SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Endovascular Graft

Device Trade Name: GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE)

Device Procode: QZK

Applicant's Name and Address: W. L. Gore & Associates, Inc.
1505 North Fourth Street
Flagstaff, AZ 86004 U.S.

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P230023

Date of FDA Notice of Approval: January 12, 2024

Breakthrough Device: Granted breakthrough device status on October 1, 2021 because of reasonable expectation that the device can provide more effective treatment of a life threatening disease, as well as due to lack of approved or cleared endovascular device alternates.

II. INDICATIONS FOR USE

The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is indicated for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy as described below:

1. Adequate iliac / femoral access and brachial / axillary access
2. Proximal (supraceliac) aortic neck treatment diameter range over 2 cm seal zone of 22 - 34 mm for aneurysms extending up to 6.5 cm or less above the origin of the most proximal branch vessel
3. Aortic neck angle ≤ 60° at the Aortic Component proximal seal zone
4. Iliac artery treatment diameter range of 8 - 25 mm and iliac artery seal zone length of at least 10 mm
5. Renal artery seal zone diameters between 4.0 - 10.0 mm
6. Celiac and superior mesenteric artery seal zone diameters between 5.0 - 12.0 mm
7. ≥ 15 mm seal zone length in renal arteries, superior mesenteric artery, and celiac artery
8. Visceral segment of aorta (3 cm proximal through 9.5 cm distal to the most proximal visceral artery) must be ≥ 20 mm in diameter

III. CONTRAINDICATIONS

The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is contraindicated in:

- Patients with known sensitivities or allergies to the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis materials including expanded polytetrafluoroethylene (ePTFE), fluorinated ethylene propylene (FEP), nickel titanium alloy (Nitinol), stainless steel, and gold.

- Patients who have a condition that threatens to infect the graft.

- Patients with known hypersensitivity to heparin, including patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II and cannot receive the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis labeling.

V. DEVICE DESCRIPTION

GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) provides endovascular treatment of aneurysms extending into the visceral segment of the aorta. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is comprised of multiple required components, the Aortic Component, the Branch Components (GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis), the Distal Bifurcated Component (DBC) (GORE® EXCLUDER® Iliac Branch Endoprosthesis - Iliac Branch Component), and the Contralateral Leg Component (GORE® EXCLUDER® AAA Endoprosthesis - Contralateral Leg Endoprosthesis and/or GORE® EXCLUDER® AAA Endoprosthesis - Iliac Extender Endoprosthesis).

In addition to the required components, the DBC Extender Component (GORE® EXCLUDER® AAA Endoprosthesis - Aortic Extender) may be used as an optional component.

The use of each component within the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is described below:

- **Aortic Component** is implanted in the visceral segment of the aorta and has four portals to position the Branch Components. The Aortic Component is designed to provide proximal (supra celiac) sealing and anchoring within the aorta and is placed proximal to the Distal Bifurcated Component. The superior mesenteric artery (SMA), celiac artery (CA), and renal arteries (RAs) are perfused via four antegrade portals in the Aortic Component.

- **Branch Components** are deployed in the four Aortic Component portals, extending into the SMA, CA and RAs.
- **Distal Bifurcated Component** is used to bifurcate from the Aortic Component to facilitate extension of the aneurysmal repair into the aortic bifurcation.
- **Contralateral Leg Component** is used to extend the repair distally into the iliac arteries. More than one Contralateral Leg Component may be used.
- **DBC Extender Component is** used as an optional component for additional sealing at the junction between the Aortic Component and the Distal Bifurcated Component.

The above device components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis and their intended anatomic treatment location are shown in **Figure 1** (TAMBE Device).

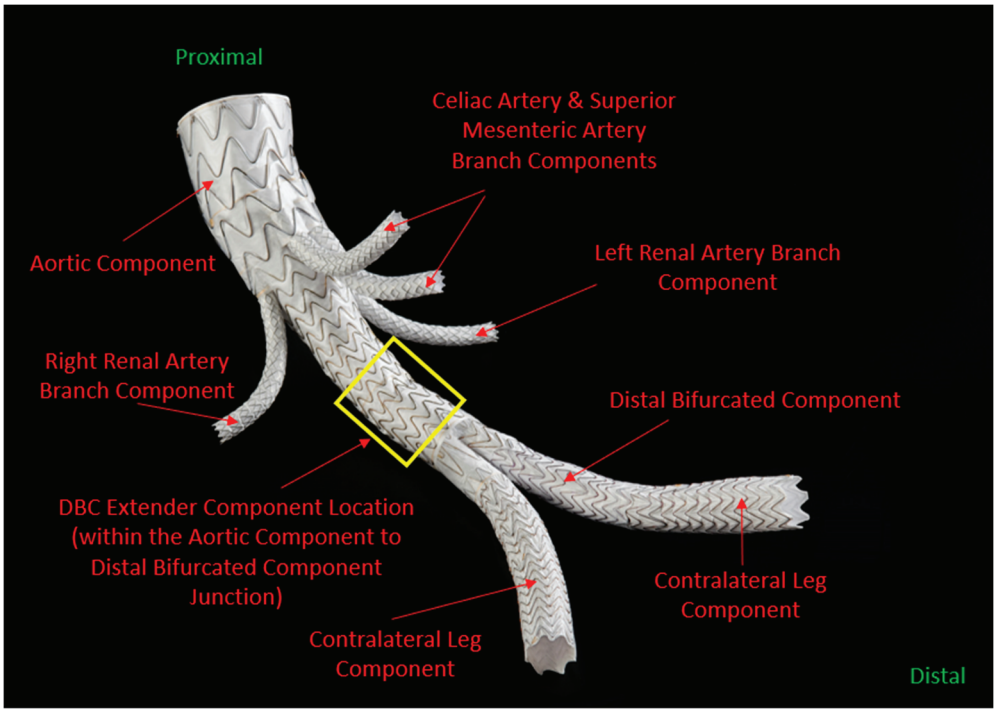

Figure 1. Illustration of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis

Aortic Component - Endoprosthesis

The Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is implanted in the visceral segment of the aorta and has four portals to position the Branch Components. The Aortic Component is designed to provide proximal (supra-celiac) sealing and anchoring within the aorta. The SMA, CA, and RAs are perfused via four antegrade portals in the Aortic Component. All Branch Components are delivered from brachial/axillary access during the endovascular repair.

Figure 2 shows the Aortic Component in a perpendicular view to the Aortic Component central axis, while the same device from a perspective parallel to the device central axis or lumen view is shown in **Figure 3**.

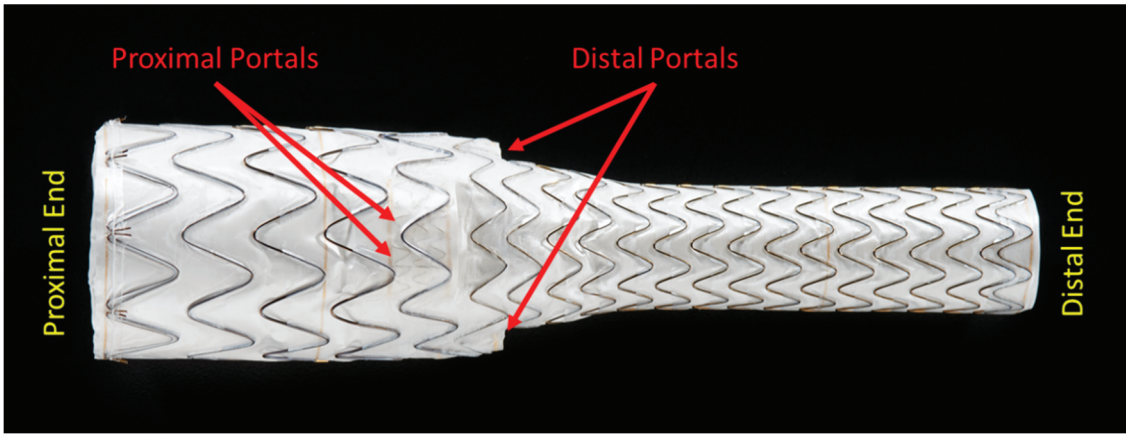

Figure 2. Aortic Component - Perpendicular View

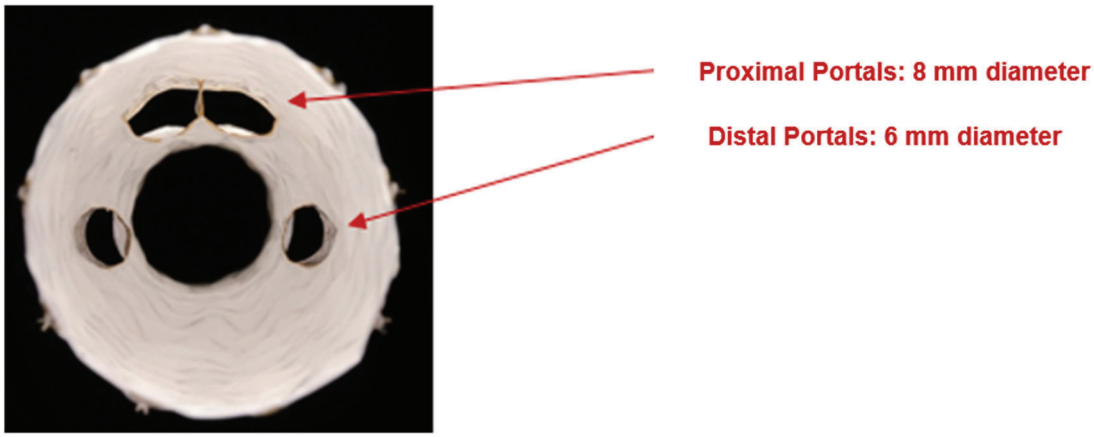

Figure 3. Aortic Component - Lumen View

The Aortic Component is constructed of an expanded polytetrafluoroethylene (ePTFE) / fluorinated ethylene propylene (FEP) graft and a Nitinol (NiTi) stent. The device is constrained on the delivery catheter by ePTFE / FEP sewn sleeves.

The Aortic Component is available in the configurations and sizes are listed in **Table 1**.

Table 1. Aortic Component Configurations and Sizes[1]

Proximal Device Diameter (mm)	Distal Device Diameter (mm)	Intended Proximal Aortic Diameters[2] (mm)	Proximal Portals Diameter (mm)	Distal Portals Diameter (mm)	Overall Device Length (mm)
31	20	22 - 29	8	6	160
37	20	27 - 34	8	6	160

[1] All device dimensions are nominal.
[2] Appropriate oversizing is built into recommended sizes.

The Aortic Component on the delivery catheter is tracked via femoral / iliac access and positioned with portals in proximity to the target branch vessels (SMA, CA, and RA). The Aortic Component utilizes multi-stage deployment to provide repositionability and to optimize working space within the aorta.

Aortic Component – Delivery System

The Aortic Component delivery system (Figure 4) consists of the constrained endoprosthesis mounted on the delivery catheter. Three ePTFE/FEP deployment sleeves are used to constrain the endoprosthesis on the leading end of the delivery catheter. The Aortic Component has four removable guidewire tubes (RGTs) to facilitate pre-cannulation of guidewires through the portals. Deployment of all three sleeves initiates from the leading end (cranial) and proceeds toward the trailing end (caudal) of the delivery catheter (Figure 5).

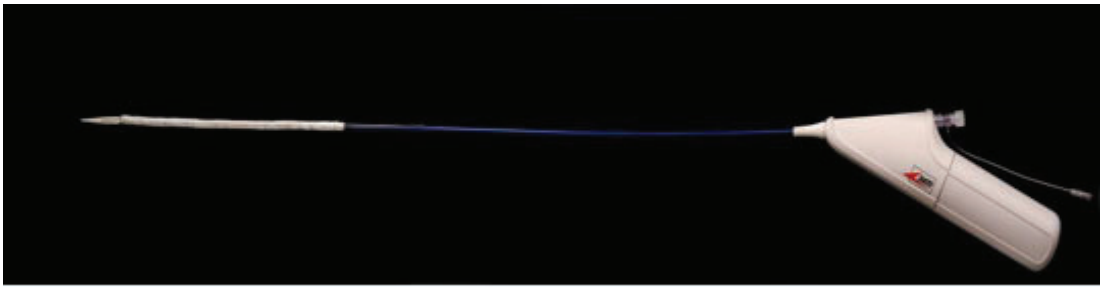

Figure 4. Aortic Component Device Delivery System

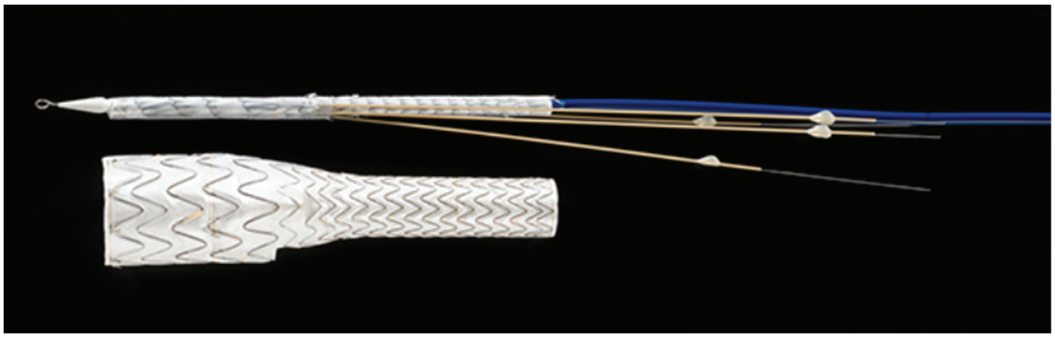

Figure 5. Aortic Component Constrained on Delivery System and Deployed

The delivery system is designed to enable partial deployment of the Aortic Component with the capability to constrain the anchors and re-position the device prior to full deployment. Additional deployment sleeves increase the ability to control the Aortic Component diameter during deployment and to facilitate the cannulation of branch vessels. The delivery system for the Aortic Component has three catheter lumens to isolate and accommodate the deployment lines.

With the Aortic Component positioned in the aorta at a level where the outlet of the proximal portals is 1 to 3 cm above the origin of the most proximal visceral artery, deployment initiates from the leading end and proceeds toward the trailing end of the delivery system.

Branch, Distal Bifurcated, Contralateral Leg and DBC Extender Components
The following W. L. Gore & Associates, Inc. commercially available medical devices listed in **Table 2** are used as components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis:

Table 2. Commercially Available Devices Used as Components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis

Device Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis	Commercially Available Device	U.S. Device Approval Status
Branch Components	GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis	Approved in PMA P160021.
Distal Bifurcated Component	GORE® EXCLUDER® Iliac Branch Endoprosthesis – Iliac Branch Component	Approved in PMA P020004.
DBC Extender Component	GORE® EXCLUDER® AAA Endoprosthesis - Aortic Extender	Approved in PMA P020004.

Device Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis	Commercially Available Device	U.S. Device Approval Status
Contralateral Leg Component	GORE® EXCLUDER® AAA Endoprosthesis - Contralateral Leg Endoprosthesis and/or GORE® EXCLUDER® AAA Endoprosthesis - Iliac Extender Endoprosthesis **Note:** The two devices listed above may be used interchangeably as needed.	Approved in PMA P020004/S004 and S124. Approved in PMA P020004.

Information regarding the overall TAMBE Device in terms of required materials, patient selection, recommended device sizing, anatomical requirements, and implant procedure are provided in the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis Instructions for Use (IFU), as is information regarding the Aortic Component of the TAMBE Device in terms of recommended device sizing, anatomical requirements, device preparation and implant procedure.

For details regarding the other components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis, please see the IFU for each of the commercially available devices listed in **Table 2**.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of thoracoabdominal aortic aneurysms (TAAA) and pararenal abdominal aortic aneurysms (PAAA) including medical management and open surgical repair. 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 expectations and lifestyle.

VII. MARKETING HISTORY

The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis has not been marketed in the United States (U.S.) or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

A list of the potential adverse effects (e.g., complications) associated with the use of the device is provided in **Table 3**.

Table 3. List of Potential Adverse Effects

allergic reaction and/or anaphylactoid response to Multiplanar Device Radiographs (X-Ray) contrast dye, anti-platelet therapy, device materials	fever
amputation	
anesthetic complications	heparin induced thrombocytopenia (HIT)

aneurysm enlargement	infection (e.g., aneurysm, device, or access sites)
aneurysm rupture	irritation/inflammation
anemia	lymph fistula/complications
arterial or venous thrombosis and/or pseudoaneurysm	neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis, numbness, spinal cord ischemia, transient ischemic attack)
arteriovenous fistula	occlusion of device or native vessel, single or multiple vessels
bleeding, hematoma, or coagulopathy	organ failure, single or multi system
bowel complications (e.g., ileus, transient ischemia, mesenteric ischemia, infarction, necrosis)	post-implantation syndrome
cardiac complications (e.g., angina, arrhythmia, myocardial infarction, congestive heart failure, hypotension, or hypertension)	prosthetic dilatation/rupture
catheter breakage	prosthetic thrombosis
death	pulmonary complications (e.g., atelectasis, pneumonia, respiratory failure, chronic obstructive pulmonary disease)
dissection, perforation, or rupture of the aortic vessel and surrounding vasculature	radiation injury
edema	renal complications (e.g., artery occlusion, contrast toxicity, insufficiency, injury, ischemia, failure)
embolism (micro and macro) with transient or permanent ischemia	reoperation/reintervention
endoleak	splenic injury (e.g., infarction, ischemia)
endoprosthesis: improper placement; incomplete deployment; migration; material failure; stent fracture; compression, kink, perigraft flow	stenosis
erectile dysfunction	surgical intervention/conversion
erosion	vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, perforation, rupture, death)
extremity ischemia or neurologic complications (e.g., nerve injury, claudication, buttock, or lower limb)	wound (e.g., infection, dehiscence, groin abscess)
genitourinary complications (e.g., ischemia, erosion, fistula, incontinence, urinary retention, hematuria, infection)	

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

IX. SUMMARY OF NONCLINICAL STUDIES

Nonclinical studies were completed to evaluate the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis that included bench, biocompatibility, sterilization, packaging and shelf life testing. The testing completed for the GORE®

EXCLUDER® Thoracoabdominal Branch Endoprosthesis is described in the following sections.

