GORE® TAG®

Thoracic Branch Endoprosthesis

INSTRUCTIONS FOR USE

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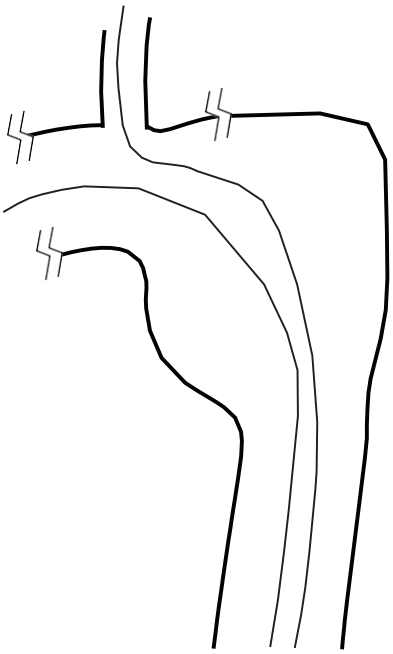
English

Procedure Illustrations

Step 1



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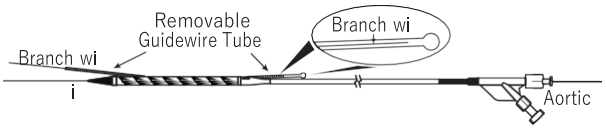

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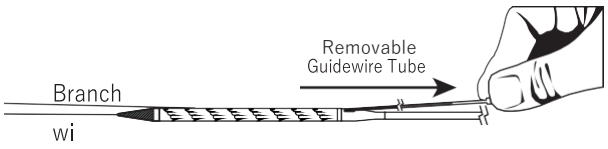
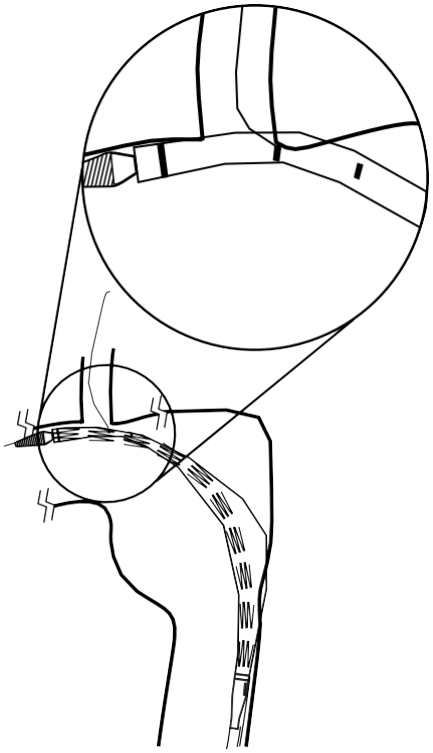


Step 4

Step 5



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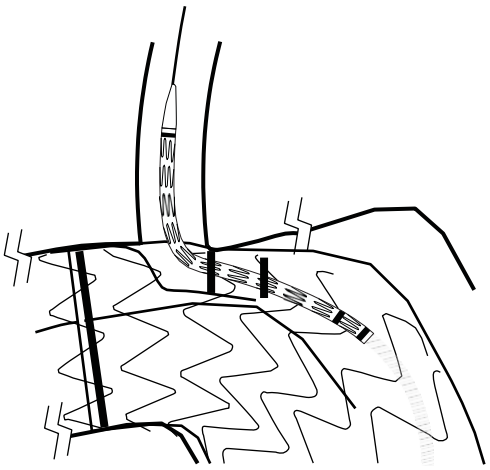

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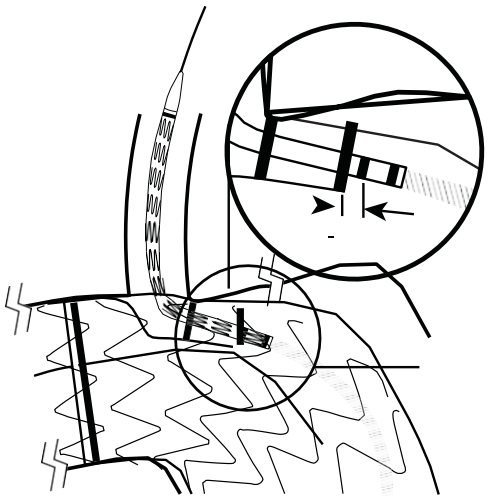

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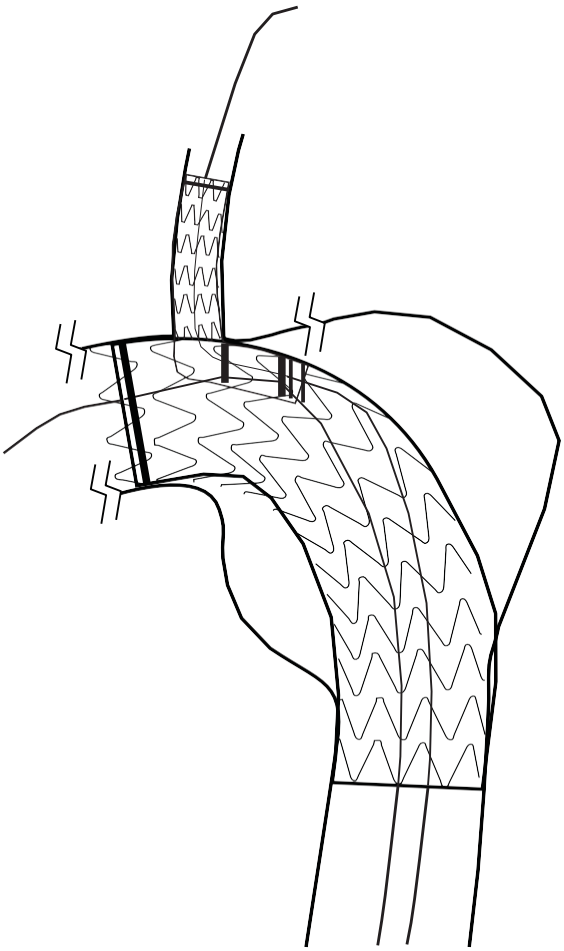


INSTRUCTIONS FOR USE

GORE® TAG® THORACIC BRANCH ENDOPROSTHESIS

- **CAUTION – USA Federal law restricts the sale, distribution, or use of this device, to, by, or on the order of a physician.**
- **Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.**
- **WARNING: The GORE® TAG® Thoracic Branch Endoprosthesis should only be delivered, positioned, and deployed by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate device training program which requires case planning/sizing and device training which includes positioning and deployment of the device. Physicians may be assisted in device preparation, delivery, and deployment by surgical team members trained in these steps.**

PRODUCT DESCRIPTION

The GORE® TAG® Thoracic Branch Endoprosthesis provides endovascular repair of pathologies of the descending thoracic aorta requiring a proximal landing zone including the 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 Stent Graft in multipledevice 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 graftmaterial 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.

Table 1. GORE® TAG® Thoracic Branch Endoprosthesis Materials

Materials
ePTFE (Polytetrafluoroethylene)
FEP (Fluoroethylpropylene)
Nitinol (Nickel, Titanium)
Gold
SB Component only - Heparin (CBAS® Heparin Surface)

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 left subclavian artery (LSA). The constrained profile of these components on a delivery catheter rangesfrom 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. The Aortic Component is intended to be delivered through an appropriately sized GORE® DrySeal Sheath (family of devices). See **Table 2** for Aortic Component dimensions and sizing requirements.

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 fromthe 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. See **Table 3** for SB Component dimensions and sizing requirements.

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. The leading end also includes an ePTFE sealing cuff. 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 26 Fr. The device is mounted onto a catheter delivery system and constrained by a sewn deployment sleeve and expands uniformly along its length by pulling the deployment knob on the hub of the catheter. Unlike other device components, the deployment sleeve of the Aortic Extender is attached to the delivery catheter and is removed from the patient following deployment. A longitudinal radiopaque marker is embedded in the deployment sleeve to allow visualization during delivery catheter withdrawal. The Aortic Extenders are intended to be delivered through an appropriately sized GORE® DrySeal Sheath(family of devices). See **Table 4** for Aortic Extender dimensions and sizing requirements.

Figure 1. GORE® TAG® Thoracic Branch Endoprosthesis

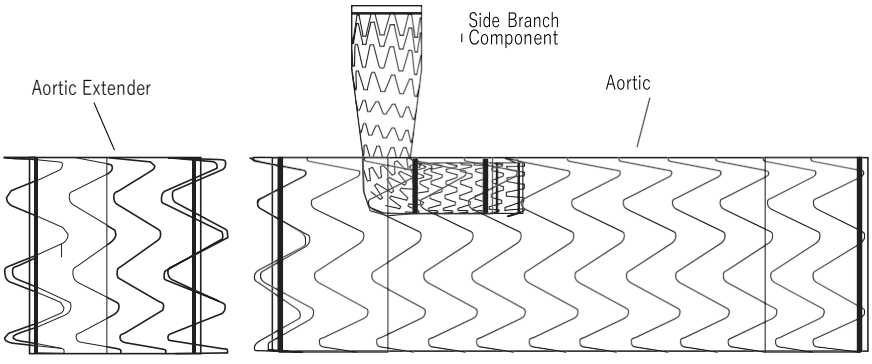


Figure 2. Aortic Component and Aortic Component Delivery System

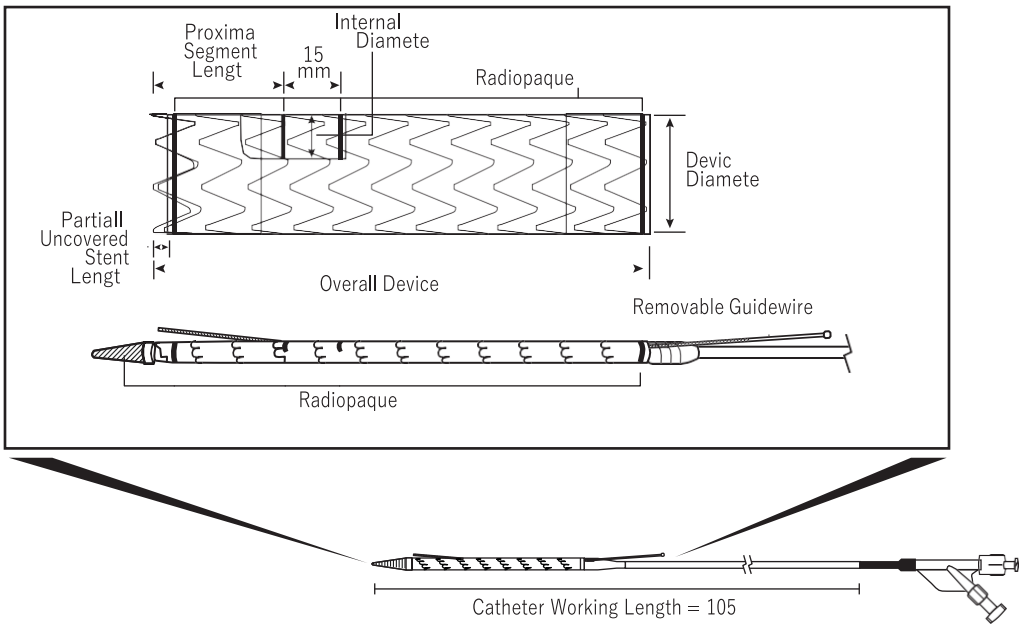


Table 2. Aortic Component Sizing Guide

	Device Dimensions[1] and Sizing Requirements							
Item Number	**Device Diameter (mm)**	**Intended Aortic Diameters[2] (mm)**	**Internal Portal Diameter (mm)**	**A: Proximal Segment Length[3,4] (mm)**	**B: Proximal Covered Length[3,5] (mm)**	**Partially Uncovered Stent Length[6] (mm)**	**Overall Device Length (cm)**	**GORE® DrySeal Sheath Size (Fr)[7]**
TAC082110	21	16 - 19.5	8	20	17	3	10	20
TAC082115	21	16 - 19.5	8	20	17	3	15	20
TAC082120	21	16 - 19.5	8	20	17	3	20	20
TAC082610	26	19.5 - 24	8	20	16	4	10	20
TAC082615	26	19.5 - 24	8	20	16	4	15	20
TAC082620	26	19.5 - 24	8	20	16	4	20	20
TAC082810	28	22 - 26	8	20	16	4	10	22
TAC082815	28	22 - 26	8	20	16	4	15	22
TAC082820	28	22 - 26	8	20	16	4	20	22
TAC083110	31	24 - 29	8	20	16	4	10	22
TAC083115	31	24 - 29	8	20	16	4	15	22
TAC083120	31	24 - 29	8	20	16	4	20	22
TAC123110	31	24 - 29	12	40	36	4	10	22
TAC123115	31	24 - 29	12	40	36	4	15	22
TAC123120	31	24 - 29	12	40	36	4	20	22
TAC083410	34	27-32	8	20	15	5	10	24
TAC083415	34	27-32	8	20	15	5	15	24
TAC083420	34	27-32	8	20	15	5	20	24
TAC123410	34	27-32	12	40	35	5	10	24
TAC123415	34	27-32	12	40	35	5	15	24
TAC123420	34	27-32	12	40	35	5	20	24
TAC083710	37	29 - 34	8	25	20	5	10	24
TAC083715	37	29 - 34	8	25	20	5	15	24
TAC083720	37	29 - 34	8	25	20	5	20	24
TAC123710	37	29 - 34	12	40	35	5	10	24
TAC123715	37	29 - 34	12	40	35	5	15	24

Item Number	Device Dimensions[1] and Sizing Requirements							
	Device Diameter (mm)	Intended Aortic Diameters[2] (mm)	Internal Portal Diameter (mm)	A: Proximal Segment Length[3,4] (mm)	B: Proximal Covered Length[3,5] (mm)	Partially Uncovered Stent Length[6] (mm)	Overall Device Length (cm)	GORE® DrySeal Sheath Size (Fr)[7]
TAC123720	37	29 - 34	12	40	35	5	20	24
TAC084010	40	31 -37	8	25	19	6	10	26
TAC084015	40	31 -37	8	25	19	6	15	26
TAC084020	40	31 -37	8	25	19	6	20	26
TAC124010	40	31 -37	12	40	34	6	10	26
TAC124015	40	31 -37	12	40	34	6	15	26
TAC124020	40	31 -37	12	40	34	6	20	26
TAC084510	45	34 - 42	8	25	18.5	6.5	10	26
TAC084515	45	34 - 42	8	25	18.5	6.5	15	26
TAC084520	45	34 - 42	8	25	18.5	6.5	20	26
TAC124510	45	34 - 42	12	40	33.5	6.5	10	26
TAC124515	45	34 - 42	12	40	33.5	6.5	15	26
TAC124520	45	34 - 42	12	40	33.5	6.5	20	26

1 All device dimensions are nominal.

2 Appropriate oversizing is built into recommended sizes.

3 Measurements A and B according to **Figure 6**

4 Minimum aortic neck length required along the outer curvature of the aorta from the distal edge of the left subclavian artery to the midpoint of left common carotid artery.

5 Minimum length required along outer curvature of the aorta from the distal edge of the left subclavian artery to the distal edge of the left common carotid artery.

6 The partially uncovered stent may be positioned such that it crosses up to half of the diameter of the left common carotid artery.

7 The GORE® DrySeal Introducer Sheath family of devices.

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

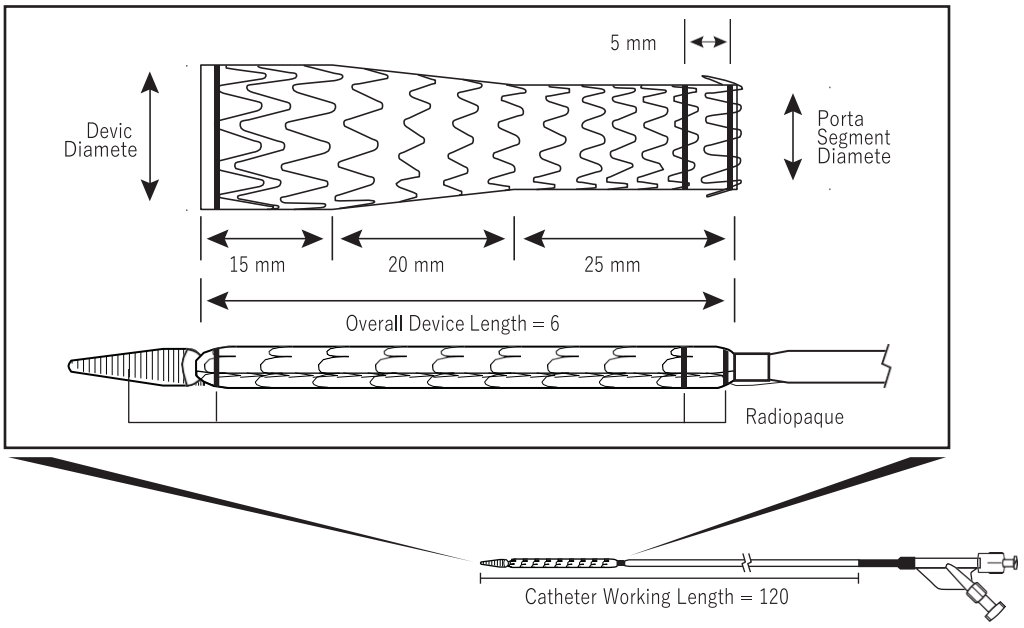


Table 3. Side Branch Component Sizing Guide

Item Number	Device Dimensions[1] and Sizing Requirements					
	Device Diameter (mm)	Intended Branch Vessel Diameter[2] (mm)	Portal Segment Diameter[3] (mm)	Overall Device Length (cm)	Required Branch Vessel Length (cm)[4]	GORE® DrySeal Sheath Size (Fr)[5]
TSB080806	8	6 - 7.5	8	6	3	14
TSB081006	10	7.5 - 9	8	6	3	14
TSB081206	12	9 - 11	8	6	3	14
TSB081506	15	11 - 13	8	6	3	14
TSB121506	15	11 - 13	12	6	2.5	14
TSB081706	17	13 - 15	8	6	3	14

TSB121706	17	13 - 15	12	6	2.5	14
TSB122006	20	15 - 18	12	6	2.5	14

[1] All device dimensions are nominal.

