

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Shunt, Portosystemic, Endoprosthesis
Device Trade Name: Liverty™ TIPS Stent Graft
Device Procode: MIR
Applicant's Name and Address: Bard Peripheral Vascular, Inc. (BPV)
1625 W 3rd Street
Tempe, AZ 85281

Date(s) of Panel Recommendation: None
Premarket Approval Application (PMA) Number: P250050
Date of FDA Notice of Approval: 09/25/2026

II. INDICATIONS FOR USE

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

III. CONTRAINDICATIONS

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

IV. WARNINGS AND PRECAUTIONS

The WARNINGS and PRECAUTIONS can be found in the Liverty™ TIPS Stent Graft labeling (Instructions for Use).

V. DEVICE DESCRIPTION

The Liverty™ TIPS Stent Graft is a self-expanding endoprosthesis comprised of ePTFE encapsulating a nitinol (nickel-titanium) stent and pre-mounted on a delivery system.

Description of Stent Graft

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 (blood-contacting surface) is carbon impregnated.

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



Figure 1: Livity™ TIPS Stent Graft (as supplied)

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).

After implantation of the Livity™ 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 2 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 2: Livity™ TIPS Stent Graft after Maximum Dilatation

Description of Delivery System

The tri-axial, over-the-wire delivery system is illustrated in Figure 3. 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) houses the compressed stent graft (implant) and a darker brown, smaller-diameter extension catheter (H). During stent graft deployment, the entire distal catheter assembly retracts towards the handle while the dark 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.



Figure 3: Liverty™ TIPS Stent Graft Delivery System

A black push button on the top of the handle (K) must be pressed before the ePTFE encapsulated stent graft can be fully released (Figure 4). The numbers 1 through 4 are printed on the top of the handle. The numbers indicate the order in which the operator is to perform the different steps of stent graft deployment.

Deployment steps:	
1	Slide the red safety lock 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.

Delivery system in locked (left) and unlocked (right) positions.

Figure 4: Delivery System User Interface

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

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several alternatives for the treatment of complications of portal hypertension. The goal of alternative treatment modalities is to reduce the portosystemic pressure gradient (PSG) or treat complications of portal hypertension.

- A. Medical Treatments: Systemic pharmaceuticals may be used to reduce PSG in patients with portal hypertension.

- B. Endoscopic Treatments: Endoscopic treatments are available to treat the complications of portal hypertension. Variceal bleeding may be treated using band ligation and sclerosing agents.
- C. Drainage Treatments: Ascites may be treated with large volume paracentesis or the placement of an indwelling peritoneal catheter or a permanent peritoneovenous shunt to drain fluid from the peritoneal cavity.
- D. Interventional Radiology Procedures: Transjugular intrahepatic portosystemic shunt (TIPS) creation using a commercially available stent graft may be performed to reduce PSG and provide alternative conduits to the systemic circulation.
- E. Surgical Procedures: Surgical creation of a portocaval shunt may be performed to reduce PSG and provide alternative conduits to the systemic circulation.
- F. Liver Transplant: Liver transplantation may be performed to replace the diseased liver in patients with liver failure.

Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets medical needs, expectations, and lifestyle.

VII. MARKETING HISTORY

The Liverty™ TIPS Stent Graft has been marketed in the European Union and Switzerland. The device has not been withdrawn from any market for any reason.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the Liverty™ TIPS Stent Graft.

Access site bleeding; Accidental puncture; Biliary injury; Cardiac arrhythmia; 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.

For specific adverse events that occurred in the clinical study, please see Section X below.

IX. SUMMARY OF NON-CLINICAL STUDIES

A. Biocompatibility

Biocompatibility testing on the Liverty™ TIPS Stent Graft was performed following the recommendations provided in ISO 10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process,” as well as the FDA guidance documents, “Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems” and “Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol.” Test samples were manufactured in accordance with standard operating procedures, were subjected to two cycles of ethylene oxide sterilization, and are representative of finished product.

The components of the stent graft and delivery system were categorized per ISO 10993-1 based on the intended duration and contact with or within the body. The stent graft was categorized as a permanent implant (>30 days) with direct contact to circulating blood. The delivery system was categorized as an externally communicating device with limited (≤24 hours) exposure to circulating blood.

Table 1 provides a listing of the tests performed for both the stent graft and delivery system biocompatibility testing, along with the corresponding results. Thrombogenicity of the stent graft and delivery system were both assessed in GLP animal studies, as outlined in Section D below. All biocompatibility tests were conducted in accordance with Good Laboratory Practices (GLP), per 21 CFR Part 58.

Table 1: Stent Graft & Delivery System Biocompatibility Testing

Stent Graft		Delivery System	
Test	Results	Test	Results
Cytotoxicity – MEM Elution	PASS	Cytotoxicity – MEM Elution	PASS
Irritation / Intracutaneous Reactivity	PASS	Irritation / Intracutaneous Reactivity	PASS
Sensitization – Kligman Maximization	PASS	Sensitization – Kligman Maximization	PASS
Acute Systemic Toxicity – Systemic Injection	PASS	Acute Systemic Toxicity – Systemic Injection	PASS
Hemocompatibility – ASTM Hemolysis (Direct & Indirect)	PASS	Hemocompatibility – ASTM Hemolysis (Direct & Indirect)	PASS
Hemocompatibility – Complement Activation: C3a & Sc5B-9	PASS	Hemocompatibility – Complement Activation: Sc5B-9	PASS
Hemocompatibility – Partial Thromboplastin Time (PTT) Assay	PASS	Hemocompatibility – Partial Thromboplastin Time (PTT) Assay	PASS
Hemocompatibility – <i>In vivo</i> Thrombogenicity	PASS	Hemocompatibility – <i>In vivo</i> Thrombogenicity	PASS
Pyrogenicity – Material Mediated	PASS	Pyrogenicity – Material Mediated	PASS
Subacute / Subchronic Toxicity – Implant Method (13-week Rat Study)	PASS		
Genotoxicity – Ames Bacterial Reverse Mutation Assay	PASS		
Genotoxicity – Mouse Lymphoma Assay (MLA)	PASS		
Implantation (1, 4 & 12 weeks)	PASS		
Nickel Ion Release	PASS		

Chronic Toxicity and Carcinogenicity of the stent graft was addressed via chemical characterization and toxicological risk assessment. Extractable studies were conducted and relevant compounds identified were subject to toxicological risk assessment. Based on the available toxicity data, exposure estimates, and safety margins, the likelihood of extractable chemicals from the Liverty™ TIPS Stent Graft producing unacceptable carcinogenic or non-carcinogenic health risks in the adult patient population under the proposed conditions and duration of clinical use (long term, >30 days for the implant) is acceptable.

B. Laboratory Studies

In vitro bench testing was conducted as part of the design verification and validation to support the safety of the Liverty™ TIPS Stent Graft. This testing was conducted based

on recommendations from risk assessments with consideration of FDA and industry-recognized standards. The bench test results are summarized in Table 2. The testing presented in Table 2 includes results from both baseline (T=0) and accelerated aged units.

