

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Endovascular Graft

Device Trade Name: GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device)

Device Procode: SDZ

Applicant's Name and Address: W. L. Gore & Associates, Inc.

3450 W. Kiltie Lane

Flagstaff, AZ

86005, USA

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P210032/S015

Date of FDA Notice of Approval: April 11, 2025

Priority Review: Granted priority review status on July 17, 2015 because the device is intended to treat a potentially life threatening disease and because of reasonable expectation that the device represents a breakthrough technology with the potential to provide a clinically meaningful advantage over existing legally marketed technology, offers significant, clinically meaningful advantages over existing legally marketed alternatives and the availability of the device is in the best interest of patients.

The original PMA (P210032) was approved on May 13, 2022 and was indicated for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who are at high risk for debranching subclavian procedures and have appropriate anatomy. In P210032/S007, which was approved on May 2, 2023, the indication was expanded to no longer limit use to patients at high risk for debranching subclavian procedures. The SSED to support these indications is available on the CDRH website and is incorporated by reference here. The current supplement was submitted to expand the indication for the TBE device to include repair of lesions of the aortic arch.

II. INDICATIONS FOR USE

The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the aortic arch and descending thoracic aorta, while maintaining flow into a single aortic arch branch vessel, in patients who have:

- Adequate iliac/femoral access

- Proximal Aortic Landing Zones:
 - For Isolated Lesion Patients: Proximal landing zone cannot be aneurysmal, dissected, heavily calcified, or heavily thrombosed
 - For Dissection Patients: Primary entry tear must be distal to the target branch vessel and the proximal extent of the landing zone must not be dissected
 - Aortic inner diameter range 16-42 mm
 - Proximal segment length (length from distal edge of target branch vessel to the midpoint of any proximal branch vessel) of at least 2.0-4.0 cm, depending on Aortic Component selection
 - Proximal covered length (measured from distal edge of target branch vessel to the midpoint of any proximal branch vessel) of at least 15–36 mm, depending on Aortic Component selection
 - For patients with prior ascending aorta or aortic arch repair with a surgical graft: at least 2 cm landing zone proximal to the distal anastomosis
- Target Branch Vessel Landing Zone:
 - Landing zone cannot be aneurysmal, dissected, heavily thrombosed and severely tortuous (180 degree turn within the treated length)
 - Target branch vessel inner diameter of 6–18 mm, depending on Side Branch Portal diameter selected
 - Target branch vessel minimum length of 2.5–3.0 cm, depending on Side Branch Portal diameter selected
- Distal Landing Zone (Isolated Lesion Patients only)
 - Outer curve length must be ≥ 2 cm proximal to celiac artery
 - Aortic inner diameter range 16-42 mm
 - Cannot be aneurysmal, dissected, heavily calcified, or heavily thrombosed
 - Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft

III. CONTRAINDICATIONS

The GORE® TAG® Thoracic Branch Endoprosthesis is contraindicated in:

- Patients with known sensitivities or allergies to the device materials
- Patients who have a condition that threatens to infect the graft
- Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) Type II

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the GORE® TAG® Thoracic Branch Endoprosthesis labeling.

V. DEVICE DESCRIPTION

The GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device) provides

endovascular repair of pathologies of the aortic arch and descending thoracic aorta requiring a proximal landing zone including the brachiocephalic, left common carotid, or left subclavian artery. The GORE® TAG® Thoracic Branch Endoprosthesis is a modular device consisting of the Aortic Component, the Side Branch (SB) Component, and an optional Aortic Extender, as shown in **Figure 1**. These components may be used together as a stand-alone device or in conjunction with the GORE® TAG® Conformable Thoracic Endoprosthesis (P040043) in multiple device combinations to accommodate the intended treatment site.

Each component of the endoprosthesis consists of an ePTFE/FEP graft supported over its entire length by a nitinol wire frame (stent). Radiopaque gold bands are embedded in the graft material for device imaging. The stent is attached to the external surface of the graft by laminated ePTFE/FEP bonding tape. For delivery, all device components are constrained on the leading end of a delivery catheter compatible with 0.035" guidewires and are delivered through a single distal access site. All device components are intended to be delivered through an appropriately sized GORE® DrySeal Flex Sheath family of devices.



Figure 1: GORE® TAG® Thoracic Branch Endoprosthesis System and Key Features

A. Aortic Component (AC)

The Aortic Component (see **Figure 2**) incorporates an internal portal that opens to the outer device surface, allowing for seal and fixation of the SB Component. Embedded in both ends of the Aortic Component and the internal portal are radiopaque gold bands that provide radiographic visibility. The leading end of the endoprosthesis consists of partially uncovered stent apices, while the trailing end of the stent is in line with the graft material, with each end including a sealing cuff bonded over the stent. This component is mounted onto a catheter delivery system for delivery from a distal access site over a primary aortic guidewire. A Removable Guidewire Tube is provided to facilitate loading of the constrained device over a secondary branch guidewire that is pre-positioned from the distal access site to the target branch vessel. The constrained profile of these components on a delivery catheter ranges from 20 to 26 Fr. The Aortic Component is constrained by a

sewn deployment sleeve, which unlaces to allow device expansion by pulling the deployment knob on the hub of the catheter. Aortic Component deployment initiates from the portal opening and extends simultaneously to the proximal and distal ends. Following deployment, the deployment sleeve remains implanted with the endoprosthesis.

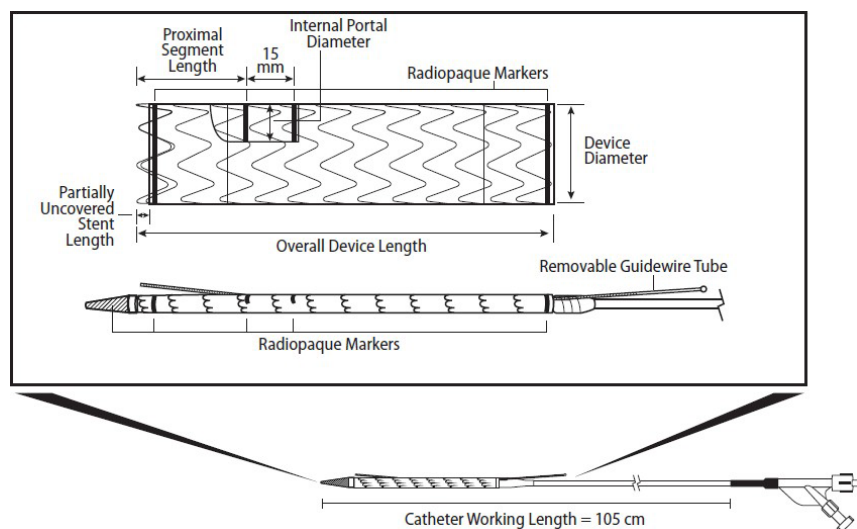


Figure 2: Aortic Component and Aortic Component Delivery

B. System Side Branch Component (SB)

The SB Component (see **Figure 3**) includes the CBAS[®] Heparin Surface which consists of stable, covalent, end-point attached heparin of porcine origin. A radiopaque gold band is embedded in the graft material at each end of the device. A third embedded radiopaque band is located 5 mm from the trailing end of the device. This inner radiopaque marker facilitates alignment of the SB Component with the Aortic Component internal portal and denotes the position of three flared stent apices. The flared stent apices protrude slightly from the underlying graft material. The SB Component is mounted onto a catheter delivery system and constrained by a sewn deployment sleeve. The device component expands from its constrained profile by pulling the deployment knob on the hub of the catheter, which unlaces the constraining sleeve from the trailing end toward the leading end. The SB Component should be selected such that the diameter of the trailing portion of the graft is the same as the portal diameter of the chosen Aortic Component. The diameter of the leading portion of the SB Component should be selected such that it is compatible with the branch vessel diameter.

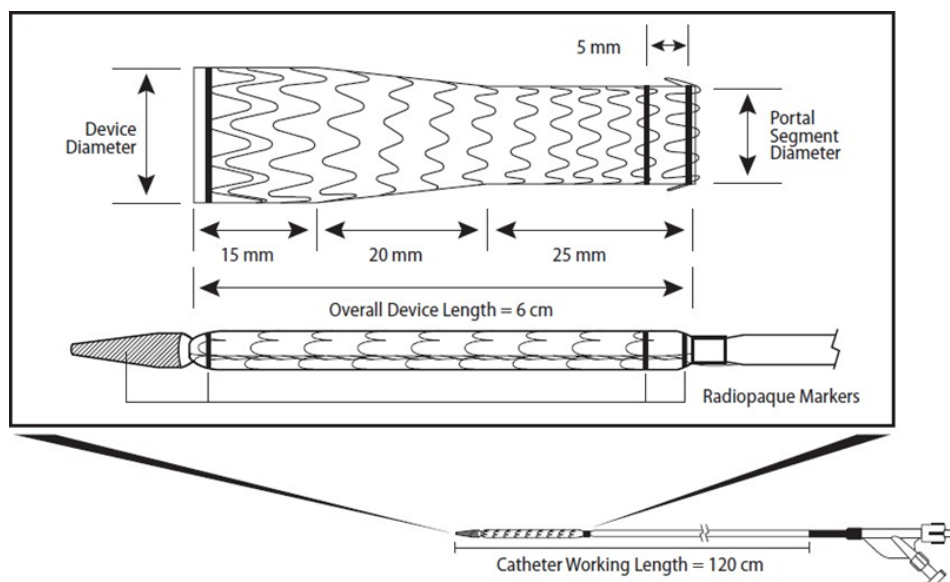


Figure 3: Side Branch (SB) Component and SB Component Delivery System

C. Aortic Extender (AE)

The Aortic Extender (see **Figure 4**) is a short, tubular device with radiopaque gold bands at each end for radiographic visibility. Both the leading and trailing ends consist of partially uncovered stent apices. This device is intended to be used to improve sealing of the Aortic Component and/or add seal length proximally within the aorta, if necessary. The compressed profile of these devices on the delivery catheter ranges from 20 to 26Fr. The device is mounted onto a catheter delivery system. A longitudinal radiopaque marker is embedded in the deployment sleeve to allow visualization during delivery catheter withdrawal.

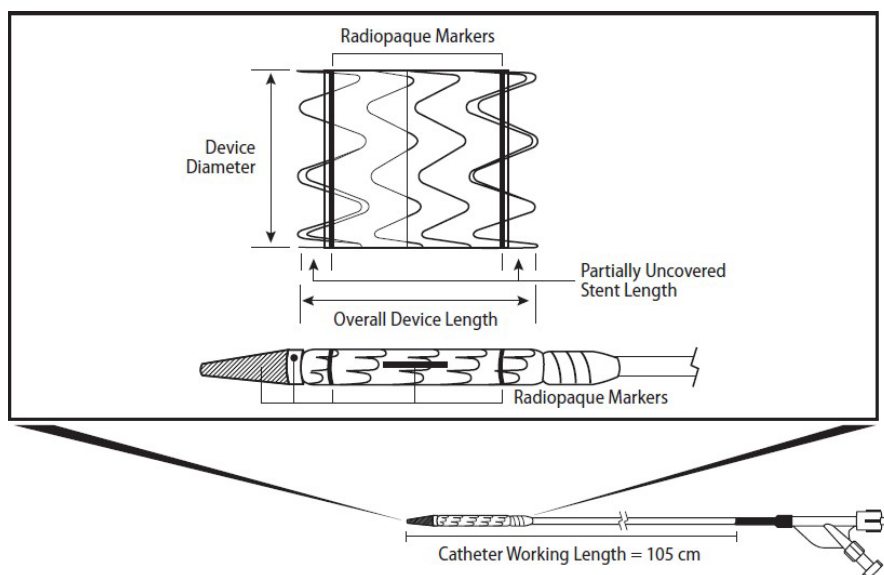


Figure 4: Aortic Extender (AE) Component and AE Component Delivery System

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of lesions of the aortic arch and descending thoracic aorta including:

- Medical management
- Open surgical repair
- Thoracic endovascular aortic repair (TEVAR) using other endovascular devices
- Hybrid surgery with TEVAR

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 TBE Device is currently approved/available for use in the United States, European Union, Australia, New Zealand, Canada, China, Japan, and Taiwan.

The TBE Device has not been withdrawn from marketing for any reason related to its safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device. For the specific adverse events that occurred in the clinical study, please see Section X.

- aortic valve injury,
- access, delivery and deployment events (e.g. access failure; deployment difficulties/failures; failure to deliver the stent graft; and insertion or removal difficulty),
- adynamic ileus,
- allergic reaction (to contrast, anti-platelet therapy, stent graft material),
- amputation,
- anesthetic complications,
- aortic expansion,
- aortic rupture,
- angina,
- atelectasis/pneumonia,
- bleeding (procedural and post-treatment),
- bowel complications (e.g., ileus, transient ischemia, infarction, necrosis),
- branch vessel occlusion or obstruction,
- cardiac complications (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension),
- catheter breakage, change in mental status,
- coagulopathy,
- contrast toxicity,
- death,
- dissection, perforation, or rupture of the aortic vessel and/or surrounding vasculature,
- edema (e.g., leg),
- embolism (micro and macro) with transient or permanent ischemia,
- endoleak,
- endoprosthesis: collapse, improper placement; incomplete deployment; migration; material failure; occlusion; infection; stent fracture; dilatation; perigraft flow,
- erectile dysfunction,
-
- erosion
- extension of dissection,
- femoral neuropathy,
- fever and localized inflammation,
- fistula (e.g., aortoenteric, arteriovenous, aortoesophageal, aortobronchial),
- genitourinary (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection),
- hematoma,
- heparin-induced thrombocytopenia (HIT),
- infection (e.g., aortic, device, or access sites),
- lymphocele/lymph fistula,
- myocardial infarction,
- neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis),
- nerve injury,
- peripheral malperfusion or ischemia,
- persistent false lumen flow,
- post-implant syndrome,
- prosthesis dilatation/rupture,
- prosthetic thrombosis,
- pseudoaneurysm,
- pulmonary complications (e.g., pneumonia, respiratory failure),
- pulmonary embolism,
- radiation injury,
- renal complications (e.g., artery occlusion, contrast toxicity, insufficiency, failure),
- reoperation,
- stenosis,
- surgical conversion,
- thrombosis,
- transient ischemic attack,
- vascular spasm,
- vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture),
- wound (e.g., infection, dehiscence)

For Zone 0/1 Patients Only

- aortic valve injury
- coronary artery occlusion or obstruction

IX. SUMMARY OF NON-CLINICAL STUDIES

Nonclinical studies were completed to evaluate the TBE Device, including non-clinical bench testing, biocompatibility, sterilization, packaging, shelf-life, and animal studies. Previously conducted bench testing incorporated evaluation of device in worst case conditions reflective of device use in the aortic arch as well as the descending thoracic aorta. The SSED containing the nonclinical studies to support the original PMA is available on the CDRH website and is incorporated by reference here. No changes have been made to the TBE Device for the expansion of the indication. These data remain applicable and support the revised indications for use.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device) for the endovascular repair of lesions of the aortic arch, while maintaining flow into a single aortic arch branch vessel (brachiocephalic or left common carotid) in the US and Japan under IDE # G130120. 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 December 28, 2016 and March 2, 2023. The database for this Panel Track Supplement reflected data collected through April 10, 2024 and included 77 patients. There were 31 investigational sites: 26 in the United States (U.S.) and five (5) in Japan.

The study was a prospective, multicenter, non-randomized clinical study with two (2) study arms specific to proximal placement of the device in Zones 0 and 1 with a total of three (3) cohorts. The arms are described as follows:

- Zone 0/1 – Aneurysm, hypothesis-driven analysis
- Zone 0/1 – Non-aneurysm aortic lesions which are anatomically suitable for treatment with the TBE Device, descriptive analysis
 - Dissection cohort
 - Other isolated lesion types

Each cohort was analyzed separately by lesion type.

The primary endpoint was Strategy Success for planned staged procedures (landing zone optimization, transposition, and device placement) through one month following last planned procedure. Strategy Success is defined as a composite of the following events from the time of enrollment through one month following the index endovascular procedure:

- Initiation of the index endovascular procedure following the debranching procedure

- Device technical success for the index endovascular procedure
- Absence of the following:
 - Aortic rupture
 - Lesion-related mortality
 - Disabling Stroke
 - Permanent paraplegia
 - Permanent paraparesis
 - New onset renal failure requiring permanent dialysis
 - Additional unanticipated post-procedural surgical or interventional procedure related to the device, procedure, or withdrawal of the delivery system.

Primary endpoint success (mixture of safety and effectiveness endpoints) was defined as the proportion of analysis-eligible subjects without a primary endpoint event that met any of the endpoint failure components (described above) and with imaging in the one-month window.

The results of the Aneurysm Cohort were tested against a performance goal of 60%, derived from outcomes from a systematic review of hybrid TEVAR repair literature. Using the performance goal of 60% with Primary Endpoint success through one month, the following hypothesis was tested:

$$H_0: P_{s01} \leq 0.60$$

$$H_A: P_{s01} > 0.60$$

Where P_{s01} is the proportion of subjects with primary endpoint success, as described above.

A 95% one-sided lower Exact confidence limit for binomial proportions was calculated. The null hypothesis was to be rejected if the lower bound exceeded the performance goal.

No hypotheses were planned for the Non-Aneurysm Cohorts.

Literature review,^[1-23] inclusive of the outcomes from both the surgical revascularization and TEVAR procedures required for hybrid Thoracic Endovascular Repair (TEVAR) procedures in Zone 0/1, was used to estimate primary endpoint success to be 78% in the Aneurysm cohort. Using the Exact Binomial Test and assuming a one-sided alpha of 0.05, a performance goal of 60%, and power of at least 80%, the sample size needed was 50 patients.

Evaluation groups used during the course of the pivotal study are described below:

- During the screening process, all patients who were assessed by an Investigator to meet all inclusion / exclusion criteria were submitted to Gore for review and case approval. A Screening Committee reviewed the pre-treatment CT imaging, head/neck imaging or imaging report and patient medical history (including atrial fibrillation and other comorbidities) and made recommendations to Gore regarding whether the patient should be excluded based on high risk of adverse neurological events (e.g. stroke). The Screening Committee was comprised of at least one physician with prior TBE experience that reviewed the patient information and imaging; Screening Committee members included an Interventional Radiologist, Vascular Surgeons, and

Cardiothoracic Surgeons. At the conclusion of the process, the Site was notified by Gore on the patient's eligibility (Accept / Reject).

- All subjects were required to have a consultation with a Surgeon or other physician with experience in ascending aortic and arch surgery (such as a Cardiothoracic Surgeon in the US and a Cardiovascular Surgeon in Japan) within 90 days of enrollment for a discussion of other treatment options, such as open surgical repair based on the subject's medical history and the subject's (high) risk for open surgical repair.
- An independent external Core Laboratory (Core Lab) was used to perform evaluations on all medical imagery submitted by clinical sites. The Core Lab reported all measurements and device assessments to Gore.
- An external Clinical Events Committee (CEC) adjudicated safety and certain effectiveness endpoint events for the study as well as reviewed inclusion / exclusion violations for potential impact on subject safety. Effectiveness endpoint events not adjudicated by the CEC were determined by the Core Lab.
- The Gore Office of Medical Affairs (OMA) provided adjudication of key adverse events where event onset was after day 546. The OMA is comprised of healthcare professionals whose responsibilities include providing healthcare provider perspective, medical expertise and judgment, and objectivity in review of patient and product safety matters, including human clinical data.
- An independent Data Safety Monitoring Board (DSMB) reviewed all available safety data on a regular basis and provided recommendations on the continuing safety, validity and scientific merit of the study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the clinical study was limited to patients who met the following inclusion criteria.

- Presence of thoracic aortic pathology deemed to warrant surgical repair which requires proximal graft placement in Zone 0/1
- Age ≥ 18 years at time of informed consent signature
- Subject is capable of complying with protocol requirements, including follow-up
- Informed Consent Form (ICF) is signed by subject or legal representative
- Must have appropriate proximal aortic landing zone
- Must have appropriate target branch vessel landing zone
- For patients with aneurysm/isolated lesion, must have appropriate distal aortic landing zone
- Subject does not have a mechanical aortic valve
- Subject is considered a high-risk candidate for conventional open surgical repair at the discretion of the investigator

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

- Concomitant disease of the ascending aorta or aneurysm of the abdominal aorta

requiring repair

- Previous endovascular repair of the ascending aorta
- Previous endovascular repair of the descending thoracic aorta (DTA) with a non-Gore device
- Surgery within 30 days prior to enrollment with the exception of surgery for Ascending Aortic Dissection and/or placement of vascular conduit for access
- Infected aorta
- Life expectancy <2 years
- Myocardial infarction within 6 weeks prior to treatment
- Stroke within 6 weeks prior to treatment, stroke defined as rapidly developing clinical signs of focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin.
- Patient has an active systemic infection (e.g., infection requiring treatment with parenteral anti-infective medication) that may place the patient at increased risk of endovascular infection. Patients with a chronic infection (such as HIV, Hepatitis C, etc.) that is well controlled under their current treatment regimen may be eligible.
- Pregnant female at time of informed consent signature
- Degenerative connective tissue disease, e.g., Marfan's or Ehler-Danlos Syndrome
- Participation in another drug or medical device study within one year of study enrollment
- Known history of drug abuse within one year of treatment
- Presence of protruding and/or irregular thrombus and/or atheroma in the aortic arch or ascending aorta
- Tortuous or stenotic iliac and/or femoral arteries preventing introducer sheath insertion and the inability to use a conduit for vascular access
- Planned coverage of celiac artery
- Patient has known sensitivities or allergies to the device materials
- Patient has known hypersensitivity or contraindication to anticoagulants or contrast media, which is not amenable to pre-treatment
- Previous instance of Heparin Induced Thrombocytopenia type 2 (HIT-2) or known hypersensitivity to heparin
- Patient with a history of a hypercoagulability disorder and/or hypercoagulability state
- Diameter taper outside of the device sizing range between proximal and distal landing zones of aorta and the inability to use additional devices of different diameters to compensate for the taper
- Mycotic aneurysm
- Persistent refractory shock (systolic blood pressure <90mmHg)

- Patient has body habitus or other medical condition which prevents adequate visualization of the aorta
- Renal failure defined as patients with an estimated Glomerular Filtration Rate (eGFR) <30 (ml/min/1.73 m²) or currently requiring dialysis
- Patient at high risk for a neurological event, e.g., stroke

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 1, 6, 12, 24, 36, 48 and 60 months. **Table 1** outlines the required screening evaluations and follow-up visit procedures for subjects. Adverse events and complications were recorded at all visits. The key timepoints are shown below in the tables summarizing safety and effectiveness.

Table 1. Schedule of Events

	Screening	Treatment			Discharge	1 month	6 months	12 months	24, 36, 48, and 60 months
		Phase 1 Procedure	Phase 1 Evaluation ^a	Phase 2 Procedure					
Physical Examination	X		X ^b		X	X	X	X	X
Serum Creatinine Concentration	X								
Spiral CTA (contrast)	X ^c					X	X	X	X
Spiral CT (non-contrast)						X			
CTA of the Head/Neck ^d	X								
Angiogram at Completion of Procedure				X					

^a Phase 1 Evaluation should be performed at least 24 hours after completion of the revascularization procedure but within 60 days post treatment ^b Subjects who are withdrawn prior to the Phase 2 Procedure should also have a Physical Exam at one month post Phase 1 procedure ^c Screening CTA must be ≤90 days prior to Phase 2 procedure. ^d Screening CTA of Head/Neck must be ≤90 days prior to Phase 1 procedure. If CT of Head/Neck is not consistent with Site's standard of care then radiological modality of evaluation is at investigator discretion (Ultrasound, MR, etc.) However, imaging of head/neck vasculature is required ≤90 days prior to Phase 1 procedure.

3. Clinical Endpoints

With regards to safety and effectiveness, the primary endpoint for all cohorts was Strategy Success for planned staged procedures (landing zone optimization, transposition, and device placement) through one month following last planned procedure (through day 59 unless otherwise specified in the component definitions below):

- Initiation of the index endovascular procedure following the debranching procedure
- Device Technical Success for the index endovascular procedure
 - Successful access and delivery to the intended implantation site, and retrieval of the device delivery system, and;

- Patency of the graft;
- The absence of unanticipated additional procedure related to the device, procedure, or withdrawal of the delivery system.
- Absence of the following:
 - Aortic rupture
 - Lesion-related mortality
 - Disabling stroke
 - *Stroke was assessed using the Modified Rankin Scale (mRS). Stroke identified as having occurred within 30 days of the index endovascular procedure, combined with $mRS \geq 2$ with an increase from baseline of at least one grade due to neurological deficits at no more than 120 days post index endovascular procedure.*
 - Permanent paraplegia
 - *Paraplegia secondary to Spinal Cord Ischemia (SCI) identified within 30 days of the index endovascular procedure combined with SCI scale grade = 3 at the one month follow-up visit.*
 - Permanent paraparesis
 - *Paraparesis secondary to SCI identified within 30 days of the index endovascular procedure, combined with SCI scale grade = 2 at the one month follow-up visit.*
 - New onset renal failure requiring permanent dialysis
 - *New onset sustained renal failure identified within 30 days of the index endovascular procedure, combined with need/requirement for dialysis at the one month follow-up visit.*
 - Additional unanticipated post-procedural surgical or interventional procedure related to the device, procedure, or withdrawal of the delivery system

With regard to overall study success, the primary endpoint performance goal of 60% for the Aneurysm cohort needed to be met in order to achieve study success. The primary endpoint analysis for the other cohorts (Dissection and Other Isolated Lesion) was analyzed for each cohort and was reported descriptively (no hypothesis tests).

