BD Liverty™ TIPS Stent Graft

Instructions for Use

BD

B06000 Rev.1/06-26

INSTRUCTIONS FOR USE

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

Read all instructions thoroughly. Information in the Instructions for Use should be discussed with the patient, at the discretion of the physician.

DEVICE DESCRIPTION

IMPLANT

The Liverty™ TIPS Stent Graft implant (Figure 1) is a flexible, self-expanding endoprosthesis comprised of expanded polytetrafluoroethylene (ePTFE) encapsulating a nitinol (nickel-titanium alloy) stent. The endoprosthesis is divided into two segments: a 2 cm long bare metal portal segment, and an ePTFE encapsulated segment in lengths from 4 cm to 10 cm. The inner surface of the ePTFE encapsulated segment is carbon impregnated.

The nominal inner diameter (ID) of the stent graft is 10 mm. When supplied, the mid segment of the 10 mm diameter device includes an ePTFE sleeve with a 6 mm or 8 mm diameter. After placement, the mid segment can be post-dilated and expanded to the desired inner diameter within the range of the supplied diameter (6 or 8 mm) to 10 mm to suit individual patient needs.

Figure 1: Liverty™ TIPS Stent Graft implant (as supplied)



X-RAY MARKERS

A highly radiopaque marker band indicates the transition from the bare to the covered stent graft segment (A). Three radiopaque markers indicate the proximal stent graft end (B) and three radiopaque markers indicate the distal stent graft end (C).

DELIVERY SYSTEM

The tri-axial, over-the-wire delivery system is illustrated in Figure 2. The inner catheter (not visible to the operator) contains the guidewire lumen. The inner catheter carries an atraumatic tip (D) at the distal end of the system and enters into a female Luer port (E) at the proximal end of the handle. A proximal, beige stability sheath (F) is connected to the distal end of the handle and remains stationary throughout the deployment process.

The distal catheter assembly (approximately 40 cm in length) consists of two segments. The transparent stent graft delivery sheath (G) which houses the compressed stent graft (implant), and a dark brown, smaller-diameter extension catheter (H). During stent graft deployment, the entire distal catheter assembly retracts towards the handle while the dark brown catheter (H) is drawn inside the beige stability sheath (F) until the stent graft is fully deployed. The inner surface of the stent graft delivery sheath has a hydrophobic coating.

Retraction of the distal catheter assembly and deployment of the bare metal segment of the implant is initiated by unlocking the red safety lock slider (I) and rotating the blue wheel (J) on the handle. A black push button on the top of the handle (K) must be pressed before the ePTFE encapsulated stent graft segment can be fully released.

Table 1: Key to Figure 2 delivery system schematic drawing

Reference	Corresponding Information
D	Delivery system tip
E	Female Luer port
F	Proximal beige stability sheath (stationary)
G	Distal transparent stent graft delivery sheath housing the compressed stent graft (retracts during deployment)
H	Distal dark brown catheter (retracts inside the beige stability sheath during deployment)
I	Red safety lock slider, allows release of bare metal segment into portal vein
J	Blue deployment wheel
K	Black push button, allows release of the covered stent graft segment

Figure 2: Delivery system schematic drawing



The numbers 1 through 4 are printed on the top of the handle (Figure 3). The numbers indicate the order in which the operator is to perform the different steps of stent graft deployment.

Figure 3: Top view of the handle in locked (left) and unlocked (right) positions



Table 2: Description of numbers on the handle

1	Slide the red safety lock slider towards the proximal end of the system to unlock the device
2	Rotate the wheel until the bare portion of the stent graft is released and resistance can be felt
3	Press the black push button
4	Continue with wheel rotation until the entire stent graft is released

The delivery system is compatible with 0.035 inch (0.89 mm) guidewires and 10F introducer sheaths and is available in a working length of 80 cm.

POST-DILATATION

After implantation of the Liverty™ TIPS Stent Graft, the device can be post-dilated with a commercially-available balloon dilatation catheter to the desired inner diameter. The maximum ID after post-dilatation is 10 mm for all stent grafts. See Figure 4 for the stent graft implant after maximum dilatation with a balloon dilatation catheter. Prolonged dilatation (at least 25 seconds) of the main tract may help to achieve a uniform expanded shunt lumen.

Figure 4: Stent graft implant after maximum dilatation with balloon dilatation catheter



INTENDED PURPOSE

The Liverty™ TIPS Stent Graft is intended for use by physicians experienced in the creation of a Transjugular Intrahepatic Portosystemic Shunt (TIPS) in adult patients suffering from complications of portal hypertension due to cirrhosis.

INDICATION FOR USE

The Liverty™ TIPS Stent Graft is indicated for the treatment of complications of portal hypertension.

CONTRAINDICATIONS

There are no known contraindications for the Liverty™ TIPS Stent Graft.

WARNINGS

- **DO NOT** use the device after the "Use By" date specified on the label.
- **DO NOT** use the device if the sterile packaging has been damaged or unintentionally opened prior to use.
- The Liverty™ TIPS Stent Graft is supplied **STERILE** (by ethylene oxide) and is intended for **SINGLE USE ONLY. DO NOT RESTERILIZE AND/OR REUSE** the device.
  Reuse, resterilization, reprocessing, and/or repackaging may create a risk to the patient or user; may lead to infection or compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure; and/or may lead to injury, illness, or death of the patient.

Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications or death.

- When placing a shunt with the final diameter of ≤ 8 mm, the leading 20 mm of the covered stent graft segment must be additionally dilated with an 8 mm balloon for at least 25 seconds. In the clinical study, thrombosis events were reported at a higher rate in patients with shunts of ≤ 8 mm diameter who did not undergo this focal dilatation.
- This device contains nitinol, an alloy made of nickel and titanium, and small components of tantalum and tungsten. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in this device, as well as the potential for allergy/hypersensitivity to these materials.
- The prophylactic use of antibiotics or anticoagulants is left to the discretion of the physician managing the patient.
- If multiple stent grafts are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol (nickel-titanium alloy)).
- The safety and effectiveness of the device has not been evaluated in the following:
  - Patients with known allergy or sensitivity to contrast media.
  - Patients with uncontrolled systemic infection, septicemia or bacteremia.
  - Patients who cannot be adequately pre-medicated.
  - Pediatric patients or in pregnant or breastfeeding women.
- The potential benefits of a Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure should be carefully weighed against the potential risks. Consult clinical practice guidelines to identify special considerations for patients with pre-existing conditions, such as:
  - Severe or rapidly progressive liver failure
  - Polycystic liver disease
  - Extensive primary or metastatic hepatic malignancy
  - Severe or uncontrolled hepatic encephalopathy
  - Unrelieved biliary obstruction
  - Congestive heart failure or severe cardiac valvular insufficiency
  - Elevated right or left heart pressure
  - Severe or moderate pulmonary hypertension
  - Severe, uncorrectable coagulopathy
  - Obstruction of all hepatic veins
  - Portal vein thrombosis
  - Thrombocytopenia
  - Uncontrolled systemic infection or sepsis
  - Cavernous portal vein occlusion or splenic vein thrombosis

PRECAUTIONS

- Prior to stent graft implantation, read the Instructions for Use.
- The Liverty™ TIPS Stent Graft is a permanent implant that is not intended to be removed after implantation.
- The delivery system is not intended for any use other than stent graft deployment.
- The stent graft implant cannot be repositioned after complete deployment of the covered stent graft segment.
- A stent graft which is misplaced and extends too far into the vena cava or portal vein may cause thrombosis and/or difficulties during liver transplant surgery.
- The stent graft is contained within the transparent stent graft delivery sheath (G). Do not use if the stent graft is partially deployed.
- Do not unlock the red safety lock slider until the stent graft is ready for deployment. Do not press the black push button until the covered section of the stent graft is ready for deployment. Do not use if the safety lock slider is unlocked or if the black push button is depressed.
- Once partially or fully deployed, the stent graft cannot be retracted or remounted onto the delivery system.
- If unusual resistance is met during delivery system introduction, the system should be removed and another stent graft system should be used. Additional balloon dilatation may facilitate the passage of the delivery system.
- **DO NOT** introduce or manipulate the delivery system without an appropriately-sized guidewire or fluoroscopic guidance.
- **DO NOT** use a kinked delivery system.
- **DO NOT** hold the dark brown catheter (H per Figure 2), if visible during stent graft deployment, since this must be free to move and slide into the beige stability sheath. Holding the dark brown catheter may lead to misplacement.
- The stent graft must not be post-dilated beyond 10 mm in diameter. The uncovered distal end (in the portal vein) does not require post-dilatation.
- Higher deployment force may be encountered with longer length stent grafts.
- The covered segment of the stent graft should line the entire parenchymal tract and hepatic vein to the hepatocaval junction. Inadequate coverage of the hepatic vein may lead to stenosis in an unlined hepatic vein segment.
- Care must be taken when crossing the stent graft with catheters and sheaths after its placement to avoid the risk of stent graft dislodgement.
- Placing the stent graft across a vessel side branch may impede blood flow and hinder or prevent future access and/or procedures.
- Care must be taken to avoid puncture of, and stent graft placement within, a biliary stent if a stent is present.
- Wait for 7 days after placement of the Liverty™ TIPS Stent Graft before performing surveillance ultrasound assessment of the shunt because air in the pores of the ePTFE may provide inaccurate information about the shunt patency.