Table 2: Summary of In Vitro Bench Testing

Test	Purpose/Objective	Summary of Acceptance Criteria	Results																
Stent Graft																			
Material Composition	To verify the chemical composition of the stent graft.	Material composition must meet product specifications. The hydrogen content of the stent shall be characterized. The surface oxide layer composition and thickness must be characterized.	PASS																
Shape Memory and Superelasticity of Intravascular Stents	To verify the transition temperature of the nitinol stent graft.	The Austenite Finish Transition Temperature (A_f) for the nitinol stent graft, measured in accordance with ASTM F2082, must be between 18°C-31°C.	PASS																
Stent Corrosion Resistance	To verify the stent graft's ability to resist corrosion.	Stent grafts must be evaluated for corrosion following trackability and deployment. The pitting corrosion evaluations, performed in accordance with ASTM F2129, must yield an average breakdown potential greater than or equal to 200 mV. The galvanic corrosion rate shall be no greater than 1 $\mu\text{m}/\text{year}$.	PASS																
Dimensional Verification*	To verify that critical stent graft dimensions (stent graft diameter and length in the unconstrained expanded condition) are met.	Stent graft must meet dimensional specifications. Implant length (freely expanded):	PASS																
		<table><tr><th>Labeled Length – covered/bare (mm)</th><th>Post Deployment Length (mm)</th></tr><tr><td>40/20</td><td>40 $\pm$ 5 / 20 $\pm$ 3</td></tr><tr><td>50/20</td><td>50 $\pm$ 5 / 20 $\pm$ 3</td></tr><tr><td>60/20</td><td>60 $\pm$ 5 / 20 $\pm$ 3</td></tr><tr><td>70/20</td><td>70 $\pm$ 6 / 20 $\pm$ 3</td></tr><tr><td>80/20</td><td>80 $\pm$ 6 / 20 $\pm$ 3</td></tr><tr><td>90/20</td><td>90 $\pm$ 7 / 20 $\pm$ 3</td></tr><tr><td>100/20</td><td>100 $\pm$ 7 / 20 $\pm$ 3</td></tr></table>		Labeled Length – covered/bare (mm)	Post Deployment Length (mm)	40/20	40 $\pm$ 5 / 20 $\pm$ 3	50/20	50 $\pm$ 5 / 20 $\pm$ 3	60/20	60 $\pm$ 5 / 20 $\pm$ 3	70/20	70 $\pm$ 6 / 20 $\pm$ 3	80/20	80 $\pm$ 6 / 20 $\pm$ 3	90/20	90 $\pm$ 7 / 20 $\pm$ 3	100/20	100 $\pm$ 7 / 20 $\pm$ 3
		Labeled Length – covered/bare (mm)		Post Deployment Length (mm)															
		40/20		40 $\pm$ 5 / 20 $\pm$ 3															
		50/20		50 $\pm$ 5 / 20 $\pm$ 3															
		60/20		60 $\pm$ 5 / 20 $\pm$ 3															
		70/20		70 $\pm$ 6 / 20 $\pm$ 3															
		80/20		80 $\pm$ 6 / 20 $\pm$ 3															
		90/20	90 $\pm$ 7 / 20 $\pm$ 3																
		100/20	100 $\pm$ 7 / 20 $\pm$ 3																
Stent graft must meet dimensional specifications. Implant inner diameter (constricted section following balloon dilatation):	PASS																		
<table><tr><th>Labeled ID (mm)</th><th>Post Deployment ID (mm)</th></tr><tr><td rowspan="5">6-10</td><td>6.0 $\pm$ 0.5</td></tr><tr><td>7.0 $\pm$ 0.5</td></tr><tr><td>8.0 $\pm$ 0.5</td></tr><tr><td>9.0 $\pm$ 0.5</td></tr><tr><td>10.0 $\pm$ 0.5</td></tr></table>		Labeled ID (mm)	Post Deployment ID (mm)	6-10	6.0 $\pm$ 0.5	7.0 $\pm$ 0.5	8.0 $\pm$ 0.5	9.0 $\pm$ 0.5	10.0 $\pm$ 0.5										
Labeled ID (mm)		Post Deployment ID (mm)																	
6-10		6.0 $\pm$ 0.5																	
	7.0 $\pm$ 0.5																		
	8.0 $\pm$ 0.5																		
	9.0 $\pm$ 0.5																		
	10.0 $\pm$ 0.5																		
Diameter Stability Over Time	To characterize the creep response of the ePTFE constraining sleeve and predict the radial growth over time.	Stent graft diameter must be stable over 10 years lifetime simulation. Diameter change < 0.5 mm.	PASS																
Percent Surface Area	For characterization purposes only to quantify the percent of stent-free surface area of the bare stent portion of the implant.																		
Foreshortening*	To quantify the percent decrease in length of the stent graft from between its crimped and deployed states.	Characterization only.	Foreshortening response characterized for inclusion in labeling																

Test	Purpose/Objective	Summary of Acceptance Criteria	Results
Stent Graft Integrity*	To evaluate the integrity of the stent graft post-deployment in singular and overlapped configurations and verify the stent graft shows no defects that would render it unsuitable for the intended use.	Implant must maintain structural integrity (e.g., no holes, tears and splitting through ePTFE, no ePTFE or strut protrusion into the inner lumen) post-deployment.	PASS
Radial Outward Force*	To characterize the force exerted by the stent graft as a function of stent graft diameter.	Chronic Outward Force (COF) ≤ 0.13 N/mm at an oversizing of 2 mm Radial Resistive Force (RRF) ≥ 0.07 N/mm at an oversizing of 0.5 mm	PASS
Mechanical Properties	For characterization purposes only to determine uniaxial tensile strength and fatigue strength to support Stress/Strain Analysis.		
Stress/Strain Analysis	For characterization purposes only to determine maximum stresses and strains experienced during loading into the catheter and deployment at the intended anatomical site.		
Fatigue Analysis	To assess durability of the device to support Accelerated Durability Testing.	N/A – Fatigue analysis was conducted to identify fatigue loading modes and establish accelerated durability test conditions.	N/A
Accelerated Durability Testing	To evaluate the structural integrity of the stent graft under cyclic free bending fatigue conditions.	Stent grafts must withstand an equivalent of 6 months (3.6 million load cycles) accelerated durability testing. Test articles shall maintain structural integrity upon completion of testing, including no Type I and II stent fractures and stent graft integrity maintained within specification. Based on the anatomic environment in which a TIPS stent is placed, it was determined that additional long-term accelerated durability evaluation was not required.	PASS
Particulate Evaluation*	To characterize the typical particulate amounts and sizes generated during simulated use.	The average number of particulates released during simulated use and device deployment must meet product specifications. Light obscuration test method: • Average number of particulates of the tested samples does not exceed 25 per mL ≥ 10 μm • Average number of particulates of the tested samples does not exceed 3 per mL ≥ 25 μm • Average number of particulates of the tested samples does not exceed 2 per mL ≥ 50 μm	PASS
MRI Safety and Compatibility	The compatibility of the implant in an MR environment has been characterized per FDA Guidance; the conditions under which the device can be safely scanned are provided in the product labeling.		
Radiopacity	To evaluate the radiopacity of the stent graft under fluoroscopy.	The visibility of the stent graft under fluoroscopy during and after deployment as well as after placement must be rated as clinically acceptable by physician experts in an animal model.	PASS
Crush Resistance / Local Compression*	To evaluate the ability of the stent graft to resist permanent deformation following collapse.	After local compression and compression between parallel plates, the stent must maintain structural integrity and return to its original shape within 8% of the original mean diameter.	PASS