A. Non-Clinical Product Bench Testing

Non-clinical product bench testing was successfully completed for the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis as summarized in **Table 4**. Non-clinical product bench testing was developed based on the device risk assessment and is consistent with *FDA's Guidance Document Non-Clinical Tests and Recommended Labeling of Intravascular Stents and Associated Delivery Systems*, April 18, 2010, its addendum, *Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems*, August 18, 2015, and BS EN ISO 25539-1.

Table 4. Summary of Non-Clinical Product Bench Testing for the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis

*Note: The specific engineering tests completed to support the three (3) year shelf life for the Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis are denoted in **Table 4** by an asterisk (*).*

Test Performed	Test Purpose	Acceptance Criteria	Results
Aortic Component - Endoprosthesis			
Post-Deployment Inspections*	Evaluate various post-deployment inspections including general visual, device integrity, and dimensional inspection.	Stent graft must meet required inspections (including measurement of length, inner diameter, portal diameter and portal to leading end stent distance) and be free of damage or other attributes that may adversely affect device function (e.g., lumen obstructions, holes, broken wire struts, gaps, delamination, pockets, flaps and misaligned portals).	PASS
Stent Graft Bond Strength*	Verify that Aortic Component stent frame is attached to graft without excessive damage when removed from deployment model.	Strength of bond securing the stent to the graft will allow the stent graft to be deployed without excessive damage.	PASS
Bend Radius*	Evaluate the minimum radius that the pressurized Aortic Component endoprosthesis can bend without kinking. Bend radius is defined as the minimum radius at which the stent graft does not kink.	The bend radius must be ≤ 12.6 mm.	PASS
Radial Force*	Measure the radial outward force of the Aortic Component endoprosthesis after deployment.	The radial outward force of the Aortic Component endoprosthesis must be comparable to that of the GORE® EXCLUDER® Conformable AAA Endoprosthesis.	PASS
Integral Water Permeability*	Evaluate the ability of the Aortic Component endoprosthesis to resist water leakage through holes in the graft material under pressure.	The water permeability of the device must be less than or equal to 5.15 mL/min/cm^2.	PASS
Nitinol Material Analysis	Evaluate the chemical elements present in the bulk and on the surface of the wire of the Aortic Component	The chemical composition of a representative Nitinol wire material lot must meet internal specifications.	PASS

Test Performed	Test Purpose	Acceptance Criteria	Results
	endoprosthesis. Also examine the wire surface for contamination and defects.	The Austenitic Finish Transition Temperature of a representative nitinol wire material lot must be ≤ 35°C. Characterization of the uniaxial tensile stress-strain behavior for each of the 6 Aortic Component Nitinol wire components.	
Nitinol Thermo-mechanical Properties	Evaluate the thermo-mechanical properties of the Aortic Component endoprosthesis.	When deployed at 37°C, the Aortic Component endoprosthesis must open without excessive invagination or any unacceptable obstruction to the flow in order to confirm the superelastic property of the Nitinol material in a final device configuration.	PASS
Corrosion Resistance	Evaluate the corrosion resistance of the Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis for characterization purposes only.	The corrosion resistance will be comparable to that of the GORE® EXCLUDER® Endoprosthesis.	PASS
Radial Pulsatile Fatigue	Evaluate the radial pulsatile fatigue of the Aortic Component endoprosthesis.	The components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis will be durable to fatigue (physiologic motion/loading conditions) for an implantation duration equivalent to 10 years, without damage that would compromise device function.	PASS
Aortic Component – Delivery Catheter			
Catheter Working Length	Measure the working length of the Aortic Component delivery system prior to device deployment.	The working length of the catheter as measured from the leading end of the strain relief to the leading olive tip shall be 66-70 cm.	PASS
Catheter Leak	Evaluate the leak resistance of the Aortic Component delivery system.	The pressure at which leakage of the delivery catheter guideline lumen occurs must be the same as the GORE® EXCLUDER® Conformable AAA Endoprosthesis catheter.	PASS
Manifold Sealing	Measure the leakage through the Aortic Component delivery system handle in a simulated use environment.	At pulsatile pressure, the manifold seal must not leak at a rate higher than 2 mL/min.	PASS
Catheter Bond Strengths*	Evaluate the bond strengths of the Aortic Component delivery system.	The outer lumen to handle must withstand a minimum 13 inch-ounces of torque. All delivery system bonds must have a tensile strength of ≥ 8.1 lb_f.	PASS
Catheter Angular Rotation to Failure	Evaluate the catheter angular rotation to failure of the Aortic Component delivery system.	With the tip restrained, the catheter shall allow at least 180° of handle rotation without mechanical damage or failure.	PASS
Lock Wire Attachment Tensile Strength*	Evaluate the tensile strength of the lock wire attachment of the Aortic Component delivery system.	The tensile strength of the lock wire bond to the handle screw assembly must be ≥ 12.0 lb_f.	PASS
Constraining Loop Attachment Tensile Strength	Evaluate the tensile strength of the constraining loop attachment bond of the Aortic Component delivery system.	The tensile strength of the constraining loop bond to the handle assembly must be ≥8.0 lb_f.	PASS
RGT Glue Beads*	Determine if the glue bead geometry of the Removable	All samples must restrict passage of the RGT through the representative sheath	PASS

Test Performed	Test Purpose	Acceptance Criteria	Results
	Guidewire Tubes (RGTs) used to aid cannulation of the Aortic Component portals will not be able to pass through the sheath alongside the Aortic Component delivery catheter. An RGT glue bead is applied to the end of the RGT to aid the physician in RGT removal and to prevent the RGT from inadvertently entering the patient during the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis procedure.	dimension (inner diameter = 0.2947") alongside the Aortic Component delivery catheter.	
Guidewire Compatibility*	Determine the compatibility of the Aortic Component delivery catheter with a 0.035" guidewire and the compatibility of the RGTs with a 0.018" guidewire.	The catheter must be compatible with a 0.035" guidewire. The RGTs must be compatible with a 0.018" guidewire. Insertion shall be without obstruction or excessive force.	PASS
Flushable Guidewire Lumen*	Determine if the guidewire lumen of the Aortic Component is flushable.	The guidewire lumen of the Aortic Component catheter must be flushable.	PASS
Torqueability*	Determine the torque strength of the Aortic Component delivery catheter.	While rotating the handle, the tip must be able to rotate 180° from neutral in each direction. The partially constrained device must be able to be rotated 90° from neutral in each direction.	PASS
Introducer Sheath Compatibility: Insertion / Removal Ability*	Determine if the Aortic Component delivery catheter with crushed stent graft can be inserted and removed through the recommended introducer sheath.	The delivery catheter loaded with the crushed stent graft must be able to successfully pass through the recommended sheath; the entire catheter must successfully exit the sheath.	PASS
Introducer Sheath Compatibility: Retraction Force	Determine the peak force as the leading tip of the Aortic Component delivery catheter retracts over the lip of the introducer sheath and through the filled hemostasis valve of the introducer sheath after device deployment in a simulated use environment.	The retraction force must be less than the tensile strength of the leading tip of the Aortic Component delivery catheter.	PASS
Pushability and Trackability*	Determine the pushability and trackability of the Aortic Component in a simulated use environment.	With a 0.035" guidewire in place, the loaded catheter must be able to successfully pass through the recommended sheath. Must be able to push the Aortic Component through bends and position correctly in the aneurysm model.	PASS
Deployment Reliability*	Determine the deployment reliability of the Aortic Component in a simulated use environment.	The sewn sleeves must constrain the Aortic Component endoprosthesis with an outer diameter capable of being passed through the introducer sheath. After deployment, delivery catheter components must be removed without disrupting or dislodging the Aortic Component and successfully exit the introducer sheath.	PASS

Test Performed	Test Purpose	Acceptance Criteria	Results
		The portals must be open upon deployment of proximal sleeve. The Aortic Component must be able to be constrained by reducing the diameter at the proximal end after the initial unconstraining. The constrained Aortic Component must be able to be moved proximally and distally and be rotated by 90º in both directions. The proximal end of the Aortic Component endoprosthesis must fully open without invagination or any obstruction to flow. The sewn sleeves must remain attached to the stent graft at deployment.	
Deployment Force*	Measure the force required to deploy each state of the Aortic Component in a simulated use environment.	The deployment force of each of the three deployment lines must be ≤ 5.0 lb_f.	PASS
Deployment Mechanism to Line Tensile Strength*	Measure tensile strength of the deployment knob to line attachment of the Aortic Component delivery catheter after deployment of the Aortic Component endoprosthesis.	The minimum acceptable knob to line tensile strength for all three deployment lines must be ≥ 5.5 lb_f.	PASS
Aortic Component and Branch Components			
Galvanic Corrosion	Determine the potential for galvanic corrosion between the Aortic Component and Branch Components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis for characterization purposes only.	The corrosion rate and mass loss rate will be calculated from the corrosion current.	Characterization
Pushability and Trackability	Evaluate pushability and trackability of the Branch Components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in a simulated use environment.	With a 0.035" guidewire in place, the loaded Branch Component catheter must be able to successfully pass through the recommended introducer sheath. Must be able to push the Branch Components through bends and position correctly in the aneurysm model.	PASS
Deployment Reliability	Assess the ability of each Branch Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis to deploy at the target location and to reliably withdraw each Branch Component catheter in a simulated use environment.	The Branch Component endoprostheses will fully deploy, and the Branch Component catheters will each be reliably withdrawn and successfully exit the sheath without dislodging the Aortic Component endoprosthesis.	PASS
Deployment Accuracy	Measure the deployment accuracy of the Aortic Component or Branch Components in a simulated use environment.	The difference between the *in-vitro* target (intended) deployment site in the aneurysm model and the actual final proximal deployed location shall be	PASS

Test Performed	Test Purpose	Acceptance Criteria	Results
		measured and be within ± 5 mm of the desired target location.	
Durability Evaluation – Aortic Component to Branch Components (Radial Pulsatile, Respiratory-Induced Motion and Musculoskeletal-Induced Motion)	Evaluate fatigue performance of the Branch Components and Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis.	The Branch and Aortic Components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis will demonstrate they are durable to physiologic motion/loading conditions for an implantation duration equivalent to 10 years, without damage that would compromise endoprosthesis function.	PASS
GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (Implant System and Component Interaction)			
Radiopacity	Evaluate the visibility of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis under fluoroscopy.	The visibility of the Aortic Component radiopaque marker bands must be similar to or greater than that of the GORE® TAG® Conformable Thoracic Endoprosthesis marker bands.	PASS
MRI Safety and Compatibility	Evaluate the safety of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in an MR environment of ≤ 3.0 Tesla.	The endoprosthesis will not present an additional hazard or risk when implanted in a patient undergoing an MRI procedure or who may be present in a MR environment of ≤ 3.0 Tesla. The device may affect MRI quality depending on the pulse sequence that is used and the imaging area of interest.	PASS
Nickel Leachability	Evaluate the nickel leachability of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis.	The nickel leachability of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis, with the additional components, must be less than 290 ug/day during the first 24 hours and 29 ug/day during the duration of the 66 day testing.	PASS
Modular Component Separation Force	Evaluate the force required to separate components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis.	The individual force to separate the Branch Components and Distal Bifurcated Component from the Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis must each be greater than or equal to the modular component separation force of the GORE® EXCLUDER® Iliac Branch Endoprosthesis with GORE® EXCLUDER® Contralateral Leg Endoprosthesis.	PASS
Acute Migration	Evaluate the ability of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis to remain at the target deployment location in a simulated use environment.	Acutely measured migration (longitudinal displacement from the initial deployment location) distance *in-vitro* must be within ±5 mm.	PASS
Sealing	Evaluate the ability of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis to seal an aneurysm in a simulated use environment for characterization purposes only.	The rate of fluid loss, due to the sealing of the device in the host vessel, the interface of the modular components, and the integral water permeability of the graft material will be characterized by junction. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis normalized sealing value	Characterization

Test Performed	Test Purpose	Acceptance Criteria	Results
		will be compared to the GORE® EXCLUDER® AAA Endoprosthesis sealing test results also normalized by the number of junctions under test.	
Branch Component Flow	Evaluate the flow rate through the Branch Components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis before and after device deployment for characterization purposes only.	Characterize the flow rate through the Branch Components before and after device deployment during simulated use testing.	Characterization
Pressure Drop	Evaluate the pressure drop for the components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in a simulated use environment.	*In-vitro* testing must demonstrate that the mean pressure drop across the Branch Components of an implanted GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis shall be less than 15 mmHg.	PASS
Deployment Accuracy for Optional DBC Extender Component	Measure the deployment accuracy of the optional DBC Extender Component in a simulated use environment.	The difference between the *in-vitro* target (intended) deployment site in the aneurysm model and the actual final proximal deployed location shall be measured and be within ± 5 mm of the desired target location.	PASS
Sealing of GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis with Optional DBC Extender Component	Evaluate the ability of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis with optional DBC Extender Component to seal an aneurysm in a simulated use environment for characterization purposes only.	The rate of fluid loss, due to the sealing of the device in the host vessel, the interface of the modular components, and the integral water permeability of the graft material will be characterized by junction. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis normalized sealing value will be compared to the GORE® EXCLUDER® AAA Endoprosthesis sealing test results also normalized by the number of junctions under test.	Characterization
Branch Component Flow of GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis with Optional DBC Extender Component	Evaluate the flow rate through the Branch Components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis with optional DBC Extender Component before and after device deployment for characterization purposes only.	Characterize the flow rate through the Branch Components before and after device deployment during simulated use testing	Characterization
Pressure Drop of GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis with Optional DBC Extender Component	Evaluate the pressure drop for the components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in a simulated use environment.	*In-vitro* testing must demonstrate that the mean pressure drop across the Branch Components of an implanted GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis shall be less than 15 mmHg.	PASS
Durability Evaluation-Aortic Component to Distal Bifurcated Component Junction with Optional DBC Extender Component (Musculoskeletal-Induced Motion)	Evaluate the fatigue durability of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis for an implant duration equivalent to ten years.	The components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis will be durable to fatigue (physiologic motion/loading conditions) for an implantation duration equivalent to 10 years without damage that would compromise device function.	PASS

B. Biocompatibility

Biocompatibility of the endoprosthesis and delivery system of Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis was assessed in accordance with the requirements of EN ISO 10993-1.

The Aortic Component endoprosthesis is a medical device categorized by ISO 10933-1 as an implant with long-term exposure (>30 days) to circulating blood. The delivery system for the Aortic Component is categorized by ISO 10993-1 as an externally communicating device with limited exposure (<24 hours) to circulating blood.

All testing performed met the pre-specified acceptance criteria. A summary of the biocompatibility testing conducted for the Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is provided in **Table 5** for the endoprosthesis and **Table 6** for the delivery system.

Table 5. Summary of GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis Biocompatibility Testing (Aortic Component only)

Test Performed	Test Purpose	Acceptance Criteria	Results
Cytotoxicity	Determine the potential biological reactivity of a mammalian cell culture (L929) in response to the test article extract.	Test article extract cytotoxicity score is ≤ 2.	PASS
Sensitization	Determine the potential allergenic or sensitizing capacity of the test article.	Less than 10% of animals have a positive sensitization response.	PASS
Irritation / Intracutaneous Reactivity	Determine the potential irritation effects of the test article extract as a result of intracutaneous injections.	The difference in the average scores between test and control extracts is ≤ 1.	PASS
Acute Systemic Toxicity	Determine the potential toxic effects of the test article extract as a result of a single-dose systemic injection.	None of the animals treated with test extracts exhibit significantly greater biological reactions than control animals.	PASS
Material-Mediated Pyrogenicity	Determine the potential presence of chemical pyrogens in extracts of solid materials in order to limit to an acceptable level the risks of febrile reaction following administration of the product to the patient.	Temperature increases in individual animals treated with test article extract are each < 0.5°C.	PASS
Implantation Effects	Evaluate the test article for local tissue responses and the potential to induce local toxic effects after implantation in the muscle tissue.	Histological evaluation of implant sites, aided by gross observation at necropsy, indicate that tissue responses surrounding test article implants are not significantly greater than those associated with the negative control article. The Bioreactivity Rating should indicate no significant difference between test and control articles (≤ 2.9).	PASS
Hemocompatibility Hemolysis	Determine the potential hemolytic activity, via the induction of increased levels of free plasma hemoglobin in blood, in response to the test article and its extract.	Hemolytic index of test article must be < 5 % above the negative control.	PASS
Hemocompatibility Partial Thromboplastin Time (PTT) Test	Determine the potential induction of coagulation of human plasma via measurement of the PTT in response to the test article.	No statistically significant difference between the clotting times of the test article and the untreated control or the negative control.	PASS

Test Performed	Test Purpose	Acceptance Criteria	Results
Hemocompatibility Complement	Determine the potential activation of the complement system in human plasma in response to the test article.	No statistically significant increase is found between the soluble complement SC5b-9 complex concentrations in the plasma exposed to test article and that of plasma exposed to either the negative control or the untreated control.	PASS
Hemocompatibility Thrombogenicity Evaluation from Pivotal Clinical Study (Aortic Component and Branch Components)	Verify the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis device is not thrombogenic.	Evidence via Computed Tomography with Angiography (CTA) that there is ongoing patency through the 1- month period based on imaging review of 10 Subjects.	PASS
Genotoxicity - Bacterial Mutagenicity Test – Ames Assay	Evaluate the mutagenic potential of the test article (or its metabolites) by measuring its ability to induce back mutations at selected loci of several strains of bacteria in the presence and absence of microsomal enzymes.	Less than a two-fold increase in the number of revertant colonies per plate over the negative control values.	PASS
Genotoxicity - Mouse Lymphoma Assay	Determine the ability of a test article to induce forward mutations at the thymidine kinase (TK) locus as assayed by colony growth of L5178Y mouse lymphoma cells in the presence of trifluorothymidine (TFT).	The test article must have an induced mutant frequency less than the assay's Global Evaluation Factor, is within the current historical range for a negative response and is statistically indistinguishable from the concurrent negative control.	PASS
Carcinogenicity[1]	To determine whether long-term (>30 days) patient exposure to levels of exhaustively extracted chemicals from the test articles could produce unacceptable human health risks; including carcinogenic and systemic non-carcinogenic risks.	In adult (including pregnant women) patient populations, demonstration of acceptable margins of safety (MOS) for all exhaustively extractable chemical groups and chemicals from the test article.	PASS
Reproductive and Developmental Toxicity[1]			
Subchronic / Chronic Toxicity[1]			

[1] These endpoints were addressed via Chemical Characterization and Toxicological Risk Assessment.