In addition to the primary endpoint analysis, Procedural and Treatment Success data was collected and analyzed for each cohort and were reported descriptively and independent of the performance goal.

Procedural Success was defined as Device Technical Success, with absence of the following events occurring from the initiation of the index endovascular procedure through 1 month (through day 59 unless otherwise specified below or in the Primary Endpoint component definitions):

- Death (Through 30 days only)
- Aortic rupture (Through 30 days only)
- Disabling stroke

- Paraplegia (Through 30 days only)
- Paraparesis (Through 30 days only)
- New onset renal failure requiring permanent dialysis
- Additional unanticipated post-procedural surgical (including conversion to open surgery) or interventional (placement of additional unanticipated endovascular devices) procedure related to the device, procedure, or withdrawal of the delivery system
- New ischemia
- Distal device-related thromboembolic adverse event requiring intervention or surgery
- Extension of a dissection (proximally or distally) (Dissection cohort only)
- New dissection
- Life-threatening bleed
- Myocardial infarction
- Prolonged intubation
- Laryngeal or Phrenic Nerve injury
- Renal dysfunction or volume overload requiring ultrafiltration
- Severe Heart Failure/Hypotension

Treatment Success was defined as Device Technical Success, with absence of the following events occurring from the initiation of the index endovascular procedure and at all appropriate follow-up windows:

- Aortic enlargement in the region encompassed by the initial lesion
- Aortic rupture
- Extension of a dissection (proximally or distally) (Dissection cohort only)
- New dissection
- False lumen perfusion through the primary entry tear (Dissection cohort only)
- False lumen perfusion through an aortic arch branch vessel (Dissection cohort only)
- Type I or III endoleak
- Fistula formation
- Lesion-related mortality
- Loss of device integrity
- Loss of aortic or aortic branch patency
- Migration
- Disabling stroke within 30 days of the index endovascular procedure only
- Paraplegia within 30 days of the index endovascular procedure only
- Paraparesis within 30 days of the index endovascular procedure only
- New ischemia

- Additional unanticipated post-procedural surgical (including conversion to open surgery) or interventional (placement of additional unanticipated endovascular devices) procedure related to the device, procedure, or withdrawal of the delivery system

The following outcomes, which were not components of Procedural or Treatment Success, were pre-defined as additional outcomes within the study protocol and collected:

- Type II or IV endoleak
- Significant Blood Loss (≥ 1000 ml) during initial endovascular treatment intervention (excluding autologous blood transfusion or cell salvage)
- False Lumen Status in treated and untreated segments (Dissection cohort only)
- False Lumen perfusion through a non-aortic arch branch vessel (Dissection cohort only)

B. Accountability of PMA Cohort

At the time of database lock, 77 subjects were eligible and included for analysis. Two subjects were excluded from analysis due to being treated with device sizes (i.e., 49 mm and 53 mm) that were removed from the TBE Device size portfolio. **Table 2** and **Table 3** summarize compliance with the follow-up visit and imaging requirements directed by the investigational plan for enrolled Aneurysm and Dissection subjects.

Table 2: Subject Disposition and Compliance by Analysis Study Window for Aneurysm Cohort

		Subjects with Data for Visit					Adequate Imaging to Assess Parameter ²					Subject Status			
Visit	Eligible for Follow-Up	Subjects with Data for that Visit	Physical Exam	CT	MRA	Subjects with Follow-Up Pending ¹	Size Increase (Aortic Enlargement)	Endoleak	Device Migration	Wire Fracture	Device Patency	Death	Conversion	LTF ³	Not Due for Next Visit ⁴
Phase 1	50	50 (100.0%)	-	-	-	0 (0%)	-	-	-	-	-	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Endovascular Procedure	50	50 (100.0%)	-	-	-	0 (0%)	-	-	-	-	50 (100.0%)	1 (2.0%)	0 (0%)	0 (0%)	0 (0%)
Post-Procedure	49	47 (95.9%)	45 (91.8%)	5 (10.2%)	0 (0%)	0 (0%)	-	3 (6.1%)	5 (10.2%)	5 (10.2%)	4 (8.2%)	2 (4.1%)	0 (0%)	0 (0%)	0 (0%)
1 Month	47	45 (95.7%)	45 (95.7%)	43 (91.5%)	0 (0%)	0 (0%)	-	43 (91.5%)	43 (91.5%)	42 (89.4%)	43 (91.5%)	1 (2.1%)	0 (0%)	0 (0%)	0 (0%)
6 Months	46	41 (89.1%)	37 (80.4%)	39 (84.8%)	0 (0%)	0 (0%)	38 (82.6%)	36 (78.3%)	39 (84.8%)	38 (82.6%)	37 (80.4%)	2 (4.3%)	0 (0%)	1 (2.2%)	0 (0%)
12 Months	43	39 (90.7%)	39 (90.7%)	39 (90.7%)	0 (0%)	0 (0%)	36 (83.7%)	38 (88.4%)	38 (88.4%)	38 (88.4%)	38 (88.4%)	2 (4.7%)	1 (2.3%)	1 (2.3%)	5 (11.6%)
24 Months	34	24 (70.6%)	22 (64.7%)	23 (67.6%)	0 (0%)	6 (17.6%)	22 (64.7%)	20 (58.8%)	22 (64.7%)	21 (61.8%)	21 (61.8%)	1 (2.9%)	0 (0%)	0 (0%)	13 (38.2%)
36 Months	20	15 (75.0%)	13 (65.0%)	15 (75.0%)	0 (0%)	2 (10.0%)	13 (65.0%)	13 (65.0%)	14 (70.0%)	14 (70.0%)	13 (65.0%)	3 (15.0%)	0 (0%)	0 (0%)	2 (10.0%)
48 Months	15	10 (66.7%)	8 (53.3%)	9 (60.0%)	0 (0%)	1 (6.7%)	8 (53.3%)	9 (60.0%)	9 (60.0%)	9 (60.0%)	9 (60.0%)	1 (6.7%)	0 (0%)	3 (20.0%)	1 (6.7%)
60 Months	10	6 (60.0%)	6 (60.0%)	6 (60.0%)	0 (0%)	3 (30.0%)	5 (50.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)	1 (10.0%)	0 (0%)	0 (0%)	3 (30.0%)

¹Subjects still within follow-up window, but data not yet available.

²Not the number of Subjects with these reported events, but rather, the number with adequate imaging as assessed by Core Lab, such as paired size data to evaluate aneurysm growth. Wire fracture is if at least partially evaluable.

³In this table, lost to follow-up (LTF) includes all other reasons for study discontinuation including Subjects that have withdrawn from the study.

⁴Those Subjects that are “Not due for next visit” are those Subjects that are not within the follow-up window for the next interval.

Study period definitions: Phase 1 (revascularization procedure, prior to endovascular procedure) Endovascular Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

Table 3: Subject Disposition and Compliance by Analysis Study Window for Dissection Cohort

		Subjects with Data for Visit					Adequate Imaging to Assess Parameter ²					Subject Status			
Visit	Eligible for Follow-Up	Subjects with Data for that Visit	Physical Exam	CT	MRA	Subjects with Follow-Up Pending ¹	Size Increase (Aortic Enlargement)	Endoleak	Device Migration	Wire Fracture	Device Patency	Death	Conversion	LTF ³	Not Due for Next Visit ⁴
Phase 1	24	23 (95.8%)	-	-	-	0 (0%)	-	-	-	-	-	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Endovascular Procedure	24	24 (100.0%)	-	-	-	0 (0%)	-	-	-	-	24 (100.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Post-Procedure	24	24 (100.0%)	24 (100.0%)	2 (8.3%)	0 (0%)	0 (0%)	-	2 (8.3%)	2 (8.3%)	2 (8.3%)	2 (8.3%)	1 (4.2%)	0 (0%)	0 (0%)	0 (0%)
1 Month	23	21 (91.3%)	19 (82.6%)	21 (91.3%)	0 (0%)	0 (0%)	-	21 (91.3%)	21 (91.3%)	20 (87.0%)	21 (91.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 Months	23	22 (95.7%)	19 (82.6%)	22 (95.7%)	0 (0%)	0 (0%)	19 (82.6%)	20 (87.0%)	21 (91.3%)	21 (91.3%)	21 (91.3%)	1 (4.3%)	0 (0%)	0 (0%)	0 (0%)
12 Months	22	20 (90.9%)	18 (81.8%)	20 (90.9%)	0 (0%)	0 (0%)	17 (77.3%)	19 (86.4%)	19 (86.4%)	19 (86.4%)	19 (86.4%)	3 (13.6%)	0 (0%)	0 (0%)	3 (13.6%)
24 Months	16	9 (56.3%)	7 (43.8%)	8 (50.0%)	0 (0%)	5 (31.3%)	6 (37.5%)	7 (43.8%)	7 (43.8%)	7 (43.8%)	7 (43.8%)	1 (6.3%)	0 (0%)	0 (0%)	6 (37.5%)
36 Months	9	7 (77.8%)	6 (66.7%)	7 (77.8%)	0 (0%)	0 (0%)	6 (66.7%)	6 (66.7%)	7 (77.8%)	6 (66.7%)	6 (66.7%)	0 (0%)	0 (0%)	1 (11.1%)	0 (0%)
48 Months	8	7 (87.5%)	6 (75.0%)	6 (75.0%)	0 (0%)	0 (0%)	4 (50.0%)	6 (75.0%)	6 (75.0%)	6 (75.0%)	6 (75.0%)	1 (12.5%)	0 (0%)	2 (25.0%)	1 (12.5%)
60 Months	4	4 (100.0%)	4 (100.0%)	4 (100.0%)	0 (0%)	0 (0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

¹Subjects still within follow-up window, but data not yet available.

²Not the number of Subjects with these reported events, but rather, the number with adequate imaging as assessed by Core Lab, such as paired size data to evaluate aneurysm growth. Wire fracture is if at least partially evaluable.

³In this table, lost to follow-up (LTF) includes all other reasons for study discontinuation including Subjects that have withdrawn from the study.

⁴Those Subjects that are “Not due for next visit” are those Subjects that are not within the follow-up window for the next interval.

Study period definitions: Phase 1 (revascularization procedure, prior to endovascular procedure) Endovascular Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

Subject compliance with follow-up visits and imaging requirements for the Other Isolated Lesion Cohort is summarized below:

- All three (100%) eligible subjects had a 1-Month visit (100%) and imaging. Three subjects were eligible for a 6-Month follow-up visit, of which two (66.7%) subjects had their 6-Month visit and completed imaging. Three subjects were eligible for a 12-Month follow-up visit, and two (66.7%) subjects had their 12-Month visit and completed imaging. Two subjects were eligible for a 24-Month follow-up visit, of which one (50%) subject had their visit and imaging. One subject (100%) completed the 36-Month and 48-Month visits and imaging. There has been one death (at 48 months) and one non-death discontinuation (at 12 months) in this cohort.

C. Study Population Demographics and Baseline Parameters

1. Demographics

The demographics of the study population are typical for a thoracic endovascular graft study performed in the US, with the exception of the proportion of Asian subjects. This is due to subjects being enrolled in both the US and Japan.

A summary of subject demographics can be found in **Table 4**. The majority (66.2%) of subjects were male (64.0% for Aneurysm, 70.8% for Dissection, and 66.7% for Other Isolated Lesion). Most subjects (57.1%) also specified white as their race (54% for Aneurysm, 58.3% for Dissection, and 100% for Other Isolated Lesion). The median ages reported were 75 years for Aneurysm, 63 years for Dissection, and 73 years for Other Isolated Lesion.

Table 4: Baseline Demographics

	Aneurysm	Dissection	Other Isolated Lesion	All
Number of Enrolled Subjects	50	24	3	77
Sex				
Male	32 (64.0%)	17 (70.8%)	2 (66.7%)	51 (66.2%)
Female	18 (36.0%)	7 (29.2%)	1 (33.3%)	26 (33.8%)
Ethnicity				
Not Hispanic or Latino	47 (94.0%)	23 (95.8%)	3 (100.0%)	73 (94.8%)
Hispanic or Latino	3 (6.0%)	1 (4.2%)	0 (0%)	4 (5.2%)
Unknown	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Race¹				
White	27 (54.0%)	14 (58.3%)	3 (100.0%)	44 (57.1%)
Black or African American	6 (12.0%)	6 (25.0%)	0 (0%)	12 (15.6%)
Asian	16 (32.0%)	2 (8.3%)	0 (0%)	18 (23.4%)
American Indian or Alaska Native	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Hawaiian or Pacific Islander	1 (2.0%)	1 (4.2%)	0 (0%)	2 (2.6%)
Other	0 (0%)	2 (8.3%)	0 (0%)	2 (2.6%)
Age (yrs)				
n	50	24	3	77
Mean (Std Dev)	74.3 (8.56)	63.0 (11.31)	73.7 (9.02)	70.8 (10.75)

	Aneurysm	Dissection	Other Isolated Lesion	All
Median	75.0	63.0	73.0	72.0
Range	(50, 89)	(41, 86)	(65, 83)	(41, 89)
BMI²				
n	49	24	3	76
Mean (Std Dev)	27.3 (5.94)	29.9 (4.44)	23.4 (2.01)	27.9 (5.57)
Median	25.6	29.0	24.4	26.9
Range	(16.8, 44.4)	(21.7, 40.2)	(21.1, 24.8)	(16.8, 44.4)
¹ More than one option can be selected.				
² Site was queried and the weight for one Subject is unavailable.				

2. Subject Baseline Medical History

A summary of subject baseline medical history is provided in **Table 5** and summary of subject risk factors prior to enrollment is provided in **Table 6**.

Table 5: Baseline Medical History

	Aneurysm	Dissection	Other Isolated Lesion	All
Number of Enrolled Subjects¹	50	24	3	77
Stroke	6/50 (12.0%)	3/24 (12.5%)	1/3 (33.3%)	10/77 (13.0%)
Transient ischemic attack	2/50 (4.0%)	1/24 (4.2%)	0/3 (0%)	3/77 (3.9%)
Myocardial infarction	6/50 (12.0%)	2/24 (8.3%)	0/3 (0%)	8/77 (10.4%)
Coronary artery bypass graft	7/50 (14.0%)	3/24 (12.5%)	1/3 (33.3%)	11/77 (14.3%)
Percutaneous coronary intervention	12/50 (24.0%)	1/24 (4.2%)	0/3 (0%)	13/77 (16.9%)
Coronary artery disease	19/50 (38.0%)	3/24 (12.5%)	1/3 (33.3%)	23/77 (29.9%)
Great vessel stenosis	2/50 (4.0%)	0/24 (0%)	0/3 (0%)	2/77 (2.6%)
Subclavian steal	0/49 (0%)	1/24 (4.2%)	0/3 (0%)	1/76 (1.3%)
Congestive heart failure	6/50 (12.0%)	2/24 (8.3%)	1/3 (33.3%)	9/77 (11.7%)
Hypercholesterolemia	32/49 (65.3%)	15/24 (62.5%)	2/3 (66.7%)	49/76 (64.5%)
Hypertension	46/50 (92.0%)	24/24 (100.0%)	3/3 (100.0%)	73/77 (94.8%)
Atrial fibrillation	8/50 (16.0%)	7/24 (29.2%)	1/3 (33.3%)	16/77 (20.8%)
Chronic obstructive pulmonary disease	19/50 (38.0%)	4/24 (16.7%)	1/3 (33.3%)	24/77 (31.2%)
Nicotine use	32/50 (64.0%)	8/24 (33.3%)	1/3 (33.3%)	41/77 (53.2%)
Diabetes mellitus	5/50 (10.0%)	1/24 (4.2%)	0/3 (0%)	6/77 (7.8%)
Renal insufficiency	8/50 (16.0%)	5/24 (20.8%)	1/3 (33.3%)	14/77 (18.2%)
Renal dialysis	0/50 (0%)	0/24 (0%)	0/3 (0%)	0/77 (0%)
Valvular heart disease	7/50 (14.0%)	1/23 (4.3%)	1/3 (33.3%)	9/76 (11.8%)
Cardiac arrhythmia	10/50 (20.0%)	3/23 (13.0%)	1/3 (33.3%)	14/76 (18.4%)
Paraplegia	0/50 (0%)	0/24 (0%)	0/3 (0%)	0/77 (0%)
Thromboembolic event	0/49 (0%)	3/23 (13.0%)	1/3 (33.3%)	4/75 (5.3%)
Prior aortic surgery	19/50 (38.0%)	21/24 (87.5%)	1/3 (33.3%)	41/77 (53.2%)
Other vascular intervention	5/50 (10.0%)	1/24 (4.2%)	1/3 (33.3%)	7/77 (9.1%)
Peripheral vascular disease	6/49 (12.2%)	0/24 (0%)	1/3 (33.3%)	7/76 (9.2%)
Erectile dysfunction (males only)	2/18 (11.1%)	0/9 (0%)	0/1 (0%)	2/28 (7.1%)
Cancer	11/50 (22.0%)	0/24 (0%)	1/3 (33.3%)	12/77 (15.6%)

Table 6: Baseline Risk Factors

	Aneurysm	Dissection	Other Isolated Lesion	All
Number of Enrolled Subjects	50	24	3	77
Reason High Risk for Open Repair				
Prior sternotomy	5/50 (10.0%)	14/24 (58.3%)	1/3 (33.3%)	20/77 (26.0%)
Advanced age (>80 years)	13/50 (26.0%)	3/24 (12.5%)	0/3 (0%)	16/77 (20.8%)
Inadequate pulmonary function	12/50 (24.0%)	1/24 (4.2%)	1/3 (33.3%)	14/77 (18.2%)
Inadequate cardiac function	2/50 (4.0%)	2/24 (8.3%)	0/3 (0%)	4/77 (5.2%)
Other ¹	18/50 (36.0%)	4/24 (16.7%)	1/3 (33.3%)	23/77 (29.9%)
Aberrant Anatomy Risk Criteria (any below)²	14/50 (28.0%)	3/24 (12.5%)	0/3 (0%)	17/77 (22.1%)
Dominant left vertebral artery	5/46 (10.9%)	2/23 (8.7%)	0/1 (0%)	7/70 (10.0%)
Occluded/stenosed right vertebral artery	0/50 (0%)	0/23 (0%)	0/3 (0%)	0/76 (0%)
Aberrant right subclavian artery	0/50 (0%)	0/24 (0%)	0/3 (0%)	0/77 (0%)
Bilateral carotid artery disease	2/50 (4.0%)	2/23 (8.7%)	0/3 (0%)	4/76 (5.3%)
Presence of a left internal mammary artery graft	3/49 (6.1%)	0/24 (0%)	0/3 (0%)	3/76 (3.9%)
Incomplete circle of willis	6/41 (14.6%)	0/15 (0%)	0/3 (0%)	6/59 (10.2%)
Left vertebral artery ending in posterior inferior cerebellar artery	1/37 (2.7%)	0/11 (0%)	0/2 (0%)	1/50 (2.0%)
Clinical Frailty Scale Score (1-9, higher is more frail)				
n	50	24	3	77
Mean (Std Dev)	3.3 (1.10)	2.9 (0.95)	3.7 (1.53)	3.2 (1.08)
Median	3.0	3.0	4.0	3.0
Range	(1, 6)	(1, 5)	(2, 5)	(1, 6)
SVS Score (0-24, higher is worse)				
n	50	24	3	77
Mean (Std Dev)	5.4 (3.30)	4.9 (2.59)	5.7 (2.52)	5.3 (3.05)
Median	5.0	6.0	6.0	6.0
Range	(0.0, 15.0)	(1.0, 11.0)	(3.0, 8.0)	(0.0, 15.0)
ASA Classification				
I - Healthy patient	7/50 (14.0%)	2/24 (8.3%)	0/3 (0%)	9/77 (11.7%)
II - Mild systemic disease - no functional limitation	11/50 (22.0%)	8/24 (33.3%)	0/3 (0%)	19/77 (24.7%)
III - Severe systemic disease - definite functional limitation	19/50 (38.0%)	10/24 (41.7%)	3/3 (100.0%)	32/77 (41.6%)
IV - Severe systemic disease that is a constant threat to life	13/50 (26.0%)	4/24 (16.7%)	0/3 (0%)	17/77 (22.1%)
V - Moribund patient unlikely to survive 24 hours with or without operation	0/50 (0%)	0/24 (0%)	0/3 (0%)	0/77 (0%)
NYHA Classification				
No cardiac disease	20/50 (40.0%)	13/24 (54.2%)	2/3 (66.7%)	35/77 (45.5%)
I - Cardiac disease, physical activity not limited	19/50 (38.0%)	8/24 (33.3%)	0/3 (0%)	27/77 (35.1%)
II - Cardiac disease, physical activity slightly limited	10/50 (20.0%)	3/24 (12.5%)	0/3 (0%)	13/77 (16.9%)
III - Cardiac disease, physical activity markedly limited	1/50 (2.0%)	0/24 (0%)	1/3 (33.3%)	2/77 (2.6%)
IV - Cardiac disease, physical activity very limited	0/50 (0%)	0/24 (0%)	0/3 (0%)	0/77 (0%)

	Aneurysm	Dissection	Other Isolated Lesion	All
¹ Other reasons for high risk for open repair included subjects with more than one reason, body habitus/anatomic reasons, other prior repairs, refuse open operation or general frailty				
² Restricted to those with information known.				

3. Subject Presenting Characteristics

A summary of the subjects, by cohort, further presented with differing characteristics by their pathology are presented in **Table 7** through **Table 9** (Site reported).

Table 7: Type of Aneurysm Treated for Aneurysm Cohort

	Aneurysm
Number of Enrolled Subjects	50
Fusiform (>55mm) aneurysm	26/50 (52.0%)
Fusiform (>2 times native aortic diameter) aneurysm	2/50 (4.0%)
Saccular aneurysm	22/50 (44.0%)

Table 8: Presenting Dissection Characteristics for Dissection Cohort

	Dissection
Number of Enrolled Subjects	24
Dissection Type	
Acute (≤ 14 days ¹) Complicated ² Type B	0 (0%)
Chronic (> 14 days ¹) Complicated ² Type B	0 (0%)
Residual ³ Complicated ² Dissection	2 (8.3%)
Acute (≤ 14 days ¹) Uncomplicated ² Type B	0 (0%)
Chronic (> 14 days ¹) Uncomplicated ² Type B	8 (33.3%)
Residual ³ Uncomplicated ² Dissection	14 (58.3%)
Complication of Aortic Dissection	2 (8.3%)
Visceral ischemia	0 (0%)
Renal ischemia	0 (0%)
Lower limb ischemia	1 (4.2%)
Spinal cord ischemia	0 (0%)
Other ischemia	1 (4.2%)
Rupture	0 (0%)
Other issues of Aortic Dissection	21 (87.5%)
Rapid enlargement	4 (16.7%)
Caused aneurysm	13 (54.2%)
Pain	4 (16.7%)
Hypertension	4 (16.7%)
Days from Onset to Treatment - Chronic Type B Dissection⁴	
n	4
Mean (Std Dev)	247.0 (249.5)
Median	153.5
Range	(75, 606)
Days Since Previous Repair - Residual Dissection	
n	16
Mean (Std Dev)	1082.2 (1327.0)
Median	479.0
Range	(34, 4024)

	Dissection
TBE Device Procedure Part of Planned Staged Procedure for Residual Dissection Subjects (following ascending procedure)	5/16 (31.3%)
Proximal Extent of Dissection (Pre-Imaging, Corelab)	
Zone 0	15 (62.5%)
Zone 1	3 (12.5%)
Zone 2	5 (20.8%)
Zone 3	0 (0%)
Zone 4	0 (0%)
Zone 5	0 (0%)
Unknown	1 (4.2%)
Distal Extent of Dissection (Pre-Imaging, Corelab)	
Aortic Arch (Zone 0,1,2)	0 (0%)
Descending Thoracic (Zone 3,4,5)	4 (16.7%)
Celiac (Zone 6)	0 (0%)
SMA (Zone 7)	0 (0%)
Renal(s) (Zone 8)	0 (0%)
Abdominal (Zone 9)	4 (16.7%)
Iliac(s) (Zone 10,11)	15 (62.5%)
Unknown	1 (4.2%)
¹ Acute Type B Dissection is defined as a newly presenting dissection being ≤14 days between reported dissection onset and treatment date (endovascular procedure for Zone 2, revascularization procedure for Zone 0/1). Chronic Type B Dissection is defined as being a newly presenting dissection >14 days. ² Complicated Dissection is defined as having ischemia or rupture. Uncomplicated dissection are all others. ³ Residual Dissection is defined as dissection that remains after previous surgical repair of the ascending aorta and/or aortic arch. ⁴ The count of Subjects with this information can be less than those defined as acute or chronic since there is an additional question which asks whether this date is unknown but the dissection is chronic.	