Test	Purpose/Objective	Summary of Acceptance Criteria	Results
Kink Resistance*	To evaluate the stent graft's flexibility in its deployed configuration.	The stent graft does not kink at oversizing and at a centerline radius of the TIPS anatomical model of 19.8 mm. The maximum radius at which the stent graft starts to kink needs to be measured. The implant must recover to its original shape after testing. Original shape is defined as no residual kinks which compromise the lumen after testing. Permanent OD reduction at the radiopaque marker band after testing is not greater than 8%.	PASS
Bending Stiffness*	To verify that the ending stiffness of the covered portion of the stent graft is acceptable for the intended use.	Bending stiffness of the stent graft in the middle of the covered section should be ≤ 1.6 N in a three-point bend test.	PASS
Migration Resistance*	To verify that the stent adequately resists displacement during use.	The force required to displace the covered section of the stent graft when deployed in a silicone tube at 1 mm oversizing (bare end located outside the silicone tube) must be ≥ 0.06 N/mm. The force required to displace the bare end of the stent graft when deployed in a silicone tube at 1 mm oversizing must be ≥ 0.12 N/mm.	PASS
Integral Water Leakage	To characterize the rate of water leakage through the stent graft covering wall.	The water leakage through the ePTFE material of the stent graft should be characterized and comparable to a clinical control.	PASS
Porosity	To characterize the porosity of the stent covering.	The Inter Nodal Distance (IND) of the covering material must be between 10 and 40 μ m.	PASS
Burst / Circumferential Strength	For characterization purposes only to quantify the circumferential tensile (burst) strength of the stent graft covering.		
Longitudinal Tensile Strength	For characterization purposes only to quantify the longitudinal tensile strength of the stent graft covering.		
Strength of Stent / Attachment System to Graft Bond*	To verify that the force required to separate the two bonded ePTFE layers (stent graft encapsulation) is acceptable for the intended use.	The stent graft covering bond peel strength must be ≥ 6 gf/mm.	PASS
Delivery System			
Dimensional Verification*	To verify that the delivery system meets dimensional criteria pre-deployment.	At least 75 cm delivery system working length. The delivery system must pass through a 10F ring gauge over its entire working length pre deployment. Delivery system inner diameter must be compatible with an 0.035" guidewire.	PASS

Test	Purpose/Objective	Summary of Acceptance Criteria	Results																														
Simulated Use (Preparation, Delivery, Deployment, and Retraction)*	To ensure that the delivery system meets its pre-determined acceptance criteria with respect to its delivery, deployment, and retraction in a simulated use environment.	Endovascular system can be flushed with saline solution using a 5ml (cc) syringe during the simulated use testing and/or in an animal model. The endovascular system must be advanced and retracted through a validated, worst case anatomical model, and stent grafts must be deployed. Trackability, pushability, and torqueability of the system during advancement and retraction, must meet the product design specifications. The deployment force must be rated ≤ 3 during simulated use testing. (Refer also to Force to Deploy test). The deployment accuracy must meet the following criteria: - Deployment accuracy in an anatomical model at the proximal end of the implant must be $\leq + 5$ mm/ - 7mm [where + indicates movement to the hepatic vein and - indicates movement to the IVC] - Deployment accuracy in an anatomical model at the distal end of the stent graft section (transition from bare stent to stent graft section) must be $\leq \pm 5$ mm [where + indicates movement in the distal (portal vein side) direction and - indicates movement in the proximal (liver parenchyma/ hepatic vein) direction] The delivery system must then be withdrawn from the landing zone and through the anatomical model following deployment. Delivery system integrity must meet product design specification post deployment. Test conditions must simulate the physiological environment of the intended indication. Stent grafts must be evaluated to various deployment configurations and with accessory devices representative of those clinically used for the procedure.	PASS																														
Catheter Bond Strength including Tip Pull Test*	To determine the bond strength of delivery system joints and verify that the strength of the bond joints are adequate for the intended use.	The delivery system must meet product design specifications for joint strength. <table><tr><th>Joint # - Joint Description</th><th>Type of Load</th><th>Specification</th></tr><tr><td>J1: Stent sheath – Proximal catheter</td><td>Tension</td><td>$F \geq 35$ N</td></tr><tr><td>J2: Tip – Crown ring – Inner catheter</td><td>Tension</td><td>$F \geq 26$ N</td></tr><tr><td>J3: Spiral – Inner catheter</td><td>Compression</td><td>$F \geq 35$ N</td></tr><tr><td>J5: Stability sheath – Strain relief</td><td>Tension</td><td>$F \geq 6$ N</td></tr><tr><td>J6: Strain relief – Grip shells</td><td>Tension</td><td>$F \geq 6$ N</td></tr><tr><td>J7: Slide block – Proximal catheter</td><td>Tension</td><td>$F \geq 35$ N</td></tr><tr><td>J8: Luer – Inner catheter</td><td>Tension</td><td>$F \geq 26$ N</td></tr><tr><td>J9: Bearing assembly – Grip shells</td><td>Tension</td><td>$F \geq 70$ N</td></tr><tr><td>J10: Line tensioner – Drive unit assembly</td><td>Tension</td><td>$F \geq 35$ N</td></tr></table>	Joint # - Joint Description	Type of Load	Specification	J1: Stent sheath – Proximal catheter	Tension	$F \geq 35$ N	J2: Tip – Crown ring – Inner catheter	Tension	$F \geq 26$ N	J3: Spiral – Inner catheter	Compression	$F \geq 35$ N	J5: Stability sheath – Strain relief	Tension	$F \geq 6$ N	J6: Strain relief – Grip shells	Tension	$F \geq 6$ N	J7: Slide block – Proximal catheter	Tension	$F \geq 35$ N	J8: Luer – Inner catheter	Tension	$F \geq 26$ N	J9: Bearing assembly – Grip shells	Tension	$F \geq 70$ N	J10: Line tensioner – Drive unit assembly	Tension	$F \geq 35$ N	PASS
Joint # - Joint Description	Type of Load	Specification																															
J1: Stent sheath – Proximal catheter	Tension	$F \geq 35$ N																															
J2: Tip – Crown ring – Inner catheter	Tension	$F \geq 26$ N																															
J3: Spiral – Inner catheter	Compression	$F \geq 35$ N																															
J5: Stability sheath – Strain relief	Tension	$F \geq 6$ N																															
J6: Strain relief – Grip shells	Tension	$F \geq 6$ N																															
J7: Slide block – Proximal catheter	Tension	$F \geq 35$ N																															
J8: Luer – Inner catheter	Tension	$F \geq 26$ N																															
J9: Bearing assembly – Grip shells	Tension	$F \geq 70$ N																															
J10: Line tensioner – Drive unit assembly	Tension	$F \geq 35$ N																															