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

Complications and Adverse Events associated with the use of the Liverty™ TIPS Stent Graft may include, but are not limited to, the following:

Access site bleeding; Accidental puncture; Biliary injury; Cardiac arrythmia; Cholestasis; Congestive heart failure; Death; Dissection; Embolism; Hemoperitoneum; Hemorrhage; Hepatic encephalopathy; Hepatic infarction; Infection; Liver failure/dysfunction; Occlusion; Perforation; Peritonitis; Recurrence of Ascites; Renal failure; Stenosis/restenosis; Thrombosis; Tissue/Organ Injury; and Vessel Injury.

SUMMARY OF CLINICAL STUDY

The Liverty™ TIPS Stent Graft was evaluated in a prospective, multi-center, single-arm clinical study (ARCH) for the treatment of complications from portal hypertension. This summary reflects the study design and study outcomes. The study enrolled 177 participants across 26 investigational sites in the United States and Europe. Indications for TIPS were recurrent or refractory ascites, hepatic hydrothorax, and/or esophagogastric variceal bleeding. Safety and effectiveness were assessed against performance goals (PG).

The endpoint analyses were conducted on participants who had reached pre-specified follow-up timepoints: 30 days for co-primary safety and 6 months for co-primary effectiveness. Participants will be followed through 24 months.

STUDY ENDPOINTS

The co-primary safety endpoint was Freedom from Major Complications through 30 days post-index procedure. Major complications were defined as device- and/or procedure-related serious adverse events such as accelerated liver failure, biliary peritonitis, caval occlusion, death, hemobilia, hemoperitoneum, hepatic artery injury, hepatic infarction, radiation skin burn, renal failure, severe hepatic encephalopathy (i.e., requiring hospitalization), and vascular perforation. The definition of major complications also included stent migration which had the potential to or was confirmed to have led to a serious adverse event. The co-primary safety endpoint was evaluated against a PG of 85%.

The co-primary effectiveness endpoint was defined as Freedom from Shunt Dysfunction through 6 months post-Treatment Completion. Shunt dysfunction was defined as both a >50% reduction in stent lumen, as confirmed by direct shunt venography, and a portosystemic gradient (PSG) exceeding the PSG achieved post-index procedure. The co-primary effectiveness endpoint was evaluated against a PG of 78%.

The secondary endpoint with hypothesis testing is 12-month survival, defined as participants who are free from death of any cause through 12 months post-Index Procedure. This secondary endpoint will be evaluated against a literature-derived Performance Goal (PG) of 67%. A one-sided p-value was derived based on an exact binomial test. The study device will be considered to have achieved this secondary endpoint with hypothesis testing if the one-sided p-value is less than 0.05. Or, equivalently, if the lower limit of the one-sided 95% confidence limit, based on the Clopper-Pearson method, is

greater than 67%. This endpoint will be evaluated using data from eligible participants who have completed 12-month follow-up; timing of this analysis will be consistent with the overall study analysis plan.

The following secondary endpoints were evaluated to provide further information related to the safety and effectiveness of the Liverty™ TIPS Stent Graft:

- **Technical Success** at Index Procedure
- **Hemodynamic Success** at Index Procedure
- **Clinical Success** at 3, 6, 12, 18, and 24 months post-Treatment Completion for participants with Recurrent or Refractory Ascites
- **Clinical Success** at 3, 6, 12, 18, and 24 months post-Treatment Completion for participants with Hepatic Hydrothorax
- **Clinical Success** at 1, 3, 6, 12, 18, and 24 months post-Treatment Completion for participants with Esophagogastric Variceal Re-Bleeding
- **Freedom from Shunt Dysfunction** at 1, 3, 12, 18, and 24 months post-Treatment Completion
- **Freedom from Shunt Re-Intervention** at 1, 3, 6, 12, 18, and 24 months post-Treatment Completion
- **Freedom from Hepatic Encephalopathy of Grade ≥3** per West Haven Criteria at 1, 3, 6, 12, 18, and 24 months post-Treatment Completion
- **Liver Transplant-Free Survival**
- **Overall Survival**
- **Health-Related Quality of Life (HRQoL)**

PARTICIPANTS STUDIED

Eligible participants were at least 18 years of age, with a life expectancy of ≥12 months to allow for adequate completion of study procedures and collection of data. Participants were required to have portal hypertension secondary to cirrhosis, with one or more of the following clinical presentations: recurrent or refractory ascites, hepatic hydrothorax, esophageal variceal bleeding, or gastric variceal bleeding. Hepatic reserve criteria included a Model for End-Stage Liver Disease (MELD) score ≤18 or Child-Pugh score ≤12, and a platelet count ≥50,000/μL.

Participants were excluded if they were pregnant, had prior transcatheter procedures for the treatment of complications from portal hypertension, had prior stent graft placement in the portal vein or inferior vena cava (IVC), were hemodynamically unstable, or had flow-limiting hepatic or portal vein thrombosis. Additional exclusion criteria included active malignancy, severe hepatic encephalopathy, certain medical conditions, or anticipated liver transplant within 6 months of enrollment.

METHODS

Participants underwent clinical evaluation at screening and were treated during the Index Procedure. A Tailored Expansion Procedure (TEP) could be performed within 8 weeks post-Index Procedure to optimize outcomes in participants without a prior confirmed shunt dysfunction or shunt re-intervention. For participants who underwent TEP, follow-up was performed based on the Index Procedure date until the TEP had been completed and was then restarted and performed based on the TEP date. Treatment Completion was defined as the latter to occur of (i) completion of the Index Procedure and (ii) if performed, the TEP. Follow-up assessments occurred at 1, 3, and 6 months post-Treatment Completion, and included physical examination, Doppler ultrasound, laboratory testing (MELD and Child-Pugh scores), and health-related quality of life (HRQoL) evaluation. PSG measurements were performed if shunt dysfunction (i.e., loss of patency) was suspected. Adverse events and device deficiencies were documented throughout the study. Independent study evaluations were provided by a Data Monitoring Committee (DMC), a Clinical Events Committee (CEC), and a Core Laboratory. The DMC conducted an ongoing review of the study for participant safety, and continued validity and scientific merit of the study. The CEC reviewed all adverse events (AEs) and adjudicated required events in accordance with the CEC charter. The Core Laboratory provided assessment of imaging endpoints. Follow-up will continue through 12, 18, and 24 months.

The Intent-to-Treat (ITT) population consists of all participants who have signed the informed consent form and had the Liverty™ TIPS Stent Graft delivery system introduced, regardless of whether the device was implanted or if another device was implanted. The Modified Intent-to-Treat (mITT) population consists of any participants in the ITT population who had only Liverty™ TIPS Stent Graft(s) implanted at Index Procedure. As pre-specified in the Statistical Analysis Plan, the safety endpoint analysis was conducted on the ITT population (177 subjects) and the effectiveness endpoint analysis was conducted on the mITT population (176 subjects).

RESULTS

Participant Demographics and Baseline Characteristics

Specific demographics and baseline characteristics for participants enrolled in the ARCH study are summarized in Table 3. The study population includes adults with portal hypertension secondary to cirrhosis, presenting with recurrent or refractory ascites, hepatic hydrothorax, esophageal variceal bleeding, or gastric variceal bleeding. Baseline hepatic reserve was assessed using MELD and Child-Pugh scores and was documented prior to treatment.

Table 3: Demographics and Baseline Characteristics (ITT Participants)

	Total
Age Category	n/N (%)
<70 years	158/177 (89.3%)
≥70 years	19/177 (10.7%)
Sex	n/N (%)
Male	105/177 (59.3%)
Female	72/177 (40.7%)
Ethnicity	n/N (%)
Hispanic or Latino	21/177 (11.9%)
Mexican, Mexican American, Chicano/a	10/177 (5.6%)
Puerto Rican	1/177 (0.6%)
Another Hispanic, Latino/a or Spanish Origin	6/177 (3.4%)
Not Hispanic or Latino	98/177 (55.4%)
Not Reported	58/177 (32.8%)
Race	n/N (%)
Black or African American	1/177 (0.6%)
White	128/177 (72.3%)
Not Reported	46/177 (26.0%)
Unknown	1/177 (0.6%)
Mixed	1/177 (0.6%)
BMI	(kg/m^2)
N	176 *
Mean (SD)	27.35 (6.843)
Median	26.05
Min - Max	15.8-60.1
MELD score Category	n/N (%)
≤9	57/177 (32.2%)
10-13	75/177 (42.4%)
14-18	41/177 (23.2%)
19-22	4/177 (2.3%)
Child-Pugh score Category	n/N (%)
5-6	31/177 (17.5%)
7-9	137/177 (77.4%)
10-12	9/177 (5.1%)

* *Baseline BMI was missing for one participant.*

Clinical characteristics such as history of variceal bleeding, ascites grade, hepatic encephalopathy status, and relevant laboratory values were collected during screening. These data provide context for evaluating procedural outcomes and safety endpoints. Medical history is presented in Table 4.