[2] Appropriate oversizing is built into recommended sizes.

[3] The SB component should be selected such that the Portal Segment Diameter is chosen to match the Internal Portal Diameter of the selected Aortic Component.

[4] Measured along the outer curvature of the left subclavian artery from the ostium to the first major branch vessel.

[5] The Gore® DrySeal Introducer Sheath family of devices

Figure 4. Aortic Extender and Aortic Extender Delivery System

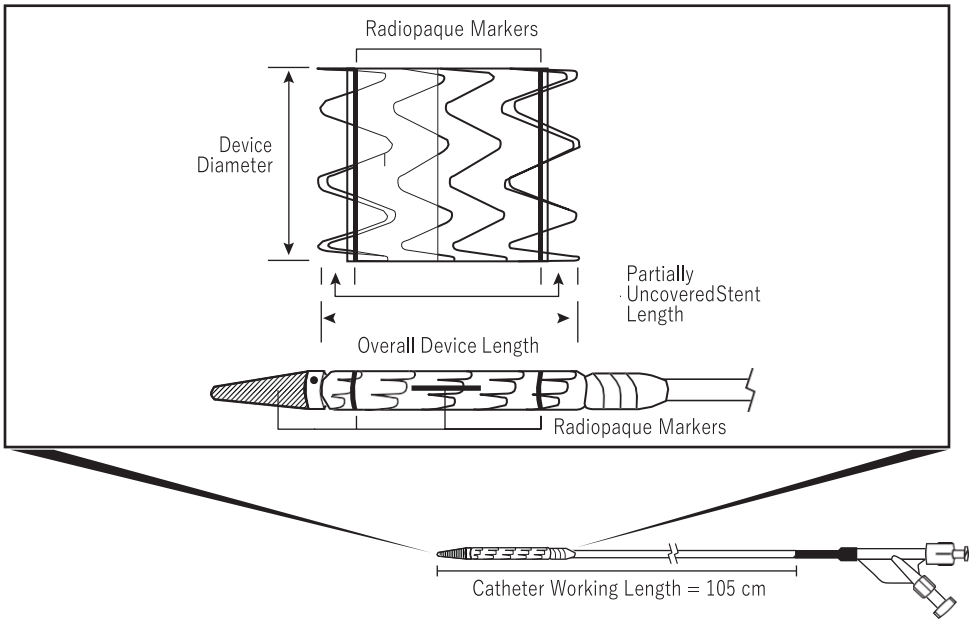


Table 4. Aortic Extender Sizing Guide

	Device Dimensions[1] and Sizing Requirements				
Item Number	**Device Diameter (mm)**	**Intended Aortic Diameters[2] (mm)**	**Overall Device Length (cm)**	**Partially Uncovered Stent Length[3] (mm)**	**GORE® DrySeal Sheath Size (Fr)[4]**
TE2136	21	16 - 19.5	3.6	3	20
TE2638	26	19.5 - 24	3.8	4	20
TE2840	28	22 -26	4.0	4	22
TE3140	31	24 - 29	4.0	4	22
TE3442	34	27 - 32	4.2	5	24
TE3742	37	29 - 34	4.2	5	24
TE4043	40	31 - 37	4.3	6	26
TE4546	45	34 - 42	4.6	6.5	26

[1] All device dimensions are nominal.

[2] Appropriate oversizing is built into recommended sizes.

[3] The proximal uncovered stent maybe positioned such that it crosses up to half of the diameter of the left common carotid artery ostium.

[4] The GORE®DrySeal Introducer Sheath family of devices.

INDICATIONS FOR USE

The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, inpatients who are at high risk for debranching subclavian procedures and 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 left subclavian artery 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 left subclavian artery to mid left common carotid ostium) of at least 2.0-4.0 cm, depending on Aortic Component selection
  - Proximal covered length (measured from distal edge of left subclavian artery to distal edge of left common carotid artery ostium) of at least 15–36 mm, depending on AorticComponent 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

- Left Subclavian Landing Zone:
  - Landing zone cannot be aneurysmal, dissected, heavily thrombosed and severely tortuous (180 degree turn within the treated length)
  - Left subclavian artery inner diameter of 6–18 mm, depending on Side Branch Portal diameter selected
  - Left subclavian artery 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
  - Non aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone
  - Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft

CONTRAINDICATIONS

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

- Patients with known sensitivities or allergies to the device materials (**Table 1**)
- 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

WARNINGS AND PRECAUTIONS

Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient (see ADVERSE EVENTS).

General

- Compliance with device sizing recommendations is critical to optimal performance of the device (refer to **Tables 2 - 4**).
- All patients should be advised this treatment modality requires long term, regular follow-up to assess patients' health status and stent graft performance. Patients with specific clinicalfindings (e.g., endoleaks, enlarging lesions) should receive enhanced follow-up (See IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
- The safety and effectiveness of the GORE® TAG® Thoracic Branch Endoprosthesis for the treatment of patients with traumatic transections, other isolated lesions (e.g. intramural hematoma), and surgical graft landing zones was determined based on limited data (See SUMMARY OF CLINICAL STUDY)..
- The safety and effectiveness of the GORE® TAG® Thoracic Branch Endoprosthesis to treat lesions of the descending thoracic aorta was determined based on 30 day and 1 year follow- up data, respectively. Due to the short-term nature of this data, all patients should be advised that long-term, regular follow-up is necessary to assess patients' health status and stentgraft performance.
- The GORE® TAG® Thoracic Branch Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed theappropriate physician training program.
- The GORE® TAG® Thoracic Branch Endoprosthesis is not recommended in patients unable to undergo, or who will not be compliant with, the necessary pre- and post-operativeimaging and follow-up described in IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP.
- Endovascular or surgical intervention, including conversion to standard open surgical repair, following initial endovascular repair should be considered for patients experiencingclinical signs of malperfusion associated with the left subclavian artery, as this may lead to ischemia (such as peripheral malperfusion or ischemia or paraplegia/paraparesis), stroke, and/or death.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aortas, endoleaks, dissectionextension, or persistent false lumen perfusion. An increase in aortic size, persistent endoleak, or continued false lumen perfusion may lead to aortic rupture.
- Always have an appropriate surgical team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
- The presence of heparin on the GORE® TAG® Thoracic Branch Endoprosthesis SB Component is not intended to serve as an alternative to the surgeon's chosen intraoperative orpostoperative anticoagulation regimens.
- If abnormal or inconsistent deployment line resistance is felt during deployment initiation, STOP deployment action immediately. If device remains constrained, remove device throughthe introducer sheath. If resistance is felt during removal through the sheath, stop and withdraw device and introducer sheath together.
- If the device is in a partially deployed state and remains attached to the catheter, physicians should strongly consider conversion to immediate open surgical repair. A partialdeployment can lead to aortic occlusion with related serious harms.

Patient Selection and Treatment

- High risk patients conditions include but are not limited to morbid obesity, potential for duct/nerve injury, and carotid stenosis.
- Successful patient selection requires specific imaging and accurate measurements (see Measurement Techniques and Imaging section).
- There is an increased risk of stroke in the branched TEVAR procedure compared to non-branched TEVAR with LSA revascularization, which has resulted in loss of motor function or death.
- There is an increased risk of new dissections in the branched TEVAR procedure compared to non-branched TEVAR with LSA revascularization. These events have resulted in the need for reintervention (e.g.. endovascular intervention, conversion to open surgical repair) or if left untreated has resulted in death.
- There is an increased risk of endoleak in the branched TEVAR procedure compared to non-branched TEVAR with LSA revascularization. These events have resulted in the need for reintervention (e.g.. endovascular intervention, conversion to open surgical repair), aortic enlargement, or if left untreated may result in death.
- Use of the GORE® TAG® Thoracic Branch Endoprosthesis outside of the recommended anatomical sizing guidelines (**Tables 2 - 4**) may result in potentially serious device-related events(e.g., endoleak, wire fracture, migration).
- The GORE® TAG® Thoracic Branch Endoprosthesis is designed to treat aortic neck diameters between 16 mm and 42 mm and left subclavian artery diameters between 6 mm and18 mm. In addition, patient anatomy must include sufficient aortic and left subclavian artery length for the selected Aortic and Side Branch Components, as defined in the sizing

guides (**Tables 2 and 3**). Distal aortic neck length of at least 2 cm proximal of the celiac artery is required. These sizing measurements are critical to the successful performance of theendovascular repair.

- The safety and effectiveness of the GORE® TAG® Thoracic Branch Endoprosthesis have not been evaluated in the following patient conditions:
  - aortic fistulas
  - aortitis or inflammatory aneurysms
  - aortic arch disease
  - mycotic aneurysms
  - previous surgical repair in the descending thoracic aortic area
  - genetic connective tissue disease (e.g., Marfans and Ehlers-Danlos syndrome)
  - patients with active systemic infections
  - patients less than 18 years old
  - pregnant or nursing females
  - thoracoabdominal disease
  - ascending aortic disease
- For initial Zone 2 GORE® TAG® Thoracic Branch Endoprosthesis cases, through-and-through wire access is recommended to aid in side branch wire manipulation throughout theprocedure.
- Differing proximal and distal aortic neck diameters (aortic taper) outside the intended aortic diameter requirements for a single Aortic Component diameter (**Table 2**) requires the useof distal extensions using the GORE® TAG® Conformable Thoracic Stent Graft. The GORE® TAG® Conformable Thoracic Stent Graft should be used according to its Instructions for Use.
- Distal GORE® TAG® Conformable Thoracic Stent Grafts that are smaller or the same diameter as the Aortic Component should be implanted first with the maximum possible overlap length being careful not to obstruct the left subclavian artery ostium. Distal GORE® TAG® Conformable Thoracic Stent Grafts that are larger than the Aortic Component should be deployed after deployment of both the Aortic and Side Branch Components. In such cases, care should be taken to ensure adequate distal length is available to allow positioning of theproximal end of distal extension(s) at least 1 cm distal to the trailing end of the deployed SB Component.
- Ilio-femoral access vessel size and morphology (e.g., minimal thrombus, calcium and/or tortuosity) should be adequate to accommodate the required Aortic Component introducersheath diameter (**Table 2**) using appropriate vascular access techniques (including surgical conduit, if needed).
- If left subclavian artery angulation is less than 30° , through-and-through wire access may be required for side branch wire manipulation to advance the SB Component.
- If through-and-through wire access is obtained, ensure the vessel size and morphology is adequate for side branch wire manipulation using appropriate vascular access techniques.Proximal access (e.g., axillary vessel) may need to be obtained if brachial access is inadequate.
- As through and through left subclavian wire access has intrinsic risk of shear injury to the vessel, appropriate protective measures should always be employed.
- Key anatomic elements that may affect successful exclusion of the lesion include severe neck angulation, short aortic neck(s), which should include assessment of the outer and inner curve, and significant thrombus and/or calcium at the arterial implantation sites. In the presence of anatomical limitations, a longer neck length may be required to obtain adequatesealing and fixation.
- Excessive thrombus or atherosclerotic plaque in the ascending aorta or the aortic arch may increase the risk of stroke secondary to the implantation procedure.
- Adjunctive surgical or interventional procedures may be required to treat Type B dissections.
- When treating Type B dissections, the proximal extent of the intended proximal landing zone must not be dissected. Landing the proximal end of the device in dissected tissue couldincrease the risk of damage to the septum and could lead to new septal tears, aortic rupture, retrograde dissection, or other complications.
- When treating Isolated Lesions, the lesion (e.g. intramural hematoma, penetrating aortic ulcer, aneurysm, etc) should not be present in the proximal and distal landing zones.
- Use caution in treating patients with concomitant ascending aortic aneurysms.
- Use caution in patients with a proximal vessel that is 30° or more anterior to the left subclavian artery. This patient anatomy may result in substantial coverage of the proximal vesselorigin with the proximal deployment sleeve on the Aortic Component.
- The GORE® TAG® Thoracic Branch Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-upimaging.
- The GORE® TAG® Thoracic Branch Endoprosthesis is not recommended in patients with previously implanted devices with an exposed stent that extends into the aortic lumen (e.g.,Zone 0 or 1 re-intervention of a previously implanted Zone 2 thoracic branch device). This has resulted in premature partial deployment of the Aortic Component during catheter retraction.
- The GORE® TAG® Thoracic Branch Endoprosthesis is not recommended in patients with severe left subclavian artery tortuosity that results in a 180° turn within the treated left subclavian artery length. There has been difficulty in advancing the Side Branch Component into the left subclavian artery in a patient with severe left subclavian tortuosity. Difficultyin advancement may lead to inability to complete the procedure, trauma to the vessel wall, and embolization with subsequent complications such as ischemia, stroke, dissection, perforation, or rupture of the aortic vessel.
- The GORE® TAG® Conformable Thoracic Stent Graft is not recommended for proximal extension of the GORE® TAG® Thoracic Branch Endoprosthesis Aortic Component. Advancing the GORE® TAG® Conformable Thoracic Stent Graft proximal to the internal portal of the Aortic Component may be difficult and require additional wire manipulation and/or an additional access site (e.g., transapical access).
- Do not use the GORE® TAG® Thoracic Branch Endoprosthesis in patients with known sensitivities or allergies to the device materials (see **Table 1**).
- This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy to the materials.
- Do not use the GORE® TAG® Thoracic Branch Endoprosthesis in patients who have a condition that threatens to infect the graft.
- Do not use the GORE® TAG® Thoracic Branch Endoprosthesis in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of HIT type
  II. With any vascular procedure, the possibility of HIT may exist. The incidence of HIT type II is extremely low in vascular patients receiving heparin over a period of several days. If HITtype II is diagnosed, established procedures for the treatment of this condition, including immediate cessation of systemic heparin administration, should be followed.[1,2] If symptoms persist, or the health of the patient appears compromised, alternative pharmaceutical or surgical procedures, including removal of the device, may be

considered at the discretion of the attending physician.

Measurement Techniques and Imaging

Contrast-enhanced spiral computed tomographic angiography (CTA) with 3-D reconstruction is the imaging modality required to accurately assess patient anatomy prior to treatment forthe GORE® TAG® Thoracic Branch Endoprosthesis.

- Diameter

  A contrast-enhanced spiral CTA is required for aortic and left subclavian artery diameter measurements. Diameter measurements must be of the inner diameter of the vessel (intima-to-intima), not including vessel wall. The spiral CTA scan must include no less than 5 cm of the great vessels through the femoral heads at an axial slice thickness of 2 mm or less.

- Length

  3-D CTA reconstruction is the imaging modality recommended to accurately assess proximal and distal outer curvature neck lengths and total treatment length for the GORE® TAG®Thoracic Branch Endoprosthesis. These reconstructions should be performed in sagittal, coronal and varying oblique views depending upon individual patient anatomy.

- Angles

  3-D CTA reconstruction is recommended to determine the angulation necessary for proper positioning of the imaging intensifier (C-arm) for accurate procedural fluoroscopic imagingand Aortic Component and Aortic Extender placement.

Device Selection

- Strict adherence to the GORE® TAG® Thoracic Branch Endoprosthesis IFU sizing guide is required when selecting the appropriate size device components (**Tables 2 - 4**). Appropriate oversizing of the GORE® TAG® Thoracic Branch Endoprosthesis has been incorporated into the IFU sizing guide. Sizing outside of this range may result in endoleak, fracture, migration,device infolding, or compression. If aortic angulation is less than 60 degrees, or if there is significant calcium or thrombus, additional neck length may be required.
- Follow the recommendations of the Instructions for Use, carefully using the sizing guide (**Tables 2 - 4**) and aortic screening measurements (**Figures 5-7**).
- The proximal aortic neck outer curvature length proximal to and including the left subclavian artery ostium must be compatible with the required Aortic Component, according to **Table 2**.
- The left subclavian artery outer curvature length proximal to its first major branch must be compatible with the required Side Branch Component, according to **Table 3**.
- A distal aortic neck length of ≥ 2 cm proximal of the celiac artery is required.
- Care should be taken to ensure that the portal segment diameter of the selected Side Branch Component is the same as the internal portal diameter of the selected Aortic Component.