Test	Purpose/Objective	Summary of Acceptance Criteria	Results												
Flexibility and Kink Test*	Characterize the ability of the delivery system to withstand flexural forces typical of clinical use.	The system must not kink during delivery, deployment, or withdrawal to and from the target deployment site in a worst-case anatomical model. The radius at which the stent sheath, the stability sheath, and the proximal stent sheath start to kink must be characterized. The stent sheath should not kink at 20 mm. The stability sheath and proximal sheath should not kink at 34 mm.	PASS												
Torque Strength*	To determine the delivery system strength under torsional forces typical of clinical use.	Joints subject to torsional load during use must meet product design specifications and the delivery system must remain functional under torsional stress. <table><tr><th>Joint # - Joint Description</th><th>Type of Load</th><th>Specification</th></tr><tr><td>J7: Slide block – Proximal catheter</td><td>Torsion</td><td>$F \geq 3.0 \text{ N}\cdot\text{cm}$</td></tr><tr><td>J8: Luer – Inner catheter</td><td>Torsion</td><td>$F \geq 1.3 \text{ N}\cdot\text{cm}$</td></tr><tr><td>J11: Drive unit assembly - Clutch</td><td>Torsion</td><td>$F \geq 11 \text{ N}\cdot\text{cm}$</td></tr></table>	Joint # - Joint Description	Type of Load	Specification	J7: Slide block – Proximal catheter	Torsion	$F \geq 3.0 \text{ N}\cdot\text{cm}$	J8: Luer – Inner catheter	Torsion	$F \geq 1.3 \text{ N}\cdot\text{cm}$	J11: Drive unit assembly - Clutch	Torsion	$F \geq 11 \text{ N}\cdot\text{cm}$	PASS
Joint # - Joint Description	Type of Load	Specification													
J7: Slide block – Proximal catheter	Torsion	$F \geq 3.0 \text{ N}\cdot\text{cm}$													
J8: Luer – Inner catheter	Torsion	$F \geq 1.3 \text{ N}\cdot\text{cm}$													
J11: Drive unit assembly - Clutch	Torsion	$F \geq 11 \text{ N}\cdot\text{cm}$													
Coating Integrity	The inner surface of the stent sheath is coated to ensure stent graft loading and deployment forces are acceptable. This test verifies that the coating remains intact and does not pose embolic risk.	For characterization only.	N/A												
Force to Deploy*	To evaluate the deployment force during simulated use testing and verify that the forces required to deploy are adequate for the intended use.	Force to deploy the stent graft must be rated ≤ 3 during simulated use testing. Required deployment force should not compromise the placement accuracy (deployment accuracy). Deployment force measured directly at the proximal catheter must be $\leq 40\text{N}$.	PASS												
Assessment of Hemostasis	To verify the ability of any seals or valves in the system to maintain a hemostatic seal which is adequate for the intended use.	Blood loss while the endovascular system is in the body due to insufficient endovascular hemostasis must be rated as clinically acceptable by physician experts in an animal model. The amount of blood loss due to leakage measured over 10 minutes must not exceed 200 mL.	PASS												
Radiopacity	To evaluate the radiopacity of the device under fluoroscopy.	Delivery System visibility must be rated clinically acceptable by physician expert in a relevant animal model or phantom.	PASS												
Tubing Tensile Strength*	To determine the longitudinal tensile strength of the catheter tubing used in the delivery system and verify that the strength is adequate for the intended use.	Samples must meet product design specifications for tubing tensile strength. <table><tr><th>Material Components</th><th>Type of Load</th><th>Specification</th></tr><tr><td>Stent sheath distal section</td><td>Tension</td><td>$F \geq 21 \text{ N}$</td></tr><tr><td>Proximal catheter</td><td>Tension</td><td>$F \geq 35 \text{ N}$</td></tr></table>	Material Components	Type of Load	Specification	Stent sheath distal section	Tension	$F \geq 21 \text{ N}$	Proximal catheter	Tension	$F \geq 35 \text{ N}$	PASS			
Material Components	Type of Load	Specification													
Stent sheath distal section	Tension	$F \geq 21 \text{ N}$													
Proximal catheter	Tension	$F \geq 35 \text{ N}$													
Luer Performance Testing*	To ensure compatibility of the delivery system Luer connection with accessory devices.	Luers shall conform to performance requirements per ISO 80369-7.	PASS												

* Testing also performed at the accelerated aged time point of 2 years.

C. **Sterility, Packaging, and Shelf-Life Testing**

The Livity™ TIPS Stent Graft is a single-use device. In accordance with AAMI/ANSI/ISO 11135, “Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices,” the Livity™ TIPS Stent Graft demonstrated a Sterility Assurance Level (SAL) of 10^{-6} . Stability testing of the device was performed and validated to ensure a 2-year shelf-life.

Baseline and aged packaging testing, including a visual assessment, bubble leak testing, and sealed seam tensile strength testing was also performed to ensure the package integrity over the device’s shelf life.

D. **Animal Studies**

Two GLP animal studies were performed to evaluate the acute and chronic safety and performance of the Livity™ TIPS Stent Graft. One study evaluated the Livity™ TIPS Stent Graft in a single-stent configuration, while the other evaluated an overlapping-stent configuration. The *in vivo* animal studies demonstrated the safety and overall product performance of the Livity™ TIPS Stent Graft in single and overlapped configurations in a swine model at 30 and 60 days. In addition, an acute evaluation of the Livity™ TIPS Stent Graft Delivery System, including thrombogenicity, was performed. These studies were conducted in accordance with FDA 21 CFR Part 58 GLP Regulations. The results of the animal study are summarized in Table 3.

Table 3: Summary Results of the GLP Animal Studies

Study	Methods	Objectives	Outcome
Single Stent Study	14 Yucatan minipigs were implanted with the Livity™ TIPS Stent Graft. There was one testing arm with two time points (30 and 60 days). Two groups were evaluated: a minimum dilated stent graft (6 mm) and a full dilated stent graft (10 mm).	Assess the local biological and systemic responses to the implant. Assess the position, structural integrity and functionality of the stent graft acutely and at study endpoint. Assess the visualization of the stent graft upon implantation. Monitor for the occurrence of adverse events and potential contributing factors.	All devices were successfully delivered and deployed. The functional requirements for both the stent graft and delivery system were met. 13 of 14 stent grafts were patent at retrieval. One stent graft was occluded at retrieval; this was attributed to an error in placement and not deemed to represent a clinically relevant issue with the device. Evaluation of local and systemic responses to the stent graft revealed favorable response in all animals and was judged to be acceptable at both gross and histological evaluation. There was no evidence of stent graft migration or stent graft covering disruption.

Study	Methods	Objectives	Outcome
Overlapping Stent Study	10 Yucatan minipigs were implanted with two Liverty™ TIPS Stent Grafts in an overlapping stent configuration. There was one testing arm with two time points (30 and 60 days). Two groups were evaluated: a minimum dilated stent graft (6 mm) and a full dilated stent graft (10 mm).	Assess the local biological and systemic responses to the implant at study endpoint. Assess the position, structural integrity and functionality of the stent graft acutely and at study endpoint. Assess the visualization of the stent graft upon implantation. Monitor for the occurrence of adverse events and potential contributing factors.	All devices were successfully delivered and deployed. The functional requirements for both the stent graft and delivery system were met. All stent grafts were patent at retrieval. Evaluation of local and systemic responses to the stent graft revealed favorable response in all animals and was judged to be acceptable at both gross and histological evaluation. There was no evidence of stent graft migration or stent graft covering disruption.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study in the US, France, and Germany under IDE # G220298 to establish a reasonable assurance of safety and effectiveness of TIPS with the Liverty™ TIPS Stent Graft for the treatment complications of portal hypertension. Data from this clinical study were the basis for the PMA approval decision. A summary of the study is presented below.

A. Study Design

The ARCH study was a global, prospective, multi-center, single-arm clinical study intended to assess the safety and effectiveness of the Liverty™ TIPS Stent Graft for the treatment of complications of portal hypertension. This includes recurrent or refractory ascites, hepatic hydrothorax, and/or variceal bleeding (esophageal and/or gastric). Co-primary safety and effectiveness measures for participants receiving the Liverty™ TIPS Stent Graft were assessed against Performance Goals (PG).

The safety endpoint was Freedom from Major Complications through 30-Days post-Index Procedure and was evaluated against a PG of 85%, which was derived from consideration of the American College of Radiology – Society of Interventional Radiology (ACR-SIR) Practice Parameter for the Creation of a TIPS¹, published literature, and physician input. The study device was considered to have achieved the safety objective if the lower limit of the one-sided 95% confidence limit, based on the Clopper-Pearson method, was greater than 85%.

