to try and maintain patency and prevent symptom recurrence. It is recommended that Doppler ultrasound be performed 72 hours post-TIPS and at specified intervals (per institutional surveillance guidelines) such as 3, 6, and 12-months post-TIPS and yearly thereafter to assess patency of the shunt.

Recatheterization of the TIPS is recommended for ultrasound findings suggesting shunt dysfunction or for recurrence of the symptoms of portal hypertension for which the TIPS was performed. Reintervention (balloon dilation, deployment of additional endoprosthesis, thrombectomy) to maintain or re-establish patency may be necessary for confirmed cases of shunt stenosis, occlusion or thrombosis.

DEFINITIONS

 Use By

 Caution

 Consult Instructions for Use

 Do Not Resterilize

 Do Not Reuse

REF Catalogue Number

LOT Batch Code

SN Serial Number

 MR Conditional

Rx Only CAUTION: USA Federal Law restricts the sale, distribution,or use of this device to, by, or on the order of a physician.

STERILE Sterile

STERILE EO Sterilized using Ethylene Oxide

 Do Not Use if Package is Damaged

 Keep Dry

 Store in a Cool Place

 Catheter Working Length

 Delivery Profile

 Diameter

 Do Not Remove Access Sleeve

 Guidewire Compatibility

 Manufacturer

 Date of Manufacture

20026324

Manufacturer
W. L. Gore & Associates, Inc.
1505 North Fourth Street
Flagstaff, Arizona 86004
United States
Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763
Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

For international contact and additional product information,
visit **www.goremedical.com**

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