Implant Procedure

- Carefully inspect the device prior to use. If the device is damaged, do not use.
- Do not use if the package is opened or damaged, or it is suspected that the sterility of the device has been compromised, as infection and related serious potential patient harms couldoccur.
- Reuse may result in infection and related serious potential patient harms. See HOW SUPPLIED.
- When catheters are in the body, manipulate only under fluoroscopic guidance.
- Appropriate procedural fluoroscopic imaging is required to successfully position the GORE® TAG® Thoracic Branch Endoprosthesis in the landing zone.
- During Aortic Component and Aortic Extender positioning and deployment, **the C-arm must be positioned such that it is perpendicular to the proximal aortic neck and theorigin of the left subclavian artery vessel**, as determined by 3-D reconstructions of pre-operative CT imaging. This angle is typically 45-75 degrees left anterior oblique (LAO). Additionally, cranial or caudal angulation of the C-arm may be necessary for accurate visualization of the origin of the left subclavian artery.
- If through-and-through wire access is necessary, it is recommended that snaring of the branch wire be performed in the descending thoracic aorta and not performed in the ascendingor aortic arch to mitigate risk of emboli during snaring.
- Care should be taken when manipulating the through wire. Manipulation of the wire has led to damage to the vessel (e.g. new dissection).
- For deployment of the Aortic Component, the side branch wire should not be too stiff (e.g. Amplatz Super stiff). In anatomies with severe angulation of the left subclavian artery, a stiffside branch wire has resulted in difficulty in advancing the Aortic Component to the target location.
- There has been difficulty in removing guidewire twists and rotational alignment in patients with tortuous anatomy. Selection of a shorter Aortic Component (e.g. 10 or 15 cm) rather than a longer Aortic Component (e.g. 20 cm) may allow for easier removal of guidewire twists and rotational alignment. Selection of longer Dryseal Sheath (e.g. 65 cm) rather than ashorter Dryseal Sheath (e.g. 33 cm) may allow for easier removal of guidewire twists.
- Before deploying the Aortic Component, ensure that the portal opening is rotationally aligned with the origin of the left subclavian artery so that the anterior proximal sleeve will notsubstantially cover the proximal vessel origin.
- For patients with a tortuous left subclavian artery, guidewire compression (e.g. pushing on both ends of the wire) may lead to Aortic Component portal flattening which can be visualized as a portal collapse. Pull tension on both ends of the side branch wire to create tension, which should mitigate portal flattening.
- In patients with lateral aortic tortuosity, rotational alignment of the Aortic Component may be difficult and additional SB Components may need to be implanted.
- If a second SB Component is required, it is recommended to extend by ≤ 20 mm. In clinical use, a second SB Component was deployed > 20 mm resulting in a type III endoleak.
- Systemic anticoagulation based on hospital and physician preferred protocol should be used during the implantation procedure to prevent thrombotic complications. If heparin iscontraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination or infection.
- Do not rotate delivery catheters with the endoprosthesis inside the introducer sheath. Catheter breakage or inadvertent deployment may occur.
- Do not rotate the SB Component delivery catheter. Catheter breakage or inadvertent deployment has occurred.
- Do not attempt to reposition the endoprosthesis after deployment has been initiated. Vessel damage or endoprosthesis misplacement may result.
- Do not continue advancement or retraction of the guidewire, sheath, or delivery catheter if resistance is felt. Stop and assess the cause of resistance. Vessel, endoprosthesis, or deliverycatheter damage may occur.

- Care should be taken to maintain aortic and side branch guidewire access. If guidewire access is lost, additional steps should be taken to regain access into the correct lumen beforeproceeding with subsequent procedural steps.
- Excessive forward pressure or pressure applied directly to the catheter shaft during deployment has resulted in inaccurate device positioning.
- Incorrect deployment or migration of the endoprosthesis has required endovascular or surgical intervention.
- Inflation of a balloon to reposition a device could increase the risk of damage to the aorta and has led to new dissection of the aorta in clinical use.
- Use caution if removing an undeployed endoprosthesis through the introducer sheath. Inadvertent endoprosthesis deployment may occur. If resistance is felt during removal of thedelivery catheter, stop and withdraw the delivery catheter and introducer sheath together.
- If removal of the undeployed Aortic Component is required, the removable guidewire tube should be re-advanced through the constrained device prior to withdrawingthe branch guidewire.
- Significant arterial branches without sufficient collateral or protected perfusion to end organs or body structures should not be obstructed with the deployed endoprosthesis. Vesselocclusion and/or tissue ischemia (including stroke) may occur.
- When treating ruptured dissections, consider extended coverage of the dissection distally to the celiac in order to promote thrombosis of the false lumen and decrease the risk ofperfusion of the ruptured false lumen through distal fenestrations in the septum.
- When treating acute dissections with multiple devices, always deploy the proximal device first. Inadvertent pressurization of the false lumen may result in retrograde dissection.
- When treating dissections and isolated lesions, ensure the distal end of the device is in a straight portion of the aorta in order to reduce risk of septum damage or vessel damage.
- When treating dissections, consider coverage of ≥ 10 cm distal to the primary entry tear to ensure adequate coverage to stabilize the septum and promote thrombosis of the falselumen.
- Deployment of the Aortic Extender such that the trailing gold band extends distally beyond the trailing end of the SB Component may result in branch vessel occlusion.
- If the deployment line cannot be completely removed from the Aortic Extender catheter and the Aortic Extender is completely deployed, the deployment line may be still engaged with the Aortic Extender. Additional manipulation may be required to disengage the deployment line from the Aortic Extender. [See DIRECTIONS FOR USE Aortic Extender ComponentPreparation and Delivery No. 9 Note.] Additional manipulation may result in new dissection or distal movement of the Aortic Extender resulting in SB component occlusion. Surgical conversion or intervention may be required if the deployed Aortic Extender moves to an undesired location (e.g. coverage of a branch vessel).
- The trailing end of the Aortic Extender sleeve may engage with a flared apex on the SB Component leading to resistance during Aortic Extender delivery catheter withdrawal. Additional manipulation may be required to disengage the Aortic Extender sleeve. [See DIRECTIONS FOR USE Aortic Extender Component Preparation and Delivery No. 9 Note]. Continued Aortic Extender delivery catheter retraction with engagement may lead to trauma to the vessel wall, SB component endoprosthesis stent detachment, and Aortic Extenderdelivery catheter damage with subsequent complications (such as new dissection or stroke).
- The Aortic Component of the GORE® TAG® Thoracic Branch Endoprosthesis is only compatible with the GORE® DrySeal Sheath family of devices. Compatibility with other sheaths hasnot been established. Use of any other introducer sheath may result in significant blood loss and/or damage to the endoprosthesis, delivery system, or catheter, which may cause premature or inadvertent deployment, or breakage. Please refer to specific GORE® DrySeal Sheath Instructions for Use.
- *In vitro* testing has shown that the GORE® TAG® Thoracic Endoprosthesis is not compatible with introducer sheaths that have multi- layer silicone disc valves. Catheter breakage hasbeen observed in clinical use with such valves.
- Gore recommends the GORE® Tri-Lobe Balloon Catheter for use with the Aortic Component and Aortic Extender of the GORE® TAG® Thoracic Branch Endoprosthesis. Data are not available for use of other balloon catheters with the Aortic Component and Aortic Extender of the GORE® TAG® Thoracic Branch Endoprosthesis. Use according to the GORE® Tri-LobeBalloon Catheter Instructions for Use.
- Care should be taken when ballooning in patients with a history of aortic dissection. Over inflation of the balloon in dissection patients has led to aortic damage including retrogradedissection and damage to the septum. Ballooning should only be completed when necessary such as treatment of an endoleak. When ballooning in dissection patients, balloon
  the proximal landing zone first and then overlapped areas (if appropriate). Do not balloon the distal neck of dissections. Inadvertent pressurization of the false lumen may result inretrograde dissection or damage to the septum.
- Care should be taken when ballooning in patients with other isolated lesions (e.g. intramural hematoma, pseudoaneurysm, etc). Over inflation of the balloon in these patients has ledto aortic damage and has led to new dissection of the aorta in clinical use. Ballooning should only be completed when necessary such as treatment of an endoleak.
- To avoid vessel trauma, do not over inflate the GORE® Tri-Lobe Balloon Catheter in relation to the diameter of the thoracic aorta or the GORE® TAG® Thoracic Branch Endoprosthesis.
- Do not inflate the GORE® Tri-Lobe Balloon Catheter in areas of significant calcified plaque. Balloon rupture and/or vessel damage may occur.
- Care should be taken not to balloon outside of the GORE® TAG® Thoracic Branch Endoprosthesis. Ballooning native vessel could lead to vessel damage, rupture, or death.
- Ballooning of the Side Branch Component should be performed using an appropriate diameter percutaneous angioplasty balloon catheter or compliant balloon catheter sizedaccording to the left subclavian artery diameter per the manufacturer's instructions for use.
- When ballooning within the region of the portal overlap between the Aortic Component and the SB Component, the balloon catheter should be inflated to profile only. In cases where the selected balloon catheter has a smaller maximum diameter than the portal diameter, a larger balloon must first be used in the region of the portal overlap, followed by the smaller balloon in the left subclavian artery.

Follow-Up

- Do not use the GORE® TAG® Thoracic Branch Endoprosthesis in patients unable to undergo the necessary pre-operative and post-operative imaging. All patients should be monitoredclosely and checked periodically for a change in the condition of their disease and the integrity of the endoprosthesis.
- Wire fractures have been reported on thoracic endoprostheses and may be more likely to occur in conditions with excessive endoprosthesis oversizing, flexion, kinking, or bending with cardiac or respiratory cycles. Wire fractures may have clinical consequences which may include, but are not limited to endoleak, endoprosthesis migration, side branch occlusion,and/or adjacent tissue damage.
- Stent-graft patency should be evaluated and monitored during follow-up. If reduced blood flow through any device or occlusion of a device is observed, a secondary intervention orsurgical procedure may be required to re-establish flow if clinically necessary.
- Non-clinical testing has demonstrated that the GORE® TAG® Thoracic Branch Endoprosthesis is MR Conditional. Please refer to the IMAGING GUIDELINES AND POST-OPERATIVEFOLLOW-UP for MR information

Potential Adverse Events

Possible adverse events and complications that may occur with the use of GORE® TAG® Thoracic Branch Endoprosthesis include, but are not limited to (shown in English alphabeticalorder):

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, aortoesophogeal, 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)

A possible complication which may occur in conjunction with the use of any heparin-containing product: HIT type II (see WARNINGS AND PRECAUTIONS).

Refer to IFU Section WARNING AND PRECAUTIONS for any additional information regarding adverse events and any steps that should be taken to avoid them, as well as informationabout other warnings and precautions.

Device Related Adverse Event Reporting

Any adverse event involving the GORE® TAG® Thoracic Branch Endoprosthesis should be reported to the manufacturer and the country specific regulatory authorities immediately. Toreport an event to W. L. Gore & Associates, email: medcomplaints@wlgore.com or contact: US: Phone: +1.800.528.1866 or +1.928.864.4922.

SUMMARY OF CLINICAL STUDY

An Investigational Device Exemption (IDE) clinical study was conducted to evaluate the safety and effectiveness of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device) in treating lesions of the thoracic aorta in Zone 2 (SSB 11-02 Pivotal). A summary of the study is provided below that includes study information and clinical data. Clinical data reported iscurrent as of April 12, 2021 and included 238 patients.

The study was a non-randomized, multicenter, prospective study. Patients were treated between September 2016 and October 2019. There were 40 investigational sites in the US. Thestudy design includes the assessment of the GORE® TAG® Thoracic Branch Endoprosthesis in treating lesions of the thoracic aorta in Zone 2.

Enrollment in SSB 11-02 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 2.
- 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 left subclavian landing zone.
- For patients with aneurysm/isolated lesion, must have appropriate distal aortic landing zone.

Patients were not permitted to enroll in the SSB11-01 02 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 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, or surgery to treat any otherpresenting injuries in Traumatic Transection Subjects only.
- 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 leadingto death, with no apparent cause other than that of vascular origin.
- Patient has a systemic infection and may be at increased risk of endovascular graft infection
- 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 compensatefor the taper
- Mycotic aneurysm
- Persistent refractory shock (systolic blood pressure <90 mm Hg)
- 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 or currently requiring dialysis

The SSB 11-02 study was a clinical study with two (2) independent arms specific to Zone 2 with a total of four (4) cohorts. The objective was to perform hypothesis-driven analysis of theTBE Device's safety and effectiveness in the treatment of aortic aneurysms requiring proximal device placement in Zone 2 of the thoracic aorta. The arms are described as follows:

- Zone 2 – Aneurysm Arm/Cohort: Primary enrollment cohort with hypothesis-driven analysis
- Zone 2 – Non-aneurysm aortic lesions which are anatomically suitable for treatment with the TBE Device, descriptive analysis

- Dissection cohort
- Traumatic Transection cohort
- Other isolated lesion types (Other Isolated Lesions are Non-Aneurysm, Non-Traumatic Transection, or Non- Dissection lesions with non-diseased proximal and distal landing zones for example intramural hematomas, aortic ulcers etc.)

Tables 5 and 6 provide the disposition and compliance for subjects in the the aneurysm and dissection cohorts.

Table 5: Subject Disposition and Compliance for Zone 2 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]
Endovascular Procedure	84	84 (100.0%)	-	-	-	0 (0%)	-	-	-	-	84 (100.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Post-Procedure	84	82 (97.6%)	80 (95.2%)	13 (15.5%)	0 (0%)	0 (0%)	-	12 (14.3%)	13 (15.5%)	13 (15.5%)	13 (15.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 Month	84	79 (94.0%)	78 (92.9%)	72 (85.7%)	1 (1.2%)	0 (0%)	-	69 (82.1%)	72 (85.7%)	72 (85.7%)	70 (83.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 Months	84	76 (90.5%)	72 (85.7%)	74 (88.1%)	0 (0%)	0 (0%)	62 (73.8%)	72 (85.7%)	73 (86.9%)	73 (86.9%)	72 (85.7%)	3 (3.6%)	0 (0%)	1 (1.2%)	0 (0%)
12 Months	80	74 (92.5%)	69 (86.3%)	68 (85.0%)	1 (1.3%)	0 (0%)	57 (71.3%)	66 (82.5%)	67 (83.8%)	66 (82.5%)	67 (83.8%)	2 (2.5%)	0 (0%)	2 (2.5%)	0 (0%)
24 Months	76	64 (84.2%)	55 (72.4%)	53 (69.7%)	0 (0%)	0 (0%)	47 (61.8%)	51 (67.1%)	53 (69.7%)	53 (69.7%)	51 (67.1%)	5 (6.6%)	0 (0%)	3 (3.9%)	0 (0%)
36 Months	68	37 (54.4%)	29 (42.6%)	33 (48.5%)	0 (0%)	24 (35.3%)	25 (36.8%)	26 (38.2%)	28 (41.2%)	28 (41.2%)	27 (39.7%)	1 (1.5%)	0 (0%)	2 (2.9%)	33 (48.5%)
48 Months	32	4 (12.5%)	2 (6.3%)	4 (12.5%)	0 (0%)	28 (87.5%)	1 (3.1%)	1 (3.1%)	1 (3.1%)	1 (3.1%)	1 (3.1%)	0 (0%)	0 (0%)	0 (0%)	32 (100.0%)

[1]Subjects still within follow-up window, but data not yet available.
[2]Not 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.
[3]In this table, lost to follow-up (LTF) includes all other reasons for study discontinuation including Subjects that have withdrawn from the study.
[4]Those 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: 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 6: Subject Disposition and Compliance for Zone 2 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]
Endovascular Procedure	132	132 (100.0%)	-	-	-	0 (0%)	-	-	-	-	132 (100.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Post-Procedure	132	129 (97.7%)	124 (93.9%)	17 (12.9%)	0 (0%)	0 (0%)	-	17 (12.9%)	16 (12.1%)	17 (12.9%)	16 (12.1%)	4 (3.0%)	0 (0%)	0 (0%)	0 (0%)
1 Month	128	119 (93.0%)	118 (92.2%)	109 (85.2%)	0 (0%)	0 (0%)	-	106 (82.8%)	109 (85.2%)	104 (81.3%)	107 (83.6%)	2 (1.6%)	0 (0%)	0 (0%)	0 (0%)
6 Months	126	113 (89.7%)	97 (77.0%)	108 (85.7%)	1 (0.8%)	0 (0%)	95 (75.4%)	103 (81.7%)	107 (84.9%)	102 (81.0%)	106 (84.1%)	5 (4.0%)	0 (0%)	0 (0%)	0 (0%)
12 Months	121	103 (85.1%)	99 (81.8%)	98 (81.0%)	0 (0%)	1 (0.8%)	90 (74.4%)	94 (77.7%)	97 (80.2%)	94 (77.7%)	95 (78.5%)	3 (2.5%)	0 (0%)	3 (2.5%)	2 (1.7%)
24 Months	113	76 (67.3%)	64 (56.6%)	68 (60.2%)	0 (0%)	24 (21.2%)	59 (52.2%)	60 (53.1%)	64 (56.6%)	60 (53.1%)	61 (54.0%)	4 (3.5%)	0 (0%)	2 (1.8%)	32 (28.3%)
36 Months	75	35 (46.7%)	29 (38.7%)	32 (42.7%)	0 (0%)	30 (40.0%)	29 (38.7%)	25 (33.3%)	29 (38.7%)	28 (37.3%)	25 (33.3%)	0 (0%)	0 (0%)	1 (1.3%)	38 (50.7%)
48 Months	36	6 (16.7%)	5 (13.9%)	6 (16.7%)	0 (0%)	28 (77.8%)	3 (8.3%)	4 (11.1%)	4 (11.1%)	4 (11.1%)	4 (11.1%)	1 (2.8%)	0 (0%)	2 (5.6%)	33 (91.7%)

[1]Subjects still within follow-up window, but data not yet available.
[2]Not 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.
[3]In this table, lost to follow-up (LTF) includes all other reasons for study discontinuation including subjects that have withdrawn from the study.
[4]Those 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: 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

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

- Traumatic Transection Cohort: All nine (100%) eligible Subjects in this cohort had a 1-Month visit and imaging. Seven (77.8%) Subjects had their 12-Month visit (66.7% had imaging). All nine Subjects were through the 12-Month follow-up window, with four Subjects in the 24-Month window and five in the 36-Month window. There have been no deaths or discontinuations in this cohort.
- Other Isolated Lesion Cohort: Twelve (92.3%) of the 13 Subjects in this cohort had a 1-Month visit and imaging. Eleven Subjects were eligible for a 12-Month follow-up visit, and 9 (81.8%) Subjects had their 12-Month visit (72.7% had imaging). Two Subjects were still in the 12-Month window, with four in the 24-Month window, one in the 36-Month window, and one in the 48-Month window. There have been four deaths and one non-death discontinuation in this cohort.