Table 4: Targeted Medical History (ITT Participants)

Targeted Medical History	Total n/N (%)
Etiology of Liver Cirrhosis	
Alcohol Abuse	105/177 (59.3%)
Cryptogenic	10/177 (5.6%)
Hepatitis B	1/177 (0.6%)
Hepatitis C	9/177 (5.1%)
Non-Alcoholic Fatty Liver Disease	44/177 (24.9%)
Other	29/177 (16.4%)
Complications of Portal Hypertension	
Ascites	149/177 (84.2%)
Esophageal Variceal Bleeding	54/177 (30.5%)
Gastric Variceal Bleeding	15/177 (8.5%)
Hepatic Hydrothorax	11/177 (6.2%)
Primary TIPS Indication	
Ascites	121/177 (68.4%)
Esophageal Variceal Bleeding	43/177 (24.3%)
Gastric Variceal Bleeding	5/177 (2.8%)
Hepatic Hydrothorax	8/177 (4.5%)

Tables 5-8 include an overview of the index procedure and study device details. The Liverty™ TIPS Stent Graft was deployed in participants with patent portal vein anatomy and adequate hepatic reserve, as defined by protocol criteria.

Table 5: Index Procedure Overview (ITT Participants)

	Total
PSG at baseline	mmHg
N	177
Mean (SD)	17.8 (4.60)
Median	17.0
Min - Max	7-33
PSG after final post-dilatation	mmHg
N	176^
Mean (SD)	7.8 (2.53)
Median	8.0
Min - Max	2-13
PSG after adjunctive procedures*	mmHg
N	32
Mean (SD)	11.2 (5.01)
Median	10.0
Min - Max	2-26
Hemodynamic success - PSG reduction target#	n/N (%)
Post Procedure PSG ≤12 mmHg	139/177 (78.5%)
PSG Reduction By ≥50% From Baseline PSG	38/177 (21.5%)

^ *In one case, the Investigator was unable to collect the pressure measurement until after completion of an adjunctive procedure.*

* *Adjunctive procedures are defined as any procedure performed at the same time as TIPS creation.*

\# *As determined at physician discretion during Index Procedure.*

Table 6: Summary of Shunt Diameter after Study Procedure (ITT Participants)

	Total
Shunt Diameter (mm) Post-Index Procedure	n/N (%)
6	47/177 (26.6%)
7	36/177 (20.3%)
8	74/177 (41.8%)
9	8/177 (4.5%)
10	12/177 (6.8%)
Shunt Diameter (mm) Post-Treatment Completion†	n/N (%)
6	40/177 (22.6%)
7	32/177 (18.1%)
8	75/177 (42.4%)
9	10/177 (5.6%)
≥10‡	20/177 (11.3%)

† *Treatment Completion was defined as the latter to occur of (i) completion of the Index Procedure and (ii) if performed, the TEP.*

‡ *A 12 mm balloon dilatation catheter was used in one TEP.*

The 7/2 and 8/2 device sizes were the most commonly implanted Liverty™ TIPS Stent Grafts, accounting for a combined 60.1% of devices used. Refer to Table 7 for a summary of study device implantations at Index Procedure. Per protocol, a second Liverty™ TIPS Stent Graft could be placed during the Index Procedure, if necessary, to ensure lining of the entire parenchymal tract and hepatic vein, and the Liverty™ TIPS Stent Graft was not to be used for shunt re-interventions post-Index Procedure (i.e., a device from another manufacturer was to be used). In total, 19 participants received devices placed in an overlapping configuration through 6 months. In 8 of those participants, a Liverty™ TIPS Stent Graft was overlapped with another Liverty™ TIPS Stent Graft (6 at Index Procedure, 2 during a re-intervention (protocol deviation)). The other 11 participants had a Liverty™ TIPS Stent Graft overlapped with a device from another manufacturer (1 at Index Procedure (protocol deviation; excluded from mITT population), 10 placed during re-interventions). Refer to Table 8 for a summary of the overlap scenarios. The shunt in 1 participant with overlapping stents was dilated with a balloon catheter 1 week after secondary stent placement for mild hepatic vein stenosis. There were no subsequent re-interventions to maintain shunt patency in any other participants following overlapping stent placement.

Table 7: Summary of Implanted Study Device at Index Procedure (ITT Participants)

Device Length (covered/uncovered) (cm)	Total Implanted Devices n/N (%)
4/2	2/183 (1.1%)
5/2	13/183 (7.1%)
6/2	34/183 (18.6%)
7/2	56/183 (30.6%)
8/2	54/183 (29.5%)
9/2	15/183 (8.2%)
10/2	9/183 (4.9%)

Table 8: Summary of Implanted Study Device at Index Procedure (ITT Participants)

Reason for Secondary Stent Placement	Overlap Configuration	
	Liverty-Liverty	Liverty-Other
Coverage of Hepatic Vein	7*	1 (Liverty-BD Fluency Plus)^
Shunt Reduction	0	1 (Liverty-BD Fluency)
Stenosis	0	1 (Liverty-BD Luminexx)†, 1 (Liverty-Gore Viatorr)
Thrombosis	1‡	6 (5 Liverty-Gore Viatorr, 1 Liverty-BSC Wallstent)
Other – Ascites Management	0	1 (Liverty-BD Venovo)

Unless otherwise specified, Liverty-Liverty overlap was completed at Index Procedure and Liverty-Other overlap was completed at re-intervention.

* *One (1) Liverty-Liverty overlap for coverage of the hepatic vein was completed at re-intervention. The remaining 6 secondary stent placements for coverage of the hepatic vein were completed at Index Procedure.*

^ *The participant with Liverty-Fluency Plus overlap at Index Procedure for coverage of the hepatic vein was excluded from the mITT population.*

† *Stenosis of the hepatic vein occurred because the initial device placement did not fully cover the hepatic vein. Secondary stent placement was completed for resolution of stenosis and to cover the hepatic vein.*

‡ *Treatment of thrombosis with placement of an additional Liverty™ TIPS Stent Graft was completed at re-intervention.*

PARTICIPANT ACCOUNTABILITY

At the time of database extract, of 177 participants treated in the clinical study, 99.4% (176) participants were available for analysis of the co-primary safety endpoint at 30-day post-index procedure and 70.6% (125) participants were available for analysis of the co-primary effectiveness endpoint at the 6-month post-Treatment Completion visit.

Twenty-three (23) participants were enrolled in the ARCH study but not treated. Of these participants, 19 did not meet the inclusion/exclusion criteria and were considered screen failures. The most common reasons for exclusion were platelet count of ≤50,000/μL and the presence of medical conditions meeting predefined exclusion criteria.

The remaining four participants who met all eligibility criteria but were not treated with the study device, were not treated due to: one participant's consent form was signed >30 days prior to the Index Procedure but the participant was already on the procedure table and could not be reconsented, therefore, a Sponsor Decision was made to not treat the participant with the study device (a commercial device was used instead); one participant was consented but, due to unavailability of study site staff to potentially support future follow-up data collection, a Sponsor Decision was made to not treat the participant with the study device; one participant was enrolled but could not be treated prior to completion of overall enrollment of the study; and one participant withdrew consent prior to their scheduled Index Procedure.

Of the 40 participants discontinued from the study prior to the end of the 6-month follow-up window, 28 (15.8%) died, five (2.8%) received a liver transplant, four (2.3%) withdrew consent, and three (1.7%) were lost to follow-up.

SUMMARY OF SAFETY

The co-primary safety endpoint of the study was Freedom from Major Complications through 30-days post-Index Procedure as adjudicated by the CEC. Major complications were defined as device- and/or procedure-related serious adverse events such as accelerated liver failure, biliary peritonitis, caval occlusion, death, hemobilia, hemoperitoneum, hepatic artery injury, hepatic infarction, radiation skin burn, renal failure, severe hepatic encephalopathy (i.e., requiring hospitalization), and vascular perforation. The definition of major complications also included stent migration which had the potential to, or was confirmed to, have led to a serious adverse event.

To demonstrate acceptable safety, the co-primary safety endpoint was evaluated against the PG of 85%, derived from consideration of the American College of Radiology - Society of Interventional Radiology (ACR-SIR) Practice Parameter for the Creation of a TIPS[1], relevant clinical literature, and physician input.

As analyzed on a pre-specified basis using the exact binomial method, the observed Freedom from Major Complications through 30 days was 85.8% (151/176) and did not meet the PG (p-value = 0.4341).