Table 6. Summary of GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis Delivery System Biocompatibility Testing

Test Performed	Test Purpose	Acceptance Criteria	Results
Cytotoxicity	Determine the potential biological reactivity of a mammalian cell culture (L929) in response to the test article extract.	Test article extract cytotoxicity score is ≤ 2.	PASS
Sensitization	Determine the potential allergenic or sensitizing capacity of the test article.	Less than 10% of animals have a positive sensitization response.	PASS
Irritation / Intracutaneous Reactivity	Determine the potential irritation effects of the test article extract as a result of an intracutaneous injections.	The difference in the average scores between test and control extracts is ≤ 1.	PASS
Acute Systemic Toxicity	Determine the potential toxic effects of the test article extract as a result of a single-dose systemic injections.	None of the animals treated with test extracts exhibit significantly greater biological reactions than control animals.	PASS
Material-Mediated Pyrogenicity	Determine the potential presence of chemical pyrogens in extracts of solid materials in order to limit to an acceptable level the risks of febrile reaction following administration of the product to the patient.	Temperature increases in individual animals treated with test article extract are each < 0.5°C.	PASS
Hemocompatibility Hemolysis	Determine the potential hemolytic activity, via the induction of increased levels of free	Hemolytic index of test article must be < 5 % above the negative control.	PASS

Test Performed	Test Purpose	Acceptance Criteria	Results
	plasma hemoglobin in blood, in response to the test article and its extract.		
Hemocompatibility Complement	Determine the potential activation of the complement system in human plasma in response to the test article.	No statistically significant increase is found between the soluble complement SC5b-9 complex concentrations in the plasma exposed to test article and that of plasma exposed to either the negative control or the untreated control.	PASS
Hemocompatibility Partial Thromboplastin Time (PTT) Test	Determine the potential induction of coagulation of human plasma via measurement of the PTT in response to the test article.	No statistically significant difference between the clotting times of the test article and the untreated control or the negative control.	PASS
Hemocompatibility Thrombogenicity – Non-anticoagulated venous implant (NAVI) and Anticoagulated Venous Implant (AVI)	Compare materials intended for blood contact to each other in the same animal. The materials intended for blood contact were evaluated for thrombogenicity properties *in-vivo*.	The amount of thrombosis is considered comparable between the test article and the control device.	PASS[1]

[1] The Aortic Component delivery system was considered non-thrombogenic under clinically relevant conditions using anticoagulants (AVI).

C. Sterilization, Packaging and Shelf Life

The Aortic Component (endoprosthesis and delivery catheter) of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is sterilized by Ethylene Oxide (EO) to provide a Sterility Assurance Level (SAL) of 10^{-6}. The EO sterilization cycles were validated in accordance with *BS EN ISO 11135 Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices*.

Packaging validation conducted for the Aortic Component demonstrated the ability of the packaging to protect the product and to maintain a sterile barrier through shipping and shelf life.

A shelf life of three (3) years was established for the Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis based on product and package shelf life testing. The specific engineering tests completed to support the shelf life are denoted by an asterisk (*) in **Table 4**.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) in the U.S. and United Kingdom (U.K.) under IDE G150071. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between July 8, 2019, and November 28, 2022. The database for this PMA reflected data collected through March 8, 2023, and included 102 Subjects meeting the clinical inclusion and exclusion criteria described below. There were 44 investigational sites (42 in the U.S. and 2 in the U.K.).

The study was a prospective, non-randomized, multicenter study. Enrollment was based on the extent of the aortic aneurysm and included Subjects with aneurysms that involved at least one visceral vessel. Specifically, TAAAs included those with a proximal extent which originated between the level of the superior mesenteric artery through as far as 65 mm proximal to the celiac artery. PAAAs included those with a proximal extent which originated at the level of the renal arteries, with no normal aorta between the upper extent of aneurysm and the renal artery(s), through as far proximally as the level of the superior mesenteric artery.

The study utilized two Co-Primary Endpoints:

- 30 day safety and effectiveness endpoint that is composite of Uncomplicated Technical Success and Procedural Safety, and
- 12 month safety and effectiveness endpoint that is composite of Clinically Significant Reintervention and Lesion-Related Mortality.

The 30 Day composite safety and effectiveness endpoint was defined as percentage of patients that achieve "uncomplicated technical success" and are free from "procedural safety" events through 30 days post index procedure. The results were tested against a performance goal of 80%, derived from open surgical repair literature available and experience from previous Gore aortic endovascular prostheses studies at the time of protocol development.

The 12 month composite safety and effectiveness endpoint was defined as percentage of patients that are free from "clinically significant reintervention" and "lesion-related mortality" through 12 months post index procedure. The results were tested against a performance goal of 68%, derived from experience of branched or fenestrated thoracoabdominal devices in the published literature available at the time of protocol development.

For each endpoint, a two-sided 90% Clopper-Pearson confidence interval (CI) was constructed ($\alpha = 0.05$).

Evaluation groups were used during the pivotal study are described below:

- A Core Laboratory was used to perform independent assessments of computed tomography (CT)/computed tomography with angiography (CTA), X-Ray and duplex ultrasound (DUS) imaging submitted by clinical sites. The Core Laboratory assessments were used in final analyses.

- An external Clinical Events Committee (CEC) adjudicated co-primary endpoint events and select adverse events and reviewed inclusion/exclusion violations for potential impact on Subject safety.

- An independent Data Safety Monitoring Board reviewed the data periodically to monitor the study for Subject safety.

- A Screening Committee provided a supplementary clinical review of medical history and imaging for all study candidates and provided a recommendation regarding whether the candidate should be included or excluded from the study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the TAMBE Pivotal Study was limited to patients who met the following inclusion criteria:

- Aortic aneurysm involving the visceral vessel(s) requiring treatment defined as at least one of the following:
    a) Fusiform aneurysm diameter ≥5 cm.
    b) Saccular aneurysm (no diameter requirement).
    c) Rapid aneurysm growth (≥5 mm in one year).
- Aortic aneurysm that involves the abdominal aorta, with:
    a) Involvement of at least one visceral vessel and aneurysmal extension as far as 65 mm proximal to the celiac artery, and/or
    b) No normal aorta between the upper extent of aneurysm and renal artery(s).
- Adequate access for TAMBE Device components (femoral, axillary, and / or brachial arteries as required).
- Age ≥19 years at the time of informed consent signature.
- Male or infertile female.
- Subject assessment favors an endovascular approach when compared to open surgical repair, as deemed by the treating physician.
- Capable of complying with protocol requirements, including follow-up.
- An Informed Consent Form signed by Subject or legal representative.
- Sufficient distal landing zones in both iliac arteries, with at least one patent internal iliac artery and without planned placement of a branched iliac device, or planned coverage/occlusion/embolization of any patent internal iliac artery.
- Appropriate aortic anatomy to receive the TAMBE Device defined as all of the following:

a) For the TAMBE Aortic Component, proximal aortic landing zone diameters between 22-34 mm.
b) Proximal seal zone ≥20 mm in length.
c) Aortic neck angle ≤60°.
d) Distal landing zone (iliac arteries) 8-25 mm.
e) Distal seal zone in iliac arteries of at least 10 mm in length.
f) Renal artery landing zone diameters between 4-10 mm.
g) Celiac and superior mesenteric artery landing zone diameters between 5-12 mm.
h) 15 mm landing zone in each branch vessel.
i) Visceral segment of aorta must be ≥20 mm in diameter.
j) Landing zones in the proximal and distal aorta and all branch vessels. cannot be aneurysmal, heavily calcified, or heavily thrombosed.
k) Patent left subclavian artery.

Patients were not permitted to enroll in the TAMBE Pivotal Study if they met any of the following exclusion criteria:

- Prior open, aortic surgery of the ascending aorta or aortic arch.
- Ruptured or leaking aortic aneurysm.
- Aneurysmal dilatation due to chronic aortic dissection.
- Infected aorta.
- Mycotic aneurysm.
- Life expectancy <2 years.
- Myocardial infarction or stroke within 1 year of treatment (staged or index procedure).
- Systemic infection which may increase risk of endovascular graft infection.
- Degenerative connective tissue disease, e.g., Marfan's or Ehlers-Danlos Syndrome.
- Participation in an investigational drug study (within 30 days of last administration) or investigational medical device study (within 1 year of implant) from the time of study screening.
- History of drug abuse, e.g., cocaine or amphetamine or alcohol, within 1 year of treatment.
- Tortuous or stenotic iliac and / or femoral arteries and the inability to use a conduit for vascular access.
- A branch vessel(s) that is dissected or has significant calcification, tortuosity, thrombus formation that would interfere with device delivery or ability to exclude from blood flow.
- Known sensitivities or allergies to the device materials.

- Previous instance of Heparin Induced Thrombocytopenia type 2 (HIT-2) or known hypersensitivity to heparin.
- Subject has body habitus or other medical condition which prevents adequate fluoroscopic and CT visualization of the aorta.
- Renal Insufficiency (creatinine value >1.8 mg/dL, glomerular filtration rate (GFR) <30, or Subject undergoing dialysis).
- Known concomitant aneurysm of the ascending aorta or aortic arch anticipated to require surgical intervention within one year of study treatment.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 1, 3, 6, 12, 24, 36, 48, and 60 months. **Table 7** outlines the required screening evaluations and follow-up visit procedures for Subjects.

Table 7. Evaluations and Post-Treatment Follow-Up Schedule

	Pre-Treatment (Screening)	Treatment	Hospital Discharge	One Month	Three Months	Six Months	1 Year then Annually through 5 Years
Informed Consent	X						
Demographics and Medical History	X						
Risk Scales (ASA, NYHA, SVS) [a]	X						
Physical examination	X		X	X	X	X	X
Medication Review	X		X	X	X	X	X
Modified Rankin Scale [b,c]	X		X	X	X *If applicable*	X	
Spinal Cord Ischemia Scale [b]	X		X	X		X	
NIH Stroke Scale [d]	X		X *If applicable*				
SF-36 Questionnaire	X			X	X	X	X
Serum Creatinine Concentration	X		X	X	X	X	X
Spiral CTA (contrast) [e]	X			X		X	X
Spiral CT (non-contrast)				X		X *Optional*	X *Optional*
Completion Angiogram		X					
Magnified Branch Visualization		X					
Abdominal Ultrasound	X		X	X	X	X	X
Multiplanar Device Radiographs (X-Ray)				X		X	X

[a] American Society of Anesthesiologists (ASA), New York Heart Association (NYHA), Society of Vascular Surgery (SVS)
[b] If Subject was unable to return to the site for a follow-up visit, they may be contacted by telephone to evaluate the Modified Rankin Scale (mRS) and Spinal Cord Ischemia Scale.
[c] For Subjects suspected of having a stroke event within 30 days following the index endovascular procedure, an additional mRS score should be completed at 90 days following the suspected stroke event but no greater than 120 days post index endovascular procedure.

[d] National Institutes of Health (NIH) Stroke Scale should be performed for any Subject suspected of having a stroke event that undergoes the treating site's stroke protocol during the study interval from the initiation of the index endovascular procedure until discharge. The scale should be performed as soon as possible after learning of the suspected event and again at the time of discharge.

[e] CTA of chest/abdomen/pelvis at Screening. CTA of abdomen and pelvis was performed at all follow-up visits. Magnetic Resonance Angiogram (MRA) may be used in place of CTA during follow-up if the Subject was contraindicated for CTA.

Adverse events and complications were recorded at all visits.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

3. Clinical Endpoints

The safety and effectiveness of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis was assessed through two independent co-primary endpoints:

1. 30 day safety and effectiveness endpoint that is a composite of Uncomplicated Technical Success and Procedural Safety,
2. 12 month safety and effectiveness endpoint that is a composite of Clinically Significant Reintervention and Lesion Related Mortality.

Co-Primary Endpoint #1 is a composite of the following events at two time points:

A. Uncomplicated technical success at the time of the index endovascular procedure:
   i. Successful Access and Delivery
   ii. Successful and Accurate Deployment
   iii. Successful Withdrawal
B. Freedom from Procedural Safety events within the first 30 days of index procedure:
   i. Stented Segment Aortic Rupture
   ii. Lesion Related Mortality
   iii. Permanent Paraplegia
   iv. Permanent Paraparesis
   v. New Onset renal Failure Requiring Dialysis
   vi. Severe Bowel Ischemia
   vii. Disabling Stroke

Co-Primary Endpoint #1 was compared to a Performance Goal (PG) of 80%.

Co-Primary Endpoint #2 is a composite of the following events through 12 months:

A. Clinically Significant Reintervention:
   i. Clinically Indicated Condition
      - Device Seal Zone Endoleak
      - Lesion Growth >5 mm
      - Rupture

ii. Device Effectiveness (Device Seal Zone / Integrity)
iii. Patient Safety Events (Total Occlusion of Device Component)
iv. Device System Prophylaxis (Reintervention requiring hospitalization)

B. Lesion-Related Mortality through 12 months

Co-Primary Endpoint #2 was compared to a PG of 68%.

With regard to success/failure criteria, the TAMBE Pivotal Study was considered to be successful if both the Co-Primary Endpoint Performance goals were met.

The following secondary endpoints were evaluated using descriptive statistics. Unless specified otherwise, the timeline for evaluation of these endpoints is through 12 months and annually thereafter through 5 years:

- Aneurysm-related mortality through 30 days
- Individual elements of Procedural Safety through 30 days
- Procedural blood loss during the index procedure
- Access-related complications through 30 days
- Procedure time
- Length of hospital stay following the index procedure
- Extended Technical Clinical Success through 30 days
- Individual elements of Clinically Significant Reintervention/Lesion-Related Mortality
- All Types of endoleaks
- Device migration
- TAAA enlargement, shrinkage and stability
    - Please note that aneurysm shrinkage and stability were not protocol-defined secondary endpoints, but they were also evaluated
- Severe distal thromboembolic events
- Aortic rupture
- Device or procedure-related laparotomy
- Conversion to open repair
- Aortoiliac device limb occlusion
- Loss of device integrity
- All reinterventions
- Branch vessel patency
- Acute kidney injury through 30 days
- Renal function deterioration

B. Accountability of PMA Cohort

At the time of database lock, 102 Subjects meeting the above inclusion and exclusion criteria were eligible and included for analysis. Information regarding Subject disposition and imaging assessment by analysis windows is provided in **Table 8**.

Table 8. Subject Disposition and Imaging Assessments by Analysis Windows

	Patient Follow-Up			Imaging Performed[3]				Imaging Adequate to Assess the Parameter					Subject Status		
Analysis Windows[1]	Eligible for Follow-Up[5]	Subjects with Any Visit in Analysis Window[2]	No Visit, Still in Analysis Window	CT Scan	MRA	X-Ray	Ultrasound	Aneurysm Size	Endoleak	Migration	Fracture	Patency	Death	Lost To Follow Up (LTFU)/ Withdrawal/ Discontinuation	Not Due for Next Visit
Procedure	102	-	-	-	-	-	-	-	-	-	-	-	0	0	0
Post-Procedure	102	96 (94.1%)	0 (0.0%)	23 (22.5%)	0 (0.0%)	15 (14.7%)	95 (93.1%)	23 (22.5%)	21 (20.6%)	23 (22.5%)	27 (26.5%)	92 (90.2%)	0	0	0
1 Month	102	97 (95.1%)	0 (0.0%)	96 (94.1%)	0 (0.0%)	94 (92.2%)	94 (92.2%)	96 (94.1%)	92 (90.2%)	96 (94.1%)	94 (92.2%)	95 (93.1%)	1	0	0
3 Months	101	82 (81.2%)	0 (0.0%)	14 (13.9%)	0 (0.0%)	10 (9.9%)	76 (75.2%)	14 (13.9%)	13 (12.9%)	14 (13.9%)	16 (15.8%)	78 (77.2%)	4	1	0
6 Months	96	81 (84.4%)	0 (0.0%)	75 (78.1%)	0 (0.0%)	70 (72.9%)	77 (80.2%)	75 (78.1%)	72 (75.0%)	72 (75.0%)	72 (75.0%)	81 (84.4%)	0	0	0
12 Months	96	88 (91.7%)	1[4] (1.0%)	87 (90.6%)	1 (1.0%)	80 (83.3%)	81 (84.4%)	87 (90.6%)	81 (84.4%)	87 (90.6%)	83 (86.5%)	86 (89.6%)	3	3	11
24 Months	79	42 (53.2%)	34 (43.0%)	42 (53.2%)	0 (0.0%)	38 (48.1%)	37 (46.8%)	42 (53.2%)	37 (46.8%)	41 (51.9%)	37 (46.8%)	42 (53.2%)	1	3	43
36 Months	32	13 (40.6%)	19 (59.4%)	11 (34.4%)	0 (0.0%)	12 (37.5%)	12 (37.5%)	11 (34.4%)	9 (28.1%)	11 (34.4%)	12 (37.5%)	12 (37.5%)	2	0	24
48 Months	6	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0	0	6
60 Months	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-

[1] Study period definitions: Procedure (day 0); Post-Procedure (1-14 days); 1 Month (15-59 days); 3 Months (60-126 days); 6 Months (127-242 days); 12 Months (243-546 days); 24 Months (547-911 days); 36 Months (912-1275 days); 48 Months (1276-1640 days); and 60 Months (1641-2006 days).

[2] Any visit consisting of physical exam, spiral CTA, spiral CT, abdominal ultrasound, X-Ray Percentages are based on number of subjects eligible for follow-up in analysis windows.

[3] At 1 Month, required imaging includes spiral CTA, spiral CT, abdominal Ultrasound, and X-Ray. At 3 Months, required imaging includes only abdominal ultrasound. For subsequent time periods, required imaging includes: spiral CTA, abdominal ultrasound, and X-Ray. MRA may be used in place of CTA during follow-up if the Subject is contraindicated for CTA.

[4] At the time of data export, one Subject had not completed their 12-month visit; however, remained within the analysis window. Subject was deemed to be lost to follow up.