Table 9: Type of Other Isolated Lesions for Zone 0/1 Other Isolated Lesion Cohort

	Zone 0/1 Other Isolated Lesion
Number of Enrolled Subjects	3
Aortic Intramural Hematoma	0/3 (0%)
Penetrating Aortic Ulcer	1/3 (33.3%)
Aortic Other Isolated Lesion	2/3 (66.7%)

4. Device Usage

Table 10 describes the initial treatment devices implanted in subjects enrolled in the study. All subjects had both the Aortic Component (AC) and Side Branch (SB) devices implanted.

Table 11 shows a summary of TBE Aortic Component sizes implanted during the index endovascular procedure (Phase 2).

Table 10: Initial Treatment Devices Implanted

	Aneurysm	Dissection	Other Isolated Lesion	All
Number of Enrolled Subjects	50	24	3	77
Number of Subjects with Both TBE Devices Implanted ¹	50 (100.0%)	24 (100.0%)	3 (100.0%)	77 (100.0%)
Subjects with Aortic Extender Implanted	4 (8.0%)	2 (8.3%)	0 (0%)	6 (7.8%)

	Aneurysm	Dissection	Other Isolated Lesion	All
Subjects with Conformable TAG Device as Distal Extension Implanted	35 (70.0%)	17 (70.8%)	1 (33.3%)	53 (68.8%)
Subjects with >1 Aortic Component Implanted	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Subjects with Other ² Device Implanted	3 (6.0%)	0 (0%)	0 (0%)	3 (3.9%)
Number of SB Components Implanted Per Subject				
1 SB Component Implanted	33 (66.0%)	19 (79.2%)	3 (100.0%)	55 (71.4%)
2 SB Components Implanted	14 (28.0%)	4 (16.7%)	0 (0%)	18 (23.4%)
3+ SB Components Implanted ³	3 (6.0%)	1 (4.2%)	0 (0%)	4 (5.2%)
Number of Aortic Extenders Implanted Per Subject				
0 Aortic Extenders Implanted	46 (92.0%)	22 (91.7%)	3 (100.0%)	71 (92.2%)
1 Aortic Extender Implanted	3 (6.0%)	1 (4.2%)	0 (0%)	4 (5.2%)
2 Aortic Extenders Implanted	0 (0%)	1 (4.2%)	0 (0%)	1 (1.3%)
3+ Aortic Extenders Implanted ⁴	1 (2.0%)	0 (0%)	0 (0%)	1 (1.3%)
Number of Conformable TAG Devices Implanted Per Subject				
0 Conformable TAG Devices Implanted	15 (30.0%)	7 (29.2%)	2 (66.7%)	24 (31.2%)
1 Conformable TAG Device Implanted	20 (40.0%)	12 (50.0%)	1 (33.3%)	33 (42.9%)
2 Conformable TAG Device Implanted	12 (24.0%)	5 (20.8%)	0 (0%)	17 (22.1%)
3+ Conformable TAG Devices Implanted	3 (6.0%)	0 (0%)	0 (0%)	3 (3.9%)

¹This includes both the aortic component and side branch component devices.

² These include one Viabahn, one Viabahn VBX, and one Excluder Contralateral Limb

³ For one subject, physician encountered difficulty rotationally aligning the AC portal to the target branch vessel. Three SB Components and a GORE® VIABAHN® Endoprosthesis were used to further extend into the innominate artery. One subject had two TBE SB Components accurately positioned and deployed. At one month an SB component and Viabahn were placed to address a Type III endoleak discussed further in the Endoleak section. Two subjects had three SB Components as part of index procedure due to unknown reasons or contributing factors.

⁴ Discussion of this subject has been included in Table 19 and Aneurysm: Technical Success

Table 11: Initial Treatment TBE Aortic Component Sizing for Zone 0/1 All Cohorts

Device Diameter (mm)	Internal Portal ¹ Diameter (mm)	Overall Device Length (cm)	Subjects (N=77)	Devices (N=77)
21	8	10	0	0
21	8	15	0	0
21	8	20	0	0
26	8	10	0	0
26	8	15	0	0
26	8	20	0	0
28	8	10	0	0
28	8	15	0	0
28	8	20	0	0
31	8	10	0	0
31	8	15	2 (2.6%)	2 (2.6%)
31	8	20	0	0
31	12	10	0	0
31	12	15	4 (5.2%)	4 (5.2%)

Device Diameter (mm)	Internal Portal ¹ Diameter (mm)	Overall Device Length (cm)	Subjects (N=77)	Devices (N=77)
31	12	20	0	0
34	8	10	0	0
34	8	15	4 (5.2%)	4 (5.2%)
34	8	20	0	0
34	12	10	0	0
34	12	15	4 (5.2%)	4 (5.2%)
34	12	20	1 (1.3%)	1 (1.3%)
37	8	10	0	0
37	8	15	0	0
37	8	20	0	0
37	12	10	0	0
37	12	15	11 (14.3%)	11 (14.3%)
37	12	20	6 (7.8%)	6 (7.8%)
40	8	10	0	0
40	8	15	0	0
40	8	20	0	0
40	12	10	0	0
40	12	15	12 (15.6%)	12 (15.6%)
40	12	20	5 (6.5%)	5 (6.5%)
45	8	10	0	0
45	8	15	1 (1.3%)	1 (1.3%)
45	8	20	0	0
45	12	10	0	0
45	12	15	14 (18.2%)	14 (18.2%)
45	12	20	13 (16.9%)	13 (16.9%)
¹ For Patients in whom the target branch vessel is the brachiocephalic artery, an Aortic Component with a 12mm internal portal is required.				

Table 12: Initial Treatment TBE Side Branch Sizing¹

Device Diameter (mm)	SB Portal ¹ Diameter (mm)	Device Length (cm)	Subjects (N=77)	Devices (N=103)
8	8	6	3 (3.9%)	4 (3.9%)
10	8	6	3 (3.9%)	3 (2.9%)
12	8	6	1 (1.3%)	1 (1.0%)
15	8	6	0	0
15	12	6	23 (29.9%)	32 (31.1%)
17	8	6	0	0
17	12	6	28 (36.4%)	38 (36.9%)
20	12	6	21 (27.3%)	25 (24.3%)
¹ For patients in whom the target branch vessel is the brachiocephalic artery, a Side Branch Component with a 12mm portal segment diameter is required.				

Table 13: Initial Treatment TBE Aortic Extender Sizing¹

Device Diameter (mm)	Device Length (cm)	Subjects (N=6)	Devices (N=9)
21	3.6	0	0
26	3.8	0	0
28	4.0	0	0
31	4.0	0	0
34	4.2	0	0
37	4.2	2 (33.3%)	2 (22.2%)
40	4.3	0	0
45	4.6	5 (83.3%)	7 (77.8%)

5. Procedure Characteristics

Subject treatment occurred in two phases. During the first phase (Phase 1, Revascularization), the great vessels distal to the target branch vessel were revascularized through bypass and/ or transposition. Subjects were considered enrolled at the initiation of the Phase 1 procedure. Following at least 24 hours of observation, and no greater than 60 days after the Phase 1 procedure, the subjects underwent the second phase of the procedure, the index endovascular procedure with the TBE Device (Phase 2). A subject was considered to have entered the second phase of treatment once a device delivery catheter has been introduced into the subject's vasculature.

Revascularization Procedure Results (Phase 1)

Table 14 provides a summary of revascularization procedure information for all enrolled subjects. All subjects survived the Phase 1 procedure and entered Phase 2.

Table 14: Revascularization (Phase 1) Procedure Data

	Aneurysm	Dissection	Other Isolated Lesion	All
Number of Enrolled Subjects	50	24	3	77
Revascularization Type¹				
Bypass	47 (94.0%)	23 (95.8%)	3 (100.0%)	73 (94.8%)
Transposition	20 (40.0%)	11 (45.8%)	0 (0%)	31 (40.3%)
Procedure Time (minutes)				
n	50	24	3	77
Mean (Std Dev)	208.3 (83.14)	193.7 (83.28)	152.7 (20.50)	201.6 (81.92)
Median	193.5	173.0	164.0	181.0
Range	(42, 499)	(65, 408)	(129, 165)	(42, 499)
Anesthesia Method				
General	50 (100.0%)	24 (100.0%)	3 (100.0%)	77 (100.0%)
Revascularization Successful²	49 (98.0%)	24 (100.0%)	3 (100.0%)	76 (98.7%)
Estimated Blood Loss During Procedure (mL)				
n	50	24	3	77
Mean (Std Dev)	302.3 (400.06)	172.0 (192.69)	66.7 (41.63)	252.5 (345.70)
Median	190.0	100.0	80.0	130.0
Range	(0, 2400) ³	(20, 900)	(20, 100)	(0, 2400)

	Aneurysm	Dissection	Other Isolated Lesion	All
Transfusion Required	6 (12.0%)	2 (8.3%)	0 (0%)	8 (10.4%)
Anticoagulant Administered	49 (98.0%)	24 (100.0%)	3 (100.0%)	76 (98.7%)
Additional Procedures Performed⁴	12 (24.0%)	1 (4.2%)	0 (0%)	13 (16.9%)
Subject Survived Procedure	50 (100.0%)	24 (100.0%)	3 (100.0%)	77 (100.0%)
Discharged Before Phase 2 Endovascular Procedure	21 (42.0%)	8 (33.3%)	2 (66.7%)	31 (40.3%)
Length of Stay (days) if discharged				
n	21	8	2	31
Mean (Std Dev)	4.2 (4.77)	2.6 (1.19)	8.0 (9.90)	4.0 (4.51)
Median	3.0	3.0	8.0	3.0
Range	(1, 22)	(1, 4)	(1, 15)	(1, 22)
Length of Stay for Revascularization (days)				
n	50	24	3	77
Mean (Std Dev)	4.3 (3.95)	5.1 (8.78)	6.7 (7.37)	4.7 (5.93)
Median	3.0	3.0	4.0	3.0
Range	(1, 22)	(1, 44)	(1, 15)	(1, 44)
¹ More than one option can be selected.				
² One Subject required a re-do revascularization procedure prior to Phase 2 because of a 'carotid-subclavian bypass graft stenosis'				
³ One subject had a subclavian vein injury during the revascularization procedure that led to high blood loss.				
⁴ Additional procedures included embolizations or vessel ligations				

Endovascular Procedure Results (Phase 2)

Table 15 summarizes the endovascular procedure information by cohort. The majority (70.1 %) of all subjects' proximal landing zone was within native aortic tissue and 29.9% landed in a surgical graft. All subjects received general anesthesia. The median procedure time was 147 minutes.

Table 15: Endovascular Procedure Information– Part 1

	Aneurysm	Dissection	Other Isolated Lesion	All
Number of Enrolled Subjects	50	24	3	77
Time Since Phase 1 Revascularization Procedure (days)				
n	50	24	3	77
Mean (Std Dev)	15.5 (19.31)	11.3 (25.24)	22.2 (23.92)	14.5 (21.32)
Median	5.8	3.5	14.8	4.2
Range	(1, 74)	(1, 126)	(3, 49)	(1, 126)
Aortic Arch Zone Treated				
Zone 0	45 (90.0%)	22 (91.7%)	3 (100.0%)	70 (90.9%)
Zone 1	5 (10.0%)	2 (8.3%)	0 (0%)	7 (9.1%)
Proximal Landing Zone				
Within Surgical Graft	7 (14.0%)	15 (62.5%)	1 (33.3%)	23 (29.9%)
Within Native Aorta	43 (86.0%)	9 (37.5%)	2 (66.7%)	54 (70.1%)
Procedure Time (minutes)¹				

	Aneurysm	Dissection	Other Isolated Lesion	All
n	50	24	3	77
Mean (Std Dev)	168.6 (71.51)	168.7 (78.83)	118.0 (29.87)	166.7 (72.79)
Median	148.0	148.5	106.0	147.0
Range	(79, 401)	(81, 423)	(96, 152)	(79, 423)
Anesthesia Method				
General	50 (100.0%)	24 (100.0%)	3 (100.0%)	77 (100.0%)
Access Method				
Percutaneous	25 (50.0%)	15 (62.5%)	1 (33.3%)	41 (53.2%)
Cut-down	22 (44.0%)	9 (37.5%)	1 (33.3%)	32 (41.6%)
Cut-down and conduit	3 (6.0%)	0 (0%)	1 (33.3%)	4 (5.2%)
Access Vessel				
Left femoral	9 (18.0%)	7 (29.2%)	1 (33.3%)	17 (22.1%)
Right femoral	33 (66.0%)	17 (70.8%)	1 (33.3%)	51 (66.2%)
Left iliac	2 (4.0%)	0 (0%)	1 (33.3%)	3 (3.9%)
Right iliac	5 (10.0%)	0 (0%)	0 (0%)	5 (6.5%)
Aortic	1 (2.0%)	0 (0%)	0 (0%)	1 (1.3%)
Unknown	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Additional Access Sites				
Left brachial	0 (0%)	2 (8.3%)	0 (0%)	2 (2.6%)
Right brachial	33 (66.0%)	13 (54.2%)	3 (100.0%)	49 (63.6%)
Left axial	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Right axial	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other ²	15 (30.0%)	8 (33.3%)	0 (0%)	23 (29.9%)
None reported	2 (4.0%)	1 (4.2%)	0 (0%)	3 (3.9%)

¹Procedure Time (min) was captured as the time the first incision was made through the time the access site was closed.
²Other access sites may include a combination of multiple access sites including radial access and/or a combination of multiple access sites

Table 16 highlights estimated blood loss, heparin usage, and endovascular procedures for the subjects. Eight (10.4 %) Subjects had site-reported blood loss $\geq 1000\text{mL}$ during the TBE Device procedure (an Other Outcome). In total, 17 (22.1 %) subjects required a transfusion with a median replaced blood volume of 600mL. Heparin was administered to all subjects with median dose administered of 12,000 units per mL. Twenty-one subjects had additional procedures to prevent Type II endoleaks. Twenty-nine (37.7%) subjects had adjunctive technique used to prevent paraplegia, with cerebral spinal fluid (CSF) drainage being the most common procedure.

Table 16: Endovascular Procedure Information - Part 2

	Aneurysm	Dissection	Other Isolated Lesion	All
Number of Enrolled Subjects	50	24	3	77
Contrast Used During Procedure (mL)				
n	50	24	3	77
Mean (Std Dev)	125.3 (65.53)	108.3 (39.15)	80.0 (59.03)	118.3 (58.71)
Median	107.5	100.0	50.0	100.0
Range	(24, 265)	(50, 200)	(42, 148)	(24, 265)
Estimated Blood Loss During Procedure (mL)				
n	49	24	3	76

	Aneurysm	Dissection	Other Isolated Lesion	All
Mean (Std Dev)	338.8 (525.06)	278.1 (506.32)	173.3 (219.39)	313.1 (507.88)
Median	150.0	100.0	100.0	120.0
Range	(0, 2440)	(10, 2500)	(0, 420)	(0, 2500)
Blood Loss $\geq$ 1000mL¹	7 (14.0%)	1 (4.2%)	0 (0%)	8 (10.4%)
Transfusion Required, blood volume replaced (mL)				
n	12	4	1	17
Mean (Std Dev)	847.5 (640.71)	1260.0 (1532.67)	300.0 (-)	912.4 (882.88)
Median	600.0	650.0	300.0	600.0
Range	(200, 2080)	(240, 3500)	(300, 300)	(200, 3500)
Heparin Administered, dose (units per mL)				
n	50	24	3	77
Mean (Std Dev)	12100.0 (6488.61)	11925.0 (5103.64)	11666.7 (5507.57)	12028.6 (5986.45)
Median	11500.0	12000.0	9000.0	12000.0
Range	(1000, 30000)	(100, 20000)	(8000, 18000)	(100, 30000)
Procedure Used to Prevent Type II Endoleaks²	13 (56.5%)	6 (66.7%)	2 (100.0%)	21 (61.8%)
Adjunctive Technique Used to Prevent Paraplegia				
None	34 (68.0%)	11 (45.8%)	3 (100.0%)	48 (62.3%)
Yes, CSF drainage	10 (20.0%)	7 (29.2%)	0 (0%)	17 (22.1%)
Yes, induced hypertension	3 (6.0%)	4 (16.7%)	0 (0%)	7 (9.1%)
Yes, CSF drainage and induced hypertension	1 (2.0%)	1 (4.2%)	0 (0%)	2 (2.6%)
Yes, other	2 (4.0%)	1 (4.2%)	0 (0%)	3 (3.9%)

¹Estimated blood loss $\geq$ 1000mL were primarily due to complicated femoral access and/or surgical interventions associated with the aortic branch vessel revascularization. A discussion of Life Threatening Bleeds is included in the Key Events section.

²Among those who responded yes or no to "If vessels distal to the target vessel were not ligated in Phase 1, was an endovascular procedure performed to prevent type II endoleaks?". These procedures included coils and/or plugs.

Table 17 outlines the length of hospital stay, with the median time being four days. Most subjects (81.8 %) were discharged home, 11.7 % were sent to a rehab facility/nursing home, and 3.9% died in hospital (all three of these subjects were in the Aneurysm cohort). The median time to return to normal activities was 27 days (21 days for Aneurysm Subjects, 28 days for Dissection Subjects, and 26 days for Other Isolated Lesion Subjects).

Table 17: Endovascular Procedure Information - Part 3

	Aneurysm	Dissection	Other Isolated Lesion	All
Number of Enrolled Subjects	50	24	3	77
Endovascular Length of Stay (days)				
n	50	24	3	77
Mean (Std Dev)	6.1 (4.84)	6.2 (6.31)	3.7 (1.53)	6.0 (5.24)
Median	5.0	4.0	4.0	4.0
Range	(0, 31)	(1, 29)	(2, 5)	(0, 31)
Discharge Location				
Home	38 (76.0%)	22 (91.7%)	3 (100.0%)	63 (81.8%)

	Aneurysm	Dissection	Other Isolated Lesion	All
Rehabilitation center/nursing facility	8 (16.0%)	1 (4.2%)	0 (0%)	9 (11.7%)
Acute care facility	1 (2.0%)	1 (4.2%)	0 (0%)	2 (2.6%)
N/A - Subject died in hospital	3 (6.0%)	0 (0%)	0 (0%)	3 (3.9%)
Return to Normal Activities (days)¹				
n	40	19	3	62
Mean (Std Dev)	39.7 (51.40)	31.2 (29.19)	22.0 (17.35)	36.2 (44.45)
Median	21.0	28.0	26.0	27.0
Range	(1, 229)	(2, 108)	(3, 37)	(1, 229)

¹Earliest reported time was used to calculate return to normal.

D. Safety and Effectiveness Results

The primary safety and effectiveness endpoint was Strategy Success for planned staged procedures (landing zone optimization, transposition, and device placement) through one month following last planned procedure. Strategy Success is defined as a composite of the following events from the time of enrollment through one month following the index endovascular procedure: initiation of the index endovascular procedure following the debanching procedure, device technical success for the index procedure and freedom from the following: aortic rupture, lesion-related mortality, disabling stroke, permanent paraplegia or paraparesis, new onset renal failure requiring permanent dialysis, and additional unanticipated procedure related to the device/procedure or withdrawal of the delivery system (i.e., protocol-defined reintervention).

1. Aneurysm: Primary Endpoint Composite

The pre-specified performance goal (PG) for freedom from primary endpoint events in the Aneurysm arm of 60% was met (n=47 subjects eligible for Primary Analysis, **Table 18**). The overall rate of freedom from a primary endpoint event was 74.5% with a 95% one-sided Exact lower confidence limit of 61.9%.

There were 52 subjects enrolled in this hypothesis-driven arm and 47 subjects were eligible for the primary endpoint analysis. Two subjects were excluded from analysis due to being treated with a 49/53 mm diameter device; two additional subjects were included (bringing the total subjects enrolled to 52) to keep the planned enrollment of 50 subjects for device sizes intended to be marketed. Three subjects were not eligible for the primary endpoint analysis since they did not have a primary endpoint event and did not have imaging within the 1-Month window. The denominator is comprised of the 43 subjects with imaging performed in the 1-Month window and an additional 4 subjects with a primary endpoint event who did not have 1-Month imaging performed.

Table 18: Primary Endpoint Composite Success (Through 1-Month) Aneurysm Cohort

Primary Endpoint Analysis	Endpoint Denominator	Endpoint Event	Percent Free from Endpoint Event (95% Exact LCL)	Reject Null Hypothesis (LCL > 60% PG)
Endpoint Eligible ¹	47	12	74.5% (61.9%)	Yes

¹Primary Endpoint composite (Through 1 Month) denominator is restricted to those with primary endpoint event or 1 Month imaging performed.
NOTE: 95% LCL represents one-sided 95% Lower Confidence Limit by exact method.

Table 19: Primary Endpoint Component Events (Through 1 Month) Aneurysm Cohort

	Phase 1	Endovascular Procedure	Post-Procedure	1 Month	Total (Through 1 Month)
Number of Enrolled Subjects ¹	50	50	49	47	50
Number of Subjects with Imaging in Follow-Up Window	-	-	5	43	45
Number of Subjects with Imaging or Primary Endpoint Event in Window	-	-	8	43	48
Subjects with Primary Endpoint Event Below ²	1/50 (2.0%)	8/50 (16.0%)	3/8 (37.5%)	2/43 (4.7%)	12/47 (25.5%)
Initiation of index endovascular procedure failure ³	0/50 (0%)	-	-	-	0/50 (0%)
Device technical failure ³	-	3/50 (6.0%)	-	-	3/50 (6.0%)
Access or Device Delivery failure	-	1/50 (2.0%)	-	-	-
Access failure	-	0/50 (0%)	-	-	-
Accurate deployment failure	-	1/50 (2.0%)	-	-	-
Device delivery system retrieval failure	-	0/50 (0%)	-	-	-
Patency failure	-	0/50 (0%)	-	-	-
Unanticipated additional procedure related to device/procedure ⁴	-	3/50 (6.0%)	-	-	-
Aortic rupture	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/47 (0%)	0/50 (0%)
Lesion-related mortality	0/50 (0%)	1/50 (2.0%)	1/49 (2.0%)	0/47 (0%)	2/50 (4.0%)
Disabling stroke ³	0/50 (0%)	4/50 (8.0%)	1/49 (2.0%)	1/47 (2.1%)	6/50 (12.0%)
Permanent paraplegia ³	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/47 (0%)	0/50 (0%)
Permanent paraparesis ³	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/47 (0%)	0/50 (0%)
New onset renal failure requiring dialysis ³	0/50 (0%)	0/50 (0%)	1/49 (2.0%)	0/47 (0%)	1/50 (2.0%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	1/50 (2.0%)	0/50 (0%)	0/49 (0%)	1/47 (2.1%)	2/50 (4.0%)

¹Subjects at risk at the start of each interval.

²Primary endpoint composite denominator is restricted to Subjects either with a primary endpoint event within window and/or imaging done in window (except Phase 1 and Endovascular Procedure are among all enrolled). Primary endpoint composite Total (Through 1 Month) denominator is further restricted to primary endpoint event in timeframe (i.e., anytime ≤ 59 days; exceptions indicated with a '-' per Protocol definitions) and/or imaging done in 1 Month window (15-59 days).

³Initiation of index endovascular procedure failures counted as occurring in Phase 1. Device technical failure events on day 0 only, others are events with onset through day 30. Study period definitions: Phase 1 (revascularization procedure, prior to endovascular procedure) Endovascular Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) Total(Phase1-59 days)

⁴ During the treatment of one subject, the investigator noticed infolding in one of two extenders and a third Aortic Extender was required to resolve this. Although the protocol states that placement of additional TBE devices would not constitute technical failure, the investigator determined it was an unanticipated additional procedure and therefore is considered a Technical Success Failure. At the time of the index endovascular operation one Subject had a bilateral neck exploration, thrombectomy of left and right CCA, thrombectomy of LSA for occluded bypass graft. The investigator did not consider this an unanticipated procedure and therefore it is not counted as a device technical failure. The core lab reported event was CEC adjudicated as a loss of patency and is considered a Treatment Success failure.

There have been 12 Aneurysm Subjects (25.5% (12/47); 74.5% free from endpoint event) that had any primary endpoint event occur. Two of these 12 subjects had more than one type of primary endpoint event: one subject had disabling stroke and lesion-related mortality and one subject had disabling stroke and new renal failure.

The index endovascular procedure was successfully initiated for all subjects and there were no reports of aortic rupture, permanent paraplegia, or permanent paraparesis through the 1-Month follow-up timeframe.

Aneurysm: Device Technical Success

Device Technical Success was achieved in 94.0% of subjects in the Aneurysm Cohort. Three subjects failed to meet the technical success criteria:

- In one subject, upon deployment, the AC portal device rotationally misaligned to the target branch vessel requiring implantation of additional Side Branch components and a GORE® VIABAHN® device.
- One subject required aortic branch vessel revascularization and additional stent

placement for a right common carotid dissection occurring immediately following closure post TBE procedure.