Table 9: Freedom from Major Complications through 30 days (ITT Participants)*

	Rate	Lower limit of the one-sided 95% confidence Interval	p-value compared to PG
Freedom from Major Complications through 30 Days	151/176 (85.8%)	80.73%	0.4341

* *One (1) participant was non-evaluable, having exited the study for liver transplant before the lower bound of the visit window.*

There were 25 participants with 29 documented major complication events in the study. Observed major complication events included accelerated liver failure (1), death (2), hepatic artery injury (1), hepatic infarction (1), renal failure (2), and severe HE (22). Of the participants who did not experience a fatal major complication, 1 began dialysis, 2 received unknown therapy, and the remaining 20 were treated with medical therapy alone (symptom resolution achieved in 18/20).

A post-hoc analysis was performed wherein West Haven Grade 1 and Grade 2 hepatic encephalopathy events resolved by medical therapy alone were counted as successes (consistent with the definition of a minor complication in the ACR-SIR Practice Parameter for the Creation of a TIPS[1]). Freedom from Major Complications through 30-days post-Index procedure was 94.3% (p-value <0.0001).

Table 10: Freedom from Major Complications through 30 Days (Post-Hoc Analysis) (ITT Participants)*

	Rate	Lower limit of the one-sided 95% confidence Interval
Freedom from Major Complications through 30 Days	166/176 (94.3%)	90.55%

* *One (1) participant was non-evaluable, having exited the study for liver transplant before the lower bound of the visit window.*

Note: The confidence interval is not adjusted for multiplicity.

A total of 640 Adverse Events (AEs), were reported in the 6-month follow-up period affecting 150 participants. An overview of the relatedness of AEs, as adjudicated by the CEC during the 6-month follow-up period, is presented in Table 11. None of the AEs were adjudicated to be causally or probably related to the Liverty™ TIPS Stent Graft. Table 12 summarizes AEs which occurred in >2% of participants.

The types of safety events experienced in the study are consistent with those expected in this patient population.

There were 28 deaths (15.8%) reported in the 6-month follow-up period. The causes of death are reported in Table 13. No (0) deaths were adjudicated to be related to the study device. No (0) deaths were causally related to either the Index Procedure or TEP.

Table 13: Deaths through 6 Months
Deaths in the Index Procedure-, and TEP-related columns were CEC adjudicated to be probably, or possibly related. No (0) deaths were adjudicated to be causally related to device, procedure, or TEP.

Cause of Death	Total	Device Related	Index Procedure Related	TEP Related
	(N=177)			
Liver disease	9 (5.1%)	0	2 (1.1%)	0
Cardiac	5 (2.8%)	0	1 (0.6%)	0
Sepsis	5 (2.8%)	0	1 (0.6%)	0
Respiratory failure	4 (2.3%)	0	1 (0.6%)	1 (0.6%)
Infection	2 (1.1%)	0	0	0
Neurologic	1 (0.6%)	0	0	0
Bowel obstruction	1 (0.6%)	0	0	0
Renal failure	1 (0.6%)	0	0	0
Total	28 (15.8%)	0	5 (2.8%)	1 (0.6%)

The timing of deaths ranged from 12 to 212 days post-Index Procedure.

Table 11: Summary of CEC Adjudicated Adverse Events

Relationship to	Device		TIPS Index Procedure		Tailored Expansion Procedure	
	By Events	By Participants	By Events	By Participants	By Events	By Participants
Relatedness of Adverse Event						
Causal	0	0	23	19 (10.7%)	0	0
Probable	0	0	63	40 (22.6%)	4	4 (2.3%)
Possible	34	26 (14.7%)	101	37 (20.9%)	7	3 (1.7%)
Not Related	411	103 (58.2%)	258	33 (18.6%)	18	3 (1.7%)
Relatedness of Serious Adverse Event						
Causal	0	0	17	15 (8.5%)	0	0
Probable	0	0	40	29 (16.4%)	3	3 (1.7%)
Possible	30	23 (13.0%)	74	37 (20.9%)	7	3 (1.7%)
Not Related	332	95 (53.7%)	231	37 (20.9%)	16	3 (1.7%)

In the By Participant columns, participants are counted in the highest severity or most-related category.
Only AE events through the upper bound of 6-month visit window post-Treatment Completion were included.

Table 12: Participants with Adverse Events through 6 Months
Adverse events in the device-related column were CEC adjudicated to be possibly, not causally or probably related. Adverse events in the Index Procedure- and TEP-related columns were adjudicated to be causally, probably, or possibly related.

Adverse Event	Total	Device Related	Index Procedure Related	TEP Related
	(N=177)			
Any Adverse Event	640	34	187	11
Any Participant with at least one AE	150 (84.7%)	26 (14.7%)	96 (54.2%)	7 (4.0%)
Adverse Events which occurred in >2% of participants				
Hepatic encephalopathy	62 (35.0%)	0	39 (22.0%)	5 (2.8%)
Ascites	27 (15.3%)	5 (2.8%)	7 (4.0%)	1 (0.6%)
Acute kidney injury	22 (12.4%)	0	2 (1.1%)	0
Edema peripheral	18 (10.2%)	0	9 (5.1%)	0
Anemia	12 (6.8%)	2 (1.1%)	4 (2.3%)	0
Vascular stent thrombosis	12 (6.8%)	12 (6.8%)	10 (5.6%)	0
Hepatic cirrhosis	12 (6.8%)	0	6 (3.4%)	0
Abdominal pain	11 (6.2%)	2 (1.1%)	5 (2.8%)	1 (0.6%)
Constipation	9 (5.1%)	0	0	0
Urinary tract infection	8 (4.5%)	0	0	0
Pleural effusion	8 (4.5%)	0	1 (0.6%)	0
Septic shock	7 (4.0%)	0	2 (1.1%)	0
Hypokalemia	7 (4.0%)	0	0	0
Incarcerated umbilical hernia	6 (3.4%)	0	6 (3.4%)	0
Hepatic failure	6 (3.4%)	0	3 (1.7%)	0
Pneumonia	6 (3.4%)	0	1 (0.6%)	0
Umbilical hernia	5 (2.8%)	0	3 (1.7%)	0
Peritonitis	5 (2.8%)	0	0	0
Hyperglycemia	5 (2.8%)	0	0	0
Acute respiratory failure	5 (2.8%)	0	2 (1.1%)	0
Thrombocytopenia	4 (2.3%)	0	0	0
Gastric antral vascular ectasia	4 (2.3%)	0	0	0
Asthenia	4 (2.3%)	0	1 (0.6%)	0
Acute or chronic liver failure	4 (2.3%)	0	0	0
Cholestasis	4 (2.3%)	0	3 (1.7%)	0
Portal vein thrombosis	4 (2.3%)	3 (1.7%)	4 (2.3%)	0
COVID-19	4 (2.3%)	0	0	0
Spontaneous bacterial peritonitis	4 (2.3%)	0	0	0
Procedural pain	4 (2.3%)	1 (0.6%)	3 (1.7%)	0
Renal failure	4 (2.3%)	0	0	0
Hypotension	4 (2.3%)	0	2 (1.1%)	0

Note: Some participants may be counted in multiple adverse event categories.

SUMMARY OF EFFECTIVENESS

The co-primary effectiveness endpoint was Freedom from Shunt Dysfunction through 6 months post-Treatment Completion. Shunt dysfunction was defined as both a >50% reduction of the lumen of the stent (confirmed by direct shunt venography for participants with suspected shunt dysfunction) and a PSG greater than the PSG achieved post-Index Procedure.

Treated participants without a prior confirmed loss of stent graft patency or shunt re-intervention were allowed to undergo an additional Tailored Expansion Procedure (TEP) to allow for expansion of the Liverty™ TIPS Stent Graft diameter within the initial 8 weeks post-Index Procedure, if necessary per the Investigator, to further optimize clinical outcomes. Treatment Completion was defined as the latter to occur of (i) completion of the Index Procedure and (ii) if performed, the TEP. For participants who underwent TEP, follow-up was performed based on the Index Procedure date until the TEP had been completed and was then restarted and performed based on the TEP date. TEP was not counted as either a primary endpoint failure or a re-intervention (censoring event).

To demonstrate acceptable effectiveness, the co-primary effectiveness endpoint was evaluated against the PG of 78%, which was derived using literature and published data on approved TIPS devices.

As analyzed on a pre-specified basis using the exact binomial method, the co-primary effectiveness endpoint result was 90.4% (p-value = 0.0002) and met the PG.

Table 14: Freedom from Shunt Dysfunction through 6 Months (mITT Participants)

	Rate	Lower limit of the one-sided 95% confidence Interval	p-value compared to PG
Freedom from Shunt Dysfunction through 6 Months	113/125 (90.4%)	84.91%	0.0002

A total of 51 participants were non-evaluable for the co-primary effectiveness endpoint; censoring events are summarized in Table 15. Censoring events occurred at rates consistent with those expected in this patient population. Refer to the discussion of secondary endpoints for further details regarding re-interventions.