[5] Eligible for Follow-Up includes Subjects who had not been in-eligible for future visits and are due for the follow-up visit.

C. Study Population Demographics and Baseline Parameters

Demographics

The demographics of the study population are typical for an endovascular graft study performed in the U.S. for the treatment of complex aneurysms involving the visceral aorta.

A summary of Subject demographics is provided in **Table 9**. The majority of Subjects were male (84/102; 82.4%). The majority of Subjects were Not Hispanic or Latino (92/99; 92.9%). The majority of Subjects were White (86/99; 86.9%). The median age was 73.0 years old (range 58-89 years). Median Body Mass Index (BMI) was 27.6 kg/m^2.

Table 9. Summary of Baseline Demographic Characteristics of Implanted Subjects

Number of Subjects	102
Sex at Birth	102
Male	84 (82.4%)
Female	18 (17.6%)
Ethnicity (U.S. Only)[1]	99
Not Hispanic or Latino	92 (92.9%)
Hispanic or Latino	2 (2.0%)
Unknown or Not Reported	5 (5.1%)
Race (U.S. Only)[1]	99
White	86 (86.9%)
Black or African American	4 (4.0%)
Asian	2 (2.0%)
American Indian or Alaska Native	2 (2.0%)
Hawaiian or Pacific Islander	1 (1.0%)
Other	5 (5.1%)
Age (years)	
n	102
Mean (Std Dev)	73.3 (6.39)
Median	73.0
Range	(58.0, 89.0)
Weight (kg)	
n	102
Mean (Std Dev)	88.1 (18.37)
Median	86.7
Range	(42.0, 142.9)
Height (cm)	
n	102
Mean (Std Dev)	176.2 (9.18)

Median	177.4
Range	(149.9, 193.0)
BMI (kg/m^2)	
n	102
Mean (Std Dev)	28.3 (5.01)
Median	27.6
Range	(17.0, 46.5)

[1] Race and ethnicity data was not collected for Subjects outside of the U.S. (n=3).

Subject Baseline Medical History

A summary of the Subject baseline medical history is provided in **Table 10**.

Table 10. Summary of Subject Baseline Medical History

Number of Subjects	102
Atrial Fibrillation	18 (17.6%)
Cancer	29 (28.4%)
Cardiac Arrhythmia	16 (15.7%)
Chronic Obstructive Pulmonary Disease	27 (26.5%)
Congestive Heart Failure	8 (7.8%)
Coronary Artery Bypass Graft	23 (22.5%)
Coronary Artery Disease	50 (49.0%)
Diabetes Mellitus	24 (23.5%)
Erectile Dysfunction (% of Male)	10 (11.9%)
Familial History of Aneurysms	17 (16.7%)
Familial History of Atherosclerosis	16 (15.7%)
Hypercholesterolemia	86 (84.3%)
Hypertension	94 (92.2%)
Myocardial Infarction	26 (25.5%)
Other Vascular Intervention	9 (8.8%)
Paraplegia	0 (0.0%)
Percutaneous Coronary Intervention	22 (21.6%)
Peripheral Vascular Disease	13 (12.7%)
Renal Dialysis	0 (0.0%)
Renal Insufficiency	11 (10.8%)
Stroke	5 (4.9%)
Thrombocytopenia	1 (1.0%)
Thromboembolic Event	3 (2.9%)
Transient Ischemic Attack (TIA)	2 (2.0%)
Valvular Heart Disease	6 (5.9%)
Visceral Artery Stenosis	2 (2.0%)
Previous Aortic Surgery	5 (4.9%)
Ascending Aorta	0 (0.0%)
Aortic Arch	0 (0.0%)
Descending Thoracic Aorta (DTA) (not involving proximal landing zone)	0 (0.0%)
Abdominal Aorta	5 (4.9%) [1]

[1] One of the five Subjects with previous abdominal aorta surgery had previous abdominal aortic aneurysm surgery reported in the Electronic Data Capture System (EDC); however, Site confirmed this was a data entry error after data export. The remaining four Subjects were prior open repairs. In all cases, the TAMBE Device seal zone was within the native aorta.

Pre-Treatment Baseline Risk Factors

A summary of pre-treatment risk factors is provided in **Table 11**.

Table 11. Summary of Baseline Risk Factors[1]

Number of Subjects	102
Diabetes	
None	81 (79.4%)
Adult Onset, Diet-Controlled	16 (15.7%)
Adult Onset, Insulin-Controlled	5 (4.9%)
Juvenile Onset	0 (0.0%)
Tobacco Use	
None or None in last 10 Years	39 (38.2%)
None currently, but smoked in last 10 Years	20 (19.6%)
Current, Less than 1 pack/day	30 (29.4%)
Current, Greater than 1 pack/day	13 (12.7%)
Hypertension	
None	9 (8.8%)
Controlled with Single Drug	35 (34.3%)
Controlled with 2 Drugs	40 (39.2%)
Requires more than 2 drugs or Uncontrolled	18 (17.6%)
Hyperlipidemia	
Cholesterol/triglycerides within normal limits for age	17 (16.7%)
Mild Elevation, controllable by Diet	23 (22.5%)
Types II, III, or IV, requiring strict dietary control	3 (2.9%)
Dietary and Drug Control	59 (57.8%)
Cardiac Status	
Asymptomatic, normal electrocardiogram	63 (61.8%)
Asymptomatic, h/o MI >6 or occult MI by ECG	28 (27.5%)
Stable Angina	11 (10.8%)
Unstable Angina	0 (0.0%)
Carotid Status	
No symptoms, bruit, or evidence of disease	88 (86.3%)
Asymptomatic, but with evidence of disease	12 (11.8%)
Transient or Temporary Stroke	2 (2.0%)
Complete Stroke with Permanent Neurologic Deficit	0 (0.0%)
Renal Status	
Creatinine less than 1.5mg/dl, Clearance >50ml/min	96 (94.1%)

1.5 - 3.0 mg/dl Creatinine, Clearance 30 - 50 ml/min	6 (5.9%)
3.0 - 6.0 mg/dl Creatinine, Clearance 15 - 30 ml/min	0 (0.0%)
Creatinine greater than 6.0 ml/dl, Clearance < 15 ml/min	0 (0.0%)
Pulmonary Status	
0 - Asymptomatic, normal chest X-Ray	81 (79.4%)
1 - Asymptomatic or mild dyspnea or exertion, mild X-Ray parenchymal changes, PFTs 65%-80% of predicted	18 (17.6%)
2 - Between 1 and 3	3 (2.9%)
3 - Vital capacity < 1.85 L, Forced Expiratory Volume (FEV_1) less than 1.2 L or less than 35% of predicted, Maximal Voluntary Ventilation less than 50% of predicted, pCO_2 greater than 45 mm/Hg. Supplemental oxygen use medically necessary, or Pulmonary Hypertension (HTN)	0 (0.0%)

[1] Categorization per Society of Vascular Surgery (SVS) Reporting Standards[1].

Pre-Treatment Aneurysm Size and Type

A summary of pre-treatment aneurysm size and type is displayed in **Table 12**. Aneurysm size represents site-reported data and aneurysm type represents the joint assessment by Gore Imaging Services and a Screening Committee comprised of consulting physicians.

Table 12. Breakdown of Pre-Index Procedure Aneurysm Size and Type

Number of Subjects	102
Aneurysm Size[1] - Type IV[2]	59 (57.8%)
<5.0 cm	0
5.00-5.49 cm	10/59 (16.9%)
5.50-5.99 cm	27/59 (45.8%)
≥6.0 cm	22/59 (37.3%)
Aneurysm Size[1] - Pararenal[2]	43 (42.2%)
<5.0 cm	1/43 (2.3%)[3]
5.00-5.49 cm	11/43 (25.6%)
5.50-5.99 cm	16/43 (37.2%)
≥6.0 cm	15/43 (34.9%)

[1] Pre-index procedure aneurysm size was determined by the Site's baseline measurement.
[2] Aneurysm type was determined via centralized review consisting of Gore Imaging Sciences and physician(s) with prior TAMBE Device experience.
[3] Saccular aneurysm. Per Principal Investigator (PI), urgent repair was needed due to unpredictability of the natural history of saccular aneurysms.

Device Usage

Table 13 summarizes the devices each Subject received during the index treatment procedure.

On average, a Subject was implanted with a total of 11 devices including 1 TAMBE Aortic Component, 7 Branch Components, 1 Distal Bifurcated Component, and 2 contralateral leg endoprostheses or iliac extenders. Forty-seven Subjects (47/102; 46.1%) received a 31 mm Aortic Component and 55 Subjects (55/102; 53.9%) received a 37 mm Aortic Component. Of all 656 Branch Components implanted, the most commonly implanted sizes [presented as diameter (mm) x length (mm)] were the following: 7 mm x 79 mm (167/656; 25.5%), 7 mm x 59 mm (81/656; 12.3%), 9 mm x 59 mm (70/656; 10.7%), and 6 mm x 79 mm (64/656; 9.8%).

Table 13. Summary of Implanted Devices

	Index Procedure
Number of Subjects with Devices Implanted	102
Subjects with TAMBE Aortic Component	102 (100.0%)
1 Device	102 (100.0%)
TAMBE Aortic Component Proximal Diameter (mm) x Distal Diameter (mm) x Length (mm)	
31 x 20 x 160	47 (46.1%)
37 x 20 x 160	55 (53.9%)
Subjects with Branch Components	102 (100.0%)
Celiac	102 (100.0%)
1 Device	59 (57.8%)
2 Devices	42 (41.2%)
3 Devices	1 (1.0%)
SMA	102 (100.0%)
1 Device	50 (49.0%)
2 Devices	50 (49.0%)
3 Devices	2 (2.0%)
Left Renal	102 (100.0%)
1 Device	30 (29.4%)
2 Devices	60 (58.8%)
3 Devices	11 (10.8%)
4 Devices	1 (1.0%)
Right Renal	102 (100.0%)
1 Device	38 (37.3%)
2 Devices	64 (62.7%)
3 Devices	
Other[1]	1 (1.0%)
1 Device	1 (1.0%)
Subjects with Distal Bifurcated Component	102 (100.0%)
1 Device	102 (100.0%)
Subjects with Contralateral Leg Endoprosthesis/Iliac Extender	102 (100.0%)
2 Devices	53 (52.0%)

	Index Procedure
3 Devices	36 (35.3%)
4 Devices	11 (10.8%)
5 Devices[2]	1 (1.0%)
6 Devices[3]	1 (1.0%)
Subjects with GORE® TAG® Conformable Thoracic Endoprosthesis[4]	4 (3.9%)
1 Device	4 (3.9%)
Subjects with Other Device[5]	23 (22.5%)
1 Device	16 (15.7%)
2 Devices	4 (3.9%)
3 Devices	1 (1.0%)
4 Devices	1 (1.0%)
5 Devices	1 (1.0%)

[1] Subject received one Branch Component in the left hepatic artery for treatment of a focal dissection.

[2] One Subject received 5 contralateral leg endoprosthesis/iliac extenders during the index procedure to achieve adequate coverage and overlap. Completion angiogram revealed the presence of a dissection of the left common iliac artery from the aortic bifurcation to the iliac bifurcation. This dissection was completely covered by the contralateral leg endoprosthesis/iliac extenders.

[3] One Subject received 6 contralateral leg endoprosthesis/iliac extenders in total during the index procedure to allow for appropriate bridging of devices to resolve a Type III endoleak detected after the completion aortogram was performed. The additional two iliac limbs implanted resolved the endoleak.[4] GORE® TAG® Conformable Thoracic Endoprosthesis were successfully implanted during the index treatment procedure in four Subjects as proximal extensions to treat intraoperative Type I endoleak or iatrogenic dissection. Use of these devices was not planned.

[5] Other devices successfully implanted during the index treatment procedure included aortic extenders, bare metal stents, embolization coils, one self-expanding stent graft and one bovine pericardial patch.

Procedure Characteristics

A summary of procedure data collected at the time of the index treatment procedure is provided in **Table 14**. All Subjects (100%) survived the index procedure.

The median procedure time was 302.5 minutes (range 163-944 min) with a median anesthesia time of 419.5 minutes (range 250-1175 min). Median procedural blood loss was 250 ml (range 10-2000 ml). Four Subjects experienced ≥ 1000ml of procedural blood loss, three of whom received a transfusion. Procedural time for these Subjects ranged from 287-531 minutes. Of the neurological protection strategies tracked within the study database, 90 Subjects (90/102; 88.2%) had at least one strategy used during the TAMBE Device index procedure. Elevated mean arterial pressure was the most common protection strategy used (49/102; 48%), and electromyography (EMG) the least used protection strategy, (2/102; 2.0%). A prophylactic Cerebrospinal fluid (CSF) drain was placed in 9.8% of Subjects (10/102).

Table 14. Summary of TAMBE Device Index Procedure

	Index Procedure
Number of Subjects	102
Procedure Time (minutes)	

	Index Procedure
Mean (Std Dev)	315.3 (103.3)
Median	302.5
Range	(163, 944[1])
Anesthesia Type	
General	102 (100.0%)
Anesthesia Time (minutes)	
Mean (Std Dev)	438.4 (117.0)
Median	419.5
Range	(250, 1175)
Access Method - Right Femoral	
Percutaneous	90 (88.2%)
Cut-down	9 (8.8%)
Cut-down and conduit	3 (2.9%)
Not Used	0 (0.0%)
Access Method - Left Femoral	
Percutaneous	90 (88.2%)
Cut-down	11 (10.8%)
Cut-down and conduit	1 (1.0%)
Not Used	0 (0.0%)
Access Method - Right Arm	
Percutaneous	2 (2.0%)
Cut-down	40 (39.2%)
Cut-down and conduit	1 (1.0%)
Not Used	59 (57.8%)
Access Method - Left Arm	
Percutaneous	5 (4.9%)
Cut-down	49 (48.0%)
Cut-down and conduit	5 (4.9%)
Not Used	43 (42.2%)
Side Aortic Component Delivered	
Left	26 (25.5%)
Right	76 (74.5%)
Time Between Aortic Component (AC) Insertion to Final Completion Angiogram (minutes)	
n	98[2]
Mean (Std Dev)	189.2 (81.18)
Median	173.0
Range	(59, 690)
Neurological Protection Strategies Used[3]	90 (88.2%)
CSF Drain	10 (9.8%)

	Index Procedure
MEP/SSEP	29 (28.4%)
NIRS	22 (21.6%)
Steroid	15 (14.7%)
Elevated Mean Arterial Pressure	49 (48.0%)
Hypothermia	4 (3.9%)
ECG	46 (45.1%)
EMG	2 (2.0%)
Total Fluoroscopic Time (minutes)	
Mean (Std Dev)	80.8 (35.85)
Median	74.5
Range	(29, 249)
Contrast Used During Procedure (mL)	
Mean (Std Dev)	153.6 (73.56)
Median	143.0
Range	(16, 420)
Total Radiation Dose (Gy cm^2)	
n	95[4]
Median	250.0
Interquartile Range (IQR)	150.0, 626.0
Estimated Blood Loss During Procedure (mL)	
Mean (Std Dev)	299.9 (295.5)
Median	250.0
Range	(10, 2000)
Transfusion Required	14 (13.7%)
Heparin Administered	102 (100.0%)
Additional Procedures Performed	32 (31.4%)[5]
Planned Additional Procedures	6 (5.9%)
Unplanned Additional Procedures	28 (27.5%)
Subject Survived Procedure	102 (100.0%)

[1] One Subject had a prolonged procedure time due to challenges with cannulation of visceral vessels and additional time spent for observation of renal outflow.

[2] Missing three Subjects due to time values for completion angiogram not being provided. Missing one subject who has a negative time value and was not counted and considered a data entry error.

[3] The neurological protection strategies in the table are not an exhaustive list, but only includes those captured in the study database; Cerebrospinal fluid (CSF) drain, motor/ somatosensory-evoked potential (MEP / SSEP) monitoring, Near-infrared spectroscopy (NIRS) monitoring, Steroid, Elevated Mean Arterial Pressure (MAP), Hypothermia, Electrocardiogram (ECG), and Electromyography (EMG).

[4] Data was based on site's calculation. Total Radiation Dose was not collected for six Subjects. For one subject, data entry field would not accept decimal; therefore, the value was rounded down to 0 and this was excluded from this analysis.

[5] This was done on a per-subject level. Two Subjects had both a planned and an unplanned procedure. These included placement of a self-expanding GORE® VIABAHN® Endoprosthesis in the left subclavian artery after extravasation of contrast visualized, prophylactic coil embolization, use of Aortic Extender to treat Type III endoleaks at the junction of Distal Bifurcated Component and the Aortic Component, use of CTAG for treatment of intraoperative Type I endoleak and iatrogenic dissections, use of bare metal stents to address iatrogenic dissection and smoothing a transition zone, use of bovine pericardial patch to

treat focal dissection, and other procedures that did not require device implantation (e.g., thrombectomy, Percutaneous Transluminal Angioplasty).

Table 15 summarizes hospital discharge details. The median length of hospital stay after the index procedure was four days with a range of 1-19 days. Ninety-one Subjects (91/102; 89.2%) were discharged home. No Subject required long-term rehabilitation.

Table 15. Summary of Index Treatment Procedure Discharge Details

Number of Subjects	102
Time in ICU (hours)	83
Mean (Std Dev)	58.7 (52.72)
Median	48.0
Range	(1, 288)
Length of Stay for TAMBE Device Procedure (days)	102
Mean (Std Dev)	4.9 (3.45)
Median	4.0
Range	(1, 19)
Time on Ventilator (hours)	102
Mean (Std Dev)	8.9 (11.43)
Median	7.0
Range	(2, 99)
Post Procedure Location	102
Post Anesthesia Recovery Unit	21 (20.6%)
ICU	69 (67.6%)
Step Down Unit	1 (1.0%)
Medical Ward (Floor)	10 (9.8%)
Other	1 (1.0%)
Discharge Location	102
Home	91 (89.2%)
Skilled Nursing	4 (3.9%)
Short Term Rehab	6 (5.9%)
Long Term Rehab	0
Other	1 (1.0%)

D. Safety and Effectiveness Results

The analyses were hypothesis-driven. The safety and effectiveness of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis was assessed through two independent composite co-primary endpoints:

1. 30 day safety and effectiveness endpoint that is a composite of Uncomplicated Technical Success and/ Procedural Safety,
2. 12 month safety and effectiveness endpoint that is a composite of Clinically Significant Reintervention and Lesion Related Mortality.