The effectiveness endpoint was Freedom from Shunt Dysfunction through 6-Months post-Index Procedure and was evaluated against a PG of 78%, which was derived using

literature and published data on approved TIPS devices. The study device was considered to have achieved the effectiveness objective if the lower limit of the one-sided 95% confidence limit, based on the Clopper-Pearson method, was greater than 78%.

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 Tailored Expansion Procedure. For participants who underwent the Tailored Expansion Procedure, follow-up was performed based on the Index Procedure date until the Tailored Expansion Procedure had been completed and was then restarted and performed based on the Tailored Expansion Procedure date.

The final study sample size was based on the number required to test the co-primary endpoints. To account for a 5% attrition rate through 30-days, it was calculated that 175 participants should be enrolled such that 166 participants were expected to provide evaluable data for the 30-day co-primary safety endpoint. To account for a 25% attrition rate through 6-months, it was calculated that 175 participants should be enrolled such that 131 participants were expected to provide evaluable data for the 6-month co-primary effectiveness endpoint.

One hundred seventy-seven (177) participants were treated with the Liverty™ TIPS Stent Graft between August 8, 2023 and October 18, 2024. The database for this PMA reflects data extracted on August 22, 2025 and included 177 treated participants (last participant 6-month data collected on June 23, 2025). There were 26 investigational sites which enrolled participants.

The analyses were conducted based on all known information for participants who had reached pre-specified time points: 30 days for the safety endpoint and 6 months for the effectiveness endpoint and secondary endpoints. Participants will be followed through 24 months.

Independent study evaluations were provided by a Data Monitoring Committee (DMC), Clinical Events Committee (CEC), and Core Laboratory, all of which operated under pre-specified procedures. 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. The Core Laboratory assessments were used in final analyses.

1. Clinical Inclusion and Exclusion Criteria

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 $\geq 50,000/\mu\text{L}$.

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.

2. Follow-up Schedule

All participants underwent a clinical evaluation at screening (prior to index procedure); treated participants underwent a clinical evaluation prior to hospital discharge. All participants were scheduled for follow-up at 30-days, 3-months, and 6-months post-operatively. Additionally, participants will be followed through 12, 18, and 24 months post-operatively.

The key timepoints are shown below in Table 4 summarizing the time and events schedule.

Table 4: Time and Events Schedule

Observation	Screening	Index Procedure or Tailored Expansion Procedure ¹	Hospital Discharge	30 d (-14/+7d)	3 mo ($\pm 30\text{d}$)	6, 12, 18, & 24 mo ($\pm 30\text{d}$)
Informed Consent	✓					
Demographics	✓					
Medical History	✓					
Relevant Concomitant Medications	✓		✓	✓	✓	✓
Comprehensive Physical Exam	✓			✓	✓	✓
HRQoL Questionnaire	✓			✓	✓	✓
Lab Tests and MELD/Child-Pugh Score Calculation	✓			✓	✓	✓
MRI, CT, or Grayscale DUS	✓					
Treatment Eligibility Assessment	✓					
TIPS Creation and implantation of Liverty™ TIPS Stent Graft		✓ ²				
Post-Dilatation of the Shunt		✓				
Final TIPS Assessment & PSG Calculation		✓				
Doppler Ultrasound (DUS)				✓	✓	✓

Observation	Screening	Index Procedure or Tailored Expansion Procedure ¹	Hospital Discharge	30 d (-14/+7d)	3 mo (± 30d)	6, 12, 18, & 24 mo (± 30d)
Shunt Dysfunction Assessment				✓	✓	✓
Direct Shunt Venography & PSG Calculation (if applicable for suspected shunt dysfunction)				✓	✓	✓
Documentation of Adverse Events, Additional Therapies, Device Deficiencies & Protocol Deviations		✓	✓	✓	✓	✓

¹ 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) within the initial 8 weeks post-Index Procedure, if necessary, to further optimize clinical outcomes. Follow-up visits began based on the date of Index Procedure (Day 1). For participants who underwent a TEP, follow-up visits began based on the date of Index Procedure (Day 1) until the TEP was performed. Once the TEP was performed, follow-up visits were restarted and performed based on the date of the TEP (New Day 1).

² TIPS creation and implantation of Liverty™ TIPS Stent Graft only occurred at the Index Procedure.

3. Clinical Endpoints

The co-primary safety endpoint was Freedom from Major Complications through 30 days Post-Index Procedure. Major Complications are defined as:

- The following Adverse Events (if determined to be related to the device and/or procedure *and* to meet the definition of a Serious Adverse Event (SAE)):
 - Accelerated Liver Failure (>3-fold increase in bilirubin or >2-fold increase in INR compared to baseline within 30 days post-TIPS)
 - Biliary Peritonitis
 - Caval Occlusion
 - Death
 - Hemobilia
 - Hemoperitoneum
 - Hepatic Artery Injury
 - Hepatic Infarction
 - Radiation Skin Burn
 - Renal Failure (requiring chronic dialysis)
 - Severe Hepatic Encephalopathy (requiring hospitalization)
 - Vascular Perforation (resulting from stent graft malposition due to excessive extension of the stent graft into the inferior vena cava or the right atrium)
- The following Device Deficiencies, if having the potential to or if confirmed to have led to a Serious Adverse Event (SAE):
 - Stent Migration (within the portal or systemic venous circulations resulting from stent graft malposition)

The co-primary safety endpoint was evaluated against a PG of 85%, derived from consideration of the ACR-SIR Practice Parameter for the Creation of a TIPS¹, relevant clinical literature, and physician input. A one-sided p-value was derived based on an exact binomial test. The study device was considered to have achieved the safety objective if the one-sided p-value was less than 0.05. Or, equivalently, if the lower limit of the one-sided 95% confidence limit, based on the Clopper-Pearson method, was greater than 85%.

The co-primary effectiveness endpoint of the study 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-TIPS Index Procedure. Treatment Completion was defined as the latter to occur of (i) completion of the Index Procedure and (ii) if performed, the Tailored Expansion Procedure (TEP).

The co-primary effectiveness endpoint was evaluated against a literature-derived Performance Goal (PG) of 78%, which was derived using literature and published data on approved TIPS devices. A one-sided p-value was derived based on an exact binomial test. The study device was considered to have achieved the co-primary effectiveness objective if the one-sided p-value was less than 0.05. Or, equivalently, if the lower limit of the one-sided 95% confidence limit, based on the Clopper-Pearson method, was greater than 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.

Secondary endpoints without hypothesis testing included the following:

- **Technical Success**, defined as the 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**, defined as the successful post-TIPS reduction of the portosystemic gradient (PSG) to an Investigator-determined target of ≤ 12 mmHg or by $\geq 50\%$ from the baseline PSG, as assessed by the Investigator during the Index Procedure.
- **Clinical Success for participants with recurrent or refractory ascites** through 3, 6, 12, 18, and 24 months post-Treatment Completion, defined as freedom from large volume paracentesis (LVP) of >5L occurring >6 weeks post-Treatment Completion.