Table 15: Summary of Reasons for Co-Primary Effectiveness Non-Evaluable Status (mITT Participants)

	Total Participants (N=176)
Evaluable	125
Non-Evaluable	51
Reason for Non-Evaluable	
Death	20/51 (39.2%)
Liver Transplant	3/51 (5.9%)
Lost to Follow-up	2/51 (3.9%)
Shunt Re-intervention	22/51 (43.1%)
Withdrawal of Consent	4/51 (7.8%)

The reasons participants failed the co-primary effectiveness endpoint were thrombus (11) and shunt occlusion without thrombus (1). All 12 participants received shunt re-intervention and showed no signs of repeat shunt failure through 6 months. Root cause analysis and eventual procedural step adjustment are discussed in the shunt diameter subgroup analysis.

A worst-case analysis (post hoc analysis) for the co-primary effectiveness endpoint was completed to identify cases where re-intervention may have been performed to address a device- or procedure-related issue, rather than to optimize the clinical response of the study participant. The goal of this analysis was to identify cases where, if re-intervention had not occurred, shunt dysfunction may have subsequently presented. This analysis identified 7 re-interventions to be considered in the worst-case analysis: 3 for stenosis in the shunt (< 50% stenosis), 2 for hepatic vein stenosis, 2 where shunt dysfunction was suspected but not confirmed via venography. These final two participants did not present with inadequate clinical response or any associated adverse events (including stenosis or thrombosis) and yet still received balloon dilatation. The PG was still met (85.6% (113/132); lower limit of 95% confidence interval = 79.60%; p-value = 0.0189) in this sensitivity analysis.

A pre-specified Kaplan-Meier analysis of the co-primary effectiveness endpoint was also performed. The proportion of participants free from co-primary effectiveness events by Kaplan-Meier estimates through 6 months was 92.4%. Refer to Figure 5 and Table 16 for the Kaplan-Meier analysis.

Figure 5: Kaplan-Meier Analysis of Freedom from Shunt Dysfunction (mITT Participants)

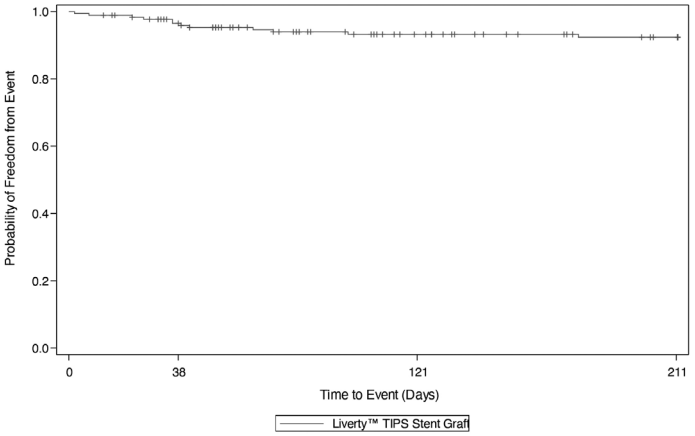


Table 16: Kaplan-Meier Analysis of Freedom from Shunt Dysfunction (mITT Participants)

Time Point	# of Participants at Risk at the End of Visit Window	# of Participants Censored	# of Participants with Failure	K-M Rate (95% CI)
30 Day	159	11	6	96.5% (92.4%, 98.4%)
3 Month	122	43	11	93.2% (88.1%, 96.2%)
6 Month	105	59	12	92.4% (86.9%, 95.6%)

SECONDARY ENDPOINTS

Table 17 presents information on additional endpoints with proportional values for all follow-up time points through 6 months. Technical Success was defined as successful creation of a Liverty™ TIPS Stent Graft lined shunt between the hepatic vein and a branch of the portal vein, as assessed by the Investigator during the Index Procedure. Hemodynamic Success was defined as the successful post-TIPS reduction of the PSG to an Investigator-determined target of ≤12 mmHg or by ≥50% from the baseline PSG, as assessed by the Investigator during the Index Procedure. The mean PSG across all procedures completed in the mITT population was reduced from 17.8 to 8.3 mmHg.

Clinical Success for recurrent or refractory ascites was defined as freedom from large volume paracentesis (LVP) of >5L occurring >6 weeks post-Treatment Completion. Clinical Success for hepatic hydrothorax was defined as freedom from large volume thoracentesis (LVT) of >1L occurring >6 weeks post-Treatment Completion. Clinical Success for esophagogastric variceal bleeding was defined as freedom from endoscopically confirmed esophagogastric variceal re-bleeding (EVB).

Liver Transplant-Free Survival post-Index Procedure was defined as the proportion of participants with freedom from death of any cause and from liver transplantation. Overall Survival post-Index Procedure was defined as the proportion of participants with freedom from death of any cause.

Table 17: Secondary Endpoints (mITT Participants)

Endpoint	Procedure n/N (%)	30 days n/N (%)	3 months n/N (%)	6 months n/N (%)
Acute Procedural Endpoints*				
Technical Success	176/176 (100.0%)	N/A	N/A	N/A
Hemodynamic Success†	167/176 (94.9%)	N/A	N/A	N/A
Target: Post Procedure PSG ≤12 mmHg	130/138 (94.2%)	N/A	N/A	N/A
Target: PSG Reduction By ≥50% from Baseline PSG	37/38 (97.4%)	N/A	N/A	N/A
Clinical Success by Indication (e.g., freedom from LVP >5L, LVT >1L, endoscopically confirmed EVB)				
Recurrent or Refractory Ascites	N/A	N/A	84/102 (82.4%)	67/88 (76.1%)
Hepatic Hydrothorax	N/A	N/A	5/7 (71.4%)	5/7 (71.4%)
Esophagogastric Variceal Bleeding	N/A	45/45 (100.0%)	36/36 (100.0%)	29/30 (96.7%)
Freedom from Shunt Dysfunction	N/A	167/173 (96.5%)	140/151 (92.7%)	113/125 (90.4%)
Freedom from Shunt Re-intervention	N/A	167/174 (96.0%)	128/158 (81.0%)	110/147 (74.8%)
Freedom from Hepatic Encephalopathy of Grade ≥3	N/A	170/171 (99.4%)	139/144 (96.5%)	110/116 (94.8%)
Survival^				
Liver Transplant-Free Survival	N/A	NR	NR	139/171 (81.3%)
Overall Survival	N/A	NR	NR	141/168 (83.9%)

Denominators differ across endpoints and timepoints. Participants with observed events are included in the denominator at all time points. Participants without events are evaluable only if they remain in follow-up beyond the lower bound of the corresponding visit window. Differences in denominators may also result from endpoint-specific evaluability criteria defined in the Statistical Analysis Plan, missing data, and analyses restricted to specific participant cohorts.

** One (1) participant had a Liverty overlapped with a non-Liverty device placed at Index Procedure and, thus, was excluded from the mITT population.*

† The investigator determined the target for PSG reduction based on individual patient factors.

^ Survival endpoints were evaluated at the analysis timepoint only (i.e., through 6 months) and not trended over time.

NR = Not Reported

There were 41 re-interventions in 37 participants (37/141; 25.2%) in the mITT population through 6-months follow-up. The types of therapies performed at re-intervention are summarized in Table 18. The reasons for re-interventions were optimization of the clinical response (48.7%; 20/41), thrombosis (29.3%; 12/41), stenosis (12.2%; 5/41), intentional shunt closure (2.4%; 1/41), suspicion of shunt dysfunction that was not confirmed via venography (4.9%; 2/41), and other (2.4%; 1/41). Refer to Table 19 for a summary of re-interventions to optimize the clinical response, which included standalone balloon dilatation to address inadequate symptom relief (e.g., recurrence of ascites/hepatic hydrothorax, variceal rebleeding) and shunt reduction to address hepatic encephalopathy. The option for a Tailored Expansion Procedure (TEP) was included in the study design. Per protocol, if a TEP occurred within 8-weeks post-TIPS, this was not counted as a re-intervention or co-primary effectiveness censoring event and follow-up restarted based on the TEP date. Several investigators conducted a standalone balloon dilatation to optimize the clinical response after the 8-week window post-TIPS. This belated adjustment of the TIPS diameter via balloon dilatation ("out-of-window TEP") counted against the secondary endpoint Freedom from Shunt Re-intervention and was censored from the co-primary effectiveness endpoint.

Table 18: Summary of Therapies Performed at Re-intervention among Participants having Shunt Re-intervention through 6 Months (mITT Participants)

Type of Therapy(ies) Performed at Re-intervention*	Total Participant n/N (%)
Balloon Dilatation (after 8 weeks)	30/41 (73.2%)
New Stent / Stent Graft Placed	12/41 (29.3%)
Thrombectomy / Thrombolysis	6/41 (14.6%)
Shunt Reduction	4/41 (9.8%)
Intentional Shunt Occlusion / Closure	1/41 (2.4%)

** Some participants had multiple therapies completed during the first re-intervention procedure.*

The timing of re-interventions ranged from 2 to 199 days post-Index Procedure.