Co-Primary Endpoint #1 is a composite of the following events at two time points:

A. Uncomplicated technical success at the time of the index endovascular procedure:
    i. Successful Access and Delivery
    ii. Successful and Accurate Deployment
    iii. Successful Withdrawal
B. Freedom from Procedural Safety events within the first 30 days of index procedure:
    i. Stented Segment Aortic Rupture
    ii. Lesion Related Mortality
    iii. Permanent Paraplegia
    iv. Permanent Paraparesis
    v. New Onset renal Failure Requiring Dialysis
    vi. Severe Bowel Ischemia
    vii. Disabling Stroke

Co-Primary Endpoint #2 is a composite of the following events through 12 months:

A. Clinically Significant Reintervention
    i. Clinically Indicated Condition
        - Device Seal Zone Endoleak
        - Lesion Growth >5 mm
        - Rupture
    ii. Device Effectiveness (Device Seal Zone / Integrity)
    iii. Patient Safety Events (Total Occlusion of Device Component)
    iv. Device System Prophylaxis (Reintervention requiring hospitalization)
B. Lesion-Related Mortality through 12 months

1. <u>Co-Primary Endpoint #1: 30 Day Safety and Effectiveness Endpoint</u>
   Table 16 displays the Composite 30 Day Safety and Effectiveness Primary Endpoint and 90% confidence interval (CI). Subgroup analysis for the endpoint results was performed by Subject's sex, aneurysm type, aneurysm size, age, and race. No statistically significant differences were identified in any of the subgroup analyses.

Table 16. Uncomplicated Technical Success and Procedural Safety

	Subjects Available for Assessment	Subjects with Success on the Endpoint	% (90% CI)
All Subjects	102		
Uncomplicated Technical Success and Procedural Safety	102	79	77.5% (69.6, 84.1)

Table 17 displays the Uncomplicated Technical Success and Procedural Safety event rates for each element of the endpoint from the time of the TAMBE Device index treatment procedure through 30-Days post-index treatment procedure.

Table 17. Summary of Composite 30 Day Primary Safety and Effectiveness Endpoint

	Subjects with Events (%)
Subjects available for assessment:	102
Subjects with Device Uncomplicated Technical Success and Freedom from Procedural Safety Event	79 (77.5%)
Uncomplicated Technical Failure at the time of index procedure	19 (18.6%)
Failure of Successful Access and Delivery	0 (0.0%)
Failure of Successful and Accurate Deployment	19 (18.6%)
Deployment/Kink/Twist/Obst/planned location	1 (1.0%)
Unplanned Placement of Non-TAMBE Device Component[1]	19 (18.6%)[2]
Use of Non-TAMBE Device Component to Correct Iatrogenic Event[3]	4 (3.9%)
Failure of Successful Withdrawal	0 (0.0%)
Procedural Safety Events in 30 Days[4]	8 (7.8%)
Stented Segment Aortic Rupture	1 (1.0%)
Lesion Related Mortality	0 (0.0%)
Permanent Paraplegia	2 (2.0%)
Permanent Paraparesis	3 (2.9%)
New Onset Renal Failure Requiring Dialysis	2 (2.0%)
Severe Bowel Ischemia	0 (0.0%)
Disabling Stroke	1 (1.0%)

[1] TAMBE Device components included the Aortic Component, Distal Bifurcated Component, Contralateral Leg Components, and Branch Components.

[2] Devices implanted that were not considered to be TAMBE Device components were bare metal stents in the visceral arteries of six Subjects (to address branch device deformity and smooth transition from Branch Component to the uncovered branch vessel in one Subject and to address visceral artery dissection in five Subjects), a GORE® TAG® Conformable Thoracic Endoprosthesis in four Subject (to mitigate concerns for Type Ia endoleak in two Subjects and to mitigate an aortic dissection in two Subjects), and the use of GORE® EXCLUDER® AAA Endoprosthesis - Aortic Extender in eight Subjects. The GORE® EXCLUDER® AAA Endoprosthesis - Aortic Extender has since been added as an optional component of the TAMBE Device (DBC Extender Component).

[3] Use of non-TAMBE Device components to correct iatrogenic complications in the treated aorta or branch vessels would be considered technical failures. Adjudicated by the CEC.

[4] Adjudicated by the CEC.

Uncomplicated Technical Success

Of the 102 Subjects analyzed, 79 Subjects (79/102; 77.5%) experienced Uncomplicated Technical Success and freedom from Procedural Safety Events, including 83 Subjects who achieved Uncomplicated Technical Success and 94 Subjects who experienced Procedural Safety. All 102 Subjects (100%) achieved successful access, delivery, and withdrawal at the time of the index treatment procedure. Nineteen Subjects (19/102; 18.6%) required the unplanned placement of a non-TAMBE Device component and failed to meet the protocol definition of Successful and Accurate Deployment as a result.

Iatrogenic events, including Type B aortic dissection and visceral artery dissection or perforation, were recurrently noted in Subjects with failure to achieve Uncomplicated Technical Success.

- Four Type B aortic dissections have been reported in the TAMBE Pivotal Study, two of which were identified and treated during the index procedure via proximal extension with a GORE® TAG® Conformable Thoracic Endoprosthesis. The other two were identified on post operative day (POD) # 1 and 3 and did not require intervention to mitigate the Type B aortic dissections. No aneurysm growth or rupture has been reported in any of the four Subjects, and three of the four Subjects experienced freedom from 30-day procedural safety endpoints. A definitive root cause of the Type B aortic dissections has not been confirmed.

- Visceral vessel iatrogenic events (including dissection or perforation of a renal, superior mesenteric or celiac artery, or distal branches thereof) have occurred in 8 (2.0%) target visceral arteries. Treatment of these iatrogenic events included placement of a bare metal stent in five impacted target arteries, placement of embolization coils in one Subject (in addition to a bare metal stent), and placement of a Branch Component in two Subjects, one of whom additionally underwent surgical abdominal exploration and evacuation of a hematoma. A splenic artery dissection was left untreated in one Subject. All impacted target arteries were patent at the conclusion of the index procedure. Further, none of the iatrogenic events that occurred in the renal arteries have resulted in acute kidney injury requiring dialysis, nor has the one in a superior mesenteric artery resulted in severe bowel ischemia. No singular, definitive root cause of visceral vessel iatrogenic events has been identified; however, the rate of visceral vessel iatrogenic complications decreased throughout the course of the TAMBE Pivotal Study enrollment following an increased emphasis on potential associated risks conveyed during training and case planning.

Since the time of protocol development in 2016, updated reporting standards have been published[1]. These updated standards clearly outline primary technical success can include the use of additional modular components, stents, or angioplasty and adjunctive surgical procedures at the time of the primary

procedure. **Table 18** provides outcomes for both the protocol defined Uncomplicated Technical Success and Technical Success as defined in reporting standards. Applying Technical Success as defined in the reporting standards yields 99% Technical Success (100 of 101 Subjects).

Table 18. Summary of Technical Success Measurements - TAMBE Pivotal Study Compared with SVS Standard[1]

Technical Success Measurement	Study Results
Uncomplicated Technical Success (TAMBE Pivotal Study Protocol)	83/102 (81%)
Technical Success (SVS Standard) *	100/101 (99%)

* Requires the following to be met:

- Successful access to the arterial system using remote arterial exposure, percutaneous technique, or open surgical conduits, successful delivery and deployment of the aortic stent graft and all modular stent graft components;
- Successful side branch catheterization and placement of bridging stents with restoration and maintenance of flow in all intended target vessels;
- Absence of Type I or Type III endoleaks at completion angiography; and
- Patency of all aortic modular stent graft components and intended side branch components at the index procedure.

Procedural Safety

All 102 Subjects (100%) were free from lesion related mortality events and severe bowel ischemia in the first 30-days post-index treatment procedure. As shown in **Table 17** above and reiterated in **Table 19**, nine procedural safety events, as adjudicated by CEC, occurred in a total of 8 Subjects (8/102; 7.8%).

- Two Subjects who experienced permanent paraparesis exhibited a spinal cord ischemia scale grade of "1: Resolved with minimal sensory deficit, able to walk independently" at their 6-month follow up visit; the third Subject did not exhibit improvement of the spinal cord ischemia scale.
- Among the five Subjects with permanent paraplegia or permanent paraparesis, one Subject had a prophylactic CSF drain placed.
- The disabling stroke event was reported as recovered with sequelae on POD 29 with no other associated adverse events.

Table 19. Summary of Procedural Safety Events in 30 Days

	Overall
	Subjects with Events (%)
Procedural Safety Events in 30 Days	8 (7.8%)
Stented Segment Aortic Rupture	1[1] (1.0%)
Lesion Related Mortality	0 (0.0%)
Permanent Paraplegia[2]	2 (2.0%)
Permanent Paraparesis[3]	3 (2.9%)
New Onset Sustained Renal Failure Requiring Dialysis[4]	2 (2.0%)
Severe Bowel Ischemia	0 (0.0%)
Disabling Stroke[5]	1 (1.0%)

[1] This Subject also experienced permanent paraplegia. The device remained implanted in this Subject through data lock.

[2] Permanent paraplegia was defined as 'secondary to spinal cord ischemia identified within 30 days of the index endovascular procedure combined with spinal cord ischemia scale grade of "3", representing a status of non-ambulatory with or without movement against gravity, at the one-month follow up visit'.

[3] Permanent paraparesis was defined as 'secondary to spinal cord ischemia identified within 30 days of the index endovascular procedure combined with spinal cord ischemia scale grade of "2: Minor motor deficit, able to walk with assistance or independently (implies the ability to move against gravity)" at the one-month follow-up visit'.

[4] New onset sustained renal failure requiring dialysis was defined as new onset renal failure identified within 30 days of the index endovascular procedure, combined with need/requirement for dialysis at the one month follow- up visit.

[5] Disabling stroke was assessed using the Modified Rankin Scale and defined as a stroke identified as having occurred within 30 days of the index endovascular procedure, combined with mRS ≥2 with an increase from baseline of at least one grade at 90 days.

2. Co-Primary Endpoint #2 - 12 Month Safety and Effectiveness Endpoint

Table 20 displays the composite 12 month primary safety and effectiveness endpoint and 90% confidence interval. Subgroup analysis for the endpoint results was performed by Subject's sex, aneurysm type, aneurysm size, age, and race. No statistically significant differences were identified in any of the subgroup analyses. The denominator for several events that comprise this co-primary endpoint is less than 102 because a follow up visit was not completed and/or Core Laboratory did not have adequate imaging available for their assessment.

Table 20. Clinically Significant Reintervention and Freedom from Lesion Related Mortality

	Subjects Available for Assessment	Subjects with Success on the Endpoint	% (90% CI)
Freedom from Clinically Significant Reintervention and Freedom from Lesion Related Mortality Through 12 Months	85	60	70.6% (61.4, 78.7)

Table 21 displays the individual elements of clinically significant reintervention and lesion related mortality following the TAMBE Device index treatment procedure through 12-months post-index treatment procedure.

Table 21. Composite 12 month Primary Safety and Effectiveness Endpoint

	Subjects Available for Assessment	Subjects with Events (%)
Freedom from Clinically Significant Reintervention and Freedom from Lesion Related Mortality Through 12 Months	85	60 (70.6%)
Clinically Significant Reintervention Through 12 Months	85[1]	25 (29.4%)
Clinically-Indicated Condition	81	6 (7.4%)
Untreated Device Seal Zone Endoleak[2]	82	0 (0.0%)
Target-Lesion Growth >5 mm[2]	84	5 (6.0%)
Rupture[3]	94	1 (1.1%)
Failure of Device Effectiveness (Compromise Device Seal Zone/Integrity[3])	94	7 (7.4%)
Patient Safety Events (Total Occlusion of Device Component[3])	95	14 (14.7%)

	Subjects Available for Assessment	Subjects with Events (%)
Complicated Device System Prophylaxis (Reintervention requiring Hospitalization[3])	95	4 (4.2%)
Lesion Related Mortality Through 12 Months	94	0 (0.0%)

[1] There were more subjects assessed for the composite endpoint than for some of the individual endpoint components because a Subject that failed any individual endpoint component could be included as assessed as part of the composite endpoint.
[2] Core Laboratory Assessment.
[3] Adjudicated by the CEC.

Clinically Indicated Condition

No Subjects (0/82; 0%) had an untreated device seal zone endoleak as assessed by the Core Laboratory. Five Subjects (5/84; 6.0%) had lesion growth >5 mm, each of which was noted in a Subject with a PAAA. Please see further discussion on these patients under *Core Laboratory Device Findings*. One Subject (1/94; 1.1%) experienced an intraoperative rupture as adjudicated by the CEC. The Subject reported a Type Ia endoleak and collapse of the iliac limb at the aortic bifurcation. The bifurcation was dilated using kissing balloons, subsequent to which, the Subject's blood pressure decreased causing concern for rupture. No post-operative rupture was reported.

Clinically Significant Reintervention

- Twenty-five Subjects (25/85; 29.4%) experienced one or more events.
- Seven Subjects (7/94; 7.4%;) experienced compromised device seal zone/integrity requiring placement of an additional stent or stent graft, with more noted in Type IV TAAA than PAAA anatomies.
- Fourteen Subjects (14/95; 14.7%;) experienced total occlusion of a device component, with more noted in PAAA than Type IV TAAA anatomies. The occlusions included 16 Branch Components, including one celiac and one superior mesenteric artery, six left renal arteries and eight right renal arteries; no occlusions were reported for any other TAMBE Device components. No surgical interventions were performed for treatment of any Branch Component occlusions. Among Subjects with Branch Component occlusions, five Subjects underwent percutaneous reinterventions on six renal branches, with restoration of branch patency in four of the six targeted Branch Components. The remaining ten occluded Branch Components had no reintervention attempted. One Subject with a SMA Branch Component occlusion experienced mesenteric ischemia and three Subjects with renal Branch Component occlusions required hemodialysis treatment within 12 months. A root cause investigation for Branch Component occlusions did not identify a singular root cause; however, diameters in the landing zone of renal Branch Component with occlusions tended to be near the lower end of the treatment range (4 mm), disproportionately relative to the overall study population.
- Four Subjects (4/95 assessable; 4.2%;) had an early reintervention requiring an extension of index hospital stay 3 days or longer (complicated

device system prophylaxis), with more noted in Type IV TAAA than PAAA anatomies. These included interventions for post operative Branch Component occlusion, Branch Component compression, paraparesis, and/or paraplegia.

Please see the section below on "Adverse Event Treatments involving the study device" for more information.

Lesion Related Mortality

No Subjects (0/94; 0%) experienced lesion related mortality through 12 months. Please see the "Deaths" section below for additional information on device and procedure related deaths.

Major Adverse Events

The SVS Reporting Standard[1] definition for major adverse events (MAEs) was not available at the time of protocol development; however, an analysis of MAEs was performed and included respiratory failure, myocardial infarction, stroke, paraplegia, acute renal failure, bowel ischemia, and death. Where possible, the MAEs are consistent with the SVS Reporting Standards; however, it should be noted that the SVS Reporting Standard definitions for MAE components are not identical to the event definitions for some components of the Co-Primary Endpoints [e.g., new onset sustained renal failure requiring dialysis (SVS Reporting Standards) vs. acute renal failure (protocol)].

In addition to MAEs, there have been two access related serious adverse events (SAEs) reported. Follow-up in the study remains ongoing; however, a summary of cumulative MAEs and access related SAEs through all available follow-up are displayed in **Table 22**Table .

Table 22. Summary of Cumulative Major Adverse Events and Access Related Serious Adverse Events

	1 Month	3 Months	6 Months	9 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total[9]
Number of Subjects	102	102	102	101	99	88	54	30	0	102
Subjects with Major Adverse Events[1]	7 (6.9%)	12 (11.8%)	13 (12.7%)	13 (12.9%)	16 (16.2%)	19 (21.6%)	21 (38.9%)	21 (70.0%)	-	21 (20.6%)
Respiratory Failure[2]	2 (2.0%)	3 (2.9%)	3 (2.9%)	3 (3.0%)	4 (4.0%)	5 (5.7%)	5 (9.3%)	5 (16.7%)	-	5 (4.9%)
Myocardial Infarction[3]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	1 (1.1%)	1 (1.9%)	1 (3.3%)	-	1 (1.0%)
Stroke[4]	1 (1.0%)	1 (1.0%)	1 (1.0%)	1 (1.0%)	1 (1.0%)	1 (1.1%)	1 (1.9%)	1 (3.3%)	-	1 (1.0%)
Paraplegia[5]	2 (2.0%)	2 (2.0%)	2 (2.0%)	2 (2.0%)	2 (2.0%)	2 (2.3%)	2 (3.7%)	2 (6.7%)	-	2 (2.0%)
Acute Renal Failure[6]	2 (2.0%)	4 (3.9%)	5 (4.9%)	5 (5.0%)	5 (5.1%)	6 (6.8%)	6 (11.1%)	6 (20.0%)	-	6 (5.9%)
Bowel Ischemia[7]	0 (0.0%)	1 (1.0%)	1 (1.0%)	1 (1.0%)	1 (1.0%)	1 (1.1%)	1 (1.9%)	1 (3.3%)	-	1 (1.0%)
Death[8]	0 (0.0%)	4 (3.9%)	5 (4.9%)	5 (5.0%)	6 (6.1%)	9 (10.2%)	11 (20.4%)	11 (36.7%)	-	11 (10.8%)
Subjects with Access Related Serious Adverse Events	1 (1.0%)	2 (2.0%)	2 (2.0%)	2 (2.0%)	2 (2.0%)	2 (2.3%)	2 (3.7%)	2 (6.7%)	-	2 (2.0%)

[1] Composite Event with the first occurrence of any of the following components.
[2] MedDRA (Medical Dictionary for Regulatory Activities) coded as Respiratory Failure with Ventilation or Intubation as description of treatment for an undetermined amount of time.
[3] MedDRA coded as Myocardial Infarction.
[4] MedDRA coded as Stroke with mRS of ≥2 And a difference of ≥1 from the Screening or adjudicated by the CEC as Disabling Stroke without Resolution at 90 Days Post-Procedure.
[5] MedDRA coded as Paraplegia or adjudicated by the CEC as Paraplegia in 30 days.
[6] MedDRA coded as Acute Kidney Injury/Acute Renal Failure with Dialysis or estimated Glomerular Filtration Rate (eGFR) drop of ≥50% at 1 month visit. Or adjudicated by the CEC as new onset of Renal Failure with Dialysis at 1 month post procedure.
[7] MedDRA coded as Bowel Ischemia with Resection or remained Unresolved, or adjudicated by the CEC as Severe Bowel Ischemia.
[8] All-Cause Mortality.
[9] Percentages in this column may be an underestimation as 5 year follow-up is not complete.