- In one subject, two AEs were placed proximal to AC in the ascending aorta to correct bird beaking of the AC. The AEs were ballooned, at which point in-folding of the second proximal cuff was noted, causing aortic stenosis, which did not resolve with ballooning. Further deployment of a third TBE AE was used in the ascending aorta, correcting the in-folding. As noted in the footnote of **Table 19**, although the protocol states that placement of additional TBE devices would not constitute technical failure, the investigator considered this event to be an unanticipated additional procedure related to the device/procedure.

There were no access failure or device delivery system retrieval failures and there were no issues with establishing Aortic Component or Side Branch graft patency during the procedure.

Aneurysm: Lesion-Related Mortality through 1-Month

There were two Aneurysm Subjects (4.0%; 2/50), as adjudicated by the CEC, which died and met the definition of lesion-related mortality within the 1-Month follow-up timeframe.

- One subject experienced infarcts in the high right frontal lobe, bilateral (left greater than right) parietal occipital regions, and broad right cerebellar infarction (with associated right tonsillar herniation) on POD 0. The subject received drug therapy. The subject died on POD 6. This event was also adjudicated for Disabling Stroke through 30 days in the Aneurysm - Disabling Stroke through 30 days section below. CEC adjudicated the event as related to the device and endovascular procedure.
- One subject experienced pulseless electrical activity arrest on POD 0. The subject received drug therapy and fluid/blood/oxygen therapy the same day. The subject died on POD 0. CEC adjudicated the event as related to the endovascular procedure.

Aneurysm: Disabling Stroke through 30 days

There were six subjects (12.0%; 6/50) that experienced disabling stroke events from the time of enrollment through 30 days post-index endovascular procedure. Any potential adverse event meeting this component definition through the timeframe was sent to the independent CEC neurologist for event adjudication.

- One subject experienced a left hemispheric stroke on POD 0 and received physical therapy/rehabilitation treatment. The event was reported by the site to be 'related to the endovascular procedure' and was ongoing at discharge on POD 9.
- One subject experienced an ischemic stroke in left MCA territory with pattern consistent with embolism on POD 0. The subject received physical therapy/rehabilitation on POD 0 and POD 9. This event resolved with sequelae on POD 0, and the site reported a relationship of 'unknown'.
- One subject experienced infarcts in the high right frontal lobe, bilateral (left greater than right) parietal occipital regions, and broad right cerebellar infarction (with associated right tonsillar herniation) POD 0. The subject received drug therapy. This event resulted in the subjects' death on POD 6.

- One subject experienced an acute ischemic stroke on POD 2. The subject was treated with drug therapy. This event resolved without sequelae on POD 121, and the site reported a relationship of ‘unknown’. The subject is active in the study as of the data export.
- One subject experienced a neurologic brain injury on POD 0. The site reported no treatment for this event. The site reported the event as ‘related to endovascular procedure.’ Note: Subject expired on POD 2 due to cardiogenic shock, which did not meet the definition of lesion-related mortality. This subject also experienced new onset renal failure within 30 days requiring permanent dialysis reported during the 1-Month follow-up window and is discussed below.
- One subject experienced weakness in the left lower limb on POD 26. On POD 28, the subject had an MRI and was admitted for a cerebral infarction and treated with drug and physical therapy. This subject was transferred to a rehabilitation hospital on POD 52, where they remained until POD 315. The subject remains active in the study as of the data export.

Aneurysm New Onset Renal Failure within 30 days Requiring Permanent Dialysis through 1-Month

There was one new onset renal failure within 30 days requiring permanent dialysis reported during the 1-Month follow-up window (2.0%; 1/50). The subject experienced acute kidney injury on POD 1 resulting in renal failure. The subject was treated with continuous renal replacement therapy. The event was reported as ‘resolved with sequelae’ on POD 2.

Aneurysm Protocol-Defined Reintervention through 1-Month

There were two subjects (4.0%; 2/50) reported to meet the definition of having had a protocol-defined reintervention.

- One subject had a Type IB endoleak involving the AC (POD 25), requiring thoracic aortic stent graft placement on POD 28. The event resolved without sequelae on the same day and was site reported as ‘related to device’.
- One subject had a thrombectomy for acute arterial occlusion of the left upper limb (POD -6), one day following the Phase 1 revascularization procedure (POD -7). The subject also received drug therapy and the site reported the event as ‘related to surgical revascularization procedure’. The event resolved without sequelae on POD -2, and the subject went on to have their endovascular procedure (Phase 2) on POD 0.

Sensitivity Analysis

Table 20 details the sensitivity analysis results on the composite primary endpoint in the primary hypothesis arm.

The PG was still met in Sensitivity Analysis #1, including the two subjects excluded due to treatment with 49/53mm devices no longer supported by the protocol (one subject had a primary endpoint event and the other subject did not have a primary endpoint event).

In Sensitivity Analysis #2, the PG was met in the worst-case tipping point analysis, when one of the excluded subjects was counted as an additional primary endpoint failure, however the PG was not met when two or more subjects excluded were counted as additional primary endpoint failures. The tipping point analysis included subjects excluded from the Primary Analysis due to missing 1-Month imaging. Subjects were added one-by-one as additional primary endpoint failures, checking at what point in the data inclusion the results changed.

Table 20: Sensitivity Analysis on Primary Endpoint Composite Success (Through 1 Month) for the Aneurysm Cohort

Primary Endpoint Analysis	Endpoint Denominator	Endpoint Event	Percent Free from Endpoint Event (95% Exact LCL)	Reject Null Hypothesis (LCL > 60% PG)
Sensitivity Analysis #1 Including 49/53mm device exclusion	49	13	73.5% (61.2%)	Yes
Sensitivity Analysis #2 Tipping Point Including Those Missing 1 Month Imaging ²				
Primary Endpoint (Through 1 Month)	47	12	74.5% (61.9%)	Yes
Add 1 failure	48	13	72.9% (60.4%)	Yes
Add 2 failures	49	14	71.4% (59.0%)	No

¹Primary endpoint composite (Through 1 Month) denominator is restricted to those with primary endpoint event or 1 Month imaging performed. This analysis includes all Subject(s) excluded due to treatment with 49/53mm devices no longer supported by the protocol.

²Tipping Point analysis incorporates those excluded (due to no 1 Month imaging) from the primary endpoint composite denominator, including them one-by-one as primary endpoint failures and checking at what point the hypothesis conclusion changes. NOTE: 95% LCL represents one-sided 95% Lower Confidence Limit by exact method.

2. Dissection: Primary Endpoint Composite

There have been four Dissection Subjects (4/22, 18.2%; 81.8% free from endpoint event) that had any primary endpoint event occur. **Table 21** displays the component level breakdown over time for the composite primary endpoint results. None of these four subjects had more than one type of primary endpoint event.

Table 21: Primary Endpoint Component Events Through 1-Month for the Dissection Cohort

	Phase 1	Endovascular Procedure	Post-Procedure	1 Month	Total (Through 1 Month)
Number of Enrolled Subjects ¹	24	24	24	23	24
Number of Subjects with Imaging in Follow-Up Window	-	-	2	21	21
Number of Subjects with Imaging or Primary Endpoint Event in Window	-	-	5	21	22
Subjects with Primary Endpoint Event Below ²	0/24 (0%)	1/24 (4.2%)	3/5 (60.0%)	0/21 (0%)	4/22 (18.2%)
Initiation of index endovascular procedure failure ³	0/24 (0%)	-	-	-	0/24 (0%)
Device technical failure ³	-	1/24 (4.2%)	-	-	1/24 (4.2%)
Access or Device Delivery failure	-	1/24 (4.2%)	-	-	-
Access failure	-	0/24 (0%)	-	-	-
Accurate deployment failure	-	1/24 (4.2%)	-	-	-
Device delivery system retrieval failure	-	0/24 (0%)	-	-	-
Patency failure	-	0/24 (0%)	-	-	-
Unanticipated additional procedure related to device/procedure	-	0/24 (0%)	-	-	-
Aortic rupture	0/24 (0%)	0/24 (0%)	0/24 (0%)	0/23 (0%)	0/24 (0%)
Lesion-related mortality	0/24 (0%)	0/24 (0%)	1/24 (4.2%)	0/23 (0%)	1/24 (4.2%)
Disabling stroke ³	0/24 (0%)	0/24 (0%)	0/24 (0%)	0/23 (0%)	0/24 (0%)
Permanent paraplegia ³	0/24 (0%)	0/24 (0%)	0/24 (0%)	0/23 (0%)	0/24 (0%)
Permanent paraparesis ³	0/24 (0%)	0/24 (0%)	0/24 (0%)	0/23 (0%)	0/24 (0%)
New onset renal failure requiring dialysis ³	0/24 (0%)	0/24 (0%)	0/24 (0%)	0/23 (0%)	0/24 (0%)

	Phase 1	Endovascular Procedure	Post-Procedure	1 Month	Total (Through 1 Month)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	0/24 (0%)	0/24 (0%)	2/24 (8.3%)	0/23 (0%)	2/24 (8.3%)

¹Subjects at risk at the start of each interval.
²Primary endpoint composite denominator is restricted to Subjects either with a primary endpoint event within window and/or imaging done in window (except Phase 1 and Endovascular Procedure are among all enrolled). Primary endpoint composite Total (Through 1 Month) denominator is further restricted to primary endpoint event in timeframe (i.e., anytime ≤ 59 days; exceptions indicated with a '-' per Protocol definitions) and/or imaging done in 1 Month window (15-59 days).
³Initiation of index endovascular procedure failures counted as occurring in Phase 1. Device technical failure events on day 0 only, others are events with onset through day 30. Study period definitions: Phase1 (revascularization procedure, prior to endovascular procedure) Endovascular Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) Total(Phase1-59 days)

- One subject had an accurate deployment failure in that the AC was deployed slightly distal and rotationally misaligned to the brachiocephalic origin. Three SB components were deployed within the BCA. A Type 1A endoleak was addressed with the deployment of two AE components. While advancing a balloon into the SB components from the brachial access site, the SB components were pushed proximally. The procedure was completed using a balloon expandable stent in the BCA.
- One subject met definition of lesion related mortality. The subject died on POD 2 from an ascending aortic dissection. The event was deemed related to endovascular procedure by the site.
- Two subjects met the definition of having had a protocol-defined reintervention.
 - One subject required a reintervention on POD 6 for a post-procedural spinal headache. The event was treated with an epidural blood patch and resolved without sequelae on the same day.
 - One subject required a laparotomy on POD 1 for abdominal exploration due to retroperitoneal hematoma. The event resolved on POD 1 after treatment with packing and blood/fluids. CEC adjudicated the event as related to the endovascular procedure.

3. Zone 0/1 Other Isolated Lesions Primary Endpoint Composite

No Zone 0/1 Other Isolated Lesion Subjects had a primary endpoint event occur (3/3, 100% free from endpoint event). Initiation of the Index Endovascular Procedure (Phase 2) was achieved in 100% of subjects, no events of device technical success failure and none of the following events occurred through 1-Month: aortic rupture, lesion-related mortality, disabling stroke, permanent paraplegia, permanent paraparesis, new onset renal failure requiring permanent dialysis, or protocol-defined reintervention.

Due to the smaller number in this cohort, it is important to note that all three subjects in the denominator reached the 1-Month window (zero subjects died prior to window closure) and all had adequate imaging at 1-Month.

4. All Cohorts Primary Endpoint Component Event Results through 12-Months

Eighteen subjects in all Cohorts (18/70, 25.7%; 74.3% free from endpoint event) had any primary endpoint event occur through 12-Months as shown in **Table 22**. The denominator is comprised of the 61 subjects with imaging performed in the 12-Month window and an additional 9 subjects with a primary endpoint event who did not have 12-Month imaging performed. This window is inclusive of the 1-Month timepoint where 16 subjects (22.2%; 16/72) had a primary endpoint occur. The events that have

not already been described above (i.e., within the 30 day window) have been discussed below:

- One Aneurysm Subject met the definition of two additional endpoint events, aortic rupture and lesion-related mortality, in the 6-Month window. This subject experienced a ruptured aorta occurring on POD 105 due to aorto-esophageal fistula that developed because of a graft infection. This event resulted in the subjects' death on the same day, POD 105. The site reported this event as 'related to device and endovascular procedure'.
- One Dissection Subject met the definition of two additional endpoint events, aortic rupture and lesion-related mortality, in the 6-Month window. The subject had an aortic rupture on POD 65. On POD 52, the subject was hospitalized due to both a urinary tract infection and sepsis. The urinary tract infection resolved without sequelae on POD 59. The subject remained hospitalized, and the sepsis was not resolved at the time of death. Imaging on POD 93 revealed a descending thoracic aorta rupture. The rupture was determined to be due to inflammatory reaction caused by sepsis, which occurred in the aortic wall. The subject expired POD 156 and the death was also adjudicated to lesion-related mortality. The event was deemed to be unrelated to device and procedures by both the site and CEC.
- One Dissection Subject experienced an additional protocol-defined reintervention. The subject had a vascular graft infection on POD 363 requiring reintervention. The event resolved without sequelae on POD 368. This event was deemed to be related to the surgical revascularization procedure by the site.

Table 22: Primary Endpoint Component Events (Through 12 Months) for All Cohorts

	Phase 1	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	Total (Through 12 Months)
Number of Enrolled Subjects ¹	77	77	76	73	72	68	77
Number of Subjects with Imaging in Follow-Up Window	-	-	7	67	63	61	72
Number of Subjects with Imaging or Primary Endpoint Event in Window	-	-	13	67	63	61	76
Subjects with Primary Endpoint Event Below ²	1/77 (1.3%)	9/77 (11.7%)	6/13 (46.2%)	2/67 (3.0%)	2/63 (3.2%)	1/61 (1.6%)	18/70 (25.7%)
Initiation of index endovascular procedure failure ³	0/77 (0%)	-	-	-	-	-	0/77 (0%)
Device technical failure ³	-	4/77 (5.2%)	-	-	-	-	4/77 (5.2%)
Access or Device Delivery failure	-	2/77 (2.6%)	-	-	-	-	-
Access failure	-	0/77 (0%)	-	-	-	-	-
Accurate deployment failure	-	2/77 (2.6%)	-	-	-	-	-
Device delivery system retrieval failure	-	0/77 (0%)	-	-	-	-	-
Patency failure	-	0/77 (0%)	-	-	-	-	-
Unanticipated additional procedure related to device/procedure	-	3/77 (3.9%)	-	-	-	-	-
Aortic rupture	0/77 (0%)	0/77 (0%)	0/76 (0%)	0/73 (0%)	2/72 (2.8%)	0/68 (0%)	2/77 (2.6%)
Lesion-related mortality	0/77 (0%)	1/77 (1.3%)	2/76 (2.6%)	0/73 (0%)	2/72 (2.8%)	0/68 (0%)	5/77 (6.5%)
Disabling stroke ³	0/77 (0%)	4/77 (5.2%)	1/76 (1.3%)	1/73 (1.4%)	-	-	6/77 (7.8%)
Permanent paraplegia ³	0/77 (0%)	0/77 (0%)	0/76 (0%)	0/73 (0%)	-	-	0/77 (0%)
Permanent paraparesis ³	0/77 (0%)	0/77 (0%)	0/76 (0%)	0/73 (0%)	-	-	0/77 (0%)
New onset renal failure requiring dialysis ³	0/77 (0%)	0/77 (0%)	1/76 (1.3%)	0/73 (0%)	-	-	1/77 (1.3%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	1/77 (1.3%)	0/77 (0%)	2/76 (2.6%)	1/73 (1.4%)	0/72 (0%)	1/68 (1.5%)	5/77 (6.5%)

¹Subjects at risk at the start of each interval. ²Primary Endpoint composite denominator is restricted to Subjects either with a primary endpoint event within window and/or imaging done in window (except Phase 1 and Endovascular Procedure are among all enrolled). Primary Endpoint composite Total (Through 12 Months) denominator is further restricted to primary endpoint event in timeframe (i.e., anytime ≤ 546 days; exceptions indicated with a '-' per Protocol definitions) and/or imaging done in 12 Month window (243-546 days). The denominator is comprised of the 61 Subjects with imaging performed in the 12-Month window and an additional 9 Subjects with a primary endpoint event who did not have 12-Month imaging performed.

³Initiation of index endovascular procedure failures counted as occurring in Phase 1. Device technical failure events on day 0 only, others are events with onset through day 30.

Study period definitions: Phase 1 (revascularization procedure, prior to endovascular procedure) Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) Total(Phase 1-546 days)

5. All Cohorts Success Outcomes Evaluations

In addition to the Primary Endpoints noted above, Procedural and Treatment Success data (aggregate and components) were collected and analyzed for all cohorts. Definitions of outcomes are presented in Section X (A) (3).

Procedural Success

A summary of Procedural Success including a breakdown of events leading to failure to achieve Procedural Success is provided in **Table 23**.

Table 23: Procedural Success through 1 Month¹ for All Cohorts

	Aneurysm	Dissection	Other Isolated Lesion	All
Number of Enrolled Subjects ²	50	24	3	77
Subjects with Procedural Success	32 (64.0%)	17 (70.8%)	3 (100.0%)	52 (67.5%)
Procedural Success Events Breakdown				
Site-Reported Outcomes				
Device technical failure ³	3 (6.0%)	1 (4.2%)	0 (0%)	4 (5.2%)
Death ³	3 (6.0%)	1 (4.2%)	0 (0%)	4 (5.2%)
Adverse Event or Treatment with Adjudication Outcomes				
Disabling stroke ³	6 (12.0%)	0 (0%)	0 (0%)	6 (7.8%)
Paraplegia ³	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Paraparesis ³	0 (0%)	0 (0%)	0 (0%)	0 (0%)
New onset renal failure requiring dialysis ³	1 (2.0%)	0 (0%)	0 (0%)	1 (1.3%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	1 (2.0%)	2 (8.3%)	0 (0%)	3 (3.9%)
New ischemia	0 (0%)	1 (4.2%)	0 (0%)	1 (1.3%)
Distal device-related thromboembolic event requiring intervention	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Life-threatening bleed ³	5 (10.0%)	2 (8.3%)	0 (0%)	7 (9.1%)
Myocardial infarction ³	2 (4.0%)	0 (0%)	0 (0%)	2 (2.6%)
Prolonged intubation ³	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Laryngeal or phrenic nerve injury ³	1 (2.0%)	2 (8.3%)	0 (0%)	3 (3.9%)
Renal dysfunction or volume overload requiring ultrafiltration	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Severe heart failure/hypotension ³	2 (4.0%)	1 (4.2%)	0 (0%)	3 (3.9%)
Adverse Event with Adjudication or Core Lab Reported Outcomes				
Aortic rupture ³	0 (0%)	0 (0%)	0 (0%)	0 (0%)
New dissection	3 (6.0%)	2 (8.3%)	0 (0%)	5 (6.5%)
Core Lab Reported Outcomes				
Extension of a dissection (Dissection cohort only) ⁴	-	0/20 (0%)	-	0/20 (0%)

¹Day 0-59 unless otherwise noted. ²Denominator restricted to those who initiated Endovascular Procedure. ³Device technical failure events on day 0 only, prolonged intubation and severe heart failure/hypotension are during index endovascular procedure hospitalization only, others are events with onset through day 30. ⁴Denominator further restricted to those with the 'Extension of dissection' Core Lab follow-up assessment known within the time window.

Device technical success, disabling stroke, paraplegia and paraparesis, new onset renal failure requiring dialysis, and protocol-defined reinterventions were previously included in the Primary Endpoint discussion (**Section 4**).

All-cause mortality, new dissections, and life-threatening bleed are also included in this endpoint and discussed in the Key Events section below (**Section 6**).

Treatment Success

A breakdown of events leading to failure to achieve Treatment Success by cohort and follow-up window is provided in **Table 24** through **Table 26**. **Table 27** presents the Treatment Success breakdown for all cohorts.

Table 24: Treatment Success by Analysis Study Window for Aneurysm Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Enrolled Subjects ²	50	49	47	46	43	28	17	14	8	50
Number of Subjects with Imaging or Event in Window	-	7	43	39	39	23	15	9	6	49
Subjects with Treatment Success ³	41/50(82.0%)	4/7(57.1%)	36/43(83.7%)	35/39(89.7%)	33/39(84.6%)	19/23(82.6%)	11/15(73.3%)	6/9(66.7%)	4/6(66.7%)	28/49(57.1%)
Treatment Success Events Breakdown										
Site-Reported Outcomes²										
Device technical failure	3/50(6.0%)	-	-	-	-	-	-	-	-	3/50(6.0%)
Adverse Event or Treatment with Adjudication Outcomes²										
Lesion-related mortality	1/50(2.0%)	1/49(2.0%)	0/47(0%)	1/46(2.2%)	0/43(0%)	0/28(0%)	0/17(0%)	0/14(0%)	0/8(0%)	3/50(6.0%)
Disabling stroke (30 days)	4/50(8.0%)	1/49(2.0%)	1/47(2.1%)	-	-	-	-	-	-	6/50(12.0%)
Paraplegia (30 days)	0/50(0%)	0/49(0%)	0/47(0%)	-	-	-	-	-	-	0/50(0%)
Paraparesis (30 days)	0/50(0%)	0/49(0%)	0/47(0%)	-	-	-	-	-	-	0/50(0%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	0/50(0%)	0/49(0%)	1/47(2.1%)	0/46(0%)	0/43(0%)	0/28(0%)	1/17(5.9%)	0/14(0%)	0/8(0%)	2/50(4.0%)
New ischemia	0/50(0%)	0/49(0%)	0/47(0%)	0/46(0%)	0/43(0%)	0/28(0%)	0/17(0%)	0/14(0%)	0/8(0%)	0/50(0%)
Adverse Event with Adjudication or Core Lab Reported Outcomes²										
Aortic rupture ²	0/50(0%)	0/49(0%)	0/47(0%)	1/46(2.2%)	0/43(0%)	0/28(0%)	0/17(0%)	0/14(0%)	0/8(0%)	1/50(2.0%)
Loss of patency ⁵	1/50(2.0%)	0/4(0%)	1/43(2.3%)	1/37(2.7%)	1/38(2.6%)	0/21(0%)	0/13(0%)	0/9(0%)	0/6(0%)	2/50(4.0%)
Fistula formation ^{2,4}	0/50(0%)	0/49(0%)	0/47(0%)	1/46(2.2%)	0/43(0%)	0/28(0%)	0/17(0%)	0/14(0%)	0/8(0%)	1/50(2.0%)
New dissection ⁵	0/50(0%)	1/4(25.0%)	2/42(4.8%)	0/36(0%)	1/38(2.6%)	0/20(0%)	0/13(0%)	0/9(0%)	0/6(0%)	4/50(8.0%)
Core Lab Reported Outcomes⁵										
Evaluable Subjects	1	5	43	39	39	23	15	9	6	46
Type I or III Endoleak	0 (0%)	0/3(0%)	3/43(7.0%)	2/36(5.6%)	2/38(5.3%)	1/20(5.0%)	1/13(7.7%)	0/9(0%)	1/6(16.7%)	6/45(13.3%)
Loss of device integrity ⁶	0 (0%)	0/3(0%)	0/41(0%)	0/37(0%)	0/36(0%)	0/21(0%)	0/14(0%)	0/9(0%)	0/6(0%)	0/44(0%)
Device migration	0 (0%)	-	0/43(0%)	0/39(0%)	0/38(0%)	0/22(0%)	0/14(0%)	0/9(0%)	0/6(0%)	0/45(0%)
Aortic enlargement	0 (0%)	-	-	0/38(0%)	3/36(8.3%)	4/22(18.2%)	4/13(30.8%)	3/8(37.5%)	2/5(40.0%)	6/41(14.6%)

¹Event percentages in this column may be an underestimation as 5 year follow-up is not complete
²Denominator is restricted to those who initiated Endovascular Procedure and are at risk at the start of each interval. There have been two Aneurysm Subject(s) excluded from this analysis due to treatment with 49/53 mm devices no longer supported by the protocol.³Treatment Success composite denominator is restricted to Subjects either with an event within window and/or imaging done in window.⁴Doesn't have to be adjudicated.⁵Denominator further restricted to those with an event or Core Lab assessment known within the window. Absence of a denominator indicates no patients were assessed.⁶This component is a combination of Sealing Stent Row Wire Fracture and/or Compression/Invagination events.
Study period definitions: Endovascular Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)