Table 19: Number of Interventions to Optimize Clinical Response through 6 Months (mITT Participants)

Type of Therapy	Total Interventions
Shunt Expansion (Standalone Balloon Dilatation)	36
< 8 weeks post Index-Procedure (TEP, allowed per protocol)	20
> 8 weeks post-Index Procedure ("out-of-window TEP" *, counted as re-intervention)	16
Shunt Reduction	4
Total	40

** "Out-of-window TEP" refers to standalone balloon dilatation to address recurrent clinical symptoms (e.g., ascites) after the 8-week window for TEP had closed.*

Secondary patency was defined as freedom from shunt dysfunction in evaluable participants, including those who underwent re-intervention.

Table 20: Secondary Patency through 6 Months (mITT Participants)

	Total Participants n/N (%)
Secondary Patency	130/142 (91.5%)

The PROMIS-29 v2.1 Health-Related Quality of Life (HRQoL) questionnaire was provided to participants in the ARCH study. The questionnaire assessed the participant's physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, pain interference, and pain intensity. According to the PROMIS scoring guidelines, a difference of two to six points, based on T-score, is considered a 'meaningful change'.[2] None of the categories showed a meaningful change (positively or negatively) through 6 months follow-up.

SUBGROUP ANALYSIS

The following characteristics were pre-specified for evaluation of potential associations with outcomes: sex, age group, geography, race, etiology of cirrhosis, primary indication for TIPS, MELD score, Child-Pugh score, shunt diameter, and TEP vs. non-TEP. Additionally, post-dilatation of Section A of the shunt was analyzed as a sub-group to evaluate a clinical protocol update (described below) in a post-hoc manner. No differences were noted based on sex, age, geography, or race. Minor differences were observed with respect to etiology of cirrhosis, primary indication for TIPS, MELD score, and Child-Pugh score and are likely due to the small sample size in the individual subgroups.

Findings from the shunt diameter, TEP vs. non-TEP, and post-dilatation of Section A subgroup analyses are discussed below for the co-primary endpoints.

Freedom from Major Complications: Subgroup analysis (Table 21) shows that there was a drop in Freedom from Major Complications with 10 mm shunt diameters (58.3% vs. >85% for all other shunt diameters). This finding indicates that 10 mm shunts were associated with a higher rate of major complications compared to 6 to 9 mm diameter shunts, through 30 days. Specifically, the 5 participants with 10 mm diameter shunts who failed the primary safety endpoint all had hepatic encephalopathy-related events which contributed to endpoint failure.

Table 21: Subgroup Analysis on Freedom from Major Complications through 30 Days (ITT Participants)*

Subgroup	n/N (%)
Freedom from Major Complications	151/176 (85.8%)
Primary Indication for TIPS	
Ascites	103/120 (85.8%)
Esophageal Variceal Bleeding	36/43 (83.7%)
Gastric Variceal Bleeding	5/5 (100.0%)
Hepatic Hydrothorax	7/8 (87.5%)
MELD Score	
≤9	48/57 (84.2%)
10-13	68/75 (90.7%)
14-18	31/40 (77.5%)
19-22	4/4 (100.0%)
Child-Pugh Score	
5-6	26/31 (83.9%)
7-9	118/137 (86.1%)
10-12	7/8 (87.5%)
Shunt Diameter Post-Index Procedure	
6-7 mm combined	74/82 (90.2%)
6 mm	43/46 (93.5%)
7 mm	31/36 (86.1%)
8-10 mm combined	77/94 (81.9%)
8 mm	63/74 (85.1%)
9 mm	7/8 (87.5%)
10 mm	7/12 (58.3%)
TEP	
Yes	19/20 (95.0%)
No	132/156 (84.6%)
Post-dilatation of Section A for Small Diameter Shunts (6-8 mm)	
Yes	32/38 (84.2%)
No	105/118 (90.0%)

** One (1) participant was non-evaluable, having exited the study for liver transplant before the lower bound of the visit window.*

Freedom from Shunt Dysfunction: A subgroup analysis (Table 22) of participants who received a TEP compared to those who did not undergo TEP indicates a trend towards greater freedom from shunt dysfunction (i.e., patency) in the TEP group. This suggests that a stepwise approach to managing the relief of clinical symptoms due to portal hypertension (e.g., ascites) does not compromise device and/or shunt effectiveness. Refer to the Shunt Diameter Subgroup Analysis for discussion of the impact of post-dilatation of Section A for 6-8 mm diameter shunts on device effectiveness.

Table 22: Subgroup Analysis on Freedom from Shunt Dysfunction through 6 Months (mITT Participants)

Subgroup	n/N (%)
Primary Indication for TIPS	
Ascites	75/81 (92.6%)
Esophageal Variceal Bleeding	28/32 (87.5%)
Gastric Variceal Bleeding	3/4 (75.0%)
Hepatic Hydrothorax	7/8 (87.5%)
MELD Score	
≤9	39/44 (88.6%)
10-13	47/54 (87.0%)
14-18	25/25 (100.0%)
19-22	2/2 (100.0%)
Child-Pugh Score	
5-6	23/27 (85.2%)
7-9	87/95 (91.6%)
10-12	3/3 (100.0%)
Shunt Diameter Post-Treatment Completion	
6-7 mm combined	41/49 (83.7%)
6 mm	22/26 (84.6%)
7 mm	19/23 (82.6%)
8-10 mm combined	72/76 (94.7%)
8 mm	55/58 (94.8%)
9 mm	5/6 (83.3%)
≥10 mm	12/12 (100.0%)
TEP	
Yes*	13/13 (100.0%)
No	100/112 (89.3%)
Post-dilatation of Section A for 6-8 mm Diameter Shunts	
Yes	23/24 (95.8%)
No	79/89 (88.8%)

** TEP was completed per Investigator discretion for inadequate clinical response. Refer to the Effectiveness Results section for a definition of TEP and when it was allowed. Shunt re-interventions, including "out-of-window TEP", were censored from this analysis.*

Clinical Success: Although the shunt diameter subgroups for each primary indication for TIPS were small and some variability was observed, subgroup analysis (Table 23) does not indicate that smaller diameter shunts (i.e., 6-7 mm) present greater risk of recurrence of clinical symptoms than standard shunt diameters (i.e., 8-10 mm).

Table 23: Subgroup Analysis on Clinical Success at 6 Months by Shunt Diameter (mITT Participants)

Subgroup	Recurrent or Refractory Ascites n/N (%)	Esophagogastric Variceal Bleeding n/N (%)
Shunt Diameter Post-Treatment Completion		
6-7 mm combined	28/33 (84.8%)	11/12 (91.7%)
6 mm	16/20 (80.0%)	5/6 (83.3%)
7 mm	12/13 (92.3%)	6/6 (100.0%)
8-10 mm combined	39/55 (70.9%)	18/18 (100.0%)
8 mm	28/41 (68.3%)	16/16 (100.0%)
9 mm	3/4 (75.0%)	1/1 (100.0%)
≥10 mm	8/10 (80.0%)	1/1 (100.0%)

Note: Only 7 participants with hepatic hydrothorax as the primary indication for TIPS were evaluable at 6-months. Due to the small sample size, subgroup analysis is not presented.

Hepatic Encephalopathy: In participants who received small shunts (6-7 mm), 94.4% were unimpaired by HE at baseline compared to 80% at 6 months. In participants who received larger shunts (8-10 mm), 83.8% were unimpaired by HE at baseline compared to 69.2% at 6 months. Approximately 15% of participants with both small and larger shunts developed new onset HE at 6-months. There were no incidences of Grade 3 or 4 HE in participants who received small shunts at any time point through 6 months. At 6 months, in

Table 24: Summary of Hepatic Encephalopathy by Group of Shunt Diameter Post-Treatment Completion at Clinical Visit (mITT Participants)

			West Haven Grade					
Shunt Diameter	Visit	No. of Participants	Unimpaired	Minimal	Grade 1	Grade 2	Grade 3	Grade 4
6-7 mm	Screening	71	67 (94.4%)	1 (1.4%)	3 (4.2%)	0	0	0
	30 Day	62	49 (79.0%)	3 (4.8%)	7 (11.3%)	3 (4.8%)	0	0
	3 Month	55	47 (85.5%)	0	5 (9.1%)	3 (5.5%)	0	0
	6 Month	55	44 (80.0%)	6 (10.9%)	3 (5.5%)	2 (3.6%)	0	0
8-10 mm	Screening	105	88 (83.8%)	7 (6.7%)	10 (9.5%)	0	0	0
	30 Day	97	68 (70.1%)	13 (13.4%)	11 (11.3%)	4 (4.1%)	1 (1.0%)	0
	3 Month	83	59 (71.1%)	10 (12.0%)	7 (8.4%)	3 (3.6%)	4 (4.8%)	0
	6 Month	78	54 (69.2%)	11 (14.1%)	11 (14.1%)	0	1 (1.3%)	1 (1.3%)

the entire cohort (N=133), 2 participants (1.5%) had grade 3 or 4 HE, and 98 participants (73.7%) were unimpaired by HE.