- **Clinical Success for participants with hepatic hydrothorax** through 3, 6, 12, 18, and 24 months post-Treatment Completion, defined as freedom from thoracentesis of >1L occurring >6 weeks post-Treatment Completion.
- **Clinical Success for participants with esophagogastric variceal bleeding** through 1, 3, 6, 12, 18, and 24 months post-Treatment Completion, defined as freedom from endoscopically-confirmed esophagogastric variceal re-bleeding.
- **Freedom from Shunt Dysfunction** through 1, 3, 12, 18, and 24 months post-Treatment Completion. Shunt Dysfunction is 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-TIPS Index Procedure.
- **Freedom from Shunt Re-Intervention** through 1, 3, 6, 12, 18, and 24 months post-Treatment Completion.
- **Freedom from Hepatic Encephalopathy of Grade ≥ 3** per West Haven Criteria through 1, 3, 6, 12, 18, and 24 months post-Treatment Completion.
- **Liver Transplant-Free Survival** post-Index Procedure, defined as the proportion of participants with freedom from death from any cause and from liver transplantation.
- **Overall Survival** post-Index Procedure, defined as the proportion of participants with freedom from death from any cause.
- **Health-Related Quality of Life (HRQoL)** at Screening and at 1, 3, 6, 12, 18, and 24 months post-Treatment Completion, as measured by PROMIS-29 Profile v2.1.

B. Accountability of PMA Cohort

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-days 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. Refer to Table 11 and Table 18 for discussion of the non-evaluable status of study participants for endpoint analysis.

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 $\leq 50,000/\mu\text{L}$ 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, 5 (2.8%) received a liver transplant, 4 (2.3%) withdrew consent, and 3 (1.7%) were lost to follow-up. Table 5 summarizes participant disposition through 6-month follow-up and the reasons for discontinuation based on the Intent to Treat (ITT) population.

Table 5: Participant Disposition through end of 6-Month Follow-Up Window

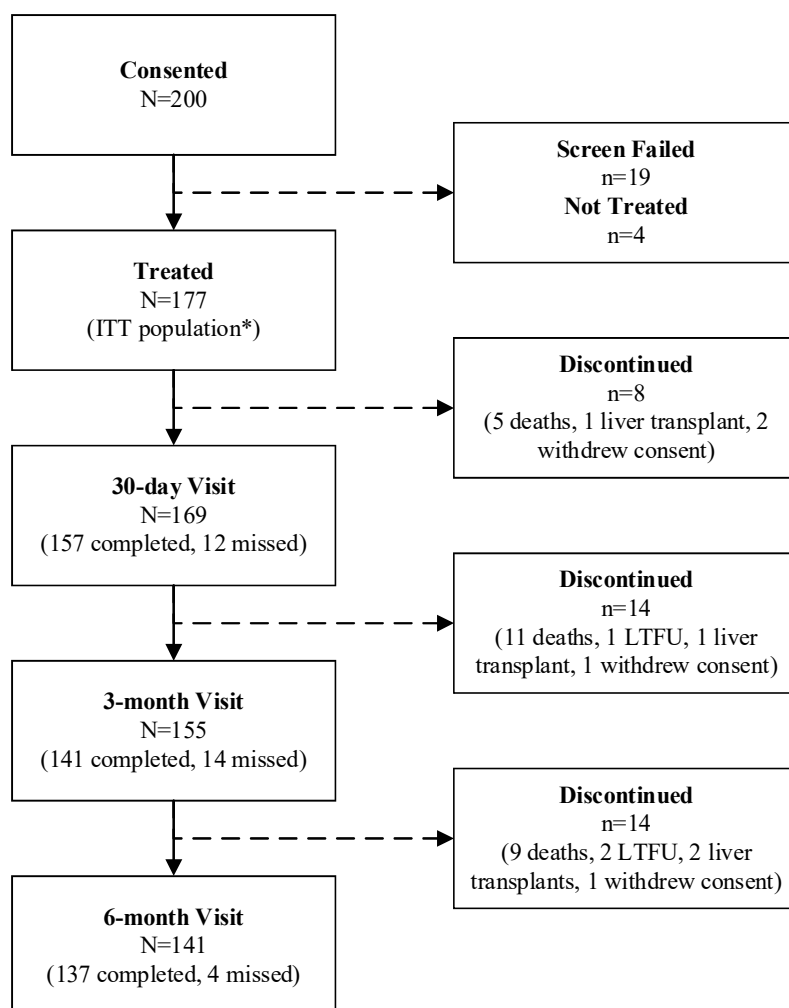
Participant Disposition	Total (N=200)
Enrolled	200
Screen Failure	19
Sponsor Decision ¹	2
Other ²	1
Withdrawal of Consent	1
Intent-to-Treat (ITT)	177 (100%)
Study Device Introduced but Not Implanted	0 (0.0%)
Treated with Study Device (mITT) ³	176 (99.4%)
Discontinued from Study	40 (22.6%)
Death	28 (15.8%)
Received liver transplant	5 (2.8%)
Withdrawal of consent	4 (2.3%)
Lost to follow-up	3 (1.7%)

¹ Sponsor Decision: Consent >30 days prior to Index Procedure, Change in site staff

² Other: Study enrollment completed prior to scheduled Index Procedure

³ mITT: One participant had a Liverty overlapped with a non-Liverty device placed at Index Procedure, see Table 11 for further information

The Intent-to-Treat (ITT) population consists of all participants who 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). Figure 5 provides participant availability based on the ITT population and by timepoint.



1. 'Not Treated' subjects = 1 subject consented > 30 days prior to Index Procedure, 1 subject not treated per sponsor decision, 1 subject withdrew consent, 1 subject Index Procedure scheduled after enrollment completion.
2. 'Completed' visits include the subjects who have completed the scheduled visit.
3. 'Discontinued' includes the subjects whose discontinuation is ≤ the upper bound of the visit window and who have not completed the visit.
4. 'Pending' visits include the subjects whose cutoff date is within the visit window but who have not yet completed the visit and have not discontinued from the study.
5. 'Non-Eligible' includes subjects whose cutoff date has not reached the lower bound of the visit window and who have not yet completed the visit and have not discontinued from the study.
6. 'Missed' visits include all other subjects who are not in any of the above conditions.

* mITT population N=176 due to placement of an overlapping non-Liverty device at Index Procedure

Note: Subject counts may not correspond to the number of evaluable subjects for endpoints, as failures can be detected outside of scheduled visits and/or prior to discontinuation; therefore, visit completion or continued follow-up is not required for evaluability. In addition, completion of a visit does not guarantee evaluability, as endpoint-specific censoring events may have occurred prior to the visit. Refer to Tables 11 and 18 for the details on endpoint-specific evaluable status.

Figure 5: Participant Disposition Flowchart

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical of a TIPS study performed in the US.

Specific demographics and baseline characteristics for participants enrolled in the ARCH study are summarized in Table 6. 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 6: 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 ¹
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%)

¹Baseline BMI was missing for one participant.

Clinical characteristics such as history of variceal bleeding, ascites grade, HE 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 7.

Table 7: Targeted Medical History (ITT Participants)

Targeted Medical History	Total n/N (%)
Etiology of Liver Cirrhosis	
Alcohol Abuse	105/177 (59.3%)

Targeted Medical History	Total n/N (%)
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 8-11 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 8: 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 ¹
Mean (SD)	7.8 (2.53)
Median	8.0
Min - Max	2-13
PSG after adjunctive procedures ²	mmHg
N	32
Mean (SD)	11.2 (5.01)
Median	10.0
Min – Max	2-26
Hemodynamic success - PSG reduction target ³	n/N (%)
Post Procedure PSG ≤ 12 mmHg	139/177 (78.5%)
PSG Reduction by ≥ 50% From Baseline PSG	38/177 (21.5%)

¹In one case, the Investigator was unable to collect the pressure measurement until after completion of an adjunctive procedure.