Table 25: Treatment Success by Analysis Study Window for Dissection Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Enrolled Subjects ²	24	24	23	23	22	12	9	8	4	24
Number of Subjects with Imaging or Event in Window	-	5	21	22	21	8	7	6	4	24
Subjects with Treatment Success ³	22/24(91.7%)	1/5(20.0%)	16/21(76.2%)	17/22(77.3%)	18/21(85.7%)	7/8(87.5%)	6/7(85.7%)	5/6(83.3%)	4/4(100.0%)	13/24(54.2%)
Treatment Success Events Breakdown										
Site-Reported Outcomes ²										
Device technical failure	1/24(4.2%)	-	-	-	-	-	-	-	-	1/24(4.2%)
Adverse Event or Treatment with Adjudication Outcomes ²										
Lesion-related mortality	0/24(0%)	1/24(4.2%)	0/23(0%)	1/23(4.3%)	0/22(0%)	0/12(0%)	0/9(0%)	0/8(0%)	0/4(0%)	2/24(8.3%)
Disabling stroke (30 days)	0/24(0%)	0/24(0%)	0/23(0%)	-	-	-	-	-	-	0/24(0%)
Paraplegia (30 days)	0/24(0%)	0/24(0%)	0/23(0%)	-	-	-	-	-	-	0/24(0%)
Paraparesis (30 days)	0/24(0%)	0/24(0%)	0/23(0%)	-	-	-	-	-	-	0/24(0%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	0/24(0%)	2/24(8.3%)	0/23(0%)	0/23(0%)	1/22(4.5%)	0/12(0%)	0/9(0%)	0/8(0%)	0/4(0%)	3/24(12.5%)
New ischemia	1/24(4.2%)	0/24(0%)	0/23(0%)	0/23(0%)	0/22(0%)	0/12(0%)	0/9(0%)	0/8(0%)	0/4(0%)	1/24(4.2%)
Adverse Event with Adjudication or Core Lab Reported Outcomes ²										
Aortic rupture ²	0/24(0%)	0/24(0%)	0/23(0%)	1/23(4.3%)	0/22(0%)	0/12(0%)	0/9(0%)	0/8(0%)	0/4(0%)	1/24(4.2%)
Loss of patency ³	0/24(0%)	0/2(0%)	0/21(0%)	0/21(0%)	0/19(0%)	0/7(0%)	0/6(0%)	0/6(0%)	0/4(0%)	0/24(0%)
Fistula formation ^{2,4}	0/24(0%)	0/24(0%)	0/23(0%)	0/23(0%)	1/22(4.5%)	0/12(0%)	0/9(0%)	0/8(0%)	0/4(0%)	1/24(4.2%)
New dissection ⁵	0/24(0%)	1/3(33.3%)	1/20(5.0%)	1/19(5.3%)	0/18(0%)	0/7(0%)	0/6(0%)	0/6(0%)	0/4(0%)	3/24(12.5%)
Core Lab Reported Outcomes ⁵										
Evaluable Subjects	0	2	21	22	20	8	7	6	4	23
Type I or III Endoleak	-	0/2(0%)	1/21(4.8%)	2/20(10.0%)	0/19(0%)	0/7(0%)	0/6(0%)	0/6(0%)	0/4(0%)	2/23(8.7%)
Loss of device integrity ⁶	-	0/2(0%)	0/19(0%)	0/21(0%)	0/19(0%)	0/7(0%)	0/6(0%)	0/6(0%)	0/4(0%)	0/23(0%)
Device migration	-	-	0/21(0%)	0/21(0%)	0/19(0%)	0/7(0%)	0/7(0%)	0/6(0%)	0/4(0%)	0/23(0%)
Aortic enlargement	-	-	-	1/19(5.3%)	1/17(5.9%)	1/6(16.7%)	1/6(16.7%)	1/4(25.0%)	0/4(0%)	1/20(5.0%)
Extension of dissection (Dissection cohort only)	-	0/2(0%)	0/20(0%)	0/19(0%)	0/18(0%)	0/7(0%)	0/6(0%)	0/6(0%)	0/4(0%)	0/23(0%)
False lumen perfusion through primary entry tear (Dissection cohort only)	-	0/2(0%)	0/21(0%)	0/21(0%)	0/19(0%)	0/7(0%)	0/7(0%)	0/6(0%)	0/4(0%)	0/23(0%)
False lumen perfusion through an aortic arch branch vessel (Dissection cohort only)	-	1/2(50.0%)	3/19(15.8%)	1/20(5.0%)	0/17(0%)	0/6(0%)	0/5(0%)	0/5(0%)	0/3(0%)	3/21(14.3%)

¹ Event percentages in this column may be an underestimation as 5 year follow-up is not complete.

²Denominator is restricted to those who initiated Endovascular Procedure and are at risk at the start of each interval. ³Treatment Success composite denominator is restricted to Subjects either with an event within window and/or imaging done in window. ⁴Doesn't have to be adjudicated. ⁵Denominator further restricted to those with an event or Core Lab assessment known within the window. Absence of a denominator indicates no patients were assessed. ⁶This component is a combination of Sealing Stent Row Wire Fracture and/or Compression/Invagination events. Study period definitions: Endovascular Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)

Table 26: Treatment Success by Analysis Study Window for Other Isolated Lesion Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Enrolled Subjects ²	3	3	3	3	3	1	1	1	0	3
Number of Subjects with Imaging or Event in Window	-	0	3	2	2	1	1	1	-	3
Subjects with Treatment Success ³	3/3(100.0%)	-	3/3(100.0%)	1/2(50.0%)	2/2(100.0%)	1/1(100.0%)	1/1(100.0%)	1/1(100.0%)	-	2/3(66.7%)
Treatment Success Events Breakdown										
Site-Reported Outcomes²										
Device technical failure	0/3(0%)	-	-	-	-	-	-	-	-	0/3(0%)
Adverse Event or Treatment with Adjudication Outcomes²										
Lesion-related mortality	0/3(0%)	0/3(0%)	0/3(0%)	0/3(0%)	0/3(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	0/3(0%)
Disabling stroke (30 days)	0/3(0%)	0/3(0%)	0/3(0%)	-	-	-	-	-	-	0/3(0%)
Paraplegia (30 days)	0/3(0%)	0/3(0%)	0/3(0%)	-	-	-	-	-	-	0/3(0%)
Paraparesis (30 days)	0/3(0%)	0/3(0%)	0/3(0%)	-	-	-	-	-	-	0/3(0%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	0/3(0%)	0/3(0%)	0/3(0%)	0/3(0%)	0/3(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	0/3(0%)
New ischemia	0/3(0%)	0/3(0%)	0/3(0%)	0/3(0%)	0/3(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	0/3(0%)
Adverse Event with Adjudication or Core Lab Reported Outcomes²										
Aortic rupture ²	0/3(0%)	0/3(0%)	0/3(0%)	0/3(0%)	0/3(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	0/3(0%)
Loss of patency ⁵	0/3(0%)	0 (0%)	0/3(0%)	0/2(0%)	0/2(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	0/3(0%)
Fistula formation ^{2,4}	0/3(0%)	0/3(0%)	0/3(0%)	0/3(0%)	0/3(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	0/3(0%)
New dissection ⁵	0/3(0%)	0 (0%)	0/3(0%)	0/2(0%)	0/2(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	0/3(0%)
Core Lab Reported Outcomes⁵										
Evaluable Subjects	0	0	3	2	2	1	1	1	-	3
Type I or III Endoleak	-	-	0/3(0%)	0/2(0%)	0/2(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	0/3(0%)
Loss of device integrity ⁶	-	-	0/3(0%)	0/2(0%)	0/2(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	0/3(0%)
Device migration	-	-	0/3(0%)	0/2(0%)	0/2(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	0/3(0%)
Aortic enlargement	-	-	-	1/2(50.0%)	0/2(0%)	0/1(0%)	0/1(0%)	0/1(0%)	-	1/3(33.3%)

¹ Event percentages in this column may be an underestimation as 5 year follow-up is not complete

²Denominator is restricted to those who initiated Endovascular Procedure and are at risk at the start of each interval. ³Treatment Success composite denominator is restricted to Subjects either with an event within window and/or imaging done in window. ⁴Doesn't have to be adjudicated. ⁵Denominator further restricted to those with an event or Core lab assessment known within the window. Absence of a denominator indicates no patients were assessed.

⁶This component is a combination of Sealing Stent Row Wire Fracture and/or Compression/Invagination events. Study period definitions: Endovascular Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)

Table 27: Treatment Success by Analysis Study Window for All Cohorts

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Enrolled Subjects²	77	76	73	72	68	41	27	23	12	77
Number of Subjects with Imaging or Event in Window	-	12	67	63	62	32	23	16	10	76
Subjects with Treatment Success³	66/77(85.7%)	5/12(41.7%)	55/67(82.1%)	53/63(84.1%)	53/62(85.5%)	27/32(84.4%)	18/23(78.3%)	12/16(75.0%)	8/10(80.0%)	43/76(56.6%)
Treatment Success Events Breakdown										
Site-Reported Outcomes²										
Device technical success failure	4/77(5.2%)	-	-	-	-	-	-	-	-	4/77(5.2%)
Adverse Event or Treatment with Adjudication Outcomes²										
Lesion-related mortality	1/77(1.3%)	2/76(2.6%)	0/73(0%)	2/72(2.8%)	0/68(0%)	0/41(0%)	0/27(0%)	0/23(0%)	0/12(0%)	5/77(6.5%)
Disabling stroke (30 days)	4/77(5.2%)	1/76(1.3%)	1/73(1.4%)	-	-	-	-	-	-	6/77(7.8%)
Paraplegia (30 days)	0/77(0%)	0/76(0%)	0/73(0%)	-	-	-	-	-	-	0/77(0%)
Paraparesis (30 days)	0/77(0%)	0/76(0%)	0/73(0%)	-	-	-	-	-	-	0/77(0%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	0/77(0%)	2/76(2.6%)	1/73(1.4%)	0/72(0%)	1/68(1.5%)	0/41(0%)	1/27(3.7%)	0/23(0%)	0/12(0%)	5/77(6.5%)
New ischemia	1/77(1.3%)	0/76(0%)	0/73(0%)	0/72(0%)	0/68(0%)	0/41(0%)	0/27(0%)	0/23(0%)	0/12(0%)	1/77(1.3%)
Adverse Event with Adjudication or Core Lab Reported Outcomes²										
Aortic rupture ²	0/77(0%)	0/76(0%)	0/73(0%)	2/72(2.8%)	0/68(0%)	0/41(0%)	0/27(0%)	0/23(0%)	0/12(0%)	2/77(2.6%)
Loss of patency ⁵	1/77(1.3%)	0/6(0%)	1/67(1.5%)	1/60(1.7%)	1/59(1.7%)	0/29(0%)	0/20(0%)	0/16(0%)	0/10(0%)	2/77(2.6%)
Fistula formation ^{2,4}	0/77(0%)	0/76(0%)	0/73(0%)	1/72(1.4%)	1/68(1.5%)	0/41(0%)	0/27(0%)	0/23(0%)	0/12(0%)	2/77(2.6%)
New dissection ⁵	0/77(0%)	2/7(28.6%)	3/65(4.6%)	1/57(1.8%)	1/58(1.7%)	0/28(0%)	0/20(0%)	0/16(0%)	0/10(0%)	7/77(9.1%)
Core Lab Reported Outcomes⁵										
Evaluable Subjects	1	7	67	63	61	32	23	16	10	72
Type I or III Endoleak	0 (0%)	0/5(0%)	4/67(6.0%)	4/58(6.9%)	2/59(3.4%)	1/28(3.6%)	1/20(5.0%)	0/16(0%)	1/10(10.0%)	8/71(11.3%)
Loss of device integrity ⁶	0 (0%)	0/5(0%)	0/63(0%)	0/60(0%)	0/57(0%)	0/29(0%)	0/21(0%)	0/16(0%)	0/10(0%)	0/70(0%)
Device migration	0 (0%)	-	0/67(0%)	0/62(0%)	0/59(0%)	0/30(0%)	0/22(0%)	0/16(0%)	0/10(0%)	0/71(0%)
Aortic enlargement	0 (0%)	-	-	2/59(3.4%)	4/55(7.3%)	5/29(17.2%)	5/20(25.0%)	4/13(30.8%)	2/9(22.2%)	8/64(12.5%)
Extension of dissection (Dissection cohort only)	0 (0%)	0/2(0%)	0/20(0%)	0/19(0%)	0/18(0%)	0/7(0%)	0/6(0%)	0/6(0%)	0/4(0%)	0/23(0%)
False lumen perfusion through primary entry tear (Dissection cohort only)	0 (0%)	0/2(0%)	0/21(0%)	0/21(0%)	0/19(0%)	0/7(0%)	0/7(0%)	0/6(0%)	0/4(0%)	0/23(0%)
False lumen perfusion through an aortic arch branch vessel (Dissection cohort only)	0 (0%)	1/2(50.0%)	3/19(15.8%)	1/20(5.0%)	0/17(0%)	0/6(0%)	0/5(0%)	0/5(0%)	0/3(0%)	3/21(14.3%)

¹ Event percentages in this column may be an underestimation as 5 year follow-up is not complete

²Denominator is restricted to those who initiated Endovascular Procedure and are at risk at the start of each interval. ³Treatment Success composite denominator is restricted to Subjects either with an event within window and/or imaging done in window. ⁴Doesn't have to be adjudicated. ⁵Denominator further restricted to those with an event or Core lab assessment known within the window. Absence of a denominator indicates no patients were assessed.

⁶This component is a combination of Sealing Stent Row Wire Fracture and/or Compression/Invagination events. Study period definitions: Endovascular Procedure (0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 day)

There have been no reports of Device Migration or Loss of Device Integrity in all Cohorts. There have been no reports of Extension of Dissection (Dissection cohort only).

Device Technical Success is discussed in the Primary Endpoint Sections. All-Cause mortality including Lesion Related Mortality, Stroke and Disabling Stroke, Life Threatening Bleed, New Dissections, and Aortic Rupture are discussed in the Key Events (Section 6) below.

A brief discussion of those Treatment Success events that are not covered in other sections is provided below:

New Ischemia

- One Dissection Subject (1.3%; 1/77) within all Cohorts had new ischemia as adjudicated by the CEC. This subject experienced bilateral lower extremity and mesenteric ischemia on POD 0. Both events were site reported as related to endovascular procedure. The events were treated on the same day with an embolectomy and stent and an exploratory laparotomy and stent, respectively. The lower extremity ischemia remains ongoing, and the mesenteric ischemia resolved without sequelae on POD 118 after a Mesenteric bypass with aorto-bi-iliac aortic repair.

Fistula Formation

- Two subjects (2.6%; 2/77) within all Cohorts (one Aneurysm and one Dissection) experienced fistula formation and were both site-reported events.
 - The Dissection Subject experienced an aortopulmonary fistula on POD 309, which the site reported as unrelated to device and procedures. The event received no treatment and remains ongoing.
 - An Aneurysm Subject experienced an aortoenteric fistula noted on POD 84. The Site reported fluid/blood/oxygen and PEG treatment on POD 85. The site reported this event as 'related to device'. This event was ongoing at the time of death from ruptured aorta on POD 105. Note: This subject was also adjudicated as having events meeting the definition of Type I endoleak (POD 25), protocol-defined reintervention (POD 28), phrenic nerve injury (POD 28), aortic rupture (POD 105), and lesion-related mortality (POD 105).

6. Key Events- All Cohorts

Stroke

There were eight subjects (10.4 %) in all Cohorts (all Aneurysm) through all available follow-up who had stroke events adjudicated by the neurologist as meeting the WHO criteria.

Table 28 summarizes the CEC neurologist/OMA adjudicated disabling strokes and/or

WHO strokes by absolute time window for all Cohorts. Through all available follow-up, eight subjects experienced nine stroke events (six of these subjects had disabling strokes). One subject experienced a disabling stroke (POD 0) and then almost five months later (POD 145), a WHO stroke.

For three subjects with disabling strokes their event resolved without clinical sequelae and for two additional subjects who experienced a disabling and / or WHO stroke, their event resolved with sequelae.

For the remaining three subjects with disabling and / or WHO stroke, their stroke adverse event was ongoing up until their death (one was adjudicated as being a lesion-related mortality).

Five stroke events were adjudicated as being Related to Endovascular Procedure or Related to Device and Endovascular Procedure, one stroke event was adjudicated as related to Surgical Revascularization Procedure and three stroke events were adjudicated as Unknown or Unrelated.

Table 28: CEC Neurologist/OMA-Adjudicated Strokes by Absolute Study Window for All Cohorts

	Phase 1	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	>5 Years to Study End	Total ¹
Number of Enrolled Subjects²	77	77	73	69	62	32	26	20	6	77
Subjects with any WHO Stroke or Disabling Stroke	1 (1.3%)	6 (7.8%)	2 (2.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	8 (10.4%)
Subjects with WHO Stroke	1 (1.3%)	6 (7.8%)	2 (2.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	8 (10.4%)
Subjects with Disabling Stroke	0 (0%)	6 (7.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (7.8%)

¹Event percentages in this column may be an underestimation as 5 year follow-up is not complete.

²Column header counts are the number of Subjects at risk at the start of each interval. Study period definitions: Phase 1 (revascularization procedure until prior to endovascular procedure) 30 Days(0-30 days) 6 Months(31-182 days) 1 Year(183-365 days) 2 Years(366-731 days) 3 Years(732-1096 days) 4 Years(1097-1461 days) 5 Years(1462-1826 days) >5 Years to Study End(1827-2006 days) Total (Phase 1-2006 days)

New Dissections

Seven subjects (9.1%; 7/77) within all cohorts (four Aneurysm and three Dissection) have had a new dissection. The location of the new dissection has varied as follows: two subjects (2.6%) in the treated branch (one treated segment and one outside treated segment), two subjects (2.6%) in the proximal aorta (both outside treated area) and three subjects (6.0%) in the distal aorta (all outside treated area). There were no new dissections reported for the untreated branches.

Of the seven subjects:

- Five subjects had no related reinterventions;
- One dissection subject experienced an ascending aortic dissection on POD 2 in the untreated segment of the proximal aorta. The subject died same day from the event.

- One aneurysm subject who experienced new dissection in the treated segment of the branch vessel required repair with a stent and revascularization, which successfully treated the new dissection.

Table 29 summarizes the new dissection events that have occurred in all Cohorts.

Table 29: New Dissection by Analysis Study Window for All Zone 0/1 Cohorts

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Enrolled Subjects²	77	76	73	72	68	41	27	23	12	77
Evaluable Subjects³	77	7	65	57	58	28	20	16	10	77
All Subjects with New Dissections (Core Lab and/or Site AE)	0 (0%)	2/7 (28.6%)	3/65 (4.6%)	1/57 (1.8%)	1/58 (1.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7/77 (9.1%)
Subjects with New Dissections Only Reported by Core Lab (No Site AE) ⁴	-	-	-	-	-	-	-	-	-	5/77 (6.5%)
New Dissection Location⁵										
Untreated Branch	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Treated Branch	0 (0%)	1 (14.3%)	1 (1.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2.6%)
Contiguous (treated area)	-	1 (14.3%)	0 (0%)	-	-	-	-	-	-	1 (1.3%)
Remote (outside treated area)	-	0 (0%)	1 (1.5%)	-	-	-	-	-	-	1 (1.3%)
Proximal Aorta	0 (0%)	1 (14.3%)	0 (0%)	1 (1.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2.6%)
Contiguous (treated area)	-	0 (0%)	-	0 (0%)	-	-	-	-	-	0 (0%)
Remote (outside treated area)	-	1 (14.3%)	-	1 (1.8%)	-	-	-	-	-	2 (2.6%)
Distal Aorta	0 (0%)	0 (0%)	2 (3.1%)	0 (0%)	1 (1.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (3.9%)
Contiguous (treated area)	-	-	0 (0%)	-	0 (0%)	-	-	-	-	0 (0%)
Remote (outside treated area)	-	-	2 (3.1%)	-	1 (1.7%)	-	-	-	-	3 (3.9%)
Unknown	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Evaluable Subjects³ - excluding proximal graft landing Subjects	54	4	46	38	41	19	13	11	7	54
Proximal Aorta	0 (0%)	1 (25.0%)	0 (0%)	1 (2.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (3.7%)
Contiguous (treated area)	-	0 (0%)	-	0 (0%)	-	-	-	-	-	0 (0%)
Remote (outside treated area)	-	1 (25.0%)	-	1 (2.6%)	-	-	-	-	-	2 (3.7%)

¹Event percentages in this column may be an underestimation as 5 year follow-up is not complete.

²Restricted to those who initiated Endovascular Procedure. ³Denominators are the number of evaluable Subjects (Subject had either event or Core Lab assessment known at each interval). All included Subjects who initiated Endovascular Procedure are counted in the denominator in the Procedure and Total columns. For proximal aortic new dissections, the denominator is alternatively restricted to those with proximal landing zone not in a graft.

⁴Core Lab only dissections are Subjects with dissections detected by Core Lab who did not have a CEC-adjudicated adverse event dissection in the same time window.

⁵Dissections marked as both treated and untreated area are counted under treated area and not untreated area. If a new dissection on the same date is reported by both the Core Lab and the Site in a window with different location information, the treated area is selected over untreated area. If a Subject has multiple new dissection records within a few days of each other with very similar location information or missing location information in one record, only one new dissection is counted (with the known location information) in a time window for the Subject. Treated area refers to a new dissection contiguous with the proximal or distal margin of the stent graft in the aorta or distal margin of the stent graft in the treated branch. Outside treated area refers to a new dissection not contiguous with the proximal or distal margin of the stent graft in the aorta or distal margin of the stent graft in the treated branch. Study period definitions: Endovascular Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)

Life-threatening bleeds

There were seven subjects (7/77; 9.1%) within all Cohorts (five Aneurysm and two Dissection) reported as having a life-threatening bleed within 30 days of the index procedure.

Of the seven subjects, there were four with life-threatening bleeding events related to procedural device access. One additional subject experienced a procedural hemorrhage (adjudicated as a life-threatening bleed) as a result of an iliac artery rupture (not adjudicated as a life-threatening bleed). The procedural hemorrhage was not counted as a serious access issue, but the iliac artery rupture was.

Five of the subjects had a serious access issue (one iliac artery rupture, one puncture site hemorrhage, one iliac artery dissection, one retroperitoneal hematoma, and one procedural hemorrhage) at procedure.

Among these five subjects, one died within 30-Days and there was one protocol-defined reintervention required within 1-Month. The cause for the life-threatening bleeding events in the remaining two subjects included acute blood loss anemia (POD 15) that was ongoing at the time of subject's death on POD 48 from hypovolaemic shock and renal hemorrhage (POD 1) that resolved without sequelae on POD 30. Life-threatening bleeding events are summarized in **Table 30**.

Table 30: Life-Threatening Bleed (through 30 Days) for All Zone 0/1 Cohorts

	All Zone 0/1
Number of Enrolled Subjects¹	77
Subjects with Life-Threatening Bleed	7/77 (9.1%)
Had Serious Access Issue	5/7 (71.4%)
No Serious Access Issue	2/7 (28.6%)
30 Day Mortality	1/7 (14.3%)
1 Month Protocol-Defined Reintervention	1/7 (14.3%)
AEs Adjudicated as Life-Threatening Bleed²	
Blood loss anemia	1/7 (14.3%)
Iliac artery dissection	1/7 (14.3%)
Iliac artery rupture	1/7 (14.3%)
Procedural haemorrhage ³	1/7 (14.3%)
Puncture site hemorrhage	1/7 (14.3%)
Renal hemorrhage	1/7 (14.3%)
Retroperitoneal hematoma	1/7 (14.3%)
¹ Restricted to those who initiated Endovascular Procedure. ² MedDRA Preferred Term Reported, serious adverse events that CEC adjudicated as being a life-threatening bleed from the time of endovascular procedure. BOLDDED terms are those considered access issues. ³ One Subject experienced a procedural hemorrhage (adjudicated as a life-threatening bleed) as a result of an iliac artery rupture (not adjudicated as a life-threatening bleed). The procedural hemorrhage was not counted as a serious access issue, but the iliac artery rupture was.	

All-Cause Mortality including Lesion related Mortality

Table 31 and **Table 32** list the subject deaths for all Cohorts, summarizing both the all-cause and (CEC adjudicated) lesion-related mortality rates over absolute time window. Note that the lesion-related mortality rates shown in this table may be different than those shown in the Primary Endpoint and Treatment Success tables for all Cohorts as the windowing is different (table below uses the absolute windows and the Primary Endpoint and Treatment Success tables use the analysis windows).

Overall, there were 22 subject deaths (14 Aneurysm, seven Dissection, one Other Isolated Lesion); there were four subject deaths within 30 days and nine subjects died within 1 Year (POD 365). Of the 22 total deaths, 13 subject deaths were site reported as Unrelated to Device or Procedure, four were site reported as Unknown, three were site reported as Related to Endovascular Procedure and two were site reported as Related to Device and Endovascular Procedure.

There were five subjects (6.5%; 5/77) that died that met the definition of lesion-related mortality within the 1-Year follow-up timeframe. Of these subjects (two Aneurysm and one Dissection), three occurred within 30-days. The events that resulted in lesion-related mortality through 30-day included disabling stroke (POD6), pulseless electrical activity (POD 0), and ascending aortic dissection (POD 2) and were adjudicated as related to device and endovascular procedure.

Two deaths meeting the definition of lesion-related mortality occurred after 30-days: one subject experienced an aortic rupture (POD105) that was adjudicated as related to device and endovascular procedure and one subject experienced a descending thoracic aorta rupture (POD 156) and was adjudicated as unrelated to device and procedures.