Shunt Diameter: During the study it was observed that when a small shunt (<8 mm) with moderate to severe curvature was created in a patient with a highly fibrotic periportal junction, a persistent recoil was noted. A root cause analysis indicated that it may have increased the risk of thrombosis and subsequent shunt dysfunction.

Following this observation, the procedural instructions in the clinical protocol and Instructions for Use were updated to require focal dilatation of the leading 20 mm of the covered section of the device ("Section A") with an 8 mm balloon when placing a 6, 7, or 8 mm diameter shunt (refer to Figure 9 and Directions for Use Step 20). The intent of this protocol update was to eliminate focal device recoil at the portal entry site due to dense periportal fibrotic tissue and ensure that the flow-limiting diameter of the shunt was the diameter selected by the investigator when dilating the main body of the device rather than a smaller-than-intended diameter imposed by dense periportal fibrotic tissue.

The effectiveness of this protocol update was evaluated by comparing the rate of stent graft thrombosis through 6 months with and without this focal dilatation. These results are presented in Table 25. Focal dilatation of Section A (Figure 9) was associated with a marked reduction in stent graft thrombosis in small shunts (6-7 mm) (2.6% (2/39) vs. 15.9% (7/44); refer to Table 25).

Table 25: Participants with Stent Graft Thrombosis Through 6 Months by Shunt Diameter and Post-Dilatation of Section A (ITT Participants)

	Thrombosis Rate n/N (%)	
Final Intended Shunt Diameter	Post-Dilatation of Section A was Performed	Post-Dilatation of Section A was not Performed
6 mm	1/27 (3.7%)	4/20 (20.0%)
7 mm	0/12 (0.0%)	3/24 (12.5%)
8 mm	1/50 (2.0%)	2/24 (8.3%)
9 mm	0	1/8 (12.5%)
10 mm	0	0/12 (0.0%)
Total Thrombosis Rate	2/99 (2.0%)	10/88 (11.4%)

"Section A" refers to the leading 20 mm of the covered device section. See Figure 9 and Directions for Use Step 20.

This result is also reflected in the Freedom from Shunt Dysfunction subgroup analysis (Table 22). When 6-8 mm diameter shunts underwent focal dilatation of Section A, Freedom from Shunt Dysfunction improved (95.8% (23/24) vs. 88.8% (79/89)). Nine (9) of the 12 Freedom from Shunt Dysfunction failures were in 6-8 mm diameter shunts that did not receive focal dilatation of Section A. Only 2 shunts of 6-8 mm diameter underwent focal dilatation of Section A and subsequently thrombosed.

Results from the analysis showed that focal dilatation of the leading 20 mm of the covered section of the device ("Section A", refer to Figure 9) with an 8 mm balloon – when placing a 6, 7 or 8 mm diameter shunt (refer to Directions for Use Step 20) – reduced the risk of thrombosis and subsequent shunt dysfunction associated with placement of a small shunt (<8 mm) with moderate to severe curvature in patients with a highly fibrotic periportal junction.

DEVICE DEFICIENCIES

There was 1 site-reported device deficiency in the ARCH study. The operator reported that the pigtail catheter got caught on the uncovered section of the stent graft. This event resolved following repeat balloon dilatation. There was no adverse event associated with this device deficiency.

CONCLUSIONS DRAWN FROM THE STUDY

The prospective, multi-center, non-randomized, single-arm study of the Liverty™ TIPS Stent Graft for the treatment of complications from portal hypertension (ARCH) compared co-primary safety and effectiveness measures to PGs to demonstrate the safety and effectiveness of the Liverty™ TIPS Stent Graft.

The proportion of participants free from major complications through 30 days was 85.8% and did not meet the PG (p-value = 0.4341). A post-hoc analysis suggests that when West Haven Grade 1 and Grade 2 hepatic encephalopathy events resolved by medical therapy alone (consistent with the definition of a minor complication in the ACR-SIR Practice Parameter for the Creation of a TIPS[1]) are counted as successes, the proportion of participants free from Major Complications through 30 days post-Index Procedure was 94.3%.

The most common adverse event observed in the ARCH study was hepatic encephalopathy (35%, 62/177). None of the adverse events observed in the study were adjudicated to be causally or probably related to the Liverty™ TIPS Stent Graft. Similarly, none of the 28 deaths in the study were adjudicated to be device related.

The proportion of participants free from shunt dysfunction (i.e., patency) through 6 months was 90.4% (p-value = 0.0002) and met the PG. The reasons participants failed the co-primary effectiveness endpoint were thrombus (11) and shunt occlusion without thrombus (1). Root cause analysis identified that 6-8 mm diameter shunts with moderate to severe curvature, in the presence of a highly fibrotic periportal junction may experience persistent recoil, which may increase the risk of thrombosis and subsequent shunt dysfunction. Focal dilatation of the leading 20 mm of the covered section of the device ("Section A") with an 8 mm balloon was implemented and was associated with a marked reduction in stent graft thrombosis in small diameter (6-7 mm) shunts (2.6% (2/39) vs. 15.9% (7/44)). Similarly, when 6-8 mm shunts underwent focal dilatation of Section A, Freedom from Shunt Dysfunction improved (95.8% (23/24) vs. 88.8% (79/89)).

The rate of freedom from shunt re-intervention through 6-months was 74.8% (110/147), wherein re-interventions to optimize the clinical response of the study participant accounted for 48.7% (20/41) of all re-interventions. The most common intervention in this study was balloon dilatation to optimize the clinical response of the participant. Additionally, 20 participants received balloon dilatation within 8-weeks of the Index Procedure. For endpoint analysis, this was considered a TEP rather than a re-intervention. Follow-up of these participants suggests that a stepwise approach to managing the relief of clinical symptoms due to portal hypertension (e.g., ascites) does not compromise device and/or shunt effectiveness.

Additionally, this study supports the use of the Liverty™ TIPS Stent Graft by showing durable freedom from variceal bleeding and LVP >5L at at 6 months. Specifically, 6-month freedom from LVP >5L in participants for whom ascites was their primary indication for TIPS was 76.1% (67/88), 6-month freedom from thoracentesis >1L in participants for whom hepatic hydrothorax was their primary indication for TIPS was 71.4% (5/7), and 6-month freedom from endoscopically confirmed

esophagogastric variceal re-bleeding in participants for whom this was their primary indication for TIPS was 96.7% (29/30).

Use of the Liverty™ TIPS Stent Graft was associated with technical and hemodynamic success rates of 100.0% and 94.9%, respectively. Secondary patency through 6 months was 91.5% (130/142).

Results from this study indicate that focal dilatation of the leading 20 mm of the covered section of the device ("Section A") with an 8 mm balloon is important to achieving optimal outcomes when placing 6, 7, or 8 mm diameter shunts. Data from the clinical trial provide a reasonable assurance that the Liverty™ TIPS Stent Graft is safe and effective when used in accordance with its labeling.

REFERENCES

1. American College of Radiology – Society of Interventional Radiology. 2022. ACR-SIR-SPR Practice Parameter for the Creation of a Transjugular Intrahepatic Portosystemic Shunt (TIPS). American College of Radiology.
2. HealthMeasures. 2021. PROMIS® Adult Profile Instruments Scoring Manual. Northwestern University.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION



MR Conditional

A person with a single and/or overlapped Liverty™ TIPS Stent Graft may be safely scanned under the following conditions:

Static Magnetic Field Strength (B0)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	40 T/m (4000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body Transmit Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2.0 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2.0 W/kg whole-body average SAR for **15 minutes** of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of the Liverty™ TIPS Stent Graft may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

NOTE: Failure to follow these conditions may result in injury to the patient. The effect of heating in the MRI environment for stents with fractured struts is not known.

STORAGE

Keep away from sunlight. Keep dry.

PATIENT IMPLANT CARD AND PATIENT INFORMATION BROCHURE

A Patient Implant Card is provided with this product. The patient, implant and hospital information should be recorded on the card as requested. Ensure a peel-away sticker from the product label is placed on the card before it is given to the patient. The sticker contains important information about the implant. The patient should carry the implant card with them and present it to any medical personnel involved in their care.

Please visit **eifu.bd.com** for the Patient Information Brochure. The brochure should be made available to the patient. It contains additional important information about this product.

STENT GRAFT SIZE SELECTION

Special care must be taken to ensure that an appropriately-sized device is selected.

Implant Diameter: It is recommended to post-dilate the stent graft with a balloon dilatation catheter to an implant diameter that allows for hemodynamic success and pressure gradient reduction as targeted by the operator. Do not post-dilate beyond 10 mm in diameter.

Implant Length: It is recommended to line the entire parenchymal tract and the hepatic vein to the hepatocaval junction with the Liverty™ TIPS Stent Graft to reduce the risk of stenosis in an unlined hepatic vein segment.

NOTE: The Liverty™ TIPS Stent Graft covered section foreshortening at full expansion is <5%.