Study period definitions: 1 Month (1-30 days); 3 Months (31-92 days); 6 Months (93-183 days); 9 Months (184-214 days); 12 Months (215-365 days); 24 Months (366-731 days); 36 Months (732-1096 days); 48 Months (1097-1461 days); and 60 Months (1462 -1826 days).

Deaths

Table 23 Error! Reference source not found.lists Subject deaths. At the time of data lock, there were 11 deaths reported (11/102; 10.8%). One Subject death was CEC adjudicated as being related to the study device, one Subject death adjudicated as study procedure related, and the remaining Subject deaths applicable for adjudication were not related or unknown. Three Subject deaths were not adjudicated since their deaths fell in the >546-day (12-month) analysis window.

The Kaplan-Meier estimated 1-year (through day 365) freedom from all-cause mortality was 94.1%. The 2-year (through day 731) estimated freedom from all-cause mortality is 89.4%.

Table 23. Listing of Subject Deaths

Study Day	Cause of Death (Lowest Level Term)	Adjudicated Relationship	CEC Adjudicated AE as Resulted in Death in 12 Months	CEC Adjudicated as Lesion Related in 12 Months
39	Mesenteric ischemia / Mesenteric arterial occlusion	Study Device related	Yes	No
60	Acute respiratory failure	Study Procedure related	Yes	No
66	Type A aortic dissection	Not related	Yes	No
88	Small cell lung cancer	Not related	Yes	No
108	Unknown cause of death	Unknown	Yes	No
251	COVID-19	Not related	Yes	No
382	Acute respiratory failure	Not related	Yes	No
474	Small cell lung cancer	Not related	Yes	No
603	Acute kidney injury	N/A	Not Adjudicated	Not Adjudicated
1000	Alzheimer's disease	N/A	Not Adjudicated	Not Adjudicated
	Failure to thrive	N/A	Not Adjudicated	Not Adjudicated
1030	Intracranial hemorrhage	N/A	Not Adjudicated	Not Adjudicated

Adverse Event Treatments Involving the Study Device

Adverse event treatments involving the study device performed after the initial endovascular procedure were reported as reinterventions. Reinterventions were

performed at the discretion of the Investigator. Follow-up in the study remains ongoing; however, **Table 24** Table 24. below displays a cumulative overview of the site-reported reinterventions by follow-up period.

Through 12-month follow-up, 15 Subjects (15/96; 15.6%) had 22 reinterventions performed. Of those 15 Subjects, 5 had more than one reintervention. There were no open conversions reported.

Table 24. Cumulative Reinterventions by Follow-up Period

	Procedure	1 Month	3 Month	6 Month	12 Month	24 Month	36 Month	48 Month	60 Month	Total[6]
Subjects at Risk[1]	102	102	102	98	96	87	56	32	0	102
Number of Subjects with any Reintervention[2]	2 (2.0%) [2]	3 (2.9%) [3]	11 (10.8%) [14]	11 (11.2%) [14]	15 (15.6%) [22]	22 (25.3%) [32]	26 (46.4%) [40]	26 (81.3%) [40]	-	26 (25.5%) [40]
Reintervention Reason/Type										
Stent Graft Stenosis	0 (0.0%) [0]	1 (33.3%) [1]	2 (18.2%) [3]	2 (18.2%) [3]	4 (26.7%) [7]	7 (31.8%) [10]	7 (26.9%) [10]	7 (26.9%) [10]	-	7 (26.9%) [10]
Balloon angioplasty with peripheral stent	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	3 (13.6%) [3]	3 (11.5%) [3]	3 (11.5%) [3]	-	3 (11.5%) [3]
Balloon angioplasty with peripheral stent graft	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [2]	1 (9.1%) [2]	1 (6.7%) [2]	1 (4.5%) [2]	1 (3.8%) [2]	1 (3.8%) [2]	-	1 (3.8%) [2]
Peripheral stent graft without balloon angioplasty	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Balloon angioplasty without stent or stent graft	0 (0.0%) [0]	1 (33.3%) [1]	1 (9.1%) [1]	1 (9.1%) [1]	2 (13.3%) [4]	2 (9.1%) [4]	2 (7.7%) [4]	2 (7.7%) [4]	-	2 (7.7%) [4]
Endoleak	0 (0.0%) [0]	0 (0.0%) [0]	4 (36.4%) [5]	4 (36.4%) [5]	5 (33.3%) [6]	8 (36.4%) [11]	12 (46.2%) [18]	12 (46.2%) [18]	-	12 (46.2%) [18]
Balloon angioplasty with peripheral stent	0 (0.0%) [0]	0 (0.0%) [0]	3 (27.3%) [3]	3 (27.3%) [3]	3 (20.0%) [3]	3 (13.6%) [3]	3 (11.5%) [3]	3 (11.5%) [3]	-	3 (11.5%) [3]
Balloon angioplasty with peripheral stent graft	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	2 (9.1%) [2]	2 (7.7%) [2]	2 (7.7%) [2]	-	2 (7.7%) [2]
Balloon angioplasty with aortic stent graft	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	2 (7.7%) [2]	2 (7.7%) [2]	-	2 (7.7%) [2]
Peripheral stent graft without balloon angioplasty	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Balloon angioplasty without stent or stent graft	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Embolization coils	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [1]	1 (9.1%) [1]	2 (13.3%) [2]	4 (18.2%) [4]	6 (23.1%) [6]	6 (23.1%) [6]	-	6 (23.1%) [6]
Other	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [1]	1 (9.1%) [1]	1 (6.7%) [1]	2 (9.1%) [2]	3 (11.5%) [3]	3 (11.5%) [3]	-	3 (11.5%) [3]
Target-lesion growth (>5 mm in max diameter)[3]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	-	0 (0.0%) [0]
Post-Treatment TAAA rupture[4]	1 (50.0%) [1]	1 (33.3%) [1]	1 (9.1%) [1]	1 (9.1%) [1]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Other	1 (50.0%) [1]	1 (33.3%) [1]	1 (9.1%) [1]	1 (9.1%) [1]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Total occlusion of a device component	1 (50.0%) [1]	1 (33.3%) [1]	3 (27.3%) [4]	3 (27.3%) [4]	5 (33.3%) [6]	6 (27.3%) [7]	6 (23.1%) [7]	6 (23.1%) [7]	-	6 (23.1%) [7]

	Procedure	1 Month	3 Month	6 Month	12 Month	24 Month	36 Month	48 Month	60 Month	Total[6]
Balloon angioplasty with peripheral stent	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [1]	1 (9.1%) [1]	2 (13.3%) [2]	2 (9.1%) [2]	2 (7.7%) [2]	2 (7.7%) [2]	-	2 (7.7%) [2]
Balloon angioplasty with peripheral stent graft	1 (50.0%) [1]	1 (33.3%) [1]	1 (9.1%) [1]	1 (9.1%) [1]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Peripheral stent without balloon angioplasty	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Balloon angioplasty without stent or stent graft	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Other	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [2]	1 (9.1%) [2]	1 (6.7%) [2]	1 (4.5%) [2]	1 (3.8%) [2]	1 (3.8%) [2]	-	1 (3.8%) [2]
An open conversion[5]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	-	0 (0.0%) [0]
Other	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [1]	1 (9.1%) [1]	2 (13.3%) [2]	3 (13.6%) [3]	4 (15.4%) [4]	4 (15.4%) [4]	-	4 (15.4%) [4]
Balloon angioplasty with peripheral stent	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (6.7%) [1]	2 (9.1%) [2]	2 (7.7%) [2]	2 (7.7%) [2]	-	2 (7.7%) [2]
Peripheral stent without balloon angioplasty	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [1]	1 (9.1%) [1]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Balloon angioplasty without stent or stent graft	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]

[1] Subjects at risk is defined as any Subject that has had a visit in the indicated window or has had a reintervention prior to the indicated window.
[2] The number in [ ] denotes total number of reinterventions. N(%)[N]; denominator is the Subjects with at least one reintervention**.**
[3] Target-lesion growth (>5 mm in max diameter) was not reported as the reason for reintervention for any subject in the EDC.
[4] One Subject experienced a rupture during the index procedure; however, Site selected Post-Treatment TAAA rupture from the dropdown options on the Reintervention Case Report Form (CRF) in the EDC.
[5] One Subject underwent surgical abdominal exploration and evacuation of a hematoma, without TAMBE Device explant.
[6] Subjects with at least one repeat intervention during the study, total number of repeat interventions are shown in [ ]. Percentages in this column may be an underestimation as 5 year follow-up is not complete.

Study period definitions: 1 Month (1-30 days); 3 Months (31-92 days); 6 Months (93-183 days); 12 Months (184-365 days); 24 Months (366-731 days); 36 Months (732-1096 days); 48 Months (1097-1461 days); and 60 Months (1462 -1826 days).

Endoleaks

Follow-up in the study remains ongoing; however, **Table 25** Table 25. summarizes site-reported endoleaks by follow-up period. At the 12-month follow-up visit, 19 Subjects (19/88 assessable; 21.6%) had one or more endoleak ongoing. A total of 69 Subjects (69/88; 78.4%) were free from any type of site-reported ongoing endoleak in the 12- month window. Through all available follow-up, there have been 62 Subjects (62/102; 60.8%) with one or more Type I, II or III endoleak ongoing in window. There have been no Type IV or Indeterminate endoleaks.

Table 25. Summary of Site Reported Endoleaks by Follow-up Period

	Post Treatment Follow-up Period										
	Procedure	Post-Procedure[1]	1 Month	3 Months[1]	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total[2]
Number of Subjects	102	102	102	101	96	94	50	17	0	0	102
Evaluable Subjects	102	29	96	23	76	88	42	13	-	-	102

	Post Treatment Follow-up Period										
	Procedure	**Post-Procedure[1]**	**1 Month**	**3 Months[1]**	**6 Months**	**12 Months**	**24 Months**	**36 Months**	**48 Months**	**60 Months**	**Total[2]**
Subjects With One or More Endoleak Ongoing in Window	8 (7.8%)	12 (41.4%)	44 (45.8%)	14 (60.9%)	16 (21.1%)	19 (21.6%)	9 (21.4%)	4 (30.8%)	-	-	62 (60.8%)
New	8 (7.8%)	9 (31.0%)	37 (38.5%)	1 (4.3%)	5 (6.6%)	10 (11.4%)	5 (11.9%)	1 (7.7%)	-	-	-
Ongoing	-	3 (10.3%)	8 (8.3%)	13 (56.5%)	11 (14.5%)	10 (11.4%)	5 (11.9%)	3 (23.1%)	-	-	-
Type I	1 (1.0%)	0 (0.0%)	3 (3.1%)	1 (4.3%)	1 (1.3%)	2 (2.3%)	3 (7.1%)	1 (7.7%)	-	-	7 (6.9%)
New	1 (1.0%)	0 (0.0%)	3 (3.1%)	0 (0.0%)	0 (0.0%)	1 (1.1%)	3 (7.1%)	0 (0.0%)	-	-	-
Ongoing	-	0 (0.0%)	0 (0.0%)	1 (4.3%)	1 (1.3%)	1 (1.1%)	0 (0.0%)	1 (7.7%)	-	-	-
Type II	7 (6.9%)	12 (41.4%)	40 (41.7%)	13 (56.5%)	15 (19.7%)	17 (19.3%)	7 (16.7%)	2 (15.4%)	-	-	60 (58.8%)
New	7 (6.9%)	9 (31.0%)	33 (34.4%)	1 (4.3%)	5 (6.6%)	8 (9.1%)	2 (4.8%)	0 (0.0%)	-	-	-
Ongoing	-	3 (10.3%)	8 (8.3%)	12 (52.2%)	10 (13.2%)	9 (10.2%)	5 (11.9%)	2 (15.4%)	-	-	-
Type III	0 (0.0%)	0 (0.0%)	2 (2.1%)	0 (0.0%)	0 (0.0%)	1 (1.1%)	0 (0.0%)	0 (0.0%)	-	-	3 (2.9%)
New	0 (0.0%)	0 (0.0%)	2 (2.1%)	0 (0.0%)	0 (0.0%)	1 (1.1%)	0 (0.0%)	0 (0.0%)	-	-	-
Ongoing	-	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	0 (0.0%)
New	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-
Ongoing	-	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-
Indeterminate	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	0 (0.0%)
New	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-
Ongoing	-	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-

[1] Contrast CT is not required.
[2] Percentages in this column may be an underestimation as 5 year follow-up is not complete.

Note: Column header counts are the number of Subjects at risk at the start of each interval. Denominators are the number of evaluable Subjects (CT imaging available or endoleak at each interval).

Study period definitions: Procedure (day 0); Post-Procedure (1-14 days); 1 Month (15-59 days); 3 Months (60-126 days); 6 Months (127-242 days); 12 Months (243-546 days); 24 Months (547-911 days); 36 Months (912-1275 days); 48 Months (1276-1640 days); and 60 Months (1641-2006 days).

Follow-up in the study remains ongoing; however, **Table 26** Table 26. summarizes Core Laboratory reported endoleaks by Follow-Up period.

From post-index treatment procedure through available follow up, the Core Laboratory identified 65 (65/99 assessable; 65.7%) Type II endoleaks and 20 (20/99; 20.2%) Indeterminate endoleaks. There have been zero Type I or Type III endoleaks reported by the Core Laboratory.

Table 26. Summary of Core Laboratory Reported Endoleaks by Follow-up Period

	Follow-up Period										
	Procedure	Post-Procedure	1 Month	3 Months	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total[2]
Number of Subjects	102	102	102	101	96	94	50	17	0	0	102
Evaluable Subjects[1]	2	21	92	13	72	81	37	9	-	-	99
Any Type I Endoleak	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0(0.0%)	-	-	0 (0.0%)
Type IA Endoleak	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	0 (0.0%)
Type IB Endoleak	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	0 (0.0%)
Type IC Endoleak	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	0 (0.0%)
Type II Endoleak	2 (100.0%)	11 (52.4%)	58 (63.0%)	5 (38.5%)	37 (51.4%)	43 (53.1%)	20 (54.1%)	4 (44.4%)	-	-	65 (65.7%)
Any Type III Endoleak	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	0 (0.0%)
Type III General Endoleak	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	0 (0.0%)
Type IIIA Endoleak	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	0 (0.0%)
Type IIIB Endoleak	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	0 (0.0%)
Type IV Endoleak	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	0 (0.0%)
Indeterminate Endoleak	0 (0.0%)	0 (0.0%)	6 (6.5%)	3 (23.1%)	6 (8.3%)	7 (8.6%)	7 (18.9%)	2 (22.2%)	-	-	20 (20.2%)

[1] Evaluable Subjects = Subjects with adequate imaging.

[2] Percentages in this column may be an underestimation as 5 year follow-up is not complete.

Note: Column header counts are the number of Subjects at risk at the start of each interval. Denominators are the number of Subjects with endoleaks evaluated.

Study period definitions: Procedure (day 0); Post-Procedure (1-14 days); 1 Month (15-59 days); 3 Months (60-126 days); 6 Months (127-242 days); 12 Months (243-546 days); 24 Months (547-911 days); 36 Months (912-1275 days); 48 Months (1276-1640 days); and 60 Months (1641-2006 days).

Keeping consistent with previous Gore and competitor aortic clinical studies, Core Laboratory evaluation of imaging data was used for primary endpoint evaluation for its objectivity and perceived benefit in the increased sensitivity and proceduralized methodology in making imaging observations. However, complete agreement between two types of image evaluators, such as a site and a Core Laboratory, may be unrealistic in a practical setting for multiple reasons. Endoleak determination by the Core Laboratory requires the ability to identify the origin of the endoleak to make a conclusive determination. Submitted imagery is reviewed by multiple Core Laboratory readers with a pre-defined process where differences between device issue events are internally adjudicated for the purpose of final reporting. Endoleak determinations are done by the Core

Laboratory on a per image basis and independent of previous scans. Physicians, by contrast, may be more likely to assess and report clinically significant observations which were reported as adverse events. Physicians may determine both the presence and type of endoleak, based on their best medical judgement, through the evaluation across multiple images sets and image modalities. In the clinical study, for several cases, the type of endoleak reported from the Core Laboratory analysis was not in accordance with the site reported data, with Type II and/or indeterminate endoleaks reported by the Core Laboratory in Subjects reported by sites as having a Type I or III endoleak. It should be noted that the Core lab assessed component separation as an additional assessment only if device migration was noted (device migration assessed longitudinal movement of all or part of the device). Since no device migration was observed by the Core lab, no subjects were listed as evaluable for component separation (as shown within **Table 27** below).

Core Laboratory Device Findings

The imaging performed at each protocolized follow-up visit was evaluated by an independent Core Laboratory for the occurrence of critical events such as endoleaks, device /vessel patency, wire fractures, and device migration /separation /compression /kinking (**Table 27**Table 27.). Please note that follow-up in the study remains ongoing.