Table 31: Mortality by Absolute Study Window for All Cohorts

	Follow-Up Absolute Time Window									
	Phase 1	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	>5 Years to Study End	Total ¹
Number of Enrolled Subjects²	77	77	73	69	62	32	26	20	6	77
Subjects with Mortality (All-Cause)	0 (0%)	4 (5.2%)	3 (4.1%)	2 (2.9%)	5 (8.1%)	2 (6.3%)	2 (7.7%)	4 (20.0%)	0 (0%)	22 (28.6%)
Subjects with CEC-Adjudicated Lesion-Related Mortality	0 (0%)	3 (3.9%)	2 (2.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (6.5%)

¹Event percentages in this column may be an underestimation as 5 year follow-up is not complete.
²Column header counts are the number of Subjects at risk at the start of each interval. There have been two Aneurysm Subject(s) excluded from this analysis due to treatment with 49/53 mm devices no longer supported by the protocol.
Study period definitions: Phase 1: revascularization procedure up to endovascular procedure 30 Days(0-30 days) 6 Months(31-182 days) 1 Year(183-365 days) 2 Years(366-731 days) 3 Years(732-1096 days) 4 Years(1097-1461 days) 5 Years(1462-1826 days) >5 Years to Study End(1827-2006 days) Total: (Phase 1 -2006 days)

Table 32: All Cohorts Deaths

Study Cohort	Study Day	Cause of Death (Associated AE) ¹	Site-Reported Relationship	Adjudicated AE Relationship ²	Adjudicated as Lesion-Related Mortality? ²
Aneurysm	519	Unknown cause of death	Unrelated to Device and Procedures	Unknown	No
Aneurysm	48	Hypovolemic shock	Unknown	Related to Endovascular Procedure	No
Aneurysm	969	Respiratory arrest	Unrelated to Device and Procedures	Unrelated to Device and Procedures	No
Aneurysm	105	Aortic rupture	Related to Device and Endovascular Procedure	Related to Device and Endovascular Procedure	Yes
Aneurysm	1247	Congestive heart failure	Unrelated to Device and Procedures	Unrelated to Device and Procedures	No
Aneurysm	6	Cerebral infarct	Related to Device and Endovascular Procedure	Related to Device and Endovascular Procedure	Yes
Aneurysm	1170	Congestive cardiac failure aggravated	Unrelated to Device and Procedures	Unknown	No
Aneurysm	0	Pulseless electrical activity	Related to Endovascular Procedure	Related to Endovascular Procedure	Yes
Aneurysm	220	Multi-organ failure	Unknown	Unknown	No
Aneurysm	501	Uremia	Unrelated to Device and Procedures	Unrelated to Device and Procedures	No
Aneurysm	2	Cardiogenic shock	Related to Endovascular Procedure	Related to Endovascular Procedure	No
Aneurysm	1762	Lymphoma	Unrelated to Device and Procedures	Unrelated to Device and Procedures	No
Aneurysm	1614	Unknown cause of death	Unknown	Unknown	No
Aneurysm	895	Acute hypoxic respiratory failure	Unrelated to Device and Procedures	Unrelated to Device and Procedures	No
Dissection	431	Unknown cause of death	Unknown	Unknown	No
Dissection	309	Pulmonary hemorrhage	Unrelated to Device and Procedures	Unrelated to Device and Procedures	No
Dissection	559	Descending thoracic aortic aneurysm enlargement	Unrelated to Device and Procedures	Unrelated to Device and Procedures	No
Dissection	464	Cardiac arrest	Unrelated to Device and Procedures	Unrelated to Device and Procedures	No
Dissection	1624	Unknown cause of death	Unrelated to Device and Procedures	Unrelated to Device and Procedures	No
Dissection	2	Dissecting aneurysm of aorta	Related to Endovascular Procedure	Related to Device and Endovascular Procedure	Yes
Dissection	156	Descending thoracic aorta rupture	Unrelated to Device and Procedures	Unrelated to Device and Procedures	Yes
Other Isolated Lesion	1569	Unknown cause of death	Unrelated to Device and Procedures	Unrelated to Device and Procedures	No

¹Based on site-reported data. Associated AE is reported as MedDRA Lower Level term.²Events occurring through 12-Month window (day 546) were adjudicated by CEC and events occurring after 12 Month window were adjudicated by Office of Medical Affairs

Endoleaks

Endoleaks were reported by both sites and Core Lab throughout the course of follow-up. While there are differences between the total number of subjects with Core Lab reported endoleaks (32) versus Site-reported endoleaks (21) through 12 months, this difference is mostly driven by differences in the reported number of subjects with indeterminate endoleaks by Core Lab (22 versus four).

During previous assessments of Core Lab and site-reported endoleaks it was determined that while Core Lab-reported indeterminate and Type II endoleak rates were higher than site reported rates, it appeared that sites reported endoleaks the investigator deemed to be clinically significant and/or sites have categorized them differently (i.e., a different endoleak Type). Core Lab and sites reported similar numbers of subjects with identifiable endoleaks (20 and 18 respectively). The analysis of site-and Core Lab-reported endoleaks suggests that sites are appropriately detecting and treating, as appropriate to the patient, Type I/III endoleaks and Type II endoleaks associated with arch branch vessels.

Endoleaks reported by Core Lab or the site are summarized by Study Period in **Table 33** through **Table 38** for Aneurysm and Dissection Cohorts and all cohorts. One subject in the Other Isolated Lesion Cohort had an indeterminate endoleak reported by the Core Lab at the 1-Month and 6-Month follow-up windows and no Site-reported endoleaks (tables not shown). Details regarding each type of endoleak and associated clinical sequelae are provide under the table. The majority of Type I endoleaks reported by the site and Core Lab were Type IB, with most presenting later in follow-up and likely due to disease progression. No subjects have experienced aortic rupture or lesion-related mortality associated with a site or Core Lab-reported endoleak. There have been seven subjects with site- and Core Lab-reported endoleaks with Core Lab-reported aortic enlargement (discussed under Key Events – Aortic enlargement). An analysis was conducted to evaluate the combined Type I/III endoleak rate relative to the limited information available on rates of endoleak reported for hybrid TEVAR, and no substantive clinically meaningful differences were noted. In addition, language specific to the prevention and monitoring of Type II endoleaks from arch branch vessels was added to the instructions for use.

Table 33: Core Lab Endoleak Findings by Analysis Study Window for Aneurysm Cohort

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Enrolled Subjects ²	49	47	46	43	28	17	14	8	49
Evaluable Subjects ³	5	43	39	39	23	15	9	6	45
Subjects with any below device event finding in window	1/5 (20.0%)	18/43 (41.9%)	13/39 (33.3%)	12/39 (30.8%)	4/23 (17.4%)	7/15 (46.7%)	5/9 (55.6%)	5/6 (83.3%)	23/45 (51.1%)
Device event findings									
Endoleak	1/3 (33.3%)	17/43 (39.5%)	12/36 (33.3%)	11/38 (28.9%)	4/20 (20.0%)	7/13 (53.8%)	5/9 (55.6%)	5/6 (83.3%)	22/45 (48.9%)
Type I	0/3 (0%)	2/43 (4.7%)	1/36 (2.8%)	1/38 (2.6%)	0/20 (0%)	1/13 (7.7%)	0/9 (0%)	1/6 (16.7%)	4/45 (8.9%)
Type IA	-	0/43 (0%)	0/36 (0%)	0/38 (0%)	-	0/13 (0%)	-	0/6 (0%)	0/45 (0%)
Type IB	-	2/43 (4.7%)	1/36 (2.8%)	1/38 (2.6%)	-	1/13 (7.7%)	-	0/6 (0%)	3/45 (6.7%)
Type IC	-	0/43 (0%)	0/36 (0%)	0/38 (0%)	-	0/13 (0%)	-	1/6 (16.7%)	1/45 (2.2%)
Type II	1/3 (33.3%)	6/43 (14.0%)	6/36 (16.7%)	6/38 (15.8%)	3/20 (15.0%)	4/13 (30.8%)	4/9 (44.4%)	3/6 (50.0%)	10/45 (22.2%)
Type III	0/3 (0%)	1/43 (2.3%)	1/36 (2.8%)	1/38 (2.6%)	1/20 (5.0%)	0/13 (0%)	0/9 (0%)	0/6 (0%)	2/45 (4.4%)
Type IIIA	-	0/43 (0%)	0/36 (0%)	0/38 (0%)	0/20 (0%)	-	-	-	0/45 (0%)
Type IIIB	-	0/43 (0%)	0/36 (0%)	0/38 (0%)	0/20 (0%)	-	-	-	0/45 (0%)
Type III Indeterminate	-	1/43 (2.3%)	1/36 (2.8%)	1/38 (2.6%)	1/20 (5.0%)	-	-	-	2/45 (4.4%)
Type IV	0/3 (0%)	0/43 (0%)	0/36 (0%)	0/38 (0%)	0/20 (0%)	0/13 (0%)	0/9 (0%)	0/6 (0%)	0/45 (0%)
Indeterminate	0/3 (0%)	9/43 (20.9%)	4/36 (11.1%)	4/38 (10.5%)	1/20 (5.0%)	4/13 (30.8%)	2/9 (22.2%)	2/6 (33.3%)	14/45 (31.1%)
NOTE: CTAG device event findings are included in this table.									
¹ Event percentages in this column may be an underestimation as 5 year follow-up is not complete.									
² Restricted to those who initiated Endovascular Procedure. Column header counts are the number of Subjects at risk at the start of each interval. There have been two Aneurysm Subject(s) excluded from this analysis due to treatment with 49/53 mm devices no longer supported by the protocol.									
³ Denominators for each device finding category time window are the number of evaluable Subjects (Subject had either CT or MR done in window) with a known evaluation in each window.									
Time window definitions: Post-Procedure(1 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-1980 days) Total(1-2006 days)									

Table 34: Site-Reported Endoleaks by Analysis Study Window for Aneurysm Cohort

	Follow-Up Visit Time Window									
	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Subjects ²	50	49	47	46	43	28	17	14	8	50
Evaluable Subjects ³	50	8	43	40	40	24	15	10	6	50
Subjects With One or More Endoleak Ongoing in Window	2 (4.0%)	3 (37.5%)	9 (20.9%)	10 (25.0%)	9 (22.5%)	6 (25.0%)	6 (40.0%)	6 (60.0%)	4 (66.7%)	14 (28.0%)
New	2 (4.0%)	2 (25.0%)	8 (18.6%)	3 (7.5%)	0 (0%)	1 (4.2%)	3 (20.0%)	1 (10.0%)	0 (0%)	-
Ongoing	-	1 (12.5%)	2 (4.7%)	8 (20.0%)	9 (22.5%)	6 (25.0%)	5 (33.3%)	5 (50.0%)	4 (66.7%)	-
Type I	1 (2.0%)	0 (0%)	2 (4.7%)	1 (2.5%)	1 (2.5%)	1 (4.2%)	2 (13.3%)	2 (20.0%)	0 (0%)	6 (12.0%)
New	1 (2.0%)	-	2 (4.7%)	0 (0%)	0 (0%)	1 (4.2%)	1 (6.7%)	1 (10.0%)	-	-
Type IA	0 (0%)	-	1 (2.3%)	-	-	0 (0%)	0 (0%)	0 (0%)	-	1 (2.0%)
Type IB	1 (2.0%)	-	1 (2.3%)	-	-	1 (4.2%)	1 (6.7%)	1 (10.0%)	-	5 (10.0%)
Type IC	0 (0%)	-	0 (0%)	-	-	0 (0%)	0 (0%)	0 (0%)	-	0 (0%)
Ongoing	-	-	0 (0%)	1 (2.5%)	1 (2.5%)	0 (0%)	1 (6.7%)	1 (10.0%)	-	-
Type II	1 (2.0%)	1 (12.5%)	4 (9.3%)	7 (17.5%)	6 (15.0%)	5 (20.8%)	5 (33.3%)	5 (50.0%)	4 (66.7%)	10 (20.0%)
New	1 (2.0%)	0 (0%)	4 (9.3%)	3 (7.5%)	0 (0%)	0 (0%)	2 (13.3%)	1 (10.0%)	0 (0%)	10 (20.0%)
Ongoing	-	1 (12.5%)	0 (0%)	4 (10.0%)	6 (15.0%)	5 (20.8%)	4 (26.7%)	4 (40.0%)	4 (66.7%)	-
Type III	0 (0%)	1 (12.5%)	2 (4.7%)	2 (5.0%)	1 (2.5%)	1 (4.2%)	1 (6.7%)	0 (0%)	0 (0%)	2 (4.0%)
New	-	1 (12.5%)	1 (2.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	-	-	-
Type IIIA	-	0 (0%)	1 (2.3%)	-	-	-	-	-	-	1 (2.0%)
Type IIIB	-	0 (0%)	0 (0%)	-	-	-	-	-	-	0 (0%)
Type III Indeterminate	-	1 (12.5%)	0 (0%)	-	-	-	-	-	-	1 (2.0%)
Ongoing	-	0 (0%)	1 (2.3%)	2 (5.0%)	1 (2.5%)	1 (4.2%)	1 (6.7%)	-	-	-
Indeterminate	0 (0%)	1 (12.5%)	2 (4.7%)	2 (5.0%)	2 (5.0%)	1 (4.2%)	1 (6.7%)	1 (10.0%)	0 (0%)	2 (4.0%)
New	-	1 (12.5%)	1 (2.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	-	-
Ongoing	-	0 (0%)	1 (2.3%)	2 (5.0%)	2 (5.0%)	1 (4.2%)	1 (6.7%)	1 (10.0%)	-	-
Subjects With No Endoleak Ongoing in Window	48 (96.0%)	5 (62.5%)	34 (79.1%)	30 (75.0%)	31 (77.5%)	18 (75.0%)	9 (60.0%)	4 (40.0%)	2 (33.3%)	36 (72.0%)
NOTE: CTAG endoleaks are included in this table.										
¹ Event percentages in this column may be an underestimation as 5 year follow-up is not complete.										
² Restricted to those who initiated Endovascular Procedure. Column header counts are the number of Subjects at risk at the start of each interval. There have been two Aneurysm Subject(s) excluded from this analysis due to treatment with 49/53 mm devices no longer supported by the protocol.										
³ Denominators are the number of evaluable Subjects (Subject had either CT or MR done in window or ongoing endoleak at each interval). All included Subjects who initiated Endovascular Procedure are counted in the denominator in the Procedure and Total columns. All percentages are calculated based on the number of evaluable Subjects in each window.										
Study period definitions: Endovascular Procedure(0 days) Post-Procedure (1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)										

Table 35: Core Lab Endoleak Findings by Analysis Study Window for Zone 0/1 Dissection Cohort

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Enrolled Subjects²	24	23	23	22	12	9	8	4	24
Evaluable Subjects³	2	21	22	20	8	7	6	4	23
Subjects with any below device event finding in window	2/2 (100.0%)	9/21 (42.9%)	4/22 (18.2%)	4/20 (20.0%)	2/8 (25.0%)	2/7 (28.6%)	1/6 (16.7%)	1/4 (25.0%)	9/23 (39.1%)
Device event findings									
Endoleak	2/2 (100.0%)	9/21 (42.9%)	4/20 (20.0%)	4/19 (21.1%)	2/7 (28.6%)	2/6 (33.3%)	1/6 (16.7%)	1/4 (25.0%)	9/23 (39.1%)
Type I	0/2 (0%)	1/21 (4.8%)	1/20 (5.0%)	0/19 (0%)	0/7 (0%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	1/23 (4.3%)
Type IA	-	1/21 (4.8%)	1/20 (5.0%)	-	-	-	-	-	1/23 (4.3%)
Type IB	-	0/21 (0%)	0/20 (0%)	-	-	-	-	-	0/23 (0%)
Type IC	-	0/21 (0%)	0/20 (0%)	-	-	-	-	-	0/23 (0%)
Type II	1/2 (50.0%)	4/21 (19.0%)	1/20 (5.0%)	1/19 (5.3%)	1/7 (14.3%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	5/23 (21.7%)
Source (Dissection cohort only)									
Innominate	0/1 (0%)	0/4 (0%)	0/1 (0%)	0/1 (0%)	0/1 (0%)	-	-	-	0/5 (0%)
LCCA	0/1 (0%)	0/4 (0%)	0/1 (0%)	0/1 (0%)	0/1 (0%)	-	-	-	0/5 (0%)
LSA	1/1 (100.0%)	2/4 (50.0%)	1/1 (100.0%)	0/1 (0%)	0/1 (0%)	-	-	-	2/5 (40.0%)
Vertebral	0/1 (0%)	0/4 (0%)	0/1 (0%)	0/1 (0%)	0/1 (0%)	-	-	-	0/5 (0%)
Intercostal	0/1 (0%)	1/4 (25.0%)	0/1 (0%)	1/1 (100.0%)	1/1 (100.0%)	-	-	-	2/5 (40.0%)
Bronchials	0/1 (0%)	1/4 (25.0%)	0/1 (0%)	0/1 (0%)	0/1 (0%)	-	-	-	1/5 (20.0%)
Other	0/1 (0%)	0/4 (0%)	0/1 (0%)	0/1 (0%)	0/1 (0%)	-	-	-	0/5 (0%)
Type III	0/2 (0%)	0/21 (0%)	1/20 (5.0%)	0/19 (0%)	0/7 (0%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	1/23 (4.3%)
Type IIIA	-	-	0/20 (0%)	-	-	-	-	-	0/23 (0%)
Type IIIB	-	-	0/20 (0%)	-	-	-	-	-	0/23 (0%)
Type III Indeterminate	-	-	1/20 (5.0%)	-	-	-	-	-	1/23 (4.3%)
Type IV	0/2 (0%)	0/21 (0%)	0/20 (0%)	0/19 (0%)	0/7 (0%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	0/23 (0%)
Indeterminate	1/2 (50.0%)	5/21 (23.8%)	1/20 (5.0%)	4/19 (21.1%)	2/7 (28.6%)	2/6 (33.3%)	1/6 (16.7%)	1/4 (25.0%)	7/23 (30.4%)
NOTE: CTAG device event findings are included in this table.									
¹ Event percentages in this column may be an underestimation as 5 year follow-up is not complete.									
² Restricted to those who initiated Endovascular Procedure. Column header counts are the number of Subjects at risk at the start of each interval.									
³ Denominators for each device finding category time window are the number of evaluable Subjects (Subject had either CT or MR done in window) with a known evaluation in each window.									
Study period definitions: Post-Procedure(1 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(1-2006 days)									

Table 36: Site-Reported Endoleaks by Analysis Study Window for Zone 0/1 Dissection Cohort

	Follow-Up Visit Time Window									
	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Subjects²	24	24	23	23	22	12	9	8	4	24
Evaluable Subjects³	24	4	21	23	21	8	7	7	4	24
Subjects With One or More Endoleak Ongoing in Window	1 (4.2%)	3 (75.0%)	4 (19.0%)	6 (26.1%)	5 (23.8%)	2 (25.0%)	1 (14.3%)	1 (14.3%)	0 (0%)	7 (29.2%)
New	1 (4.2%)	2 (50.0%)	2 (9.5%)	2 (8.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	-	-
Ongoing	-	1 (25.0%)	2 (9.5%)	4 (17.4%)	5 (23.8%)	2 (25.0%)	1 (14.3%)	1 (14.3%)	-	-
Type I	0 (0%)	1 (25.0%)	0 (0%)	1 (4.3%)	1 (4.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8.3%)
New	-	1 (25.0%)	-	1 (4.3%)	0 (0%)	-	-	-	-	-
Type IA	-	1 (25.0%)	-	1 (4.3%)	-	-	-	-	-	2 (8.3%)
Type IB	-	0 (0%)	-	0 (0%)	-	-	-	-	-	0 (0%)
Type IC	-	0 (0%)	-	0 (0%)	-	-	-	-	-	0 (0%)
Ongoing	-	0 (0%)	-	0 (0%)	1 (4.8%)	-	-	-	-	-
Type II	0 (0%)	1 (25.0%)	1 (4.8%)	2 (8.7%)	2 (9.5%)	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	2 (8.3%)
New	-	1 (25.0%)	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	-	-	-	2 (8.3%)
Source (Dissection cohort only)										
Innominate	-	0 (0%)	-	0 (0%)	-	-	-	-	-	0 (0%)
LCCA	-	0 (0%)	-	0 (0%)	-	-	-	-	-	0 (0%)
LSA	-	0 (0%)	-	1 (100.0%)	-	-	-	-	-	1 (50.0%)
Vertebral	-	0 (0%)	-	0 (0%)	-	-	-	-	-	0 (0%)
Intercostal	-	1 (100.0%)	-	0 (0%)	-	-	-	-	-	1 (50.0%)
Bronchials	-	0 (0%)	-	0 (0%)	-	-	-	-	-	0 (0%)
Other	-	0 (0%)	-	0 (0%)	-	-	-	-	-	0 (0%)
Ongoing	-	0 (0%)	1 (4.8%)	1 (4.3%)	2 (9.5%)	1 (12.5%)	-	-	-	-
Type III	0 (0%)	0 (0%)	1 (4.8%)	1 (4.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4.2%)
New	-	-	1 (4.8%)	0 (0%)	-	-	-	-	-	-
Type IIIA	-	-	0 (0%)	-	-	-	-	-	-	0 (0%)
Type IIIB	-	-	0 (0%)	-	-	-	-	-	-	0 (0%)
Type III Indeterminate	-	-	1 (4.8%)	-	-	-	-	-	-	1 (4.2%)
Ongoing	-	-	0 (0%)	1 (4.3%)	-	-	-	-	-	-
Indeterminate	1 (4.2%)	1 (25.0%)	2 (9.5%)	2 (8.7%)	2 (9.5%)	1 (12.5%)	1 (14.3%)	1 (14.3%)	0 (0%)	2 (8.3%)
New	1 (4.2%)	0 (0%)	1 (4.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	-	-
Ongoing	-	1 (25.0%)	1 (4.8%)	2 (8.7%)	2 (9.5%)	1 (12.5%)	1 (14.3%)	1 (14.3%)	-	-
Subjects With No Endoleak Ongoing in Window	23 (95.8%)	1 (25.0%)	17 (81.0%)	17 (73.9%)	16 (76.2%)	6 (75.0%)	6 (85.7%)	6 (85.7%)	4 (100.0%)	17 (70.8%)

	Follow-Up Visit Time Window									
	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
NOTE: CTAG endoleaks are included in this table.										
¹ Event percentages in this column may be an underestimation as 5 year follow-up is not complete.										
² Restricted to those who initiated Endovascular Procedure. Column header counts are the number of Subjects at risk at the start of each interval.										
³ Denominators are the number of evaluable Subjects (Subject had either CT or MR done in window or ongoing endoleak at each interval). All included Subjects who initiated Endovascular Procedure are counted in the denominator in the Procedure and Total columns. All percentages are calculated based on the number of evaluable Subjects in each window except percentages for Source of Type II endoleaks are among those with new Type II endoleaks.										
Study period definitions: Endovascular Procedure(0 days) Post--Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)										

Table 37: Core Lab Endoleak Findings by Analysis Study Window for All Cohorts

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Enrolled Subjects ²	76	73	72	68	41	27	23	12	76
Evaluable Subjects ³	7	67	63	61	32	23	16	10	71
Subjects with any below device event finding in window	3/7 (42.9%)	28/67 (41.8%)	18/63 (28.6%)	16/61 (26.2%)	6/32 (18.8%)	9/23 (39.1%)	6/16 (37.5%)	6/10 (60.0%)	33/71 (46.5%)
Device event findings									
Endoleak	3/5 (60.0%)	27/67 (40.3%)	17/58 (29.3%)	15/59 (25.4%)	6/28 (21.4%)	9/20 (45.0%)	6/16 (37.5%)	6/10 (60.0%)	32/71 (45.1%)
Type I	0/5 (0%)	3/67 (4.5%)	2/58 (3.4%)	1/59 (1.7%)	0/28 (0%)	1/20 (5.0%)	0/16 (0%)	1/10 (10.0%)	5/71 (7.0%)
Type IA	-	1/67 (1.5%)	1/58 (1.7%)	0/59 (0%)	-	0/20 (0%)	-	0/10 (0%)	1/71 (1.4%)
Type IB	-	2/67 (3.0%)	1/58 (1.7%)	1/59 (1.7%)	-	1/20 (5.0%)	-	0/10 (0%)	3/71 (4.2%)
Type IC	-	0/67 (0%)	0/58 (0%)	0/59 (0%)	-	0/20 (0%)	-	1/10 (10.0%)	1/71 (1.4%)
Type II	2/5 (40.0%)	10/67 (14.9%)	7/58 (12.1%)	7/59 (11.9%)	4/28 (14.3%)	4/20 (20.0%)	4/16 (25.0%)	3/10 (30.0%)	15/71 (21.1%)
Type III	0/5 (0%)	1/67 (1.5%)	2/58 (3.4%)	1/59 (1.7%)	1/28 (3.6%)	0/20 (0%)	0/16 (0%)	0/10 (0%)	3/71 (4.2%)
Type IIIA	-	0/67 (0%)	0/58 (0%)	0/59 (0%)	0/28 (0%)	-	-	-	0/71 (0%)
Type IIIB	-	0/67 (0%)	0/58 (0%)	0/59 (0%)	0/28 (0%)	-	-	-	0/71 (0%)
Type III Indeterminate	-	1/67 (1.5%)	2/58 (3.4%)	1/59 (1.7%)	1/28 (3.6%)	-	-	-	3/71 (4.2%)
Type IV	0/5 (0%)	0/67 (0%)	0/58 (0%)	0/59 (0%)	0/28 (0%)	0/20 (0%)	0/16 (0%)	0/10 (0%)	0/71 (0%)
Indeterminate	1/5 (20.0%)	15/67 (22.4%)	6/58 (10.3%)	8/59 (13.6%)	3/28 (10.7%)	6/20 (30.0%)	3/16 (18.8%)	3/10 (30.0%)	22/71 (31.0%)
NOTE: CTAG device event findings are included in this table.									
¹ Event percentages in this column may be an underestimation as 5 year follow-up is not complete.									
² Restricted to those who initiated Endovascular Procedure. Column header counts are the number of Subjects at risk at the start of each interval. There have been two Zone 0/1 Aneurysm Subject(s) excluded from this analysis due to treatment with 49/53 mm devices no longer supported by the protocol.									
³ Denominators for each device finding category time window are the number of evaluable Subjects (Subject had either CT or MR done in window) with a known evaluation in each window.									
Study period definitions: Post-Procedure(1 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(1-2006 days)									