Subject Characteristics

Table 7 shows a summary of subject baseline demographics for the SSB11-02 study.

Table 7: Baseline Demographics

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Sex					
Male	53 (63.1%)	99 (75.0%)	8 (88.9%)	6 (46.2%)	166 (69.7%)
Female	31 (36.9%)	33 (25.0%)	1 (11.1%)	7 (53.8%)	72 (30.3%)
Ethnicity					
Not Hispanic or Latino	82 (97.6%)	123 (93.2%)	5 (55.6%)	10 (76.9%)	220 (92.4%)
Hispanic or Latino	2 (2.4%)	7 (5.3%)	4 (44.4%)	3 (23.1%)	16 (6.7%)
Unknown	0 (0%)	2 (1.5%)	0 (0%)	0 (0%)	2 (0.8%)
Race[1]					
White	67 (79.8%)	96 (72.7%)	5 (55.6%)	9 (69.2%)	177 (74.4%)
Black or African American	12 (14.3%)	29 (22.0%)	0 (0%)	2 (15.4%)	43 (18.1%)
Asian	4 (4.8%)	3 (2.3%)	0 (0%)	0 (0%)	7 (2.9%)
American Indian or Alaska Native	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Hawaiian or Pacific Islander	2 (2.4%)	1 (0.8%)	0 (0%)	0 (0%)	3 (1.3%)
Other	0 (0%)	3 (2.3%)	4 (44.4%)	2 (15.4%)	9 (3.8%)
Age (yrs)					
N	84	132	9	13	238
Mean (Std Dev)	70.3 (11.11)	62.5 (11.29)	42.4 (18.95)	64.8 (13.28)	64.6 (12.93)
Median	72.0	64.0	43.0	67.0	67.0
Range	(33, 87)	(23, 88)	(22, 76)	(30, 79)	(22, 88)
BMI					
N	84	132	9	13	238
Mean (Std Dev)	28.8 (6.30)	30.5 (6.47)	29.5 (5.03)	25.8 (5.33)	29.6 (6.39)
Median	28.3	29.5	29.1	25.8	29.0
Range	(18.9, 51.7)	(16.0, 53.9)	(23.8, 38.8)	(18.9, 38.4)	(16.0, 53.9)

[1]One Zone 2 Aneurysm Subject had two races selected (Asian and Pacific Islander)

A summary of the Zone 2 Subject baseline medical history is displayed in **Table 8**.

Table 8: Baseline Medical History

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Atrial fibrillation	16/83 (19.3%)	25/132 (18.9%)	0/9 (0%)	4/13 (30.8%)	45/237 (19.0%)
Cancer	21/83 (25.3%)	20/130 (15.4%)	1/9 (11.1%)	1/13 (7.7%)	43/235 (18.3%)
Cardiac arrhythmia	15/83 (18.1%)	46/132 (34.8%)	0/9 (0%)	5/13 (38.5%)	66/237 (27.8%)
Chronic obstructive pulmonary disease	16/84 (19.0%)	16/131 (12.2%)	0/9 (0%)	3/13 (23.1%)	35/237 (14.8%)
Congestive heart failure	14/84 (16.7%)	11/132 (8.3%)	0/9 (0%)	0/13 (0%)	25/238 (10.5%)
Coronary artery bypass graft	12/83 (14.5%)	7/132 (5.3%)	0/9 (0%)	0/13 (0%)	19/237 (8.0%)
Coronary artery disease	27/83 (32.5%)	19/126 (15.1%)	1/9 (11.1%)	3/13 (23.1%)	50/231 (21.6%)
Diabetes mellitus	14/84 (16.7%)	19/132 (14.4%)	1/9 (11.1%)	2/13 (15.4%)	36/238 (15.1%)
Erectile dysfunction (males only)	7/27 (25.9%)	4/44 (9.1%)	1/5 (20.0%)	0/3 (0%)	12/79 (15.2%)
Great vessel stenosis	1/83 (1.2%)	1/129 (0.8%)	0/9 (0%)	0/11 (0%)	2/232 (0.9%)
Hypercholesterolemia	44/84 (52.4%)	55/127 (43.3%)	1/9 (11.1%)	6/13 (46.2%)	106/233 (45.5%)

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Hypertension	72/84 (85.7%)	127/132 (96.2%)	4/9 (44.4%)	11/13 (84.6%)	214/238 (89.9%)
Myocardial infarction	14/83 (16.9%)	10/127 (7.9%)	0/9 (0%)	2/12 (16.7%)	26/231 (11.3%)
Nicotine use	30/84 (35.7%)	47/132 (35.6%)	2/9 (22.2%)	7/13 (53.8%)	86/238 (36.1%)
Other vascular intervention	11/83 (13.3%)	8/131 (6.1%)	0/9 (0%)	2/13 (15.4%)	21/236 (8.9%)
Paraplegia	1/84 (1.2%)	0/132 (0%)	0/9 (0%)	0/13 (0%)	1/238 (0.4%)
Percutaneous coronary intervention	14/82 (17.1%)	3/132 (2.3%)	0/9 (0%)	2/13 (15.4%)	19/236 (8.1%)
Peripheral vascular disease	11/83 (13.3%)	8/128 (6.3%)	1/9 (11.1%)	1/13 (7.7%)	21/233 (9.0%)
Prior aortic surgery	32/84 (38.1%)	36/132 (27.3%)	0/9 (0%)	7/13 (53.8%)	75/238 (31.5%)
Renal dialysis	0/83 (0%)	2/132 (1.5%)	1/9 (11.1%)	0/13 (0%)	3/237 (1.3%)
Renal insufficiency	14/84 (16.7%)	24/132 (18.2%)	1/9 (11.1%)	0/13 (0%)	39/238 (16.4%)
Stroke	12/84 (14.3%)	12/132 (9.1%)	1/9 (11.1%)	1/13 (7.7%)	26/238 (10.9%)
Subclavian steal	0/82 (0%)	0/126 (0%)	0/9 (0%)	0/9 (0%)	0/226 (0%)
Thromboembolic event	7/83 (8.4%)	10/132 (7.6%)	0/9 (0%)	0/13 (0%)	17/237 (7.2%)
Transient ischemic attack	6/84 (7.1%)	2/132 (1.5%)	0/9 (0%)	0/13 (0%)	8/238 (3.4%)
Valvular heart disease	20/83 (24.1%)	21/131 (16.0%)	0/9 (0%)	3/13 (23.1%)	44/236 (18.6%)

Table9: Baseline Risk Factors

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Dominant left vertebral artery[1]	5/65 (7.7%)	5/105 (4.8%)	0/7 (0%)	1/6 (16.7%)	11/183 (6.0%)
Occluded/stenosed right vertebral artery[1]	1/69 (1.4%)	2/108 (1.9%)	0/7 (0%)	0/7 (0%)	3/191 (1.6%)
Aberrant right subclavian artery[1]	1/83 (1.2%)	4/128 (3.1%)	0/9 (0%)	3/12 (25.0%)	8/232 (3.4%)
Bilateral carotid artery disease[1]	5/73 (6.8%)	3/118 (2.5%)	0/8 (0%)	1/9 (11.1%)	9/208 (4.3%)
Presence of a left internal mammary artery graft[1]	5/82 (6.1%)	0/129 (0%)	0/9 (0%)	0/12 (0%)	5/232 (2.2%)
Incomplete circle of willis[1]	0/49 (0%)	0/78 (0%)	0/6 (0%)	0/6 (0%)	0/139 (0%)
Left vertebral artery ending in posterior inferior cerebellar artery[1]	0/47 (0%)	0/76 (0%)	0/5 (0%)	0/5 (0%)	0/133 (0%)
Clinical Frailty Scale Score (1-9, higher is more frail)					
n	83	131	8	13	235
Median	3.0	3.0	2.0	3.0	3.0
SVS Score (0-24, higher is worse)					
n	84	132	9	13	238
Median	5.0	5.0	0.0	4.0	5.0
ASA Classification					
I	5/84 (6.0%)	8/132 (6.1%)	2/9 (22.2%)	1/13 (7.7%)	16/238 (6.7%)
II	20/84 (23.8%)	36/132 (27.3%)	3/9 (33.3%)	3/13 (23.1%)	62/238 (26.1%)
III	39/84 (46.4%)	43/132 (32.6%)	0/9 (0%)	4/13 (30.8%)	86/238 (36.1%)
IV	20/84 (23.8%)	44/132 (33.3%)	4/9 (44.4%)	4/13 (30.8%)	72/238 (30.3%)
V	0/84 (0%)	1/132 (0.8%)	0/9 (0%)	1/13 (7.7%)	2/238 (0.8%)
NYHA Classification					
No cardiac disease	28/84 (33.3%)	48/132 (36.4%)	8/9 (88.9%)	5/13 (38.5%)	89/238 (37.4%)

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
I	31/84 (36.9%)	55/132 (41.7%)	1/9 (11.1%)	3/13 (23.1%)	90/238 (37.8%)
II	22/84 (26.2%)	24/132 (18.2%)	0/9 (0%)	5/13 (38.5%)	51/238 (21.4%)
III	3/84 (3.6%)	5/132 (3.8%)	0/9 (0%)	0/13 (0%)	8/238 (3.4%)
IV	0/84 (0%)	0/132 (0%)	0/9 (0%)	0/13 (0%)	0/238 (0%)
[1]Restricted to those with information known					

Table 0: Baseline Core Lab Aortic Treated (Aneurysm/Lesion/Treated Segment) Diameters

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Maximum Transverse Aortic Diameter of Aneurysm/Lesion[1] (mm)					
n	84	123	9	13	229
Median	56.6	47.2	34.8	42.2	50.2
[1]Maximum Aortic Diameter in Treated Segment for Dissection Subjects.					

Table 11 summarizes the baseline (Core Lab) description of the extent of the Dissection treated in the Dissection cohort. For the majority of the Dissection Subjects, proximal extent of Dissection was Zone 2 (70.5%), although all of the Dissection Subjects required the device to be proximally landed in Zone 2. The distal extent of the treated dissection extended to the iliac arteries in the majority of Subjects (56.8%), followed by the abdominal aorta (12.9%), and then the DTA (12.1%, Zone 3-5).

Table 1: Baseline Core Lab Treated Dissection Extent for Zone 2 Dissection Cohort

	Zone 2 Dissection
Number of Enrolled Subjects	132
Proximal Extent of Dissection (Pre-Imaging, Core Lab)[1]	
Zone 0/1	0 (0%)
Zone 2	93 (70.5%)
Zone 3	26 (19.7%)
Zone 4	5 (3.8%)
Zone 5	0 (0%)
Distal Extent of Dissection (Pre-Imaging, Core Lab)[2]	
Aortic Arch (Zone 0,1,2)	0 (0%)
Descending Thoracic (Zone 3,4,5)	16 (12.1%)
Celiac (Zone 6)	4 (3.0%)
SMA (Zone 7)	3 (2.3%)
Renal(s) (Zone 8)	5 (3.8%)
Abdominal (Zone 9)	17 (12.9%)
Iliac(s) (Zone 10,11)	75 (56.8%)
[1]Eight subjects did not have this information reported and were not included in the table. Therefore, the total percentages do not equal 100% [2] Twelve Subjects did not have this information reported and were not included in the table missing this information, therefore this does not add up to 100%.	

Table 12 describes the initial treatment devices implanted in Zone 2 Subjects enrolled in the study. One Zone 2 Dissection Subject did not have both the AC and SB devices implanted andis considered a 'Technical failure' in the Dissection cohort Primary Endpoint results.

Table 12: Treatment Devices Implanted

	Aneurysm Arm		Non-Aneurysm Arm		Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238

	Aneurysm Arm		Non-Aneurysm Arm		Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Subjects with Both GORE® TAG® Thoracic Branch Endoprosthesis s Implanted[1]	84 (100.0%)	131 (99.2%)	9 (100.0%)	13 (100.0%)	237 (99.6%)
Subjects with >1 Aortic Component Implanted	3 (3.6%)	1 (0.8%)	0 (0%)	0 (0%)	4 (1.7%)
Subjects with Aortic Extender Implanted	18 (21.4%)	13 (9.8%)	0 (0%)	1 (7.7%)	32 (13.4%)
Subjects with Other Devices Implanted[2]	2 (2.4%)	1 (0.8%)	0 (0%)	1 (7.7%)	4 (1.7%)
Subjects with CTAG as Distal Extension Implanted	43 (51.2%)	90 (68.2%)	0 (0%)	4 (30.8%)	137 (57.6%)
SB Components Implanted Per Subject[2]					
1 SB Component Implanted	76 (90.5%)	130 (98.5%)	9 (100.0%)	12 (92.3%)	227 (95.4%)
2 SB Components Implanted	8 (9.5%)	1 (0.8%)	0 (0%)	1 (7.7%)	10 (4.2%)
Aortic Extenders Implanted Per Subject					
0 Aortic Extenders	66 (78.6%)	119 (90.2%)	9 (100.0%)	12 (92.3%)	206 (86.6%)
1 Aortic Extender	15 (17.9%)	12 (9.1%)	0 (0%)	1 (7.7%)	28 (11.8%)
2 Aortic Extenders	3 (3.6%)	1 (0.8%)	0 (0%)	0 (0%)	4 (1.7%)
CTAG Devices Implanted Per Subject					
0 CTAGs	41 (48.8%)	42 (31.8%)	9 (100.0%)	9 (69.2%)	101 (42.4%)
1 CTAG	30 (35.7%)	80 (60.6%)	0 (0%)	2 (15.4%)	112 (47.1%)
2 CTAGs	11 (13.1%)	9 (6.8%)	0 (0%)	2 (15.4%)	22 (9.2%)
3+ CTAGs	2 (2.4%)	1 (0.8%)	0 (0%)	0 (0%)	3 (1.3%)

[1]This includes both the aortic and side branch components.

[2]Other devices implanted included the following: One Subject used a GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis device to extend/reinforce the SB Component, another Subject had a GORE® VIABAHN® Endoprosthesis device plus a GORE® EXCLUDER® AAA Endoprosthesis device to treat an access related complication (iliac rupture), a third Subject had two GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis devices used as the SB Component (physician choice, due to difficulty advancing SB Component), and the last Subject had two GORE® VIABAHN® Endoprosthesis devices implanted to treat access related complications (iliac rupture).

Table 3: GORE® TAG® Thoracic Branch Endoprosthesis Aortic Component Sizing

Device Diameter (mm)	SB Portal Diameter (mm)	Device Length (cm)	Subjects (N=238)	Devices (N=242)
21	8	10	2 (0.8%)	2 (0.8%)
26	8	10	3 (1.3%)	3 (1.2%)
26	8	15	1 (0.4%)	1 (0.4%)
28	8	10	5 (2.1%)	5 (2.1%)
28	8	15	3 (1.3%)	3 (1.2%)
31	8	15	16 (6.7%)	16 (6.6%)
31	8	20	11 (4.6%)	11 (4.5%)
34	8	15	37 (15.5%)	37 (15.3%)
34	8	20	17 (7.1%)	17 (7.0%)
34	12	15	1 (0.4%)	1 (0.4%)
34	12	20	9 (3.8%)	9 (3.7%)
37	8	10	3 (1.3%)	3 (1.2%)
37	8	15	28 (11.8%)	28 (11.6%)
37	8	20	17 (7.1%)	17 (7.0%)

Device Diameter (mm)	SB Portal Diameter (mm)	Device Length (cm)	Subjects (N=238)	Devices (N=242)
37	12	15	4 (1.7%)	4 (1.7%)
37	12	20	12 (5.0%)	12 (5.0%)
40	8	15	13 (5.5%)	13 (5.4%)
40	8	20	29 (12.2%)	31 (12.8%)
40	12	20	3 (1.3%)	3 (1.2%)
45	8	15	11 (4.6%)	11 (4.5%)
45	8	20	9 (3.8%)	9 (3.7%)
45	12	15	3 (1.3%)	3 (1.2%)
45	12	20	2 (0.8%)	3 (1.2%)

Table 4: GORE® TAG® Thoracic Branch Endoprosthesis Side Branch Sizing

Device Diameter (mm)	SB Portal Diameter (mm)	Device Length (cm)	Subjects (N=237)	Devices (N=247)
8	8	6	3 (1.3%)	4 (1.6%)
10	8	6	22 (9.3%)	22 (8.9%)
12	8	6	100 (42.2%)	103 (41.7%)
15	8	6	66 (27.8%)	69 (27.9%)
15	12	6	25 (10.5%)	27 (10.9%)
17	8	6	13 (5.5%)	13 (5.3%)
17	12	6	8 (3.4%)	9 (3.6%)

Table 5: Initial Treatment GORE® TAG® Thoracic Branch Endoprosthesis Aortic Extender Sizing

Device Diameter (mm)	Device Length (cm)	Subjects (N=32)	Devices (N=36)
34	4.2	10 (31.3%)	12 (33.3%)
37	4.2	10 (31.3%)	11 (30.6%)
40	4.3	9 (28.1%)	10 (27.8%)
45	4.6	3 (9.4%)	3 (8.3%)

Tables 16-18 summarize the endovascular procedure information by cohort.