- Endoleaks: The Core Laboratory reported zero Type I, III and IV endoleaks. At 12 Months, Type II endoleaks were identified for 64/92 evaluable Subjects (69.6%) and Indeterminate endoleaks identified for 14/92 (15.2%). In total, Type II endoleaks were identified for 65/99 evaluable Subjects (65.7%) from 1-Month through 36-Months post-treatment procedure and Indeterminate endoleaks were identified for 20/99 evaluable Subjects (20.2%) during the same time period. The overall rate of Subjects identified as having a Type II endoleak is likely driven by the extent of coverage across the thoracoabdominal aorta and the associated presence of multiple potential sources of Type II endoleak, including the lumbar and intercostal arteries, the inferior mesenteric artery, and in some cases, accessory renal arteries.
- Patency: At 12-Months, the Core Laboratory reported 14/88 evaluable Subjects (15.9%) as having non-patent side branch component/vessel. There were no reports of loss of patency of the aortoiliac components (Aortic Component/vessel, Distal Bifurcated Component or Contralateral Leg Component(s)).
- Device Integrity Events: At 12-Months, the Core Laboratory reported 3/83 evaluable (3.6%) Subjects with wire fracture. Each wire fracture was subsequently reported by sites as a device deficiency [as defined in International Organization for Standardization (ISO) 14155]; no clinical sequelae were reported as a result of any reported wire fracture. A root cause investigation concluded that one of the wire fractures was the result of the increased strain imparted on the Aortic Component from the

orientation of the Branch Components between the TAMBE Aortic Component and the arcuate ligament, combined with the radial inward pressure created from a pressurized endoleak and dissection-induced false lumen. Accordingly, a warning was added to the TAMBE Device IFU stating it is not recommended to cross Branch Components within a narrow visceral aortic lumen. A step in the manufacturing process was identified as the root cause for the other two reported wire fractures, and associated manufacturing process improvements were implemented for TAMBE Aortic Components used in all TAMBE Device procedures beginning in June 2022. No wire fractures attributable to this root cause have been reported in TAMBE Aortic Components manufactured after implementation of the manufacturing process improvements.

- Device Compression, Migration and Kink: At 12-Months, 11/90 evaluable Subjects (12.2%) had device compression. Compressions occurred in one Contralateral Leg Component which did not necessitate reintervention and did not result in loss of patency and one Aortic Component compression secondary to a Type A aortic dissection. The remaining nine reported compressions occurred in Branch Components; three compressed Branch Component required reintervention and seven were patent at 12 months. No Subjects with reported Branch Compression have experienced mesenteric ischemia or acute kidney injury requiring dialysis, per site-reported adverse events; however, four Subjects with reported renal Branch Component compression subsequently exhibited renal function deterioration (a sustained >25% decrease in eGFR over two consecutive study visits compared to baseline). Half of the compressed Branch Components occluded with patency successfully restored in two instances. Branch Compressions were identified at the time of the first follow up CT in seven out of the ten instances; therefore, diligence to ensure that all TAMBE Device components are appropriately dilated and free from compression at the completion of the index procedure is warranted, as is routine follow-up imaging as outlined in the TAMBE Device IFU. Additionally, a warning was added to the TAMBE Device IFU stating it is not recommended to cross Branch Components within a narrow visceral aortic lumen. There were no evaluable Subjects with reported device migration or kink.
- Component Separation: There were no evaluable Subjects with reported component separation.
- Aortic Enlargement: Aortic enlargement was noted for 5/84 Subjects that had an aneurysm measurement (6.0%) through 12-months. The Core Laboratory reported these Subjects as having either Type II or Indeterminate endoleaks. Four of the Subjects had Site reported adverse events of endoleak that were treated with coil embolization or balloon angioplasty at some timepoint after the aneurysm growth was reported by the Core Laboratory. One Subject did not require treatment. There was no post-operative aneurysm rupture, and no CEC adjudicated lesion related mortality through 12 month follow up in any Subject.

Table 27. Summary of Cumulative Core Laboratory Device Findings by Follow-up

	Post-Treatment Follow-up Period								
	1 Month	3 Months[1]	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total[4]
Number of Subjects	**102**	**101**	**96**	**94**	**50**	**17**	**0**	**0**	**102**
Number of Subjects with CT Scan in Window	**96**	**14**	**75**	**88**	**42**	**11**	**0**	**0**	**101**
Number of Subjects with DUS in Window	**94**	**76**	**77**	**81**	**37**	**12**	**0**	**0**	**99**
Number of Subjects with X-Ray in Window	**94**	**10**	**70**	**80**	**38**	**12**	**0**	**0**	**100**
Endoleaks Evaluable	**93**	**72**	**90**	**92**	**77**	**71**	**0**	**0**	**99**
Endoleak	66 (71.0%)	67 (93.1%)	67 (74.4%)	68 (73.9%)	70 (90.9%)	70 (98.6%)	-	-	70 (70.7%)
Type I	0	0	0	0	0	0	-	-	0
Type II	62 (66.7%)	63 (87.5%)	64 (71.1%)	64 (69.6%)	65 (84.4%)	65 (91.5%)	-	-	65 (65.7%)
Type III	0	0	0	0	0	0	-	-	0
Type IV	0	0	0	0	0	0	-	-	0
Indeterminate	6 (6.5%)	8 (11.1%)	11 (12.2%)	14 (15.2%)	19 (24.7%)	20 (28.2%)	-	-	20 (20.2%)
Patency Evaluable	**97**	**80**	**81**	**88**	**51**	**28**	**0**	**0**	**100**
Non-patent Component/Vessel	**5 (5.2%)**	**6 (7.5%)**	**9 (11.1%)**	**14 (15.9%)**	**19 (37.3%)**	**19 (67.9%)**	**-**	**-**	**19 (19.0%)**
Non-patent Aortic Component	0	0	0	0	0	0	-	-	0
Non-patent Celiac Side Branch	0	0	1 (1.2%)	2 (2.3%)	3 (5.9%)	3 (10.7%)	-	-	3 (3.0%)
Non-patent SMA Side Branch	0	0	0	0	1 (2.0%)	1 (3.6%)	-	-	1 (1.0%)
Non-patent Left Renal Artery Side Branch	4 (4.1%)	5 (6.3%)	5 (6.2%)	7 (8.0%)	7 (13.7%)	7 (25.0%)	-	-	7 (7.0%)
Non-patent Right Renal Artery Side Branch	1 (1.0%)	1 (1.3%)	4 (4.9%)	7 (8.0%)	9 (17.6%)	9 (32.1%)	-	-	9 (9.0%)
Non-patent Distal Bifurcated	0	0	0	0	0	0	-	-	0
Non-patent Contra-Lateral Limb	0	0	0	0	0	0	-	-	0
Non-patent Contra-Lateral Iliac Extender	0	0	0	0	0	0	-	-	0
Non-patent Ipsi-Lateral Iliac Extender	0	0	0	0	0	0	-	-	0
Non-patent Proximal Aorta Vessel	0	0	0	0	0	0	-	-	0
Non-patent Celiac Artery Vessel	0	0	1 (1.2%)	1 (1.1%)	1 (2.0%)	1 (3.6%)	-	-	1 (1.0%)
Non-patent SMA Vessel	0	0	0	0	1 (2.0%)	1 (3.6%)	-	-	1 (1.0%)
Non-patent Left Renal Artery Vessel	0	0	0	1 (1.1%)	1 (2.0%)	2 (7.1%)	-	-	2 (2.0%)
Non-patent Right Renal Artery Vessel	0	0	0	0	1 (2.0%)	1 (3.6%)	-	-	1 (1.0%)
Wire Fracture Evaluable	**94**	**16**	**72**	**83**	**40**	**15**	**0**	**0**	**100**
Wire Fracture	0	0	2 (2.8%)	3 (3.6%)	3 (7.5%)	3 (20.0%)	-	-	3 (3.0%)
Device Migration Evaluable	**96**	**14**	**72**	**87**	**41**	**11**	**0**	**0**	**101**
Device Migration[2]	0	0	0	0	0	0	-	-	0
Component Separation Evaluable[3]	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Component Separation	-	-	-	-	-	-	-	-	-
Device Compression Evaluable	**96**	**21**	**79**	**90**	**47**	**19**	**0**	**0**	**101**
Device Compression/Invagination	7 (7.3%)	10 (47.6%)	11 (13.9%)	11 (12.2%)	12 (25.5%)	12 (63.2%)	-	-	12 (11.9%)
Device Kink Evaluable	**96**	**14**	**74**	**87**	**42**	**11**	**0**	**0**	**101**
Device Kink	0	0	0	0	0	0	-	-	0

[1] CT not required.

[2] Protocol defined as: Longitudinal movement of all or part of the device for a distance ≥10 mm, as confirmed by CT scan, relative to anatomical landmarks and device positioning at the first post-operative CT scan.

[3] Core lab assessed component separation as an additional assessment only if device migration was noted (device migration assessed longitudinal movement of all or part of the device). Since no device migration was observed by the Core lab, no subjects were listed as evaluable for component separation.

[4] Percentages in this column may be an underestimation as 5 year follow-up is not complete.

Note: Denominators are the number of evaluable Subjects which include at least one variable involved in the calculation being evaluable (Not unknown or missing).

Baseline measurements are derived from the first post-operative CT scan within the 30-day follow-up.

Study period definitions: 1 Month (15-59 days); 3 Months (60-126 days); 6 Months (127-242 days); 12 Months (243-546 days); 24 Months (547-911 days); 36 Months (912-1275 days); 48 Months (1276-1640 days); and 60 Months (1641-2006 days).

As shown in **Table 28** 28, five Subjects (5/84; 6.0%) were reported by the Core Laboratory as having aneurysm growth >5 mm through 12 months. Among these five Subjects, one was reported by the site to have a Type III endoleak which was successfully resolved via percutaneous transluminal angioplasty of a branch component. The other four Subjects had only Type II endoleaks reported, three of which had been resolved via coil embolization and one of which had not been treated as of the date of data lock. In addition, through 12 months, twenty Subjects (20/84; 23.8%) were reported as having >5 mm of shrinkage in aneurysm size and 59 Subjects (59/84; 70.2%) were reported as having a stable aneurysm that was within 5 mm of the baseline measurement. At the time of data lock, a total of 9 subjects were reported by the Core Laboratory as having aneurysm growth > 5 mm.

Table 28 28. Summary of Core Laboratory Aneurysm Growth/Shrinkage By Follow-up

	1 Month	3 Months[1]	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total[2]
Number of Subjects at risk at the beginning of each period	**96**	**95**	**90**	**89**	**49**	**16**	**0**	**0**	**96**
Number of Subjects with Aneurysm Measurement in Window	96	10	73	84	42	10	-	-	96
Subjects with Aneurysm Growth > 5mm	0	0	2 (2.7%)	5 (6.0%)	4 (9.5%)	4 (40.0%)	-	-	9 (9.4%)
Subjects with Aneurysm Shrinkage > 5mm	0	0	15 (20.5%)	20 (23.8%)	11 (26.2%)	2 (20.0%)	-	-	26 (27.1%)
Stable Subjects (Aneurysm within 5 mm of the Baseline)	96 (100.0%)	10 (100.0%)	56 (76.7%)	59 (70.2%)	27 (64.3%)	4 (40.0%)	-	-	61 (63.5%)

[1] CT imaging not required.
[2] Percentages in this column may be an underestimation as 5 year follow-up is not complete.

Note: Denominators are the number of evaluable Subjects (CT Image or Aneurysm Growth available or Growth/Shrinkage >5 mm). Baseline measurements are derived from the post-operative CT scan at the 1 Month follow-up window.

Study period definitions: 1 Month (15-59 days); 3 Months (60-126 days); 6 Months (127-242 days); 12 Months (243-546 days); 24 Months (547-911 days); 36 Months (912-1275 days); 48 Months (1276-1640 days); and 60 Months (1641-2006 days).

3. Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes: Subject's sex, aneurysm type, aneurysm size, age and race. To maintain Type I and Type II errors, no formal hypotheses testing was performed for these sub-groups. A primary endpoint subgroup analysis was not performed by region due to the small sample size of Subjects implanted in the U.K. (n=3).

Endpoint Analysis by Sex

For analysis of the 30-day Primary Composite Endpoint (of Uncomplicated Technical Success and Procedural Safety), 84 male Subjects and 18 female Subjects were eligible. Sixty-four male Subjects (64/84; 76.2%) and 15 female Subjects (15/18; 83.3%) experienced uncomplicated technical success and freedom from procedural safety events. Failure to achieve the Uncomplicated Technical Success endpoint element was observed in 19.0% of male Subjects

and 16.7% of female Subjects. For procedural safety, two female Subjects (2/18; 11.1%) experienced events in 30 days as compared to 6/84 (7.1%) male Subjects. There do not appear to be clinically meaningful differences by sex for this composite 30 day Primary Endpoint.

For analysis of the 12 month Primary Composite endpoint of Clinically Significant Reinterventions and Lesion Related Mortality 70 male Subjects and 15 female Subjects were eligible. Fifty-one male Subjects (51/70; 72.9%) and nine (9/15; 60.0%) female Subjects experienced freedom from clinically significant reintervention and lesion related mortality through 12 months. Failure of clinically significant reintervention was observed in 19/70 (27.1%) of male Subjects as compared to 6/15 (40%) of female Subjects. No lesion related mortality through 12 months was observed in either male or female Subjects. While the sample size is limited, it does not appear that there are clinically meaningful differences by sex for this composite 12 month Primary Endpoint.

Endpoint Analysis by Aneurysm Type

TAAAs included those with a proximal extent which originated between the level of the superior mesenteric artery through as far as 65 mm proximal to the celiac artery. PAAAs included those with a proximal extent which originated at the level of the renal arteries, with no normal aorta between the upper extent of aneurysm and the renal artery(s), through as far proximally as the level of the superior mesenteric artery.

For analysis of the 30-day Primary Composite Endpoint, 59 Subjects with a TAAA and 43 Subjects with a PAAA were eligible. Forty-eight (48/59; 81.4%) TAAA Subjects and 31 (31/43; 72.1%) PAAA Subjects experienced uncomplicated technical success and freedom from procedural safety events (**Table 29**). Based on the statistical test performed, there do not appear to be differences by aneurysm type for this composite Primary Endpoint. However, the analysis is limited by the small sample size.

Event failures for uncomplicated technical success occurred in 9 TAAA Subjects (9/59; 15.3%) and in 10 PAAA Subjects (10/43; 23.3%). For the procedural safety component analysis, 3 TAAA Subjects (3/59; 5.1%) and 5 PAAA Subjects (5/43; 11.6%) experienced procedural safety events. See **Table 29**Table 29.

Table 29. Summary of the Uncomplicated Technical Success/Procedural Safety Endpoint Analysis by Aneurysm Type

	Overall		TAAA		PAAA	
	Subjects Available for Assessment	Subjects with Events (%)	Subjects Available for Assessment	Subjects with Events (%)	Subjects Available for Assessment	Subjects with Events (%)
All Subjects	102		59		43	
Subjects with Device Uncomplicated Technical Success and Freedom from Procedural Safety Event	102	79 (77.5%)	59	48 (81.4%)	43	31 (72.1%)

	Overall		TAAA		PAAA	
	Subjects Available for Assessment	Subjects with Events (%)	Subjects Available for Assessment	Subjects with Events (%)	Subjects Available for Assessment	Subjects with Events (%)
Failure of Device Uncomplicated Technical Success	102	19 (18.6%)	59	9 (15.3%)	43	10 (23.3%)
Failure of Successful Access and Delivery	102	0 (0.0%)	59	0 (0.0%)	43	0 (0.0%)
Failure of Successful and Accurate Deployment	102	19 (18.6%)	59	9 (15.3%)	43	10 (23.3%)
Deployment/Kink/Twist/Obst/planned location	102	1 (1.0%)	59	1 (1.7%)	43	0 (0.0%)
Unplanned Placement of Non-TAMBE Device Component	102	19 (18.6%)	59	9 (15.3%)	43	10 (23.3%)
Use of Non-TAMBE Device Component to Correct Iatrogenic Event[1]	102	4 (3.9%)	59	4 (6.8%)	43	0 (0.0%)
Failure of Successful Withdrawal	102	0 (0.0%)	59	0 (0.0%)	43	0 (0.0%)
Procedural Safety Events in 30 Days[2]	102	8 (7.8%)	59	3 (5.1%)	43	5 (11.6%)
Stented Segment Aortic Rupture	102	1 (1.0%)	59	1 (1.7%)	43	0 (0.0%)
Lesion Related Mortality	102	0 (0.0%)	59	0 (0.0%)	43	0 (0.0%)
Permanent Paraplegia	102	2 (2.0%)	59	2 (3.4%)	43	0 (0.0%)
Permanent Paraparesis	102	3 (2.9%)	59	0 (0.0%)	43	3 (7.0%)
New Onset Renal Failure Requiring Dialysis	102	2 (2.0%)	59	1 (1.7%)	43	1 (2.3%)
Severe Bowel Ischemia	102	0 (0.0%)	59	0 (0.0%)	43	0 (0.0%)
Disabling Stroke	102	1 (1.0%)	59	0 (0.0%)	43	1 (2.3%)

[1] Use of non-TAMBE Device Components to correct iatrogenic complications in the treated aorta or branch vessels would be considered technical failures. Adjudicated by the CEC.

[2] Adjudicated by the CEC.

For analysis of the 12 month Primary Composite endpoint, 47 Subjects with a TAAA and 38 Subjects with a PAAA were eligible. Thirty-seven TAAA Subjects (37/47; 78.7%) and 23 PAAA Subjects (23/38; 60.5%) experienced freedom from clinically significant reintervention through 12 months (**Table 30**). There were no lesion related mortalities through 12 months. There do not appear to be differences by aneurysm type for this composite Primary Endpoint.

Ten TAAA Subjects (10/47; 21.3%) and 15 PAAA Subjects (15/38; 39.5%) experienced clinically significant reintervention in 12 months. Of note, a higher percentage of PAAA Subjects experienced target-lesion growth >5 mm (13.5% vs. 0%) and total occlusion of device component (22% vs. 9.3%) compared to TAAA Subjects. A higher percentage of TAAA Subjects (9.4%) experienced failure of device effectiveness versus 4.9% of PAAA Subjects. See **Table 30**.