Table 38: Site-Reported Endoleaks by Analysis Study Window for All Cohorts

	Follow-Up Visit Time Window									
	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Subjects²	77	76	73	72	68	41	27	23	12	77
Evaluable Subjects³	77	12	67	65	63	33	23	18	10	77
Subjects With One or More Endoleak Ongoing in Window	3 (3.9%)	6 (50.0%)	13 (19.4%)	16 (24.6%)	14 (22.2%)	8 (24.2%)	7 (30.4%)	7 (38.9%)	4 (40.0%)	21 (27.3%)
New	3 (3.9%)	4 (33.3%)	10 (14.9%)	5 (7.7%)	0 (0%)	1 (3.0%)	3 (13.0%)	1 (5.6%)	0 (0%)	-
Ongoing	-	2 (16.7%)	4 (6.0%)	12 (18.5%)	14 (22.2%)	8 (24.2%)	6 (26.1%)	6 (33.3%)	4 (40.0%)	-
Type I	1 (1.3%)	1 (8.3%)	2 (3.0%)	2 (3.1%)	2 (3.2%)	1 (3.0%)	2 (8.7%)	2 (11.1%)	0 (0%)	8 (10.4%)
New	1 (1.3%)	1 (8.3%)	2 (3.0%)	1 (1.5%)	0 (0%)	1 (3.0%)	1 (4.3%)	1 (5.6%)	-	-
Type IA	0 (0%)	1 (8.3%)	1 (1.5%)	1 (1.5%)	-	0 (0%)	0 (0%)	0 (0%)	-	3 (3.9%)
Type IB	1 (1.3%)	0 (0%)	1 (1.5%)	0 (0%)	-	1 (3.0%)	1 (4.3%)	1 (5.6%)	-	5 (6.5%)
Type IC	0 (0%)	0 (0%)	0 (0%)	0 (0%)	-	0 (0%)	0 (0%)	0 (0%)	-	0 (0%)
Ongoing	-	0 (0%)	0 (0%)	1 (1.5%)	2 (3.2%)	0 (0%)	1 (4.3%)	1 (5.6%)	-	-
Type II	1 (1.3%)	2 (16.7%)	5 (7.5%)	9 (13.8%)	8 (12.7%)	6 (18.2%)	5 (21.7%)	5 (27.8%)	4 (40.0%)	12 (15.6%)
New	1 (1.3%)	1 (8.3%)	4 (6.0%)	4 (6.2%)	0 (0%)	0 (0%)	2 (8.7%)	1 (5.6%)	0 (0%)	12 (15.6%)
Ongoing	-	1 (8.3%)	1 (1.5%)	5 (7.7%)	8 (12.7%)	6 (18.2%)	4 (17.4%)	4 (22.2%)	4 (40.0%)	-
Type III	0 (0%)	1 (8.3%)	3 (4.5%)	3 (4.6%)	1 (1.6%)	1 (3.0%)	1 (4.3%)	0 (0%)	0 (0%)	3 (3.9%)
New	-	1 (8.3%)	2 (3.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	-	-	-
Type IIIA	-	0 (0%)	1 (1.5%)	-	-	-	-	-	-	1 (1.3%)
Type IIIB	-	0 (0%)	0 (0%)	-	-	-	-	-	-	0 (0%)
Type III Indeterminate	-	1 (8.3%)	1 (1.5%)	-	-	-	-	-	-	2 (2.6%)
Ongoing	-	0 (0%)	1 (1.5%)	3 (4.6%)	1 (1.6%)	1 (3.0%)	1 (4.3%)	-	-	-
Indeterminate	1 (1.3%)	2 (16.7%)	4 (6.0%)	4 (6.2%)	4 (6.3%)	2 (6.1%)	2 (8.7%)	2 (11.1%)	0 (0%)	4 (5.2%)
New	1 (1.3%)	1 (8.3%)	2 (3.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	-	-
Ongoing	-	1 (8.3%)	2 (3.0%)	4 (6.2%)	4 (6.3%)	2 (6.1%)	2 (8.7%)	2 (11.1%)	-	-
Subjects With No Endoleak Ongoing in Window	74 (96.1%)	6 (50.0%)	54 (80.6%)	49 (75.4%)	49 (77.8%)	25 (75.8%)	16 (69.6%)	11 (61.1%)	6 (60.0%)	56 (72.7%)

NOTE: CTAG endoleaks are included in this table.
¹Event percentages in this column may be an underestimation as 5 year follow-up is not complete.
²Restricted to those who initiated Endovascular Procedure. Column header counts are the number of Subjects at risk at the start of each interval. There have been two Aneurysm Subject(s) excluded from this analysis due to treatment with 49/53 mm devices no longer supported by the protocol.
³Denominators are the number of evaluable Subjects (Subject had either CT or MR done in window or ongoing endoleak at each interval). All included Subjects who initiated Endovascular Procedure are counted in the denominator in the Procedure and Total columns. All percentages are calculated based on the number of evaluable Subjects in each window.
Study period definitions: Endovascular Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)

Type I Endoleaks

Five subjects had Core Lab reported Type I endoleak through all available follow-up. One subject experienced a Type IA endoleak (no treatment and no endoleak-related clinical sequelae). Three subjects experienced a Type IB endoleak, and two of the three subjects had treatment (endoleak resolved without sequelae). One of these subjects was also treated for a Type II endoleak. The untreated subject had no endoleak-related clinical sequelae. One subject experienced a Type IC endoleak (no treatment and no endoleak-related clinical sequelae).

Eight subjects experienced a site-reported Type I endoleak through all available follow-up. One additional subject had a site-reported Type IA or Type III (which was coded as an IND endoleak). This subject has not had any treatment related to the reported endoleaks. Five subjects were treated for the Type I endoleak:

- One subject had a Type IB endoleak (POD 1089) treated with Thoracic Aortic Stent graft placement (POD 1161) which resolved without sequelae.
- One subject had a Type IB endoleak (POD 25) treated with Thoracic Aortic Stent graft placement (POD 28) which resolved without sequelae.
 - *After later reviewing the imaging, the Investigator believed that the subject may not have had a Type IB endoleak as originally reported, but what was seen on CT was the early stages of graft infection.*
- One subject had a Type IB endoleak during the index endovascular procedure (POD 0) which was treated with Thoracic Aortic Stent graft placement (POD 0). The subject experienced pulseless electrical activity and died POD 0. The death was CEC adjudicated as meeting the definition of lesion-related mortality. The site-reported and CEC adjudicated relationship was Related to Endovascular Procedure.
- One subject had a Type IA endoleak (POD 2) treated with Thoracic Aortic Stent graft placement (POD 5) which resolved with sequelae (multiple adverse events which all resolved without sequelae).
- One subject had a Type IB endoleak (POD 1556) which was treated with Thoracic Aortic Stent graft placement (POD 1603) which resolved without sequelae.

Three subjects with Core Lab or site-reported Type I endoleaks had Core Lab reported aortic enlargement reported (discussed under Key Events – Aortic enlargement) and one subject experienced an aortic rupture unrelated to the endoleak (discussed under Key Events – Aortic Rupture).

Type II Endoleaks

There were 15 subjects that had a Core Lab reported Type II endoleak through all available follow-up. Five subjects with Core Lab-reported Type II endoleaks were treated for either a Type II or other type of endoleak and for all subjects the adverse event resolved with or without sequelae. Two subjects were treated for Type II endoleaks (resolved without sequelae), one subject was treated for a Type IA endoleak (no Site-reported Type II endoleak), and two subjects were treated for a Type IB endoleak (both subjects also had Site-reported Type II endoleaks that were

not treated).

Twelve subjects experienced a site-reported Type II endoleak through all available follow-up. Four subjects were treated (via embolization on POD 1, 154, 254, and 951) for the Type II endoleak and for all of these subjects, the endoleak resolved without sequelae.

Five subjects with Core Lab or site-reported Type II endoleaks had Core Lab-reported aortic enlargement reported (discussed under Key Events – Aortic enlargement)

Type III Endoleaks

Three subjects experienced a Core Lab reported Type III endoleak through all available follow-up and one subject with a Core Lab-reported Type III endoleak was treated for a Type III endoleak (resolved without sequelae). Two subjects with Core Lab reported Type III endoleaks were treated for other types of endoleaks (one subject for a Type IA endoleak, which was not Core Lab reported and one subject for a Type II endoleak, which was also Core Lab reported).

Three subjects experienced a site-reported Type III endoleak through all available follow-up. One subject was treated for the Type III endoleak. On POD 84 the subject underwent selective innominate artery cannulation, placement of a SB component and Viabahn extension. On POD 237 the subject was converted to open repair and the endoleak was resolved. One additional subject had a site-reported Type IA or Type III (which was coded as an IND endoleak). This subject has not had any treatment related to the reported endoleak.

Two subjects with Core Lab or Site-reported Type III endoleaks had Core Lab-reported aortic enlargement reported (discussed under Key Events – Aortic enlargement) and one subject experienced an aortic rupture unrelated to the endoleak (discussed under Key Events – Aortic Rupture).

Indeterminate (IND) Endoleaks

There were 22 subjects that experienced a Core Lab-reported IND endoleak through all available follow-up. Seven subjects with IND endoleaks identified only by the Core Lab, also had other types of site-reported endoleaks and three subjects had treatment for endoleaks. One subject underwent embolization for a Type II endoleak prior to the Core Lab-reported IND endoleak and had a Site-reported Type IA endoleak (untreated). Two subjects underwent treatment for site reported Type II endoleaks after the Core Lab assessment of the IND endoleaks.

Four subjects experienced a Site-reported IND endoleak through all available follow-up, none of which were treated.

Five subjects with Core Lab or Site-reported IND endoleaks had Core Lab-reported aortic enlargement reported (discussed under Key Events – Aortic enlargement) and one subject experienced an aortic rupture unrelated to the endoleak (discussed under Key Events – Aortic Rupture).

Loss of Patency

Two subjects (2.6%, 2/77) within all Cohorts (Aneurysm) experienced loss of aortic or aortic branch patency.

- One subject experienced right common carotid artery to left subclavian artery bypass graft occlusion during the endovascular procedure, requiring re-do bilateral neck exploration, right CCA to left SCA bypass graft thrombectomy, and left CCA thrombectomy on the same day. The event resolved without sequelae on the same day.
- One subject experienced loss of LCCA side branch patency reported by the Core Lab from imaging taken at the 1-Month, 6-Month, and 12-Month follow up visits. No adverse events or treatment related to loss of patency has been reported and the event is ongoing.

Aortic Rupture

Two subjects (2.6%; 2/77) within all Cohorts (one Aneurysm and one Dissection) experienced an aortic rupture.

- One aneurysm subject experienced a ruptured aorta on POD 105 due to aorto-esophageal fistula that developed because of a graft infection. This event resulted in the subject's death on same day. CEC adjudicated the death as related to device and endovascular procedure.
- One dissection subject had an aortic rupture on POD 65. On POD 52, the subject was hospitalized due to both a urinary tract infection and sepsis. The urinary tract infection resolved without sequelae on POD 59. The subject remained hospitalized, and the sepsis was not resolved at the time of death. Imaging on POD 93 revealed a descending thoracic aorta rupture. The rupture was determined to be due to inflammatory reaction caused by sepsis, which occurred in the aortic wall. The subject later expired, POD 156, and the death was also adjudicated to lesion-related mortality. CEC adjudicated the death as unrelated to device and endovascular procedure.

Aortic enlargement

There were eight subjects (12.5%) for all cohorts (six Aneurysm, one Dissection, one Other Isolated Lesion) with aortic enlargement as assessed by Core Lab as of the data export. There have been no reports of aneurysm rupture or unexplained / sudden death for any of these subjects.

- Two subjects were treated for endoleaks (Type II endoleaks originating from the aortic arch for two subjects and one subject was also treated for a Type IB endoleak).
- Two subjects did not have treatment for their aortic enlargement but saw regression of their aorta after initial enlargement. One subject presented with Type II endoleak from an intercostal, and the other subject presented with false lumen perfusion.
- One subject had aortic enlargement in the 60-Month follow-up window which

was untreated at the time of data export.

- Two subjects withdrew from this Study without reported treatment for the aortic enlargement.
- One subject died from unrelated causes prior to treatment.

False Lumen Perfusion and False Lumen Status: Dissection Cohort Only

There were no reports from the Core Lab of false lumen perfusion through the primary intimal tear.

False lumen perfusion through an aortic arch branch vessel was reported in three (3/21; 14.3%) subjects by the Core Lab with flow from the LCCA in one subject and from the LSA in two subjects. Two subjects had no Core Lab report of aortic enlargement and no site-reported Type II endoleaks. One subject had no Core Lab report of aortic enlargement and had a site reported a Type II stent-graft endoleak. There was no treatment to resolve the endoleak and it remains ongoing.

The majority of the false lumen perfusions reported were through a non-aortic arch branch vessel (19/23; 82.6%). This is not unexpected when considering the majority of subjects presented with dissections extending distally between Zone 6 and Zone 10/11 (19/24; 79.2% per **Table 8** among those with distal extent assessable) and the majority of these vessels are outside of the treated segment of aorta, and provide the on-going potential to continue perfusing the false lumen.

False lumen perfusion from the proximal aorta was observed in three (3/22; 13.6%) subjects. There were no Core Lab reports of aortic enlargement. One subject had a stent graft placement on POD 5 for the false lumen perfusion due to a Type IA endoleak on POD 2 that resolved with sequelae. The investigator did not consider this an unanticipated reintervention.

False lumen perfusion from the distal aorta was reported in 19 subjects (19/22; 86.4%). There was one subject with aortic enlargement reported by Core Lab (first reported at 6-Months). This subject did not undergo any treatment for the aortic enlargement and no aortic enlargement was reported at the 60-Month follow-up. One subject had descending thoracic aortic aneurysm enlargement reported by the site at 24 Months. A surgical repair was attempted for treatment of thoracoabdominal aortic aneurysm (POD 559) along with a left heart bypass, however the subject did not survive the procedure. The death was adjudicated as unrelated to device and procedure.

False Lumen Status: Dissection Cohort Only

All subjects had partial or complete thrombosis in the treated segment by the 1-Month window. The percent of subjects with complete thrombosis in the treated segment is, in general, increasing in follow-up as presented in **Table 39**. All subjects have a patent or partially thrombosed false lumen in the distal (untreated) aorta (an additional ‘other outcome’). However, the percent of subjects with partial thrombosis in the distal aorta increases in follow-up while the percentage of subjects with patent false lumen in the distal aorta decreases in the follow-up.

Table 39: Core Lab False Lumen Perfusion and Status by Analysis Study Window for Dissection Cohort

	Follow-Up Visit Time Window								
	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Number of Subjects ²	24	23	23	22	12	9	8	4	24
Number of Subjects with Imaging ³	2	21	22	20	8	7	6	4	23
False Lumen Perfusion through primary intimal tear ⁴	0/2 (0%)	0/21 (0%)	0/21 (0%)	0/19 (0%)	0/7 (0%)	0/7 (0%)	0/6 (0%)	0/4 (0%)	0/23 (0%)
False Lumen Perfusion - Source of Perfusion: Proximal Aorta	1/2 (50.0%)	2/20 (10.0%)	1/19 (5.3%)	0/17 (0%)	0/7 (0%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	3/22 (13.6%)
False Lumen Perfusion through a branch vessel	1/2 (50.0%)	19/21 (90.5%)	17/21 (81.0%)	15/19 (78.9%)	7/7 (100.0%)	5/6 (83.3%)	5/6 (83.3%)	4/4 (100.0%)	20/23 (87.0%)
Through an Aortic Arch Branch Vessel ⁴	1/2 (50.0%)	3/19 (15.8%)	1/20 (5.0%)	0/17 (0%)	0/6 (0%)	0/5 (0%)	0/5 (0%)	0/3 (0%)	3/21 (14.3%)
Innominate	0/2 (0%)	0/19 (0%)	0/20 (0%)	0/17 (0%)	0/6 (0%)	0/5 (0%)	0/5 (0%)	0/3 (0%)	0/21 (0%)
LCCA	0/2 (0%)	1/19 (5.3%)	0/20 (0%)	0/17 (0%)	0/6 (0%)	0/5 (0%)	0/5 (0%)	0/3 (0%)	1/21 (4.8%)
LSA	1/2 (50.0%)	2/19 (10.5%)	1/20 (5.0%)	0/17 (0%)	0/6 (0%)	0/5 (0%)	0/5 (0%)	0/3 (0%)	2/21 (9.5%)
Other	0/2 (0%)	0/19 (0%)	0/20 (0%)	0/17 (0%)	0/6 (0%)	0/5 (0%)	0/5 (0%)	0/3 (0%)	0/21 (0%)
Through a Non-Aortic Arch Branch Vessel ⁶	1/2 (50.0%)	18/21 (85.7%)	16/21 (76.2%)	15/19 (78.9%)	7/7 (100.0%)	5/6 (83.3%)	5/6 (83.3%)	4/4 (100.0%)	19/23 (82.6%)
Celiac	0/2 (0%)	4/21 (19.0%)	3/21 (14.3%)	4/19 (21.1%)	2/7 (28.6%)	2/6 (33.3%)	1/6 (16.7%)	1/4 (25.0%)	5/23 (21.7%)
SMA	0/2 (0%)	0/21 (0%)	1/21 (4.8%)	0/19 (0%)	1/7 (14.3%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	1/23 (4.3%)
Rt. Renal	0/2 (0%)	3/21 (14.3%)	2/21 (9.5%)	1/19 (5.3%)	0/7 (0%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	3/23 (13.0%)
Lt. Renal	1/2 (50.0%)	6/21 (28.6%)	7/21 (33.3%)	8/19 (42.1%)	3/7 (42.9%)	2/6 (33.3%)	2/6 (33.3%)	1/4 (25.0%)	8/23 (34.8%)
Rt. Com Iliac	0/2 (0%)	2/21 (9.5%)	1/21 (4.8%)	0/19 (0%)	0/7 (0%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	2/23 (8.7%)
Lt. Com Iliac	0/2 (0%)	3/21 (14.3%)	2/21 (9.5%)	2/19 (10.5%)	2/7 (28.6%)	1/6 (16.7%)	1/6 (16.7%)	1/4 (25.0%)	3/23 (13.0%)
Other ⁷	1/2 (50.0%)	18/21 (85.7%)	15/21 (71.4%)	15/19 (78.9%)	6/7 (85.7%)	5/6 (83.3%)	4/6 (66.7%)	4/4 (100.0%)	19/23 (82.6%)
False Lumen Perfusion - Source of Perfusion: Distal Aorta	1/2 (50.0%)	17/20 (85.0%)	17/19 (89.5%)	15/17 (88.2%)	7/7 (100.0%)	6/6 (100.0%)	6/6 (100.0%)	4/4 (100.0%)	19/22 (86.4%)
False Lumen Status ^{5,6} - Treated Segment									
Patent	0/2 (0%)	0/21 (0%)	0/21 (0%)	0/19 (0%)	0/7 (0%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	0/23 (0%)
Partial thrombosis	2/2 (100.0%)	15/21 (71.4%)	13/21 (61.9%)	12/19 (63.2%)	4/7 (57.1%)	4/6 (66.7%)	2/6 (33.3%)	1/4 (25.0%)	19/23 (82.6%)
Complete thrombosis	0/2 (0%)	6/21 (28.6%)	8/21 (38.1%)	7/19 (36.8%)	3/7 (42.9%)	2/6 (33.3%)	4/6 (66.7%)	3/4 (75.0%)	4/23 (17.4%)
False Lumen Status ^{5,6} - Untreated (Distal) Aorta									

	Follow-Up Visit Time Window								
	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total ¹
Patent	0/1 (0%)	4/16 (25.0%)	2/16 (12.5%)	3/16 (18.8%)	0/7 (0%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	5/19 (26.3%)
Partial thrombosis	1/1 (100.0%)	12/16 (75.0%)	14/16 (87.5%)	13/16 (81.3%)	7/7 (100.0%)	6/6 (100.0%)	6/6 (100.0%)	4/4 (100.0%)	14/19 (73.7%)
Complete thrombosis	0/1 (0%)	0/16 (0%)	0/16 (0%)	0/16 (0%)	0/7 (0%)	0/6 (0%)	0/6 (0%)	0/4 (0%)	0/19 (0%)

¹Event percentages in this column may be an underestimation as 5 year follow-up is not complete.
²Column header counts are the number of Subjects at risk at the start of each interval.
³Denominators for each device finding category time window are the number of evaluable Subjects (Subject had either CT or MR done in window) with a known evaluation in each window.
⁴These are Treatment Success Outcomes.
⁵If there is more than one evaluation for a Subject in a time window, the worst finding is reported for that window (Patent is worst, followed by Partial thrombosis).
⁶These are Other Success Outcomes.
⁷Other sources primarily included: intercostal arteries, vertebral arteries, bronchial arteries, lumbar arteries, IMA, accessory renal arteries, distal secondary tears, and right/left external iliacs.
Study period definitions: Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(1-2006 days)

Reported Treatment of Adverse Events

Adverse event treatments, reported for study subjects, by absolute window for all Cohorts are displayed in **Table 40**. Of all treatments completed, drug therapy was the most common (67.5%). One subject underwent a conversion to open repair and one subject underwent open surgical repair without device explant. There were 36 subjects (46.8 %) that underwent ‘Other surgery, treatment or procedure’ such as balloon angioplasty and endoscopy.