Table 16: Procedural Information – Part 1

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Proximal Landing Zone					
Within Surgical Graft	4 (4.8%)	25 (18.9%)	0 (0%)	1 (7.7%)	30 (12.6%)
Within Native Aorta	80 (95.2%)	107 (81.1%)	9 (100.0%)	12 (92.3%)	208 (87.4%)
Procedure Time[1] (minutes)					
n	84	132	9	13	238
Median	154.5	129.0	109.0	142.0	132.5
Anesthesia Method					
General	83 (98.8%)	131 (99.2%)	9 (100.0%)	13 (100.0%)	236 (99.2%)
Regional	0 (0%)	1 (0.8%)	0 (0%)	0 (0%)	1 (0.4%)
Local	1 (1.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.4%)
Access Method					
Percutaneous	49 (58.3%)	105 (79.5%)	6 (66.7%)	6 (46.2%)	166 (69.7%)
Cut-down	28 (33.3%)	26 (19.7%)	3 (33.3%)	6 (46.2%)	63 (26.5%)

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Cut-down and conduit	7 (8.3%)	1 (0.8%)	0 (0%)	1 (7.7%)	9 (3.8%)
Access Vessel					
Left femoral	21 (25.0%)	44 (33.3%)	5 (55.6%)	5 (38.5%)	75 (31.5%)
Right femoral	52 (61.9%)	85 (64.4%)	4 (44.4%)	8 (61.5%)	149 (62.6%)
Left iliac	3 (3.6%)	0 (0%)	0 (0%)	0 (0%)	3 (1.3%)
Right iliac	8 (9.5%)	3 (2.3%)	0 (0%)	0 (0%)	11 (4.6%)
Aortic	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Additional Access Sites[3]					
Left brachial	51 (60.7%)	97 (73.5%)	6 (66.7%)	9 (69.2%)	163 (68.5%)
Left axial	4 (4.8%)	6 (4.5%)	0 (0%)	1 (7.7%)	11 (4.6%)
Other[2]	28 (33.3%)	28 (21.2%)	2 (22.2%)	3 (23.1%)	61 (25.6%)

[1]Procedure Time (min) was captured as the time the first incision was made through the time the access site was closed.
[2]Other access sites may include a combination of multiple access sites including radial access and/or a combination of multiple access sites
[3]Three Subjects did not report additional access sites used, therefore, the total doesn't add up to 100%.

Table 17: Procedural Information – Part 2

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Contrast Used During Procedure (mL)					
n	84	130	8	13	235
Mean (Std Dev)	139.0 (99.28)	126.8 (53.76)	74.4 (17.82)	96.1 (29.13)	127.7 (73.09)
Estimated Blood Loss During Procedure (mL)					
n	83	130	9	13	235
Mean (Std Dev)	247.4 (340.61)	198.6 (708.18)	112.2 (97.57)	191.2 (242.02)	212.1 (566.94)
Blood Loss ≥ 1000mL	5 (6.0%)	3 (2.3%)	0 (0%)	0 (0%)	8 (3.4%)
Transfusion Required	11 (13.1%)	11 (8.3%)	0 (0%)	0 (0%)	22 (9.2%)
Transfusion Required, blood volume replaced (mL)					
n	9[2]	11	0	0	20
Mean (Std Dev)	678.9 (444.25)	1467.5 (2510.76)	-	-	1112.6 (1887.58)
Heparin Administered	84 (100.0%)	132 (100.0%)	9 (100.0%)	13 (100.0%)	238 (100.0%)
Heparin Administered, dose (units per mL) [3]					
n	76	124	9	13	222
Mean (Std Dev)	10098.7 (5039.19)	10791.9 (5318.91)	7444.4 (3643.87)	12230.8 (7811.89)	10503.2 (5368.16)
Adjunctive Technique Used to Prevent Paraplegia					
No	42 (50.0%)	49 (37.1%)	8 (88.9%)	9 (69.2%)	108 (45.4%)
Yes, CSF drainage	35 (41.7%)	70 (53.0%)	1 (11.1%)	4 (30.8%)	110 (46.2%)
Yes, induced hypertension	0 (0%)	5 (3.8%)	0 (0%)	0 (0%)	5 (2.1%)

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Yes, CSF drainage and induced hypertension	2 (2.4%)	2 (1.5%)	0 (0%)	0 (0%)	4 (1.7%)
Yes, other[1]	5 (6.0%)	6 (4.5%)	0 (0%)	0 (0%)	11 (4.6%)

[1]Other adjunctive techniques included induced hypotension, permissive hypertension, and SSEP.
[2]Two Subjects did not have the transfusion volume recorded.
[3]There were eight Aneurysm and eight Dissection Subjects where the heparin dosage was not recorded.

Table 18: Procedural Information – Part 3

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Length of Stay (days)					
n	84	132	9	13	238
Mean (Std Dev)	5.9 (5.49)	7.2 (8.21)	16.6 (17.04)	5.4 (3.59)	7.0 (7.89)
Discharge Location					
Home	74 (88.1%)	119 (90.2%)	7 (77.8%)	11 (84.6%)	211 (88.7%)
Rehabilitation center/nursing facility	9 (10.7%)	9 (6.8%)	1 (11.1%)	2 (15.4%)	21 (8.8%)
Acute care facility	1 (1.2%)	1 (0.8%)	1 (11.1%)	0 (0%)	3 (1.3%)
N/A - Subject died in hospital	0 (0%)	3 (2.3%)	0 (0%)	0 (0%)	3 (1.3%)
Return to Normal Activities (days)[1]					
n	84	129	9	13	235
Mean (Std Dev)	5.0 (5.11)	4.3 (3.51)	11.3 (11.50)	2.3 (1.25)	4.7 (4.77)

[1]Earliest reported time was used to calculate return to normal

Safety and Effectiveness Outcomes

This study has a composite primary endpoint design, of which, there are eight (8) overall components. The components are a mixture of effectiveness and safety variables.
The primary endpoint was a composite of the following events from the time of enrollment through one year:

- Device Technical Success
  - *Successful access and delivery to the intended implantation site, and retrieval of the device delivery system, and;*
  - *Patency of the graft, and;*
  - *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≥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

Primary Endpoint Composite

Each cohort was analyzed separately by lesion type, and analysis of the hypothesis-driven aneurysm cohort and the non-aneurysm cohort was performed after the 12-month follow-upfor the hypothesis-driven cohort was complete.

There have been 12 Aneurysm Subjects (12/74, 16.2%; 83.8% free from endpoint event) that had any primary endpoint event occur as shown in **Table 19**. The denominator is comprisedof the 69 Subjects with imaging performed in the 12-month window and an additional five Subjects with a primary endpoint event who did not have 12 month imaging performed. Table 19 displays the component level event rate over time for each component of the composite Primary Endpoint. Three of these 12 Subjects had more than one type of

primary endpoint event.

The majority (seven of 12, 58.3%) of Subjects with a primary endpoint failure had a technical success failure (three with an inaccurate delivery failure, three with an unanticipated additional procedure failure, and one Subject with a failure to retrieve the delivery system and with an unanticipated additional procedure). There were no failures to achieve side branchpatency at the procedure, and none of the following events occurred through 12 months: aortic rupture, lesion-related mortality, and new onset renal failure requiring permanent dialysis.

Table19: Primary Endpoint Composite Success for Aneurysm Cohort

Primary Endpoint Analysis	Endpoint Denominator	Endpoint Event	Percent Free from Endpoint Event (95% Exact LCL)	Reject Null Hypothesis (LCL > 64% PG)
Endpoint Eligible[1]	74	12	83.8% (75.1%)	Yes

[1]Primary Endpoint composite (Through 12 Months) denominator is restricted to those with primary endpoint event or 12 Month imaging performed. There has been one Subject excluded from this analysis due to having a CEC-adjudicated major inclusion/exclusion criteria violation.
NOTE: 95% LCL represents one-sided 95% Lower Confidence Limit by exact method.

Table 20: Primary Endpoint Component Events for Zone 2 Aneurysm Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	Total (Through 12 Months)
Number of Enrolled Subjects[1]	84	84	84	84	80	84
Number of Subjects with Imaging in Follow-Up Window	-	13	73	74	69	84
Number of Subjects with Imaging or Primary Endpoint Event in Window	-	16	73	74	69	84
Subjects with Primary Endpoint Event[2] Below[3,5]	9/84 (10.7%)	5/16 (31.3%)	0/73 (0%)	0/74 (0%)	1/69 (1.4%)	12/74 (16.2%)
Device Technical Success failure[4]	7/84 (8.3%)	-	-	-	-	7/84 (8.3%)
Access or Device Delivery failure	4/84 (4.8%)	-	-	-	-	-
Access failure	0/84 (0%)	-	-	-	-	-
Accurate deployment failure	3/84 (3.6%)	-	-	-	-	-
Device delivery system retrieval failure	1/84 (1.2%)	-	-	-	-	-
Patency failure	0/84 (0%)	-	-	-	-	-
Unanticipated additional procedure related to device/procedure	4/84 (4.8%)	-	-	-	-	-
Aortic rupture	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/84 (0%)
Lesion-related mortality	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/84 (0%)
Disabling stroke[4]	1/84 (1.2%)	2/84 (2.4%)	0/84 (0%)	-	-	3/84 (3.6%)
Permanent paraplegia[4]	1/84 (1.2%)	0/84 (0%)	0/84 (0%)	-	-	1/84 (1.2%)
Permanent paraparesis[4, 5]	1/84 (1.2%)	2/84 (2.4%)	0/84 (0%)	-	-	3/84 (3.6%)
New onset renal failure requiring permanent dialysis[4]	0/84 (0%)	0/84 (0%)	0/84 (0%)	-	-	0/84 (0%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	0/84 (0%)	1/84 (1.2%)	0/84 (0%)	0/84 (0%)	1/80 (1.3%)	1/84 (1.2%)

[1]Subjects at risk at the start of each interval.
[2]Definitions for all Primary Endpoints are provided above.
[3]Primary Endpoint composite denominator is restricted to Subjects either with a primary endpoint event within window and/or imaging done in window. 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). Primary Endpoint Component Event Rates are based on all enrolled subjects.
[4]Device technical success failure events on day 0 only, others are events with onset through day 30.
[5]One Subject had been CEC-adjudicated as having both Permanent paraplegia and permanent paraparesis. The CEC adjudication data has since been updated to reflect only having permanent paraplegia. A second Subject also had adjudication updated and no longer meets the definition of permanent paraparesis. This would result in an overall permanent paraparesis rate of 1.2% (1/84) and a change in the Primary Endpoint composite Total rate to 15.1% (11/73; the second Subject only had the permanent paraparesis event among the Primary Endpoint components and did not have 12-Month imaging performed).
Study period definitions: Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) Total(0-546 days)

Aneurysm: Device Technical Success

Device Technical Success was achieved in 91.7% of Subjects in the Aneurysm Cohort. Device Technical Success for all components were reported by each Site investigator.

In the Aneurysm Cohort, seven Subjects (8.3%; 7/84) failed to meet the definition of technical success. As noted earlier, one Subject had two events.

- Four Subjects (4.8%) had device delivery failure (three due to AC not being deployed accurately and one due to delivery system retrieval failure).
- Four Subjects (4.8%) required an unanticipated, additional procedure related to device/procedure (One Subject also had the retrieval failure described above).

The procedure was completed in all Subjects and there were no issues with establishing AC or SB graft patency during the procedure.

Aneurysm Permanent Paraplegia/Paraparesis

There was one Aneurysm Subject (1.2%; 1/84) that has been identified as having permanent paraplegia. This Subject had a site-reported adverse event of spinal cord ischemia on the day of the endovascular procedure, with a SCI scale = 3a at the 1-Month follow-up visit. Although also adjudicated as having permanent paraparesis prior to export, the CEC has since removed the permanent paraparesis adjudication from meeting permanent paraparesis criteria and only meeting the definition for permanent paraplegia.

Two additional Aneurysm Subjects (3.6%) have been identified as having isolated permanent paraparesis:

- One subject had a non-serious adverse event of 'mild muscle weakness lower limbs' was reported on POD 11. This was site-reported as unrelated to the device and the procedures. This event is ongoing, and no treatment information has been reported. After data export, the CEC removed this event from meeting permanent paraparesis criteria.

- One Subject had experienced an SAE of 'spinal cord infarct' that was reported on POD 1 and was deemed to be related to the endovascular procedure. The event resolved without sequelae on POD 197. The SCI score at the 1-Month follow-up visit = 2.

Aneurysm Unanticipated additional procedure related to device/procedure

There was one Aneurysm Subject (1/84; 1.2%) reported to meet the Protocol definition of having had an unanticipated additional procedure related to device/procedure. This Subject required a reintervention for a Type III endoleak involving the SB Component, occurring on POD 8 and an additional reintervention on POD 420 for a Type III endoleak at the juncture of the proximal aortic extender and aortic component of the TBE device.

Table 21: Primary Endpoint Composite Success for Dissection, Traumatic Transection and Other Isolated Lesions Cohorts

Primary Endpoint Analysis	Endpoint Denominator[1]	Endpoint Event	Percent Free from Endpoint Event
Dissection	103	12	88.3%
Traumatic Transection	6	0	100%
Other Isolated Lesion	8	1	87.5%

[1]Primary Endpoint composite (Through 12 Months) denominator is restricted to those with primary endpoint event or 12 Month imaging performed.
There has been one Subject excluded from this analysis due to having a CEC-adjudicated major inclusion/exclusion criteria violation one Subject in this cohort has been excluded from all analysis

There have been 12 Dissection Subjects (12/132, 11.7%; 88.3% free from endpoint event) that had any primary endpoint event occur as shown in **Table 22**. This table displays thecomponent level breakdown over time for the composite Primary Endpoint results. Two of these 12 Subjects had more than one type of primary endpoint event.

Half (six of 12) of Subjects with a primary endpoint failure had a reintervention primary endpoint event; three had technical success failure, and three experienced lesion-relatedmortality. There were none of the following events through 12 months: permanent paraplegia/paraparesis and new onset renal failure requiring dialysis.

Table 22: Primary Endpoint Component Events for Zone 2 Dissection Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	Total (Through 12 Months)
Number of Enrolled Subjects	132	132	128	125	114	132
Number of Subjects with Imaging in Follow-Up Window	-	17	109	109	98	124
Number of Subjects with Imaging or Primary Endpoint Event in Window	-	18	110	109	98	127
Subjects with Primary Endpoint Event Below[1]	4/132 (3.0%)	2/18 (11.1%)	2/110 (1.8%)	4/109 (3.7%)	0/98 (0%)	12/103 (11.7%)
Device technical success failure[2]	3/132 (2.3%)	-	-	-	-	3/132 (2.3%)
Access or Device Delivery failure	2/132 (1.5%)	-	-	-	-	-
Access failure	0/132 (0%)	-	-	-	-	-
Accurate deployment failure	2/132 (1.5%)	-	-	-	-	-
Device delivery system retrieval failure	0/132 (0%)	-	-	-	-	-
Patency failure	0/132 (0%)	-	-	-	-	-
Unanticipated additional procedure related to device/procedure	3/132 (2.3%)	-	-	-	-	-
Aortic rupture	1/132 (0.8%)	0/132 (0%)	0/128 (0%)	0/125 (0%)	0/114 (0%)	1/132 (0.8%)
Lesion-related mortality	0/132 (0%)	1/132 (0.8%)	1/128 (0.8%)	1/125 (0.8%)	0/114 (0%)	3/132 (2.3%)
Disabling stroke[2]	1/132 (0.8%)	0/132 (0%)	0/128 (0%)	-	-	1/132 (0.8%)
Permanent paraplegia[2]	0/132 (0%)	0/132 (0%)	0/128 (0%)	-	-	0/132 (0%)
Permanent paraparesis[2]	0/132 (0%)	0/132 (0%)	0/128 (0%)	-	-	0/132 (0%)
New onset renal failure requiring permanent dialysis[2]	0/132 (0%)	0/132 (0%)	0/128 (0%)	-	-	0/132 (0%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	0/132 (0%)	1/132 (0.8%)	1/128 (0.8%)	4/125 (3.2%)	0/114 (0%)	6/132 (4.5%)

[1]Primary Endpoint composite denominator is restricted to Subjects either with a primary endpoint event within window and/or imaging done in window. Primary Endpoint Component Event Rates are based on all enrolled subjects.
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).
[2]Device technical failure events on day 0 only, others are events with onset through day 30.
Study period definitions: Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) Total(0-546 days)

Traumatic Transection Cohort: Primary Endpoint Composite

There have not been any Traumatic Transection Subjects that had any primary endpoint event occur (6/6, 100% free from endpoint event). One Subject in this cohort was excluded from all analysis.

Other Isolated Lesion Cohort: Primary Endpoint Composite

There has been one Other Isolated Lesion Subject (1/8, 12.5%; 87.5% free from endpoint event) that had any primary endpoint event occur. This Subject had two types of primary endpoint events –

aortic rupture and lesion-related mortality. This Subject (underlying pathology was IMH) had a reported adverse event of "Aortic Aneurysm Rupture" (since the date of export, the adverse event description has been updated to "New stent induced entry tear with Aortic Aneurysm Rupture") on POD 534 and was planned to have a reintervention with stent placement later in the week. However, the Subject died due to aortic rupture prior to treatment.

Success Outcomes and Other Outcomes

In addition to the Primary Endpoints noted above, Procedural and Treatment Success data were collected and analyzed for all study cohorts.