MATERIALS REQUIRED FOR THE LIVERTY™ TIPS STENT GRAFT PROCEDURE

- Normal, sterile saline
- Sterile syringes
- Contrast medium
- 0.035 inch (0.89 mm) stiff guidewire of at least 220 cm length to allow safe delivery of the stent graft and removal of the delivery system
- Introducer sheath with at least 10F inner diameter. NOTE: long or short sheaths can be used for the procedure.
- Diagnostic catheters and accessories
- Radiopaque measuring catheter
- Balloon dilatation catheter for pre- and post-dilatation. NOTE: If the intended shunt diameter is 6 mm or 7 mm, an 8 mm balloon is additionally required for post-dilatation to mitigate the risk of thrombosis.
- Inflation device for pre- and post-dilatation

DIRECTIONS FOR USE

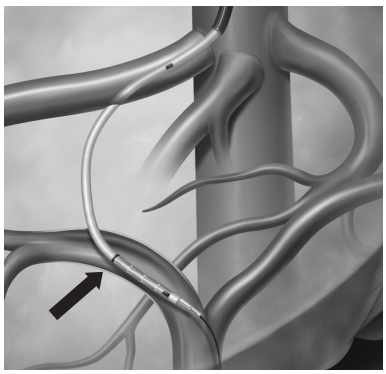
Preparation

1. Use standard portal vein access techniques to create the shunt and introduce a guidewire.
2. Dilate the parenchymal tract with a balloon dilatation catheter of appropriate length and diameter.
3. Measure the length of the tract with a measuring catheter.
4. Select the appropriate stent graft length to allow for full coverage of the parenchymal tract and the hepatic vein to the hepatocaval junction. If curvature is noted in the tract, add 1 cm to the total length measurement of the tract.
5. Using fluoroscopy, advance a 0.035 inch (0.89 mm) stiff guidewire across the parenchymal tract into the portal vein.
6. Open the box and confirm the sterile barrier is intact. Open the pouch and carefully remove the delivery system from the tray.
7. Inspect the delivery system to ensure it is undamaged and sterile; do not use if sterility or performance is in doubt.
8. Verify the safety lock slider is locked and the black push button is not depressed (Figure 3); do not use if either control is in the incorrect position.
9. Confirm the stent graft is fully contained within the transparent stent graft delivery sheath (G); do not use if partially deployed.
10. Wipe the working length (F, G & H per Figure 2) of the delivery system with gauze soaked with sterile saline.
11. Flush the delivery system guidewire lumen through the Luer port at the proximal end of the handle (E per Figure 2) with normal, sterile saline until saline drips from the tip of the system.

Delivery System Introduction

12. Under radiographic guidance, advance the delivery system over the guidewire from the jugular vein access site through the hepatic vein and the liver tract into the portal vein until the radiopaque marker band located at the transition of the covered to the bare stent graft segment is positioned well inside the portal vein (Figure 6).

Figure 6: Position of the radiopaque marker band (arrow) well inside the portal vein



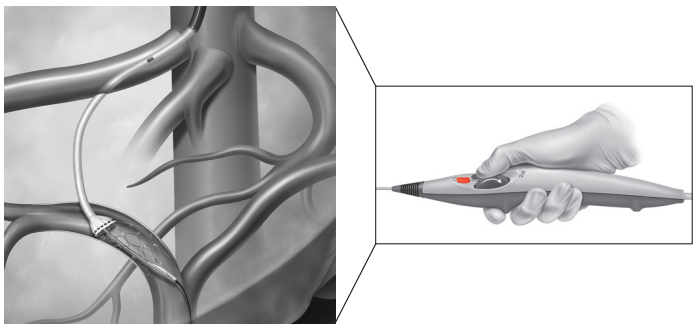
NOTE: Injection of contrast media through the side port of a 10F sheath is possible at any time if additional visualization is desired.

Stent Graft Deployment

13. Prior to stent graft deployment, unlock the red safety lock slider by pressing down and pulling it back towards the end of the handle from the locked position into the unlocked position. Ensure that the red safety lock slider is completely retracted and that the symbol for the unlocked position is fully visible (Figure 3).
14. Slowly and carefully activate the stent graft release mechanism by rotating the blue wheel on the top of the handle backwards until you feel firm resistance. Confirm that the bare stent graft segment, along with a few millimeters of the covered stent graft segment containing the marker band, has been released (Figure 7).

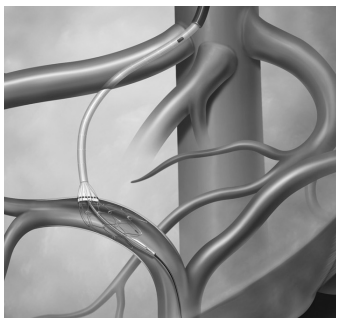
    NOTE: Ensure that the 10F introducer sheath does not cover any portion of the implant during stent graft release.

Figure 7: Release of the bare stent graft segment



15. If needed for correct positioning, pull the delivery system with the expanded bare metal segment to the final position at the parenchymal/ portal vein junction (Figure 8).

Figure 8: Final position of stent graft bare metal end



16. When the final stent graft position is confirmed, push the black button on the delivery system handle (Figure 3).
17. Continue to rotate the blue wheel until the covered segment of the stent graft is fully deployed.

    IMPORTANT: With your fingers, hold the beige stability sheath (F per Figure 2) as close as possible to the introducer sheath hub. Maintain the beige stability sheath straight and keep the handle stationary.
18. Carefully remove the delivery system under fluoroscopy while maintaining guidewire access. Visually confirm the integrity of the delivery system.
19. Post-dilate the stent graft segment inside the liver tract with a balloon dilatation catheter to the desired shunt diameter.

    NOTE: - It is recommended to advance the balloon dilatation catheter through the deployed stent graft under fluoroscopy to mitigate the risk of potential stent graft dislodgement.
    - Prolonged dilatation (at least 25 seconds) of the main tract will help to achieve a uniform expanded shunt lumen.
20. **IMPORTANT:** For 6 mm, 7 mm and 8 mm shunts: The leading 20 mm long covered stent graft segment (Section A in Figure 9) must be additionally dilated with an 8 mm balloon for at least 25 seconds. If this section demonstrates inadequate dilatation, it can be focally dilated again to 8 mm or larger.

Table 26: Post-dilatation of leading covered stent graft end

Final shunt diameter	Additional post-dilatation of leading covered stent graft end (Section A per Figure 9)
6 mm	8 mm
7 mm	
8 mm	
9 mm	Not required
10 mm	

Figure 9: Liverty™ TIPS Stent Graft leading 20 mm covered end – Section A



21. Using standard procedures, verify the location and patency of the stent graft.

    NOTE: If necessary for complete coverage of the intrahepatic shunt and the hepatic vein to the hepatocaval junction, a second stent graft may be placed in overlapped fashion.
22. Remove the guidewire and introducer sheath from the body and close the entry site wound as appropriate.

    NOTE: Physician experience and discretion will determine the appropriate drug regimen for each individual patient.

DISPOSAL INSTRUCTIONS

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

LIMITED PRODUCT WARRANTY

Angiomed GmbH & Co. Medizintechnik KG warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, or refunding your net price paid, in Angiomed GmbH & Co. Medizintechnik KG's sole discretion. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL ANGIOMED GMBH & CO. MEDIZINTECHNIK KG BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

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SYMBOLS USED ON LABELING

Consult instructions for use or consult electronic instructions for use

Keep away from sunlight

Keep dry

Do not use if the product sterile barrier system or its packaging is compromised

Single use

Do not resterilize

Contents

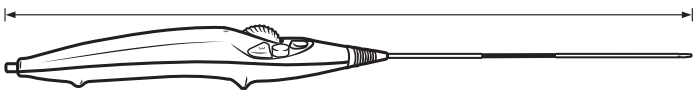
MR conditional

Not made with natural rubber latex

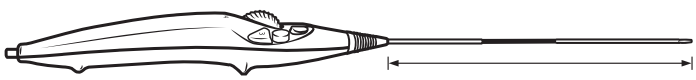
Non-pyrogenic

Catalogue number

Lot number



System length



Working length

Sterilized using ethylene oxide

Use by

Labeling issue date 2026-06

Manufacturer

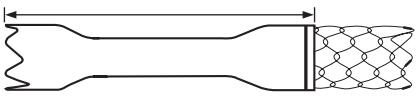
Single sterile barrier system

Patient information website

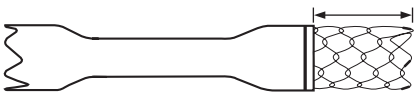
Unique device identifier

Minimum introducer

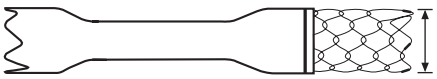
Recommended guidewire



Covered stent graft length



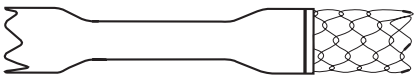
Uncovered stent graft length



Stent graft ends diameter



Stent graft mid diameter



Stent graft

Material of construction: Nitinol

Self-expanding stent

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

RFID Tag

Distributor

BD Liverty™ TIPS Stent Graft

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