Table 30. Summary of the Clinically Significant Reintervention / Lesion-Related Mortality Endpoint Analysis by Aneurysm Type

	Overall		TAAA		PAAA	
	Subjects Available for Assessment	Subjects with Events (%)	Subjects Available for Assessment	Subjects with Events (%)	Subjects Available for Assessment	Subjects with Events (%)
All Subjects	102		59		43	
Freedom from Clinically Significant Reintervention and Freedom from Lesion Related Mortality Through 12 Months	85	60 (70.6%)	47	37 (78.7%)	38	23 (60.5%)
Clinically Significant Reintervention Through 12 Months	85	25 (29.4%)	47	10 (21.3%)	38	15 (39.5%)
Clinically-Indicated Condition	81	6 (7.4%)	46	1 (2.2%)	35	5 (14.3%)

	Overall		TAAA		PAAA	
	Subjects Available for Assessment	Subjects with Events (%)	Subjects Available for Assessment	Subjects with Events (%)	Subjects Available for Assessment	Subjects with Events (%)
Untreated Device Seal Zone Endoleak[1]	82	0 (0.0%)	47	0 (0.0%)	35	0 (0.0%)
Target-Lesion Growth >5 mm[1]	84	5 (6.0%)	47	0 (0.0%)	37	5 (13.5%)
Rupture[2]	94	1 (1.1%)	53	1 (1.9%)	41	0 (0.0%)
Failure of Device Effectiveness (Compromise Device Seal Zone/Integrity[2])	94	7 (7.4%)	53	5 (9.4%)	41	2 (4.9%)
Patient Safety Events (Total Occlusion of Device component[2])	95	14 (14.7%)	54	5 (9.3%)	41	9 (22.0%)
Complicated Device System Prophylaxis (Reintervention requiring Hospitalization[2])	95	4 (4.2%)	54	3 (5.6%)	41	1 (2.4%)
Lesion Related Mortality Through 12 Months	94	0 (0.0%)	53	0 (0.0%)	41	0 (0.0%)

[1] Core Laboratory Assessment.
[2] Adjudicated by the CEC.

Endpoint Analysis by Aneurysm Size

The site reported size of pre-treatment aneurysms was categorized into groups and endpoint results were tabulated for each size category. The descriptive analysis of the endpoints was performed by aneurysm size by using the cut-off of 5.5 cm.

For analysis of the 30-day Primary Composite Endpoint, 22 Subjects with an aneurysm diameter <5.5 cm and 80 Subjects with an aneurysm diameter ≥5.5 cm were eligible. Sixteen Subjects (17/22; 77.3%) with <5.5 cm diameter aneurysm and 62 Subjects (62/80; 77.5%) with ≥5.5 cm experienced uncomplicated technical success and freedom from procedural safety events. Four Subjects with <5.5 cm aneurysm diameter (4/22; 18.2%) and 15 Subjects with ≥5.5 cm aneurysm diameter (15/80; 18.8%) did not meet the uncomplicated technical success endpoint. For the procedural safety endpoint, two Subjects with <5.5 cm aneurysm diameter (2/22; 9.1%) and 6 Subjects with ≥5.5 cm aneurysm diameter (6/80; 7.5%) experienced procedural safety events in the first 30 days. There were no differences by aneurysm size for this composite Primary Endpoint.

For analysis of the 12-month Primary Composite Endpoint, 19 Subjects with an aneurysm diameter <5.5 cm and 66 Subjects with an aneurysm diameter ≥5.5 cm were eligible. Thirteen Subjects with <5.5 cm diameter aneurysm (13/19; 68.4%) and 47 Subjects with ≥5.5 cm aneurysm diameter (47/66; 71.2%) experienced freedom from clinically significant reintervention through 12 months. Failure of this endpoint analysis centered around occlusion of device components noted in 14.3% of <5.5 cm aneurysm diameter Subjects and 14.9% of ≥5.5 cm aneurysm diameter Subjects. There were zero lesion related mortalities for both groups. There do not appear to be differences by aneurysm size for this composite Primary Endpoint.

Endpoint Analysis by Age

Analysis of the endpoints was performed by the Subjects' age by dichotomizing the overall median age of 73 years. For analysis of the 30-day Primary

Composite Endpoint, 47 Subjects aged <73 years and 55 Subjects aged ≥73 years were eligible. Thirty-six Subjects <73 years (36/47; 76.6%;) and 43 Subjects ≥73 years (43/55; 78.2%) experienced uncomplicated technical success and freedom from procedural safety events. Eight Subjects <73 years (8/47; 17.0%) and 11 Subjects ≥73 years (11/55; 20.0%) did not meet the uncomplicated technical success endpoint. Five Subjects <73 years (5/47; 10.6%) and 3 Subjects ≥73 years (3/55; 5.5%) experienced procedural safety events in the first 30 days. There was no difference between the age groups for this composite Primary Endpoint rate by age.

For analysis of the 12-month Primary Composite Endpoint, 39 Subjects aged <73 years and 46 Subjects aged ≥73 years were eligible for analysis of. Twenty-four Subjects (61.5%; 24/39) <73 years and 36 Subjects (78.3%; 36/46) ≥73 years experienced freedom from clinically significant reintervention through 12 months. Event failures for the clinically significant reintervention endpoint occurred in 15 Subjects (38.5%) <73 years compared to ten Subjects (21.7%) ≥73 years. Of particular interest is the patient safety event component regarding total occlusion of device component. The younger age group had a 20.5% event failure rate whereas the older age group only had a 9.8% event failure rate through 12 month follow up. There were no lesion related mortalities in either age group. There do not appear to be differences by age for this composite Primary Endpoint.

Endpoint Analysis by Race

Descriptive analysis of the endpoints was performed by the Subjects' Race for U.S. Sites. For analysis of the 30-day Primary Composite Endpoint,102 Subjects were available for assessment. Seventy-nine Subjects (79/102; 77.5%) experienced uncomplicated technical success and freedom from procedural safety events. Based on Subject assessment availability for each race, 100% of Black or African American and Other Race Subjects, 76.7% of White Subjects, and 50% of American Indian or Alaska Native and Asian Subjects experienced uncomplicated technical success and freedom from procedural safety events.

For analysis of the 12-month Primary Composite Endpoint,85 of 102 Subjects were available for assessment. Sixty Subjects (60/85; 70.6%;) experienced freedom from clinically significant reintervention through 12 months. Based on Subject assessment availability for each race, 100% of Asian and Black or African American Subjects, 69.9% of White Subjects, and 66.7% of Other Race Subjects experienced freedom from clinically significant reintervention through 12 months.

4. 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 199 investigators of which 0 were full-time or part-time employees of the sponsor and 10 investigators 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: 0
- Significant payment of other sorts: 10
- Proprietary interest in the product tested held by the investigator: 0
- Significant equity interest held by investigator in sponsor of covered study: 0

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. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

A Continued Access Study, which allowed additional study enrollment once the pivotal study completed enrollment, was conducted and the pivotal study protocol followed. As of the date of data lock, March 8, 2023, a total of 20 Subjects were enrolled in the Continued Access Arm. Through limited follow-up, Continued Access Arm results are aligned with outcomes from the pivotal study. All Subjects survived the index procedure with implantation of all required index procedure devices. Median length of hospital stay was 5 days, 19/20 Subjects were discharged to home, and one Subject required long-term rehabilitation. No unique risks have been observed in the Continued Access Arm Study.

The TAMBE Early Feasibility Study (EFS) experience encompassed two separate clinical investigational protocols (Brazil and U.S.) that were intended to enroll a similar patient population. For the purposes of clinical evaluation, Gore considered combined outcomes between the U.S. and Brazil protocols to assess the TAMBE Device performance and to inform the TAMBE Pivotal Study. The EFS protocol incorporated two configurations of the Aortic Component (retrograde and antegrade), as well as two options for Branch Components (GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis and GORE® VIABAHN® Endoprosthesis). During the EFS, the Aortic

Component was transitioned from the retrograde configuration to the antegrade configuration. Choice of the Branch Component was at the discretion of the investigator, but no Subjects received the GORE® VIABAHN® Endoprosthesis as a Branch Component. There were 16 Subjects enrolled in the TAMBE EFS between the U.S. and Brazil protocols. Technical success was reported in 15 of the 16 Subjects. Four (4) Subjects experienced procedural blood loss ≥1000 mL. There were no reported deaths, stroke, severe bowel ischemia, paraplegia, respiratory failure, or severe renal failure within 30 days. This early clinical experience supported the pivotal study design and the overall conclusion that treating patients with a spectrum of aortic aneurysms involving the renal-mesenteric arteries with the TAMBE Device is feasible. During the TAMBE EFS, the antegrade configuration of the Aortic Component was chosen and the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis branch component were chosen to investigate in the pivotal study.

As of the date of data lock on March 8, 2023, six Subjects were implanted under the provision of Compassionate Use. There were no Emergency Use Subjects.

This supplementary clinical data further support the safety and effectiveness of the TAMBE Device.

XIII. 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 Circulatory 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.

XIV. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety and Effectiveness Conclusions

The following are key conclusions based on the totality of available data for assessing the safety and effectiveness of the TAMBE Device in the treatment of thoracoabdominal and pararenal aortic aneurysms in patients with appropriate anatomy:

The TAMBE Pivotal Study, a multicenter, prospective clinical investigation of a complete endovascular system for the treatment of thoracoabdominal and pararenal aortic aneurysms, in addition to non-clinical evaluations, served as the data sources that support the PMA approval.

The principal clinical benefit the TAMBE Device offers is a minimally invasive endovascular treatment option which resulted in fewer mortality and morbidity events than are expected with the alternative of open surgical repair (based upon literature reported values).

- Although the 30-day primary composite endpoint was not met when compared to the originally developed Performance Goal, the study results demonstrate favorable early safety outcomes and several meaningful benefits of the TAMBE Device for treatment of TAAA and high-surgical risk PAAA patients:
    - Technical success (per SVS reporting standard published in 2021) was 99%. The device achieved the desired exclusion of the aneurysm (with the implantation of additional device components).
        - Iatrogenic complications, including aortic dissection in two Subjects and visceral vessel dissection and/or perforation in eight Subjects, were reported during the index procedure. Endoleaks were observed and mitigated procedurally. No Type I or Type III endoleaks were reported as ongoing at the conclusion of the index procedure.

          Training and refinement of the Instructions for Use were implemented as mitigation strategies to reduce the risk of these events. Implantation of additional optional TAMBE Device components were effective at treating these events.
    - Major adverse events at 30 days were:
        - Mortality: 0%
        - Disabling stroke: 1%
        - Permanent paraplegia: 2%
        - Permanent paraparesis: 2.9%
        - Bowel ischemia: 1%
        - Renal failure requiring dialysis: 2%

      For reference, the published literature reports the following 30 day outcomes for open surgical repair: 2-5% mortality[2,3], 1-7% stroke[2,4], 1-2% permanent paraplegia[3,5], 1-2% permanent paraparesis[3,6], 1-3% bowel ischemia[4,6], 2-5% renal failure requiring dialysis[4,5,8].
    - Average hospital stay was 4 days and no pivotal study subjects required long term rehabilitation.

- Although the 12-month composite primary endpoint was not met, the results demonstrate favorable mid-term safety and effectiveness outcomes for treatment of TAAA and high-surgical risk PAAA patients. The reported outcomes included universal freedom from aneurysm-related mortality, as well as anticipated events for treatment of these lesions with a complex endovascular device system including endoleak, branch vessel complications, and associated reinterventions. The following key pivotal study outcomes were reported through 12-months:
    - Aneurysm-related mortality was 0%
        - One subject experienced device-related mortality on POD39 (mesenteric artery occlusion and ischemia) and one subject experienced procedure-related mortality on POD 60 (acute respiratory failure).
    - One subject (1.1%) experienced an intraprocedural aortic rupture, requiring surgical abdominal exploration and evacuation of a hematoma without TAMBE Device explant.

- 23.8% of subjects had aneurysm shrinkage, 70.2% of subjects had stable aneurysms, and 6% had aneurysm expansion.
- 29.4% of subjects had a clinically significant reintervention as defined by the 12-month composite primary endpoint.
- 15.9% of subjects had a non-patent side branch component/vessel as evaluated by the Core lab.
    - The vessel-level incidence of post-operative visceral branch occlusions reported was 5.4% (22 of 407 visceral arteries in 19 of 102 Subjects) through all follow up at the time of data lock. This rate is within the expected range of literature-reported results from similarly designed devices[9]. Through all follow up at the time of data lock, patency was restored in five of eight visceral vessels in whom minimally invasive reintervention was attempted while fourteen target vessels were untreated per the discretion of the treating physician.
    - Among Subjects with Branch Component occlusions through twelve months, one Subject with a SMA Branch Component occlusion experienced mesenteric ischemia and three Subjects with renal Branch Component occlusions required hemodialysis treatment within 12 months.
- 7.4% of subjects experienced compromised device seal zone/integrity requiring placement of an additional stent or stent graft.

- A subgroup analysis of each co-primary endpoint by Aneurysm Type did not demonstrate a statistical difference between PAAA and TAAA. However, a higher percentage of Pararenal aneurysm Subjects experienced target-lesion growth >5 mm and total occlusion of a device component compared to TAAA Subjects. For low surgical risk patients with PAAA, the benefit/risk of the TAMBE Device is less certain based on the present data. Based on this observation, the indications for use are limited to high-surgical risk PAAA patients.

- In summary, the totality of data from the TAMBE Pivotal Study indicate that the TAMBE Device is safe and effective for endovascular repair in patients with TAAA and high-surgical risk PAAA patients who have appropriate anatomy.

B. Benefit-Risk Determination

- The probable benefits of the device are based on data collected in a clinical study conducted to support PMA approval as described above. The anticipated benefit to a patient implanted with the TAMBE Device is a minimally invasive approach for treatment of their aneurysm with a high likelihood of technical success and an anticipated lower risk of operative mortality and other key safety outcomes as compared to open surgical repair.

- The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The anticipated risks to a patient are the adverse events described above. The probability of reintervention following TAMBE Device implantation is higher than the expected probability of reintervention following open surgical repair. Of note, reinterventions following TAMBE Device implantation were frequently performed in a minimally invasive manner.
- An additional factor to be considered in determining probable risks and benefits for the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis device includes the absence of longer-term clinical follow-up data (e.g., full 5-year follow-up from the pivotal study).

1. Patient Perspective

   This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device. However, the FDA considered the historical information with regard to aortic patient preference for endovascular rather than open surgical repair.

While risks have been identified with the use of the TAMBE Device, the overall benefit/risk balance is positive. Specifically, the TAMBE Device is a minimally invasive treatment option which can be successfully implanted to exclude TAAA and PAAA from blood flow with low risk of operative mortality and other key safety outcomes when compared with literature reports of open surgical repair. This treatment option may also provide a benefit for patients who would presently be denied surgical repair due to patient-specific factors that place the patient at prohibitive risk for open surgical repair but who may be deemed suitable for endovascular repair. The TAMBE Pivotal Study results confirm that frequently the risks associated with endovascular repair using the TAMBE Device can be successfully identified through perioperative monitoring and routine follow up and can often be successfully mitigated with additional minimally invasive procedures.

In conclusion, given the available information above, the data support that, for the endovascular treatment of patients with TAAA and high-surgical-risk patients with PAAA who have appropriate anatomy, the probable benefits of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis outweigh the probable risks.

C. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The pre-clinical testing performed in accordance with applicable guidance documents and national and international standards confirmed that the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis met its performance and design specifications. The totality of the data from the TAMBE Pivotal Study

indicates that the TAMBE Device is a safe and effective option for the endovascular treatment of TAAA and PAAA when used in accordance with the indications for use (patients with TAAA and high-surgical risk patients with PAAA who have appropriate anatomy).

XV. CDRH DECISION

Center for Devices and Radiological Health (CDRH) issued an approval order on January 12, 2024. The final conditions of approval cited in the approval order are described below.

1. 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 available subjects from the IDE Pivotal Study and the continued access subjects. The study design includes the assessment of the TAMBE Device in treating patients with thoracoabdominal and pararenal aortic aneurysms. A total of 102 subjects were enrolled in the primary arm and eligible for analysis in the pivotal study and 65 subjects have been approved for the continued access cohort. The remaining subjects will be followed annually for 5 years. Clinical endpoints include a composite of Uncomplicated Technical Success and Procedural Safety, as well as a composite of Clinically Significant Reintervention and Lesion-related Mortality. In addition, technical, treatment and clinical success as defined in the Society for Vascular Surgery "Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries" will be presented. These endpoints will be analyzed descriptively.

2. GORE TAMBE Post Approval Study: This is a prospective, non-randomized, multi-center study collecting data from consecutively treated patients. The objective of the study is to capture longer term outcome data on use of TAMBE in real-world use and to assess the adequacy of the TAMBE training program. This study will enroll a minimum of 300 all comer subjects treated with TAMBE with at least 100 subjects evaluable at 5 years post-implantation. Follow-up will occur at 30 days, 6 months, 1 year and yearly thereafter through 10 years or until lost to follow-up including subject death. This study will have a minimum of 10 new sites without prior TAMBE Device implant experience, and at least 70 subjects will be enrolled at these new sites. Core Lab imaging analysis will be conducted through 5 years follow-up. The data collection will include: patient and anatomical characteristics, procedural characteristics and outcomes. The co-primary endpoints will be technical success and clinical success. The following secondary outcomes will be also reported: procedure and lesion-related mortality, primary/assisted primary clinical success and secondary clinical success, and target vessel related outcomes. Outcomes will be reported using descriptive statistics and definitions will align with the reporting standards. A subset analysis of select outcomes will be conducted to assess whether the training program is adequate to support the safe use of TAMBE in the real-world. The results of this subgroup analysis, as well as learnings and any resulting modifications to the training program will be included in the post approval study reports.

3. Clinical Update: Gore has agreed to provide a Clinical Update to physician users at least annually. At a minimum, this update will include, for the IDE and Post-Approval studies, respectively, a summary of the number of patients for whom data are available, with the rates of mortality (device-and lesion-related), aortic rupture, stroke, paraplegia/paraparesis, renal events, mesenteric events, respiratory events, cardiac dysfunction, aortic enlargement, Type I/III endoleaks, loss of device integrity, loss of aortic/aortic branch patency, device migration, and additional surgical or interventional procedures related to the device or procedure. Reasons for secondary interventions and conversion to open surgery, as well as causes of lesion-related death and rupture are to be described. Additional relevant information from commercial experience within and outside the United States is to be included. A summary of any explant analysis findings is also to be included. The clinical update for physician users and the information supporting the updates must be provided in the Annual Report.

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

XVI. APPROVAL SPECIFICATIONS

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.

XVII. REFERENCES

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