- Procedural Success- defined as Device Technical Success, with absence of the following from the initiation of the endovascular procedure through the one month follow-up window (59 days) unless otherwise noted below:
  - Death (Through 30 days only)
  - Aortic rupture (Through 30 days only)
  - Disabling stroke (Through 30 days only)
  - Paraplegia (Through 30 days only)
  - Paraparesis (Through 30 days only)
  - New onset renal failure requiring dialysis (Through 30 days only)
  - Additional unanticipated 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 (Through 30 days only)
  - Myocardial infarction (Through 30 days only)
  - Prolonged intubation
  - Laryngeal or Phrenic Nerve injury (Through 30 days only)
  - Renal dysfunction or volume overload requiring ultrafiltration
  - Severe Heart Failure/Hypotension
- Treatment Success- 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 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 endoleak
  - Type IV endoleak
  - Significant Blood Loss
  - False Lumen Status in treated and untreated segments (Dissection cohort only)
  - False Lumen perfusion through a non-aortic arch branch vessel (Dissection cohort only)

Procedural Success

Table23: Procedural Success through 1 Month1 for Aneurysm Cohort

	Zone 2 Aneurysm
Number of Enrolled Subjects	84
Subjects with Procedural Success[3]	62 (73.8%)

	Zone 2 Aneurysm
Procedural Success Events Breakdown	
Site-Reported Outcomes	
Device technical success failure[2]	7 (8.3%)
Death[2]	0 (0%)
Adverse Event or Treatment with CEC Adjudicated Outcomes	
Disabling stroke[2]	3 (3.6%)
Paraplegia[2]	1 (1.2%)
Paraparesis[2,3]	3 (3.6%)
New onset renal failure requiring permanent dialysis[2]	0 (0%)
Unanticipated additional procedure related to device/procedure	1 (1.2%)
New ischemia	0 (0%)
Distal device-related thromboembolic event requiring intervention	0 (0%)
Life-threatening bleed[2]	6 (7.1%)
Myocardial infarction[2]	1 (1.2%)
Prolonged intubation	1 (1.2%)
Laryngeal or phrenic nerve injury[2]	0 (0%)
Renal dysfunction or volume overload requiring ultrafiltration	0 (0%)
Severe heart failure/hypotension	3 (3.6%)
Adverse Event with CEC Adjudicated or Core Lab Reported Outcomes	
Aortic rupture[2]	0 (0%)
New dissection	5 (6.0%)

[1]Day 0-59 unless otherwise noted. Definitions for all events are in Protocol Section 3.4.3.

[2]Device technical failure events on day 0 only, others are events with onset through day 30.

[3]One Subject had been CEC-adjudicated as having both Permanent paraplegia and permanent paraparesis. The CEC adjudication data has since been updated to reflect only having permanent paraplegia. A second Subject had a Site reported non-serious adverse event of 'mild muscle weakness' reported. CEC data has since been updated and this no longer meets the definition of paraparesis. This would result in a paraparesis rate of 1.2% (1/84) and a change in the Procedural Success rate to 75.0% (63/84; the second only had the paraparesis event among the Procedural Success components).

Table 4: Procedural Success through 1 Month for Dissection Cohort

	Zone 2 Dissection
Number of Enrolled Subjects	132
Subjects with Procedural Success	110 (83.3%)
Procedural Success Events Breakdown	
Site-Reported Outcomes	
Device technical success failure[2]	3 (2.3%)
Death[2]	6 (4.5%)
Adverse Event or Treatment with CEC Adjudicated Outcomes	
Disabling stroke[2]	1 (0.8%)
Paraplegia[2]	0 (0%)
Paraparesis[2]	0 (0%)
New onset renal failure requiring permanent dialysis[2]	0 (0%)
Unanticipated additional procedure related to device/procedure	2 (1.5%)
New ischemia	1 (0.8%)
Distal device-related thromboembolic event requiring intervention	0 (0%)
Life-threatening bleed[2]	6 (4.5%)
Myocardial infarction[2]	0 (0%)
Prolonged intubation	1 (0.8%)
Laryngeal or phrenic nerve injury[2]	1 (0.8%)
Renal dysfunction or volume overload requiring ultrafiltration	1 (0.8%)
Severe heart failure/hypotension	0 (0%)
Adverse Event with CEC Adjudicated or Core Lab Reported Outcomes	
Aortic rupture[2]	1 (0.8%)
New dissection	8 (6.1%)
Core Lab Reported Outcomes	
Extension of a dissection[3]	0/110 (0%)

[1]Day 0-59 unless otherwise noted.

[2]Device technical failure events on day 0 only, others are events with onset through day 30.

[3]Denominator further restricted to those with the 'Extension of dissection' Core Lab follow-up assessment known within the time window.

Traumatic Transection Cohort: Procedural Success

Of the nine Traumatic Transection Subjects enrolled and eligible for analysis, 100% have met the definition for Procedural Success.

Other Isolated Lesion Cohort: Procedural Success

Of the 13 Other Isolated Lesion Subjects enrolled and eligible for analysis, 92.3% have met the definition for Procedural Success. There was one Subject (1/13; 7.7%) reported as having a life-threatening bleed within 30 days of the index procedure.

Treatment Success

Aneurysm and Dissection Results are presented in **Table 2**5 and **Table 2**6. The Treatment Success composite rate for Traumatic Transection and Isolated Lesion was 88.9% (8/9) and 84.6% (11/13) (data tables not presented).

Table 25: Treatment Success for Zone 2 Aneurysm Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Enrolled Subjects[1]	84	84	84	84	80	74	40	6	84
Number of Subjects with Imaging or Event in Window	-	16	73	74	69	53	33	4	84
Subjects with Treatment Success[2,6]	75/84 (89.3%)	9/16 (56.3%)	63/73 (86.3%)	66/74 (89.2%)	64/69 (92.8%)	44/53 (83.0%)	32/33 (97.0%)	4/4 (100.0%)	59/84 (70.2%)
Treatment Success Events Breakdown									
Site-Reported Outcomes[1]									
Device technical success failure	7/84 (8.3%)	-	-	-	-	-	-	-	7/84 (8.3%)
Adverse Event or Treatment with CEC Adjudicated Outcomes[1]									
Lesion-related mortality	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/74 (0%)	0/40 (0%)	0/6 (0%)	0/84 (0%)
Disabling stroke (30 days)	1/84 (1.2%)	2/84 (2.4%)	0/84 (0%)	-	-	-	-	-	3/84 (3.6%)
Paraplegia (30 days)	1/84 (1.2%)	0/84 (0%)	0/84 (0%)	-	-	-	-	-	1/84 (1.2%)
Paraparesis (30 days)[6]	1/84 (1.2%)	2/84 (2.4%)	0/84 (0%)	-	-	-	-	-	3/84 (3.6%)
Unanticipated additional procedure related to device/procedure	0/84 (0%)	1/84 (1.2%)	0/84 (0%)	0/84 (0%)	1/80 (1.3%)	0/74 (0%)	0/40 (0%)	0/6 (0%)	1/84 (1.2%)
New ischemia	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/74 (0%)	0/40 (0%)	0/6 (0%)	0/84 (0%)
Adverse Event with CEC Adjudicated or Core Lab Reported Outcomes[1]									
Aortic rupture[1]	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/74 (0%)	0/40 (0%)	0/6 (0%)	0/84 (0%)
Loss of patency[4]	0/84 (0%)	0/13 (0%)	0/70 (0%)	0/72 (0%)	0/67 (0%)	0/51 (0%)	0/27 (0%)	0/1 (0%)	0/84 (0%)
Fistula formation[1,3]	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/74 (0%)	0/40 (0%)	0/6 (0%)	0/84 (0%)
New dissection[4]	0/84 (0%)	2/13 (15.4%)	3/66 (4.5%)	2/71 (2.8%)	0/64 (0%)	0/51 (0%)	0/26 (0%)	0/1 (0%)	7/84 (8.3%)
Core Lab Reported Outcomes[4]									
Evaluable Subjects	0	13	73	74	69	53	33	4	84
Type I or III Endoleak	-	1/12 (8.3%)	7/69 (10.1%)	6/72 (8.3%)	5/66 (7.6%)	5/51 (9.8%)	0/26 (0%)	0/1 (0%)	8/82 (9.8%)
Loss of device integrity[5]	-	0/13 (0%)	0/71 (0%)	0/71 (0%)	0/66 (0%)	0/53 (0%)	0/28 (0%)	0/1 (0%)	0/84 (0%)
Device migration	-	-	-	0/73 (0%)	0/67 (0%)	0/53 (0%)	0/28 (0%)	0/1 (0%)	0/78 (0%)
Aortic enlargement	-	-	-	1/62 (1.6%)	0/57 (0%)	4/47 (8.5%)	1/25 (4.0%)	0/1 (0%)	4/66 (6.1%)

[1]Denominator is restricted to those at risk at the start of each interval.
[2]Treatment Success composite denominator is restricted to Subjects either with an event within window and/or imaging done in window (except Endovascular Procedure is among all enrolled).
[3]Doesn't have to be adjudicated.
[4]Denominator further restricted to those with an event or Core Lab assessment known within the window (except Endovascular Procedure is among all enrolled). Absence of a denominator indicates no patients were assessed.
[5]This component is a combination of Sealing Stent Row Wire Fracture and/or Compression/Invagination events.
[6]One Subject had been CEC-adjudicated as having both Permanent paraplegia and permanent paraparesis. The CEC adjudication data has since been updated to reflect only having permanent paraplegia. A second Subject had a Site reported non-serious adverse event of 'mild muscle weakness' reported. CEC data has since been updated and this no longer meets the definition of paraparesis. This would result in a paraparesis rate of 1.2% (1/84) and a change in the Treatment Success rate to 71.4% (60/84; the second Subject only had the paraparesis event among the Treatment Success components).

Study period definitions: 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 for Zone 2 Dissection Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Enrolled Subjects[1]	132	132	128	125	114	85	41	8	132
Number of Subjects with Imaging or Event in Window	-	19	110	109	98	68	32	6	127
Subjects with Treatment Success[2]	127/132 (96.2%)	13/19 (68.4%)	101/110 (91.8%)	99/109 (90.8%)	88/98 (89.8%)	67/68 (98.5%)	32/32 (100.0%)	4/6 (66.7%)	92/127 (72.4%)
Treatment Success Events Breakdown									
Site-Reported Outcomes[1]									
Device technical success failure	3/132 (2.3%)	-	-	-	-	-	-	-	3/132 (2.3%)
Adverse Event or Treatment with CEC Adjudicated Outcomes[1]									
Lesion-related mortality	0/132 (0%)	1/132 (0.8%)	1/128 (0.8%)	1/125 (0.8%)	0/114 (0%)	0/85 (0%)	0/41 (0%)	0/8 (0%)	3/132 (2.3%)
Disabling stroke (30 days)	1/132 (0.8%)	0/132 (0%)	0/128 (0%)	-	-	-	-	-	1/132 (0.8%)
Paraplegia (30 days)	0/132 (0%)	0/132 (0%)	0/128 (0%)	-	-	-	-	-	0/132 (0%)
Paraparesis (30 days)	0/132 (0%)	0/132 (0%)	0/128 (0%)	-	-	-	-	-	0/132 (0%)

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Unanticipated additional procedure related to device/procedure	0/132 (0%)	1/132 (0.8%)	1/128 (0.8%)	4/125 (3.2%)	0/114 (0%)	0/85 (0%)	0/41 (0%)	0/8 (0%)	6/132 (4.5%)
New ischemia	0/132 (0%)	1/132 (0.8%)	0/128 (0%)	0/125 (0%)	0/114 (0%)	0/85 (0%)	0/41 (0%)	0/8 (0%)	1/132 (0.8%)
Adverse Event with CEC Adjudicated or Core Lab Reported Outcomes[1]									
Aortic rupture[1]	1/132 (0.8%)	0/132 (0%)	0/128 (0%)	0/125 (0%)	0/114 (0%)	0/85 (0%)	0/41 (0%)	0/8 (0%)	1/132 (0.8%)
Loss of patency[4]	0/132 (0%)	0/17 (0%)	0/107 (0%)	0/106 (0%)	1/96 (1.0%)	0/61 (0%)	0/25 (0%)	0/4 (0%)	1/132 (0.8%)
Fistula formation[1,3]	0/132 (0%)	0/132 (0%)	0/128 (0%)	0/125 (0%)	0/114 (0%)	0/85 (0%)	0/41 (0%)	0/8 (0%)	0/132 (0%)
New dissection[4]	1/132 (0.8%)	4/18 (22.2%)	4/107 (3.7%)	2/104 (1.9%)	4/95 (4.2%)	0/59 (0%)	0/24 (0%)	1/4 (25.0%)	15/132 (11.4%)
Core Lab Reported Outcomes[4]									
Evaluable Subjects	0	17	109	109	98	68	32	6	124
Type I or III Endoleak	-	1/17 (5.9%)	4/106 (3.8%)	2/103 (1.9%)	2/94 (2.1%)	0/60 (0%)	0/25 (0%)	0/4 (0%)	5/122 (4.1%)
Loss of device integrity[5]	-	0/17 (0%)	0/104 (0%)	0/102 (0%)	0/93 (0%)	0/60 (0%)	0/28 (0%)	0/4 (0%)	0/121 (0%)
Device migration	-	-	-	0/107 (0%)	0/97 (0%)	0/64 (0%)	0/29 (0%)	0/4 (0%)	0/117 (0%)
Aortic enlargement	-	-	-	3/95 (3.2%)	3/90 (3.3%)	1/59 (1.7%)	0/29 (0%)	1/3 (33.3%)	6/105 (5.7%)
Extension of dissection (Dissection cohort only)	-	0/15 (0%)	0/107 (0%)	1/103 (1.0%)	0/94 (0%)	0/60 (0%)	0/24 (0%)	0/4 (0%)	1/123 (0.8%)
False lumen perfusion through primary entry tear (Dissection cohort only)	-	0/17 (0%)	0/109 (0%)	0/107 (0%)	0/97 (0%)	0/64 (0%)	0/29 (0%)	0/4 (0%)	0/123 (0%)
False lumen perfusion through an aortic arch branch vessel (Dissection cohort only)	-	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)

[1]Denominator is restricted to those at risk at the start of each interval.
[2]Treatment Success composite denominator is restricted to Subjects either with an event within window and/or imaging done in window (except Endovascular Procedure is among all enrolled).
[3]Doesn't have to be adjudicated.
[4]Denominator further restricted to those with an event or Core Lab assessment known within the window (except Endovascular Procedure is among all enrolled).
[5]This 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)

Traumatic Transection Cohort: Treatment Success

Of the nine Traumatic Transection Subjects enrolled and eligible for analysis, 88.9% of the Subjects have met the definition of Treatment Success as of the data export (those still in study are in the 24-Month follow-up window or later). One Subject (11.1%) failed to meet the definition of Treatment Success due to loss of patency. This Subject experienced an occlusion of the left subclavian artery stent (SB Component) on POD 176. The Site reported this adverse event as non-serious and related to the device. No treatment has been administered to date.

Other Isolated Lesion Cohort: Treatment Success

Of the 13 Other Isolated Lesion Subjects enrolled and eligible for analysis, 84.6% of the Subjects have met the definition of Treatment Success as of the data export (those still in study are in the 24-Month follow-up window or later). Two Other Isolated Lesion Subjects (15.4%) have failed to meet the definition of Treatment Success (one Subject due to lesion-related mortality and aortic rupture on POD 534, and one Subject due to new dissection on POD 203).

Key Events – All Cohorts

Life Threatening Bleed

There were six (7.1%) Aneurysm Subjects reported as having a life-threatening bleed within 30 days of the index procedure. Of these subjects, four a serious access issue (all iliac artery ruptures) at procedure.

There were six Dissection Subjects (4.5%) reported as having a life-threatening bleed within 30 days of the index procedure. Four of the Subjects were affiliated with a serious access issue. Two Subjects experienced iliac artery ruptures and one Patient a groin hematoma. In addition, one Subject experienced a serious femoral pseudoaneurysm. The other two Patients with a life-threatening bleed were results of an aortic rupture and gastrointestinal (GI) hemorrhage (not access-related). Among these six Patients, none required Protocol-defined reinterventions within 1 Month; two died within 30 days of their procedure (the Patient with the GI hemorrhage died of their bleed on POD 2 and the Patient with the groin hematoma died of an embolic stroke on POD 2).

There were no Traumatic Transection Subjects with a reported life-threatening bleed within 30 days of the index procedure.

There was one Other Isolated Lesion Subject (1/13; 7.7%) reported as having a life-threatening bleed within 30 days of the index procedure. This Subject experienced a life-threatening bleed affiliated with a serious access issue (iliac artery rupture) at procedure. The event was resolved without sequelae during the procedure with the deployment of two GORE® VIABAHN® Endoprostheses, and the Subject has since not required any additional unanticipated procedure.

Stroke

Seven (8.3%) Aneurysm Subjects had stroke events adjudicated by the CEC neurologist/OMA as meeting the WHO criteria. Four of these Subjects had WHO strokes within 30 days (three meeting the Primary Endpoint Disabling Stroke criteria) and three Subjects had a WHO stroke after 30-Days.

Seven (5.3%) Dissection Subjects had stroke events adjudicated by the CEC neurologist/OMA as meeting the WHO criteria. Two of these Subjects had WHO strokes within 30 days (one meeting the Primary Endpoint Disabling Stroke criteria) and five Subjects had a WHO stroke after 30 days.