²Adjunctive procedures are defined as any procedure performed at the same time as TIPS creation.

³As determined at physician discretion during Index Procedure.

Table 9: Summary of Shunt Diameter after Study Procedures (ITT Participants)

	Total n/N (%)
Shunt Diameter Post-Index Procedure	
6 mm	47/177 (26.6%)
7 mm	36/177 (20.3%)
8 mm	74/177 (41.8%)
9 mm	8/177 (4.5%)
10 mm	12/177 (6.8%)
Shunt Diameter Post-Treatment Completion ¹	
6 mm	40/177 (22.6%)
7 mm	32/177 (18.1%)
8 mm	75/177 (42.4%)
9 mm	10/177 (5.6%)
≥10 mm ²	20/177 (11.3%)

¹Treatment Completion was defined as the latter to occur of (i) completion of the Index Procedure and (ii) if performed, the TEP.

²A 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 10 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 for 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 (one at Index Procedure (protocol deviation; excluded from mITT population), 10 placed during re-interventions). Refer to Table 11 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 participant following overlapping stent placement.

Table 10: 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 11: Summary of Overlapping Stent Configurations (ITT Participants)

Reason for Secondary Stent Placement	Overlap Configuration	
	Liverty-Liverty	Liverty-Other
Coverage of Hepatic Vein	7 ¹	1 (Liverty-BD Fluency Plus) ²
Shunt Reduction	0	1 (Liverty-BD Fluency)
Stenosis	0	1 (Liverty-BD Luminexx) ³ , 1 (Liverty-Gore Viatorr)
Thrombosis	1 ⁴	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.

¹ 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.

² The participant with Liverty-Fluency Plus overlap at Index Procedure for coverage of the hepatic vein was excluded from the mITT population.

³ 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.

⁴ Treatment of thrombosis with placement of an additional Liverty™ TIPS Stent Graft was completed at re-intervention.

D. Safety and Effectiveness Results

1. Safety Results

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 the following Adverse Events (if determined to be related to the device and/or procedure and to meet the definition of a Serious Adverse Event (SAE)):

- Accelerated Liver Failure (>3-fold increase in bilirubin or >2-fold increase in INR compared to baseline within 30 days post-TIPS)
- Biliary Peritonitis
- Caval Occlusion
- Death
- Hemobilia
- Hemoperitoneum
- Hepatic Artery Injury
- Hepatic Infarction
- Radiation Skin Burn
- Renal Failure (requiring chronic dialysis)
- Severe Hepatic Encephalopathy (requiring hospitalization)
- Vascular Perforation (resulting from stent graft malposition due to excessive extension of the stent graft into the inferior vena cava or the right atrium)

The following Device Deficiencies, if having the potential to or if confirmed to have led to a Serious Adverse Event (SAE):

- Stent Migration (within the portal or systemic venous circulations resulting from stent graft malposition)

To demonstrate acceptable safety, the co-primary safety endpoint was evaluated against the PG of 85%, derived from consideration of the ACR-SIR Practice Parameter for the Creation of a TIPS¹, 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 12: Freedom from Major Complications through 30 Days (ITT Participants)*

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

**One 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 hepatic encephalopathy (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 HE 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 TIPS¹). Freedom from Major Complications through 30-days post-Index Procedure was 94.3% (p-value <0.0001).

Table 13: 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 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.

Adverse Events that occurred in the ARCH Study

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 14. None of the AEs were adjudicated to be causally or probably related to the Liverty™ TIPS Stent Graft. Table 15 summarizes adverse events which occurred in >2% of participants.

Table 14: 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 15: 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%)
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

Adverse Event	Total	Device Related	Index Procedure Related	TEP Related
	(N=177)			
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.

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 16. 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 16: 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.

2. Effectiveness Results

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

	Rate	Lower limit of the one-sided 95% confidence Interval	P-value
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 18. Censoring events occurred at rates consistent with those expected in this patient population. Refer to Section X.D.3 for further details regarding re-interventions.

Table 18: 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 (Section X.D.4).

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 6 and Table 19 for the Kaplan-Meier analysis.

Figure 6: Kaplan Meier Analysis of Freedom from Shunt Dysfunction (mITT Participants)

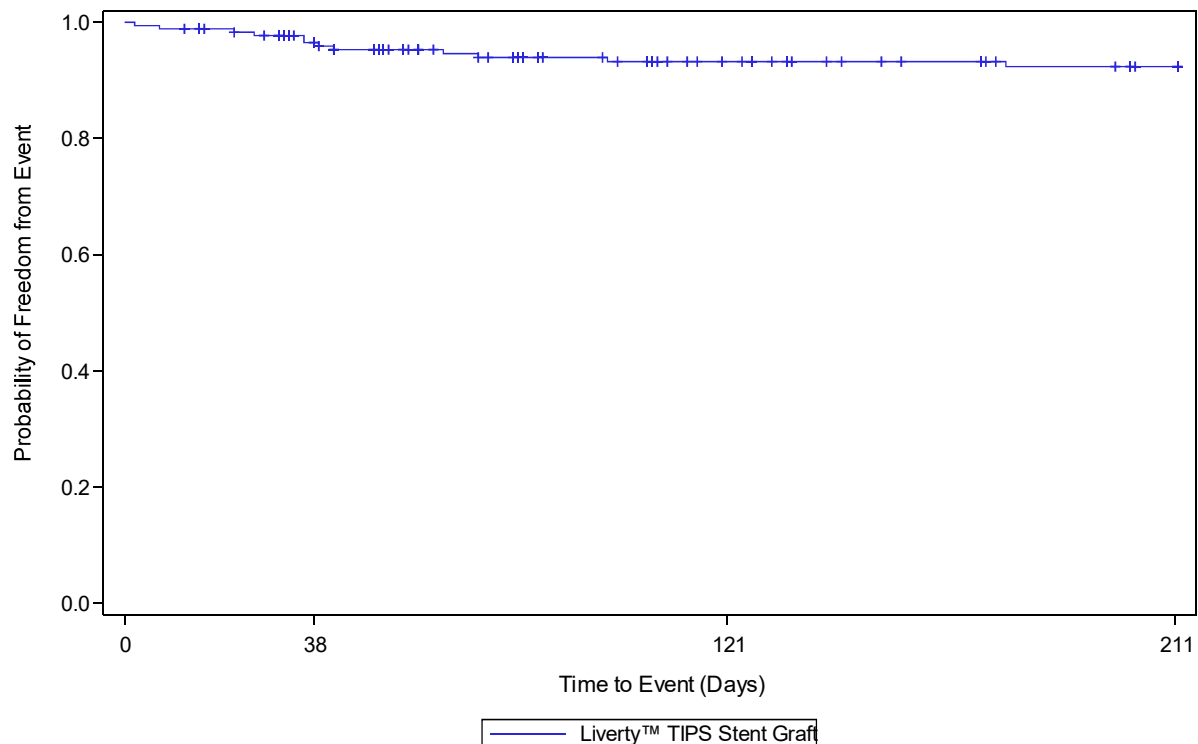


Table 19: Kaplan-Meier Analysis of Freedom from Shunt Dysfunction (mITT Participants)

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%)

3. Secondary Endpoints

Table 20 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 $\geq 50\%$ 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 >5 L occurring >6 weeks post-Treatment Completion. Clinical Success for hepatic hydrothorax was defined as freedom from large volume thoracentesis (LVT) of >1 L 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 20: Secondary Endpoints (mITT Participants)

Endpoint	Procedure n/N (%)	30 days n/N (%)	3 months n/N (%)	6 months n/N (%)
Acute Procedural Endpoints ¹				
Technical Success	176/176 (100.0%)	N/A	N/A	N/A
Hemodynamic Success ²	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 $\geq 50\%$ from Baseline PSG	37/38 (97.4%)	N/A	N/A	N/A
Clinical Success by Indication (e.g., freedom from LVP >5 L, LVT >1 L, 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 ³				
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 patient cohorts.