Table 40: Adverse Event Treatments by Absolute Study Window for All Cohorts

	Follow-Up Absolute Time Window										
	Phase 1	Endovascular Procedure	1 Month	6 Months	1 Years	2 Years	3 Years	4 Years	5 Years	>5 Years to Study End	Total¹
Number of Enrolled Subjects²	77	77	76	73	69	62	32	26	20	6	77
Subjects with any Adverse Event Treatment	15 (19.5%)	24 (31.2%)	40 (52.6%)	24 (32.9%)	20 (29.0%)	20 (32.3%)	10 (31.3%)	6 (23.1%)	10 (50.0%)	1 (16.7%)	65 (84.4%)
Adverse Event Treatment Categorization³											
Conversion to open repair with Study Device Explant	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)
Open Surgical Repair without Study Device Explant	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)
Transposition/ Bypass post initial treatment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Surgical Bypass Graft⁴	2 (2.6%)	2 (2.6%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (6.5%)
Debranching procedure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Aortic branch vessel revascularization	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	1 (1.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2.6%)
Left Subclavian surgical revascularization	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Thoracic aortic stent graft placement	0 (0%)	1 (1.3%)	2 (2.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3.8%)	1 (5.0%)	0 (0%)	5 (6.5%)
Abdominal aortic stent graft placement	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Stent	0 (0%)	6 (7.8%)	1 (1.3%)	1 (1.4%)	0 (0%)	0 (0%)	1 (3.1%)	0 (0%)	0 (0%)	0 (0%)	8 (10.4%)

	Follow-Up Absolute Time Window										
	Phase 1	Endovascular Procedure	1 Month	6 Months	1 Years	2 Years	3 Years	4 Years	5 Years	>5 Years to Study End	Total ¹
Endovascular intervention (non-stent) PTA/ Balloon Angioplasty	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)
Device Retrieval Procedure (snaring, etc.)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Spinal drain	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Artery Repair	0 (0%)	2 (2.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (3.9%)
Thrombectomy	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)
Embolectomy	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)
Embolization	0 (0%)	0 (0%)	1 (1.3%)	1 (1.4%)	1 (1.4%)	0 (0%)	1 (3.1%)	0 (0%)	0 (0%)	0 (0%)	4 (5.2%)
Cardiopulmonary Resuscitation	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)
Intubation/Ventilator	2 (2.6%)	4 (5.2%)	5 (6.6%)	1 (1.4%)	0 (0%)	1 (1.6%)	1 (3.1%)	0 (0%)	0 (0%)	0 (0%)	10 (13.0%)
Chest Tube/Thoracentesis	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	1 (1.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2.6%)
CT/X-ray/Angio/Ultrasound Diagnostic Imaging	0 (0%)	0 (0%)	4 (5.3%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (6.5%)
Diagnostic Procedure (Laparoscopy/ Colonoscopy/ EKG etc.)	0 (0%)	1 (1.3%)	1 (1.3%)	1 (1.4%)	0 (0%)	0 (0%)	1 (3.1%)	1 (3.8%)	0 (0%)	0 (0%)	4 (5.2%)
Endoscopy	0 (0%)	0 (0%)	0 (0%)	2 (2.7%)	2 (2.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (3.9%)
Drug therapy	9 (11.7%)	8 (10.4%)	30 (39.5%)	18 (24.7%)	14 (20.3%)	13 (21.0%)	7 (21.9%)	4 (15.4%)	5 (25.0%)	0 (0%)	52 (67.5%)
Fluid/blood/oxygen therapy	8 (10.4%)	12 (15.6%)	11 (14.5%)	6 (8.2%)	4 (5.8%)	5 (8.1%)	6 (18.8%)	2 (7.7%)	3 (15.0%)	0 (0%)	36 (46.8%)
Physical therapy/rehabilitation	0 (0%)	1 (1.3%)	3 (3.9%)	1 (1.4%)	2 (2.9%)	0 (0%)	1 (3.1%)	1 (3.8%)	0 (0%)	0 (0%)	5 (6.5%)
Other surgery, treatment, or procedure	3 (3.9%)	1 (1.3%)	13 (17.1%)	11 (15.1%)	6 (8.7%)	7 (11.3%)	2 (6.3%)	3 (11.5%)	4 (20.0%)	1 (16.7%)	36 (46.8%)
Observation	0 (0%)	0 (0%)	2 (2.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2.6%)

¹Event percentages in this column may be an underestimation as 5 year follow-up is not complete.
²Column header counts and denominators are the number of Subjects at risk at the start of each interval. There have been two Aneurysm Subject(s) excluded from this analysis due to treatment with 49/53 mm devices no longer supported by the protocol.
³This table shows additional categorizations than available in the database (in BOLD above).
⁴One Subject had treatment with 'nutrition supplementation' (POD 10) for 'malnutrition'. The treatment was inadvertently miscategorized as 'Surgical Bypass Graft' and will be corrected.
Study period definitions: Phase 1 (revascularization procedure until prior to endovascular procedure) Endovascular Procedure(0 days) 1 Month(1-30 days) 6 Months(31-182 days) 1 Year(183-365 days) 2 Years(366-731 days) 3 Years(732-1096 days) 4 Years(1097-1461 days) 5 Years(1462-1826 days) >5 Years to Study End(1827-2006 days) Total (Phase 1-2006 days)

All Cohorts Protocol-Defined Unanticipated Reintervention

Six subjects (7.8%) in all Cohorts (three Aneurysm, three Dissection) had a protocol-defined unanticipated reintervention (surgical or interventional procedures, which were unanticipated as noted by study investigators, related to the device, procedure, or withdrawal of delivery system), as shown in

Table 41 through all available follow-up. Note that the rates shown in this table may be different than those shown in the Treatment Success table as the windowing is different (table below uses the absolute windows and the Treatment Success table uses the analysis windows).

Two subjects had stent graft placement for Type IB endoleaks, one subject had a thrombectomy for acute arterial occlusion of the left upper limb, one subject had an epidural blood patch to treat post-procedural spinal headache, one subject had abdominal exploration due to retroperitoneal hematoma, and one subject required an aortic branch vessel revascularization to treat a vascular graft infection.

Table 41: Protocol-Defined Reinterventions by Absolute Study Window for All Cohorts

	Follow-Up Absolute Time Window									
	Phase 1	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	>5 Years to Study End	Total ¹
Number of Enrolled Subjects²	77	77	73	69	62	32	26	20	6	77
Subjects with Protocol-Defined Reintervention (Unanticipated CEC Adjudicated Reintervention) ³	1 (1.3%)	3 (3.9%)	0 (0%)	0 (0%)	1 (1.6%)	0 (0%)	1 (3.8%)	0 (0%)	0 (0%)	6 (7.8%)
¹ Event percentages in this column may be an underestimation as 5 year follow-up is not complete. ² Column header counts are the number of Subjects at risk at the start of each interval. T There have been two Aneurysm Subject(s) excluded from this analysis due to treatment with 49/53 mm devices no longer supported by the protocol. ³ For SSB 11-02 Pivotal Protocol, reintervention refers to any unanticipated additional procedure related to the device, procedure, or withdrawal of the delivery system. Anticipated or unanticipated status is determined at the discretion of the Site investigator. Does not include treatments performed during the initial endovascular procedure. Study period definitions: Phase 1 (revascularization procedure until prior to endovascular procedure) 30 Days(0-30 days) 6 Months(31-182 days) 1 Years(183-365 days) 2 Years(366-731 days) 3 Years(732-1096 days) 4 Years(1097-1461 days) 5 Years(1462-1826 days) >5 Years to Study End(1827-2006 days) Total (Phase 1-2006 days)										

All Cohorts Site-Reported Reintervention

Table 42 summarizes site-reported reinterventions for all Cohorts. Overall, nine subjects (11.7%) from all Cohorts (seven Aneurysm, two Dissection) had a site-reported reintervention. Six subjects had reinterventions for stent-graft endoleaks (five resolved without sequelae, one resolved with sequelae), two subjects had reinterventions to treat vascular graft stenosis or occlusion (one resolved without sequelae, one resolved with sequelae), and one subject had treatment for vascular graft infection (resolved with sequelae).

Table 42: Site-Reported Reinterventions by Absolute Study Window for All Cohorts

	Follow-Up Absolute Time Window									
	Phase 1	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	>5 Years to Study End	Total ¹
Number of Enrolled Subjects²	77	77	73	69	62	32	26	20	6	77
Subjects with Site-Reported Reintervention³	1 (1.3%)	3 (3.9%)	1 (1.4%)	2 (2.9%)	1 (1.6%)	0 (0%)	1 (3.8%)	1 (5.0%)	0 (0%)	9 (11.7%)
¹ Event percentages in this column may be an underestimation as 5 year follow-up is not complete. ² Column header counts are the number of Subjects at risk at the start of each interval. There have been two Aneurysm Subject(s) excluded from this analysis due to treatment with 49/53 mm devices no longer supported by the protocol. ³ Based on Site-reported data. Reintervention was defined as any adverse event treatment where the Site reported a 'yes' to the question: 'Was reintervention on the treated segment of the branch vessel or the aorta performed?' Study period definitions: Phase 1 (revascularization procedure until prior to endovascular procedure) 30 Days(0-30 days) 6 Months(31-182 days) 1 Years(183-365 days) 2 Years(366-731 days) 3 Years(732-1096 days) 4 Years(1097-1461 days) 5 Years(1462-1826 days) >5 Years to Study End(1827-2006 days) Total (Phase 1-2006 days)										

7. Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes: sex and country. No additional subgroup analyses were performed.

Subgroup analysis on the composite primary endpoint results for the Aneurysm arm was performed by sex. Freedom from a primary endpoint event was observed in 86.7% of male Aneurysm Subjects and 52.9% of female Aneurysm Subjects. Based on the statistical test performed, there is a statistically significant difference in the composite primary endpoint rate by sex (p-value=0.016). The difference in outcomes by sex may be predominantly driven by a higher rate of disabling stroke for females (22.0%) than males (6.3%) and a higher rate of lesion-related mortality for females (11%) than males (0%). These observed differences are consistent with reports from the published literature for outcomes by sex for standard TEVAR treatment of descending thoracic aortic aneurysms^[26] and open surgical repair in the thoracic aortic arch^[27].

Subgroup analysis on the composite primary endpoint results for the Aneurysm arm was performed by country. For Japan-only Subjects, the rate of freedom from a primary endpoint event was 80% (8/10), and for US only Subjects 73% (27/37). The composite primary endpoint rate by country was not statistically different (p-value >0.99).

8. 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 239 investigators of which none were full-time or part-time employees of the sponsor and 25 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: 25
- 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

There were 9 Early Feasibility Study (EFS) Subjects enrolled prior to the Pivotal Study. The primary endpoints of the study were successful access and deployment of the TBE Device and primary patency of the side branch assessed by angiography at the conclusion of the Endovascular Procedure. The primary endpoint was successful in 100% of subjects. The secondary endpoints at 1-Month also achieved 100% success (SB patency and no device-related endoleaks). Three subjects reported stroke events during the study, two of which were procedural (these subjects also had late strokes reported), while one subject reported a late stroke only (after 5-year absolute window). Three subject deaths were reported in the study, none of which were CEC adjudicated as device or procedural deaths. No events of aortic arch rupture, side branch patency loss, device migration, wire fracture, extrusion/erosion, or device compression were reported by the Core Lab through 5 years. All follow-up in the study is now complete. This EFS experience supported the pivotal study design and the overall conclusion that endovascular treatment of patients with lesions of the aortic arch, while maintaining flow in the branch vessels, is feasible with the TBE 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 Aneurysm hypothesis-driven cohort was successful in meeting its performance goal of 60% for the primary endpoint, Strategy Success. Strategy Success was defined as a composite of Initiation of the index endovascular procedure (following the debranching procedure), Device Technical Success (DTS) for the index (endovascular) procedure and absence of: aortic rupture, lesion-related mortality, disabling stroke, permanent paraplegia, permanent paraparesis, new onset renal failure requiring permanent dialysis and protocol defined reintervention through 1-Month. Primary endpoint success through 1-Month was achieved in 74.5% of subjects (35/47 evaluable subjects at 1-Month) with a 95% one-sided Exact lower confidence limit of freedom from primary endpoint events of 61.9%.

There were no pre-specified statistical hypotheses for the Dissection cohort or Other Isolated Lesions cohorts. However, outcomes were collected and summarized similar to the Aneurysm cohort. The following summarizes Primary Endpoint success results for each of these cohorts.

- Dissection cohort, 81.8% (18/22 evaluable subjects at 1-Month)
- Other Isolated Lesion cohort 100% (3/3 evaluable subjects at 1-Month)

When considering the totality of the data for the Zone 0/1 Arm of the Pivotal study, primary endpoint success through 1-Month was observed in 77.8% (56/72) of subjects.

Primary endpoint success through 12-Months was also analyzed for all cohorts with 74.3% (52/70) free from endpoint event.

In addition to Primary Endpoint, success outcomes were analyzed for all cohorts. Procedural Success through 1 month was the absence of DTS failure and 16 success outcomes (17 success outcomes for Dissection Cohort only) described under Section X (A) (3). Procedural Success results by cohort are as follows:

- Aneurysm Cohort: 64.0% (32/50)
- Dissection Cohort: 70.8% 17/24)
- Other Isolated Lesion Cohort: 100% (3/3)

Outcomes of Treatment Success, as defined in Section X (A) (3), for all Zone 0/1 Cohorts are as follows (note that this is through 5 years, however, follow-up was ongoing):

- Aneurysm Cohort: 57.1% (28/49). Twenty-four of the 50 subjects remain in follow-up and were in the 12-Month or later windows at the time of export.
- Dissection Cohort: 54.2% (13/24) Ten of the 24 subjects remain in follow-up and were in the 12-Month or later windows at time of export.
- Other Isolated Lesion Cohort: 66.7% (2/3) one subject remains in follow-up and was in the 24-Month window at time of export.

Based on the clinical endpoint outcomes presented above, there is reasonable assurance of the safety and effectiveness of the GORE® TAG® Thoracic Branch Endoprosthesis Device for the proposed intended use of endovascular repair of lesions of the aortic arch while maintaining flow into a single aortic arch branch vessel.

B. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The Aneurysm hypothesis-driven cohort was successful in meeting its performance goal for the composite safety and effectiveness primary endpoint. After an initial surgical debranching procedure, the TBE Device facilitates endovascular repair of lesions of the thoracic aortic arch, while maintaining flow into the brachiocephalic or left common carotid artery. Treatment with TBE device allows for elimination of Deep Hypothermic Circulatory Arrest (DHCA) and Cardiopulmonary Bypass (CPB) techniques which are required for open surgical repair and often associated with higher morbidity and mortality.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. These risks include aortic rupture (2.6%; through 12 months), lesion related mortality (6.5%; through 12 months), disabling stroke (7.8%; through 30 days), life-threatening bleeds (9.1%, through 30

days), permanent paraparesis (1.3%; through 12 months), new onset renal failure requiring dialysis (1.3%; through 30 days), unanticipated reintervention (6.5%; through 12 months), aortic enlargement (12.5%, through all available follow-up), Type I and Type III endoleaks (7.0% and 4.2% respectively, through all available follow-up), and new dissections (9.1% through all available follow-up). The rates of key safety events are similar to the rates reported in the literature for Zone 0/1 hybrid TEVAR. For example, literature suggests a 30-day stroke rate of 7.1-8.9% in patients who underwent Zone 0/1 hybrid TEVAR^[24, 25]. Although a direct comparison to reported rates for open surgical repair is not feasible because the TBE clinical study enrolled patients who are high risk for conventional open repair, a recent meta-analysis^[28] reported a stroke rate of 5.7%, with proportions from the included 8 articles^[29-36] ranging between 0-16.7%.

Additional factors to be considered in determining probable risks and benefits for the GORE® TAG® Thoracic Branch Endoprosthesis included:

- limitation on the number of subjects in Other Isolated Lesions cohort; and
- absence of full 5-year subject follow-up data
- enrollment of only those subjects who are considered high risk for conventional open repair

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.

In conclusion, given the available information above, the data support that for endovascular repair of lesions of the aortic arch and descending thoracic aorta, while maintaining flow into a single aortic arch branch vessel, the probable benefits outweigh the probable risks.

C. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of the device when used in accordance with the indications for use.

The clinical study met the pre-specified performance goal for safety and effectiveness. Therefore, it is reasonable to conclude that the benefits of use of the device for the indicated population outweigh the risk of illness or injury when used as indicated in accordance with the Instructions for Use (IFU).

XV. CDRH DECISION

CDRH issued an approval order on April 11, 2025. The final clinical conditions of approval cited in the approval order are described below.

1. 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 (all-cause and lesion-related), stroke, paraplegia / paraparesis,

aortic enlargement in the region encompassed by the initial lesion, aortic rupture, endoleaks, new dissections, loss of device integrity, device migration, loss of aortic / aortic branch patency, and reintervention. 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 also to be included. A summary of any explant analysis findings is to be included. The clinical update for physician users and the information supporting the updates must be provided in the Annual Report.

2. 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. The study design includes the assessment of the GORE® TAG® Thoracic Branch Endoprosthesis in treating lesions of the aortic arch. A total of 77 subjects were enrolled and eligible for analysis in the study across the three cohorts. The remaining subjects will be followed annually for 5 years. Clinical outcomes include Procedural Success (defined as Device Technical Success with the absence of serious adverse events at 30 days, including: death, disabling stroke, paraplegia, paraparesis, new onset renal failure requiring permanent dialysis, unanticipated reintervention related to the device or the procedure, new ischemia, distal device-related thromboembolic events requiring intervention, life threatening bleed, myocardial infarction, prolonged intubation, laryngeal or phrenic nerve injury, renal dysfunction or volume overload requiring ultrafiltration, severe heart failure or hypotension, aortic rupture, new dissection, or extension of a dissection (Dissection Cohort only)) and Treatment Success (defined as Device Technical Success, with absence of all of the following at all appropriate follow-up windows: lesion-related mortality, disabling stroke, paraplegia and paraparesis, protocol-defined reintervention, new ischemia, aortic rupture, loss of patency, fistula formation, loss of device integrity, device migration, new dissection, Type I/III endoleak, aortic enlargement, extension of dissection (Dissection Cohort only), false lumen perfusion through primary entry tear (Dissection Cohort only), and false lumen perfusion through an aortic arch branch vessel (Dissection Cohort only). Other outcomes including Type II/IV Endoleak, significant blood loss ($\geq 1000\text{mL}$), and false lumen status in treated and untreated segments and false lumen perfusion through a non-aortic arch branch vessel will also be evaluated at all appropriate follow up intervals. These endpoints will be analyzed descriptively, and annual reports submitted on a yearly basis.
3. GORE® TAG® TBE Zone 0/1 New Enrollment Post Approval Study: This is a prospective, multi-center, single-arm post-market study. The objective of the study is to evaluate the GORE® Thoracic TAG® Branch Endoprosthesis (TBE) device in the treatment of patients with lesions of the aortic arch. The study will prospectively enroll a minimum of 125 subjects treated with the TBE Device in Zone 0 or 1 at up to 50 sites in the US, with at least 50 subjects evaluable at 5 years post-implantation. Follow-up will occur at 1 month, 6 months, 1 year, and yearly thereafter through at least 5 years from the index procedure. Patients will be consented for follow-up through 10 years. The primary endpoint is a composite of the following events: initiation of TBE implantation procedure following the debranching procedure, device technical success at the end of index procedure, and freedom from the following events through all follow-up windows: lesion-related mortality, disabling stroke, permanent paraplegia, permanent paraparesis,

new onset renal failure, lesion rupture (treated area), loss of aortic or side branch patency, endoleaks and reinterventions. Secondary endpoints such as life threatening bleeds, all-cause mortality, new dissections, as defined in the protocol, will be collected and reported at each follow-up time point. Outcomes will be reported using descriptive statistics.

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

1. Andersen, N.D., et al., *Results with an algorithmic approach to hybrid repair of the aortic arch*. J Vasc Surg, 2013. **57**(3): p. 655-67; discussion 666-7.
2. Antoniou, G.A., et al., *Hybrid repair of the aortic arch in patients with extensive aortic disease*. Eur J Vasc Endovasc Surg, 2010. **40**(6): p. 715-21.
3. Bavaria, J., et al., *Classic hybrid evolving approach to distal arch aneurysms: toward the zone zero solution*. J Thorac Cardiovasc Surg, 2010. **140**(6 Suppl): p. S77-80; discussion S86-91.
4. Bergeron, P., et al., *Great vessel management for endovascular exclusion of aortic arch aneurysms and dissections*. Eur J Vasc Endovasc Surg, 2006. **32**(1): p. 38-45.
5. Bunker, C.M., et al., *Hybrid aortic arch repair for complicated type B aortic dissection*. J Vasc Surg, 2013. **58**(6): p. 1490-6.
6. Cochenne, F., et al., *Hybrid repair of aortic arch dissections*. J Vasc Surg, 2013. **57**(6): p. 1560-7.
7. Czerny, M., et al., *Targeting landing zone 0 by total arch rerouting and TEVAR: midterm results of a transcontinental registry*. Ann Thorac Surg, 2012. **94**(1): p. 84-9.
8. Deriu, G., et al., *Unusual inflow sources and device introduction sites in aortic arch debranching*. J Cardiovasc Surg (Torino), 2012. **53**(2): p. 143-51.
9. Ferrero, E., et al., *Is total debranching a safe procedure for extensive aortic-arch disease? A single experience of 27 cases*. Eur J Cardiothorac Surg, 2012. **41**(1): p. 177-82.
10. Geisbusch, P., et al., *Complications after aortic arch hybrid repair*. J Vasc Surg, 2011. **53**(4): p. 935-41.
11. Goksel, O.S., et al., *Debranching solutions in endografting for complex thoracic aortic dissections*. Arq Bras Cardiol, 2014. **103**(2): p. 154-60.
12. Ham, S.W., et al., *Arch and visceral/renal debranching combined with endovascular repair for thoracic and thoracoabdominal aortic aneurysms*. J Vasc Surg, 2011. **54**(1): p. 30-40; discussion 40-1.
13. Hiraoka, A., et al., *Clinical outcomes of different approaches to aortic arch disease*. J Vasc Surg, 2015. **61**(1): p. 88-95.
14. Holt, P.J., et al., *Outcomes of the endovascular management of aortic arch aneurysm: implications for management of the left subclavian artery*. J Vasc Surg, 2010. **51**(6): p. 1329-38.
15. Hughes, G.C., et al., *"Hybrid" repair of aneurysms of the transverse aortic arch: midterm results*. Ann Thorac Surg, 2009. **88**(6): p. 1882-7; discussion 1887-8.
16. Kent, W.D., et al., *Results of type II hybrid arch repair with zone 0 stent graft deployment for complex aortic arch pathology*. J Thorac Cardiovasc Surg, 2014. **148**(6): p. 2951-5.

17. Melissano, G., et al., *Analysis of stroke after TEVAR involving the aortic arch*. Eur J Vasc Endovasc Surg, 2012. **43**(3): p. 269-75.
18. Saleh, H.M., *Hybrid repair of aortic arch aneurysm*. Acta Chir Belg, 2007. **107**(2): p. 173-80.
19. Schumacher, H., et al., *Hybrid aortic procedures for endoluminal arch replacement in thoracic aneurysms and type B dissections*. J Cardiovasc Surg (Torino), 2006. **47**(5): p. 509-17.
20. Shimizu, H., et al., *Cerebral blood flow after hybrid distal hemiarch repair*. Interact Cardiovasc Thorac Surg, 2013. **17**(1): p. 73-8.
21. Shirakawa, Y., et al., *The efficacy and short-term results of hybrid thoracic endovascular repair into the ascending aorta for aortic arch pathologies*. Eur J Cardiothorac Surg, 2014. **45**(2): p. 298-304; discussion 304.
22. Vallabhajosyula, P., et al., *Type I and Type II hybrid aortic arch replacement: postoperative and mid-term outcome analysis*. Ann Cardiothorac Surg, 2013. **2**(3): p. 280-7.
23. Vallejo, N., et al., *Hybrid repair of thoracic aortic lesions for zone 0 and 1 in high-risk patients*. J Vasc Surg, 2012. **55**(2): p. 318-25.
24. DiBartolomeo, A.D., et al., *Risk of Stroke with Thoracic Endovascular Aortic Repair of the Aortic Arch*. Annals of Vascular Surgery, 2023. **97**: p. 37-48.
25. Vekstein, A.M., et al., *Long-term outcomes for hybrid aortic arch repair*. Journal of Vascular Surgery, 2024. **79**(4): p. 711-720.e2.
26. Yousef, S., et al., *Sex-Related Differences in Clinical Outcomes After Thoracic Endovascular Aortic Repair*. Journal of the American Heart Association, 2023. **12**(5).
27. Chung, J., et al., *Sex-Related Differences in Patients Undergoing Thoracic Aortic Surgery: Evidence from the Canadian Thoracic Aortic Collaborative*. Circulation, 2019. **139**(9): p. 1177-1184.
28. Chen, C.W., et al., *The outcomes of aortic arch repair between open surgical repair and debranching endovascular hybrid surgical repair: A systematic review and meta-analysis*. Journal of Vascular Surgery, 2024. **79**(6): p. 1510-1524.
29. Benrashid, E., et al., *Evolving practice pattern changes and outcomes in the era of hybrid aortic arch repair*. Journal of Vascular Surgery, 2016. **63**(2): p. 323-331.
30. Kang, W.C., et al., *Comparison of hybrid endovascular and open surgical repair for proximal aortic arch diseases*. International Journal of Cardiology, 2016. **203**: p. 975-979.
31. Milewski, R.K., et al., *Have hybrid procedures replaced open aortic arch reconstruction in high-risk patients? A comparative study of elective open arch debranching with endovascular stent graft placement and conventional elective open total and distal aortic arch reconstruction*. Journal of Thoracic and Cardiovascular Surgery, 2010. **140**(3): p. 590-596.
32. Murashita, T., et al., *Less invasive surgical treatment for aortic arch aneurysms in high-risk patients: A comparative study of hybrid thoracic endovascular aortic repair and conventional total arch replacement*. Journal of Thoracic and Cardiovascular Surgery, 2012. **143**(5): p. 1007-1013.
33. Murphy, E.I.I., et al., *Combined aortic debranching and thoracic endovascular aneurysm repair (TEVAR) effective but at a cost*. Archives of Surgery, 2009. **144**(3): p. 222-227.
34. Seike, Y., et al., *Total arch replacement versus debranching thoracic endovascular aortic repair for aortic arch aneurysm: What indicates a high-risk patient for arch repair in octogenarians?* General Thoracic and Cardiovascular Surgery, 2018. **66**(5): p. 263-269.
35. Sood, V., et al., *Open and endovascular repair of the nontraumatic isolated aortic arch aneurysm*. Journal of Vascular Surgery, 2014. **60**(1): p. 57-63.
36. Souza, L.O., et al., *Hybrid Treatment with Complete Transposition of Supra-Aortic Trunks versus Conventional Surgery for the Treatment of Aortic Arch Aneurysm*. Brazilian journal of cardiovascular surgery, 2017. **32**(5): p. 354-360.