Aneurysm and Dissection Cohort events are summarized in **Table 27** and **Table 28**.

No Traumatic Transection Subjects and one Other Isolated Lesion Subject (7.7%) had a stroke event adjudicated by the neurologist as meeting the WHO criteria. This Subject's WHO stroke was after 30 days.

Table 7: CEC Neurologist/OMA-Adjudicated Strokes by Absolute Study Window for Aneurysm Cohort

	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	Total
Number of Enrolled Subjects[1]	84	84	81	78	65	25	3	84
Subjects with any WHO Stroke or Disabling Stroke	4 (4.8%)	2 (2.4%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	7 (8.3%)
Subjects with WHO Stroke	4 (4.8%)	2 (2.4%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	7 (8.3%)
Subjects with Disabling Stroke	3 (3.6%)	1 (1.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (4.8%)

[1]Column header counts and denominators are the number of Subjects at risk at the start of each interval.
Study period definitions: 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) Total(0-1826 days)

Table 28: CEC Neurologist/OMA-Adjudicated Strokes by Absolute Study Window for Dissection Cohort

	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	Total
Number of Enrolled Subjects[1]	132	126	118	109	67	28	1	132
Subjects with any WHO Stroke or Disabling Stroke	2 (1.5%)	1 (0.8%)	1 (0.8%)	2 (1.8%)	1 (1.5%)	0 (0%)	0 (0%)	7 (5.3%)
Subjects with WHO Stroke	2 (1.5%)	1 (0.8%)	1 (0.8%)	2 (1.8%)	1 (1.5%)	0 (0%)	0 (0%)	7 (5.3%)
Subjects with Disabling Stroke	1 (0.8%)	0 (0%)	1 (0.8%)	1 (0.9%)	0 (0%)	0 (0%)	0 (0%)	3 (2.3%)

[1]Column header counts and denominators are the number of Subjects at risk at the start of each interval.
Study period definitions: 30 days(0-30 days) 6 Months(31-182 days) 1 Year(183-365 days) 2 Years(366-731 days) 3 Years (731-1096 days) 4 Years(1097 -1461 days) 5 Years(1462 -1826 days)

New Dissections

Seven (8.3%) Aneurysm Subjects had a new dissection. The location for the new dissection has varied as follows: one Subject (1.2%) in the treated branch (untreated segment), one Subject (1.2%) in the proximal aorta (treated segment), and five Subjects (6.0%) in the distal aorta (treated segment). There were no new dissections reported for untreated branches.

Fifteen Dissection Subjects (11.4%) have had a new dissection. The location for the new dissection has varied as follows: six Subjects (4.5%) in the treated branch (five in the untreated segment; one within treated segment) and nine Subjects (6.8%) in the proximal aorta (two in the untreated segment; seven within treated segment).

No Traumatic Transection Subjects and two Other Isolated Lesion Subjects had a new dissection. The location of the new dissection for both Subjects was the distal aorta (one inside the treated area; one outside the treated area).

Eleven Subjects underwent a reintervention: eight Subjects underwent an open repair, one Subject had an additional stent placed, and two Subjects were treated with drug therapy. Two Subjects died due to their new dissection prior to treatment.

Lesion related Mortality:

There were no Aneurysm Subjects (0%; 0/84) that died that met the definition of lesion-related mortality within the 12-Month follow-up timeframe.

There were three Dissection Subjects (2.3%; 3/132) that died and met the definition of lesion-related mortality through the 12-Month follow-up timeframe.

- Subject died from cardiac arrest on POD 25 (no further details are known and site-reported relationship to devices and procedure is unknown).
- Subject died from cardiac tamponade due to ruptured aortic dissection in the ascending aorta (outside of the treated segment) on POD 6.
- Subject died from cardiac arrest on POD 79 after undergoing surgical reintervention for an ascending aortic dissection on POD 77.

There were no Traumatic Transection Subjects (0%; 0/9) that died that met the definition of lesion-related mortality within the 12-Month follow-up timeframe.

There was one Other Isolated Lesion Subject who died from aortic aneurysm rupture on POD 534. This Subject is fully discussed in the Other Isolated Lesion Primary Composite Endpoint discussion.

Endoleaks

For the Aneurysm Cohort, 78.6% of Subjects were free from any type of Site-reported endoleak. **Table 29** summarizes the Site Reported Endoleaks by Study Period.

Six Aneurysm Subjects (7.1%) had Type IA endoleaks reported. Four of these endoleaks were reported during the procedure and the other two occurred at other times throughout follow-up. No Site-

reported adverse events of aortic enlargement have been reported for any of the Type IA endoleaks. Two Subjects (2.4%) have required treatment for the Type IA endoleaks:

- One Subject– Type IA endoleak noted during the procedure, requiring balloon angioplasty at the proximal landing zone.
- One Subject– Type IA endoleak noted on POD 766 which was treated with stents to successfully resolve the endoleak.

The Subject with the Type IA endoleak on POD 766 also had one Type IB endoleak reported and treated with a stent on POD 3 (no Site-reported adverse events for aortic enlargement have been reported for this Subject). However, this endoleak was an iliac endoleak related to a previous abdominal aortic procedure and was not related to the GORE® TAG® Thoracic Branch Endoprosthesis.

Nine Subjects (10.7%) had a Site-reported Type II endoleak. There have been no Site-reported treatments for these endoleaks. Two Subjects (2.4%) had a Site-reported Type III endoleak and one Subject required treatment.

Table29: Site-Reported Endoleaks by Analysis Study Window for Zone 2 Aneurysm Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Subjects[1]	84	84	84	84	80	74	40	6	84
Evaluable Subjects[2]	84	19	74	76	72	55	33	4	84
Subjects With One or More Endoleak Ongoing in Window	7 (8.3%)	10 (52.6%)	15 (20.3%)	13 (17.1%)	11 (15.3%)	9 (16.4%)	2 (6.1%)	0 (0%)	18 (21.4%)
New	7 (8.3%)	3 (15.8%)	9 (12.2%)	1 (1.3%)	1 (1.4%)	1 (1.8%)	0 (0%)	-	-
Ongoing	-	7 (36.8%)	7 (9.5%)	12 (15.8%)	11 (15.3%)	8 (14.5%)	2 (6.1%)	-	-
Type I	4 (4.8%)	5 (26.3%)	5 (6.8%)	2 (2.6%)	2 (2.8%)	3 (5.5%)	0 (0%)	0 (0%)	6 (7.1%)
New	4 (4.8%)	1 (5.3%)	1 (1.4%)	0 (0%)	0 (0%)	1 (1.8%)	-	-	-
Type IA	4 (4.8%)	0 (0%)	1 (1.4%)	-	-	1 (1.8%)	-	-	6 (7.1%)
Type IB	0 (0%)	1 (5.3%)[3]	0 (0%)	-	-	0 (0%)	-	-	1 (1.2%)[3]
Type IC	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)	-	-	0 (0%)
Ongoing	-	4 (21.1%)	4 (5.4%)	2 (2.6%)	2 (2.8%)	2 (3.6%)	-	-	-
Type II	1 (1.2%)	3 (15.8%)	7 (9.5%)	7 (9.2%)	5 (6.9%)	3 (5.5%)	1 (3.0%)	0 (0%)	9 (10.7%)
New	1 (1.2%)	2 (10.5%)	5 (6.8%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	-	-
Ongoing	-	1 (5.3%)	2 (2.7%)	6 (7.9%)	5 (6.9%)	3 (5.5%)	1 (3.0%)	-	-
Type III	1 (1.2%)	1 (5.3%)	2 (2.7%)	2 (2.6%)	2 (2.8%)	1 (1.8%)	1 (3.0%)	0 (0%)	2 (2.4%)
New	1 (1.2%)	0 (0%)	2 (2.7%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	-	-
Type IIIA	0 (0%)	-	0 (0%)	-	1 (1.4%)	-	-	-	1 (1.2%)
Type IIIB	0 (0%)	-	0 (0%)	-	0 (0%)	-	-	-	0 (0%)
Type III Indeterminate	1 (1.2%)	-	2 (2.7%)	-	0 (0%)	-	-	-	2 (2.4%)
Ongoing	-	1 (5.3%)	0 (0%)	2 (2.6%)	2 (2.8%)	1 (1.8%)	1 (3.0%)	-	-
Indeterminate	1 (1.2%)	1 (5.3%)	2 (2.7%)	2 (2.6%)	2 (2.8%)	2 (3.6%)	0 (0%)	0 (0%)	2 (2.4%)
New	1 (1.2%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	0 (0%)	-	-	-
Ongoing	-	1 (5.3%)	1 (1.4%)	2 (2.6%)	2 (2.8%)	2 (3.6%)	-	-	-
Subjects With No Endoleak Ongoing in Window	77 (91.7%)	9 (47.4%)	59 (79.7%)	63 (82.9%)	61 (84.7%)	46 (83.6%)	31 (93.9%)	4 (100.0%)	66 (78.6%)

[1]Column header counts are the number of subjects at risk at the start of each interval.
[2]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.
[3]This Subject reported a Type IB endoleak but it was not related to the GORE® TAG® Thoracic Branch Endoprosthesis; it was related to an abdominal aortic endovascular device previously implanted.
Study period definitions: 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)

Core Lab identified three Aneurysm Subjects (3.7%) with Type I endoleaks at any timepoint, 21 Subjects (25.6%) with Type II endoleaks, and five Subjects (6.1%) with Type III endoleaks.

Three Subjects with reported aortic enlargement also had endoleaks reported by the Core Lab (two Subjects with a reported Type II endoleak and one Subject with a Type III endoleak). **Table 30** summarizes the Core Lab device event findings by study period.

Table30: Core Lab Device Event Findings by Analysis Study Window for Zone 2 Aneurysm Cohort

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Enrolled Subjects[1]	84	84	84	80	74	40	6	84
Evaluable Subjects[2]	13	73	74	69	53	33	4	84
Subjects with any below device event finding in window	6/13 (46.2%)	27/73 (37.0%)	24/74 (32.4%)	21/69 (30.4%)	13/53 (24.5%)	2/33 (6.1%)	0/4 (0%)	36/84 (42.9%)
Device event findings								
Endoleak	6/12 (50.0%)	27/69 (39.1%)	24/72 (33.3%)	21/66 (31.8%)	13/51 (25.5%)	2/26 (7.7%)	-	36/82 (43.9%)

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Type I	0/12 (0%)	2/69 (2.9%)	3/72 (4.2%)	3/66 (4.5%)	3/51 (5.9%)	0/26 (0%)	-	3/82 (3.7%)
Type IA	-	1/69 (1.4%)	2/72 (2.8%)	2/66 (3.0%)	2/51 (3.9%)	-	-	2/82 (2.4%)
Type IB	-	1/69 (1.4%)	1/72 (1.4%)	1/66 (1.5%)	1/51 (2.0%)	-	-	1/82 (1.2%)
Type IC	-	0/69 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	-	-	0/82 (0%)
Type II	3/12 (25.0%)	13/69 (18.8%)	13/72 (18.1%)	14/66 (21.2%)	8/51 (15.7%)	1/26 (3.8%)	-	21/82 (25.6%)
Type III	1/12 (8.3%)	5/69 (7.2%)	3/72 (4.2%)	2/66 (3.0%)	2/51 (3.9%)	0/26 (0%)	-	5/82 (6.1%)
Type IIIA	0/12 (0%)	0/69 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	-	-	0/82 (0%)
Type IIIA involving SB	0/12 (0%)	0/69 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	-	-	0/82 (0%)
Type IIIB	0/12 (0%)	0/69 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	-	-	0/82 (0%)
Type III Indeterminate	1/12 (8.3%)	5/69 (7.2%)	3/72 (4.2%)	2/66 (3.0%)	2/51 (3.9%)	-	-	5/82 (6.1%)
Type III Indeterminate involving SB	0/12 (0%)	3/69 (4.3%)	1/72 (1.4%)	1/66 (1.5%)	1/51 (2.0%)	-	-	3/82 (3.7%)
Type IV	0/12 (0%)	0/69 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	0/26 (0%)	-	0/82 (0%)
Indeterminate	1/12 (8.3%)	9/69 (13.0%)	7/72 (9.7%)	4/66 (6.1%)	3/51 (5.9%)	1/26 (3.8%)	-	19/82 (23.2%)
Aortic Device Loss of Patency	0/13 (0%)	0/70 (0%)	0/72 (0%)	0/67 (0%)	0/51 (0%)	0/27 (0%)	-	0/82 (0%)
SB Loss of Patency	0/13 (0%)	0/70 (0%)	0/72 (0%)	0/67 (0%)	0/51 (0%)	0/27 (0%)	-	0/82 (0%)
Aortic Rupture	0/13 (0%)	0/70 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	0/26 (0%)	-	0/83 (0%)
Device Migration	0/13 (0%)	0/72 (0%)	0/73 (0%)	0/67 (0%)	0/53 (0%)	0/28 (0%)	-	0/84 (0%)
Wire Fracture	0/13 (0%)	0/72 (0%)	0/73 (0%)	0/66 (0%)	0/53 (0%)	0/28 (0%)	-	0/84 (0%)
Extrusion/Erosion	0/13 (0%)	0/72 (0%)	0/74 (0%)	0/67 (0%)	0/53 (0%)	0/28 (0%)	-	0/84 (0%)
Device Compression/Invagination	0/13 (0%)	0/72 (0%)	0/74 (0%)	0/67 (0%)	0/53 (0%)	0/28 (0%)	-	0/84 (0%)
Other anatomical findings								
Aortic Enlargement (≥ 5mm)[3]	-	-	1/62 (1.6%)	0/57 (0%)	4/47 (8.5%)	1/25 (4.0%)	0/1 (0%)	4/66 (6.1%)

[1]Column header counts are the number of subjects at risk at the start of each interval.

[2]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.

[3]Aortic enlargement is based on Maximum Transverse Diameter of Aneurysm. Subjects evaluated for change from baseline are those subjects that have both a baseline measurement and a measurement in each follow-up time window. If there is more than one non-missing measurement in a time window, the largest (worst) aneurysm diameter is kept for analysis.

Study period definitions: 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)

For the Dissection Cohort 89.4% of Subjects were free from any type of Site-reported endoleak. Table 31 summarizes the Site Reported Endoleaks by Study Period.

Four Subjects (3.0%) had Type IA endoleaks. Three of these endoleaks were reported during the procedure and the other one occurred during the 1-Month absolute window. No Site-reported adverse events of aortic enlargement have been reported for any of the Type IA endoleaks. Two Subjects (1.5%) have required treatment for the Type IA endoleaks.

- One Subject– Type IA endoleak noted on POD 32, requiring embolization on POD 145.
- One Subject– Type IA endoleak noted during the procedure, requiring thoracic stent graft placement on POD 84.

Three Subjects had a Site-reported Type IB endoleak. One Subject required treatment for the Type IB endoleak with a thoracic aortic stent graft placed on POD 253. No Site-reported adverse events of aortic enlargement have been reported for any of the Type IB endoleaks.

Eight Subjects (6.1%) had a Type II endoleak reported. Of the eight Subjects with reported Type II endoleaks, one Subject required treatment on POD 1159 (drug therapy) and POD 1162 (thoracic stent graft placement with embolization).

One Subject (0.8%) had a Type III endoleak reported. No treatment has been reported for this Subject.

Table31: Site-Reported Endoleaks by Analysis Study Window for Zone 2 Dissection Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Subjects[1]	132	132	128	125	114	85	41	8	132
Evaluable Subjects[2]	132	24	110	110	99	68	33	6	132
Subjects With One or More Endoleak Ongoing in Window	3 (2.3%)	8 (33.3%)	12 (10.9%)	10 (9.1%)	9 (9.1%)	4 (5.9%)	4 (12.1%)	1 (16.7%)	14 (10.6%)
New	3 (2.3%)	5 (20.8%)	4 (3.6%)	1 (0.9%)	1 (1.0%)	0 (0%)	1 (3.0%)	0 (0%)	-
Ongoing	-	3 (12.5%)	8 (7.3%)	9 (8.2%)	8 (8.1%)	4 (5.9%)	3 (9.1%)	1 (16.7%)	-
Type I	3 (2.3%)	5 (20.8%)	6 (5.5%)	5 (4.5%)	3 (3.0%)	0 (0%)	0 (0%)	0 (0%)	7 (5.3%)
New	3 (2.3%)	2 (8.3%)	1 (0.9%)	1 (0.9%)	0 (0%)	-	-	-	-
Type IA	3 (2.3%)	0 (0%)	1 (0.9%)	0 (0%)	-	-	-	-	4 (3.0%)
Type IB	0 (0%)	2 (8.3%)	0 (0%)	1 (0.9%)	-	-	-	-	3 (2.3%)
Type IC	0 (0%)	0 (0%)	0 (0%)	0 (0%)	-	-	-	-	0 (0%)

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Ongoing	-	3 (12.5%)	5 (4.5%)	4 (3.6%)	3 (3.0%)	-	-	-	-
Type II	0 (0%)	3 (12.5%)	6 (5.5%)	4 (3.6%)	5 (5.1%)	4 (5.9%)	4 (12.1%)	1 (16.7%)	8 (6.1%)
New	-	3 (12.5%)	3 (2.7%)	0 (0%)	1 (1.0%)	0 (0%)	1 (3.0%)	0 (0%)	-
Innominate	-	0 (0%)	0 (0%)	-	0 (0%)	-	0 (0%)	-	-
LCCA	-	0 (0%)	0 (0%)	-	0 (0%)	-	0 (0%)	-	-
LSA[3]	-	0 (0%)	1 (33.3%)	-	0 (0%)	-	0 (0%)	-	-
Vertebral	-	1 (33.3%)	0 (0%)	-	0 (0%)	-	0 (0%)	-	-
Intercostal	-	1 (33.3%)	1 (33.3%)	-	0 (0%)	-	0 (0%)	-	-
Bronchials	-	0 (0%)	0 (0%)	-	0 (0%)	-	0 (0%)	-	-
Other	-	1 (33.3%)	1 (33.3%)	-	1 (100.0%)	-	1 (100.0%)	-	-
Ongoing	-	0 (0%)	3 (2.7%)	4 (3.6%)	4 (4.0%)	4 (5.9%)	3 (9.1%)	1 (16.7%)	-
Source (Dissection cohort only)									
Type III	0 (0%)	1 (4.2%)	1 (0.9%)	1 (0.9%)	1 (1.0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.8%)
New	-	1 (4.2%)	0 (0%)	0 (0%)	0 (0%)	-	-	-	-
Type IIIA	-	0 (0%)	-	-	-	-	-	-	0 (0%)
Type IIIB	-	0 (0%)	-	-	-	-	-	-	0 (0%)
Type III Indeterminate	-	1 (4.2%)	-	-	-	-	-	-	1 (0.8%)
Ongoing	-	0 (0%)	1 (0.9%)	1 (0.9%)	1 (1.0%)	-	-	-	-
Indeterminate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
New	-	-	-	-	-	-	-	-	-
Ongoing	-	-	-	-	-	-	-	-	-
Subjects With No Endoleak Ongoing in Window	129 (97.7%)	16 (66.7%)	98 (89.1%)	100 (90.9%)	90 (90.9%)	64 (94.1%)	29 (87.9%)	5 (83.3%)	118 (89.4%)

[1]Column header counts are the number of subjects at risk at the start of each interval.