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

² The investigator determined the target for PSG reduction based on individual patient factors.

³ 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 shunt re-interventions in 37 participants (37/147; 25.2%) in the mITT population through 6-months follow-up. The types of therapies performed at re-intervention are summarized in Table 21. 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 22 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 21: 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 Participants n/N (%)
Balloon Dilatation	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 a single re-intervention procedure.

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

Table 22: 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” ¹ , counted as re-intervention)	16
Shunt Reduction	4
Total	40

¹ “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 23: 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.

4. Subgroup Analysis

The following characteristics were pre-specified for evaluation of potential association 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 was analyzed as a subgroup 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 24) 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 co-primary endpoint all had HE-related events which contributed to endpoint failure.

Table 24: 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 (6-8mm)	
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 25) 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 a discussion of the impact of post-dilatation of Section A for 6-8 mm diameter shunts on device effectiveness.

Table 25: 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%)

Subgroup	n/N (%)
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 ¹	13/13 (100.0%)
No	100/112 (89.3%)
Post-dilatation of Section A for Small Diameter Shunts (6-8mm)	
Yes	23/24 (95.8%)
No	79/89 (88.8%)

¹ 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 26) 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 26: 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 the entire cohort (N=133), 2 participants (1.5%) had grade 3 or 4 HE, and 98 participants (73.7%) were unimpaired by HE.

Table 27: Summary of Hepatic Encephalopathy by Group of Shunt Diameter Post-Treatment Completion at Clinical Visit (mITT Participants)

Shunt Diameter	Visit	No. of Participants	West Haven Grade					
			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%)

Shunt Diameter: During the study it was observed that when a small shunt (<8 mm) with moderate to severe curvature was created in a participant 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. 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 28. Focal dilatation of Section A was associated with a marked reduction in stent graft thrombosis in small (6-7 mm) shunts (2.6% (2/39) vs. 15.9% (7/44)).

Table 28: Participants with Stent Graft Thrombosis Through 6 Months by Shunt Diameter and Post-Dilatation of Section A (ITT Participants)

Final Intended Shunt Diameter	Thrombosis Rate n/N (%)	
	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.

This result is also reflected in the Freedom from Shunt Dysfunction subgroup analysis (Table 25). 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 two 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”) with an 8 mm balloon – when placing a 6, 7 or 8 mm diameter shunt – 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.

5. 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.

6. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

XI. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 137 investigators of which none were full-time or part-time employees of the sponsor and 3 had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: none
- Significant payments of other sorts: 3
- Proprietary interest in the product tested held by the investigator: none
- Significant equity interest held by investigator in sponsor of covered study: none

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Cardiovascular System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

Freedom from Shunt Dysfunction through 6-months was 90.4% (113/125), with a one-sided 95% confidence interval lower bound of 84.91% and met the PG of 78% (p-value = 0.0002). The reasons participants failed the co-primary effectiveness endpoint were thrombus (11) and shunt occlusion without thrombus (1). Root cause analysis identified that small shunts (< 8 mm) 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 (6-7 mm) shunts (2.6% (2/39) vs. 15.9% (7/44)). Similarly, 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)).

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 demonstrating durable freedom from variceal bleeding and LVP >5L 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% (29/3).

Use of the Liverty™ TIPS Stent Graft was associated with technical and hemodynamic success rates of 100.0% (176/176) and 94.9% (167/176), 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 helpful to reduce the risk of

thrombosis and achieve optimal outcomes when placing shunts of 6, 7, or 8 mm diameter shunts. The results from the ARCH clinical study are adequate to provide a reasonable assurance of the effectiveness of the Liverty™ TIPS Stent Graft for the proposed intended use.

B. Safety Conclusions

The risks of the device are based on non-clinical laboratory and animal studies as well as data collected in a clinical study conducted to support PMA approval as described above.

The observed freedom from major complications through 30 days was 85.8% (151/176) and did not meet the PG (p-value = 0.4341). A post-hoc analysis suggests that when West Haven Grade 1 and Grade 2 HE 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 TIPS¹) are counted as successes, the proportion of participants free from major complications 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.

Overall, the clinical study results are adequate to provide a reasonable assurance of the safety of the Liverty™ TIPS Stent Graft for the treatment of complications of portal hypertension from cirrhosis.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in the ARCH clinical study conducted to support PMA approval, as described above. The observed rate of Freedom from Shunt Dysfunction through 6-months was 90.4%, which exceeded the pre-determined PG (p-value = 0.0002). The probable benefit of creation of a TIPS using the Liverty™ TIPS Stent Graft is durable freedom from clinical symptoms (e.g., ascites, variceal bleeding).

The probable risks of the device are also based on data collected in the ARCH clinical study conducted to support PMA approval, as described above. The observed rate of Freedom from Major Complications through 30 days was 85.8%. However, when West Haven Grade 1 and Grade 2 HE events resolved by medical therapy alone were counted as minor complications (consistent with the definition in the ACR-SIR Practice Parameter for the Creation of a TIPS¹), the proportion of participants free from major complications was 94.3%. The most common adverse event observed in the ARCH study was HE (35%).

1. Patient Perspective

This submission did not include specific information on patient perspectives for this device.

In conclusion, given the available information above, the data support that the probable benefits outweigh the probable risks for using the Liverty™ TIPS Stent Graft for the treatment of complications of portal hypertension.

D. Overall Conclusions

The clinical and non-clinical data in this application support the reasonable assurance of safety and effectiveness of the devices when used in accordance with the indications for use. The results of the prospective, multi-center, non-randomized, single-arm ARCH clinical study demonstrate that the Liverty™ TIPS Stent Graft is safe and effective in the treatment of the complications of portal hypertension when used in accordance with the labeling and Instructions for Use.

XIV. CDRH DECISION

CDRH issued an approval order on September 25, 2026. The final conditions of approval cited in the approval order are described below.

Continued Follow-up of the IDE Study Subjects: This study is a non-randomized, multicenter, prospective study that consists of continued follow-up of all subjects from the IDE Pivotal Study. A total of 177 subjects were enrolled and eligible for analysis in the pivotal study. The remaining subjects will be followed every 6 months through 2 years. Clinical endpoints include assessment of the following events through all follow-up intervals: freedom from shunt dysfunction, freedom from shunt reinterventions, clinical success for participants with recurrent or refractory ascites, clinical success for participants with hepatic hydrothorax, clinical success for participants with esophagogastric variceal bleeding, freedom from Hepatic Encephalopathy of Grade > 3, liver transplant-free survival, overall survival and health-related quality of life assessment. Adverse events (e.g., renal failure, vascular perforation) and device deficiencies will be presented through all follow-up intervals. Hypothesis testing will be performed on overall survival through 12 months post-index procedure. Remaining endpoints will be presented descriptively.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality Management System (QMSR) regulation (21 CFR 820).

XV. APPROVAL SPECIFICATION

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XVI. 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.