[2]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.

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)

[3]Upcon further review of the Type II endoleak in the LSA, the Site PI for Subject 1102-192-117 has determined this to be a data entry error and no endoleak is present.The database has since been updated to reflect this information.

Core Lab identified three (2.5%) Subjects with Type I endoleaks at any timepoint, 23 (18.9%) Subjects with Type II endoleaks, and in two (1.6%) Subjects with Type III endoleaks.

Two Subjects with reported aortic enlargement also had endoleaks reported by the Core Lab (both indeterminate endoleaks). Table 32 summarizes the Core Lab device event findings by study period.

Table 12: Core Lab Device Event Findings by Analysis Study Window for Zone 2 Dissection Cohort

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Enrolled Subjects[1]	132	128	125	114	85	41	8	132
Evaluable Subjects[2]	17	109	109	98	68	32	6	124
Subjects with any below device event finding in window	3/17 (17.6%)	34/109 (31.2%)	17/109 (15.6%)	16/98 (16.3%)	10/68 (14.7%)	0/32 (0%)	2/6 (33.3%)	47/124 (37.9%)
Device event findings								
Endoleak	3/17 (17.6%)	34/106 (32.1%)	17/103 (16.5%)	15/94 (16.0%)	10/60 (16.7%)	-	2/4 (50.0%)	47/122 (38.5%)
Type I	1/17 (5.9%)	3/106 (2.8%)	1/103 (1.0%)	1/94 (1.1%)	0/60 (0%)	-	0/4 (0%)	3/122 (2.5%)
Type IA	0/17 (0%)	1/106 (0.9%)	0/103 (0%)	0/94 (0%)	-	-	-	1/122 (0.8%)
Type IB	1/17 (5.9%)	2/106 (1.9%)	1/103 (1.0%)	1/94 (1.1%)	-	-	-	2/122 (1.6%)
Type IC	0/17 (0%)	0/106 (0%)	0/103 (0%)	0/94 (0%)	-	-	-	0/122 (0%)
Type II	0/17 (0%)	13/106 (12.3%)	7/103 (6.8%)	5/94 (5.3%)	5/60 (8.3%)	-	1/4 (25.0%)	23/122 (18.9%)
Source (Dissection cohort only)								
Vertebral	-	1/13 (7.7%)	1/7 (14.3%)	0/5 (0%)	0/5 (0%)	-	0/1 (0%)	2/23 (8.7%)
Intercostal	-	12/13 (92.3%)	5/7 (71.4%)	5/5 (100.0%)	4/5 (80.0%)	-	1/1 (100.0%)	19/23 (82.6%)
Bronchials	-	0/13 (0%)	1/7 (14.3%)	0/5 (0%)	0/5 (0%)	-	1/1 (100.0%)	2/23 (8.7%)
Other	-	0/13 (0%)	0/7 (0%)	0/5 (0%)	1/5 (20.0%)	-	0/1 (0%)	1/23 (4.3%)
Type III	0/17 (0%)	1/106 (0.9%)	1/103 (1.0%)	1/94 (1.1%)	0/60 (0%)	-	0/4 (0%)	2/122 (1.6%)
Type IIIA	-	0/106 (0%)	0/103 (0%)	0/94 (0%)	-	-	-	0/122 (0%)

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Type IIIA involving SB	-	0/106 (0%)	0/103 (0%)	0/94 (0%)	-	-	-	0/122 (0%)
Type IIIB	-	0/106 (0%)	0/103 (0%)	0/94 (0%)	-	-	-	0/122 (0%)
Type III Indeterminate	-	1/106 (0.9%)	1/103 (1.0%)	1/94 (1.1%)	-	-	-	2/122 (1.6%)
Type III Indeterminate involving SB	-	1/106 (0.9%)	0/103 (0%)	0/94 (0%)	-	-	-	1/122 (0.8%)
Type IV	0/17 (0%)	0/106 (0%)	0/103 (0%)	0/94 (0%)	0/60 (0%)	-	0/4 (0%)	0/122 (0%)
Indeterminate	2/17 (11.8%)	18/106 (17.0%)	10/103 (9.7%)	10/94 (10.6%)	5/60 (8.3%)	-	2/4 (50.0%)	28/122 (23.0%)
Aortic Device Loss of Patency	0/17 (0%)	0/107 (0%)	0/106 (0%)	0/96 (0%)	0/61 (0%)	-	0/4 (0%)	0/123 (0%)
SB Loss of Patency	0/16 (0%)	0/107 (0%)	0/106 (0%)	1/95 (1.1%)	0/61 (0%)	-	0/4 (0%)	1/123 (0.8%)
Aortic Rupture	0/17 (0%)	0/107 (0%)	0/105 (0%)	0/96 (0%)	0/61 (0%)	-	0/4 (0%)	0/123 (0%)
Device Migration	0/16 (0%)	0/109 (0%)	0/107 (0%)	0/97 (0%)	0/64 (0%)	-	0/4 (0%)	0/123 (0%)
Wire Fracture	0/17 (0%)	0/104 (0%)	0/102 (0%)	0/94 (0%)	0/60 (0%)	-	0/4 (0%)	0/121 (0%)
Extrusion/Erosion	0/17 (0%)	0/109 (0%)	0/107 (0%)	0/97 (0%)	0/64 (0%)	-	0/4 (0%)	0/123 (0%)
Device Compression/Invagination	0/17 (0%)	0/109 (0%)	0/107 (0%)	0/97 (0%)	0/64 (0%)	-	0/4 (0%)	0/123 (0%)
Other anatomical findings								
Aortic Enlargement (≥ 5mm)[3]	-	-	3/95 (3.2%)	3/90 (3.3%)	1/59 (1.7%)	0/29 (0%)	1/3 (33.3%)	6/105 (5.7%)

[1]Column header counts are the number of subjects at risk at the start of each interval.

[2]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.

[3]Aortic enlargement is based on Maximum Aortic Diameter in Treated Segment for Dissection Subjects. Subjects evaluated for change from baseline are those subjects that have both a baseline measurement and a measurement in each follow-up time window. If there is more than one non-missing measurement in a time window, the largest (worst) aneurysm diameter is kept for analysis.

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)

There have been no Site or Core Lab reported endoleaks for the Traumatic Transection Cohort. A Core Lab identified Type II endoleak has been identified in one Other Isolated Lesion Subject (7.7%); there have been no Site-reported endoleaks for this cohort.

False Lumen Perfusion and False Lumen Status: Dissection Cohort Only

Table 33 provides a summary of false lumen perfusion and false lumen status by follow-up period for Dissection Subjects, as reported by Core Lab. Note that both false lumen perfusion through the primary intimal tear and through an aortic arch branch vessel are Treatment Success components (and are shown as well in Table 28). The GORE® TAG® Thoracic Branch Endoprosthesis device was completely successful in negating both of these types of false lumen perfusion.

The majority of the reported false lumen perfusions reported were through a non-aortic arch branch vessel (88.5%).

False lumen perfusion through the proximal aorta was observed in nine Subjects. Eight of these Subjects had a new dissection in the proximal aorta; the other Subject had a Type IA endoleak observed at 1 month (Core Lab reported, no treatment required).

It can be seen that a large majority of Subjects (>80%) experienced this over time. This is not unexpected when considering the majority of Subjects presented with dissections extending distally between Zone 6 and Zone 10/11 (86.7%, 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. The majority of Subjects (>75%) have a patent or partially thrombosed false lumen in the distal (untreated) aorta. However, it can be seen that the percent of Subjects with complete 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.

False lumen status in the treated segment was an additional 'other outcome'. One Subject had no thrombosis in the treated segment in the 24-Month window. The percent of Subjects with complete thrombosis in the treated segment is, in general, increasing in follow-up. For example, 35.8% of Subjects had complete thrombosis at 1-Month and then 55.3% of Subjects had complete thrombosis at 12-Months.

Table 23: Core Lab False Lumen Perfusion and Status by Analysis Study Window for Zone 2 Dissection Cohort

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Subjects[1]	132	128	125	114	85	41	8	132
Number of Subjects with Imaging[2]	17	109	109	98	68	32	6	124
False Lumen Perfusion through primary intimal tear[3]	0/17 (0%)	0/109 (0%)	0/107 (0%)	0/97 (0%)	0/64 (0%)	0/29 (0%)	0/4 (0%)	0/123 (0%)
False Lumen Status[4,5] - Treated Segment								
Patent	0/17 (0%)	0/106 (0%)	0/104 (0%)	0/94 (0%)	1/61 (1.6%)	0/25 (0%)	0/4 (0%)	1/122 (0.8%)
Partial thrombosis	12/17 (70.6%)	68/106 (64.2%)	53/104 (51.0%)	42/94 (44.7%)	28/61 (45.9%)	8/25 (32.0%)	2/4 (50.0%)	81/122 (66.4%)

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Complete thrombosis	5/17 (29.4%)	38/106 (35.8%)	51/104 (49.0%)	52/94 (55.3%)	32/61 (52.5%)	17/25 (68.0%)	2/4 (50.0%)	40/122 (32.8%)
False Lumen Perfusion – Source of Perfusion: Proximal Aorta	1/17 (5.9%)	2/106 (1.9%)	3/104 (2.9%)	4/95 (4.2%)	2/61 (3.3%)	0/25 (0%)	1/4 (25.0%)	9/122 (7.4%)
False Lumen Perfusion through a branch vessel	13/16 (81.3%)	96/106 (90.6%)	88/105 (83.8%)	81/96 (84.4%)	52/61 (85.2%)	21/25 (84.0%)	3/4 (75.0%)	108/123 (87.8%)
Through an Aortic Arch Branch Vessel[3]	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)
Innominate	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)
LCCA	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)
LSA	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)
Other	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)
Through a Non-Aortic Arch Branch Vessel[5]	13/16 (81.3%)	96/106 (90.6%)	88/104 (84.6%)	81/95 (85.3%)	52/61 (85.2%)	21/25 (84.0%)	3/4 (75.0%)	108/122 (88.5%)
Celiac	5/16 (31.3%)	25/106 (23.6%)	18/104 (17.3%)	20/95 (21.1%)	12/61 (19.7%)	6/25 (24.0%)	1/4 (25.0%)	32/122 (26.2%)
SMA	2/16 (12.5%)	10/106 (9.4%)	7/104 (6.7%)	10/95 (10.5%)	5/61 (8.2%)	3/25 (12.0%)	0/4 (0%)	13/122 (10.7%)
Right Renal	5/16 (31.3%)	31/106 (29.2%)	31/104 (29.8%)	26/95 (27.4%)	14/61 (23.0%)	3/25 (12.0%)	1/4 (25.0%)	39/122 (32.0%)
Left Renal	9/16 (56.3%)	38/106 (35.8%)	31/104 (29.8%)	28/95 (29.5%)	16/61 (26.2%)	6/25 (24.0%)	1/4 (25.0%)	44/122 (36.1%)
Right Com Iliac	1/16 (6.3%)	5/106 (4.7%)	7/104 (6.7%)	7/95 (7.4%)	5/61 (8.2%)	2/25 (8.0%)	1/4 (25.0%)	12/122 (9.8%)
Left Com Iliac	3/16 (18.8%)	5/106 (4.7%)	11/104 (10.6%)	3/95 (3.2%)	3/61 (4.9%)	2/25 (8.0%)	0/4 (0%)	15/122 (12.3%)
Other[6]	11/16 (68.8%)	91/106 (85.8%)	85/104 (81.7%)	76/95 (80.0%)	51/61 (83.6%)	20/25 (80.0%)	3/4 (75.0%)	103/122 (84.4%)
False Lumen Perfusion – Source of perfusion: Distal Aorta	12/17 (70.6%)	91/106 (85.8%)	83/104 (79.8%)	79/95 (83.2%)	49/61 (80.3%)	21/25 (84.0%)	3/4 (75.0%)	103/122 (84.4%)
False Lumen Status[4,5] – Untreated Aorta								
Patent	8/12 (66.7%)	16/96 (16.7%)	14/90 (15.6%)	10/85 (11.8%)	4/54 (7.4%)	1/23 (4.3%)	0/3 (0%)	29/109 (26.6%)
Partial thrombosis	4/12 (33.3%)	79/96 (82.3%)	72/90 (80.0%)	70/85 (82.4%)	46/54 (85.2%)	20/23 (87.0%)	3/3 (100.0%)	79/109 (72.5%)
Complete thrombosis	0/12 (0%)	1/96 (1.0%)	4/90 (4.4%)	5/85 (5.9%)	4/54 (7.4%)	2/23 (8.7%)	0/3 (0%)	1/109 (0.9%)

[1]Subjects at risk at the start of each interval.

[2]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.

[3]These are Treatment Success Outcomes.

[4]If 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).

[5]These are Other Success Outcomes as described under Section X(A)(3).

[6]Other sources primarily included: intercostal arteries, vertebral 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)

Aortic Enlargement

There were four (6.1%) Aneurysm Subjects with aortic enlargement as assessed by Core Lab. The implanting sites also recorded enlargement for two of these subjects. There have been no reports of aneurysm rupture or unexplained / sudden death for any of these Subjects and no Site-reported additional interventions or treatments have been required.

There were six (5.7%) Subjects with aortic enlargement as assessed by Core Lab in the Dissection cohort. The implanting sites also recorded aortic enlargement for five subjects. One Subject also had a Site-reported adverse event of aneurysm sac enlargement on POD 314 that required a stent. The remaining five Subjects have had no Site-reported aortic rupture, unexplained sudden death or treatments associated with aortic enlargement.

There were no reports of aortic enlargement in the Traumatic Transection or Other Isolated Lesion cohorts.

New Renal Failure requiring dialysis- All Cohorts

There were no new onset renal failure requiring permanent dialysis events reported during the 30-day follow-up window for any of the Subjects in the Aneurysm, Dissection, Traumatic Transection, or Other Isolated Lesion Cohorts.

Unanticipated reinterventions related to device/procedure

There was one Aneurysm Subject (1.2%) who required an unanticipated additional procedure related to device/procedure. This Subject required a reintervention for a Type III endoleak involving the SB Component, occurring on POD 8 and an additional reintervention on POD 420 for a Type III endoleak at the juncture of the proximal aortic extender and aortic component of the TBE device.

Six (4.5%) Dissection Subjects required a reintervention, all occurring within 6-Months of the endovascular procedure.

- One Subject required open total arch replacement on POD 132 due to a retrograde Type A dissection.

- Another Subject had a Type IA endoleak treated with embolization on POD 145 which resolved without sequelae on the same day.
- A Subject underwent aortic root replacement and ascending and transverse aortic arch replacement on POD 77 for treatment of a retrograde aortic dissection extending from the proximal end of the TBE device with onset on POD 76. The Subject died on POD 80 due to cardiac arrest.
- An additional Subject had total aortic arch replacement on POD 13 for treatment of a retrograde aortic dissection with onset on POD 12. The new dissection resolved without sequelae on the same day as treatment.
- A Subject was treated on POD 84 with a thoracic stent for a Type IA endoleak. The endoleak resolved without sequelae on the same day as treatment.
- A Subject underwent open repair of an ascending aortic dissection (distal ascending and proximal transverse thoracic aorta with onset on POD 27) with a hemiarch procedure on POD 45. The new dissection resolved without sequelae on the same day as treatment.

No Traumatic Transection or Other Isolated Lesion Subjects required an unanticipated additional procedure related to device/procedure.

Mortality

The Kaplan-Meier estimated 1-year (through day 365) freedom from all-cause mortality is 95.2% for the Zone 2 Aneurysm Cohort.

Table 34: Mortality for Zone 2 Aneurysm Cohort

	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	Total
Number of Enrolled Subjects[1]	84	84	81	78	65	25	3	84
Subjects with Mortality (All-Cause)	0 (0%)	3 (3.6%)	1 (1.2%)	4 (5.1%)	3 (4.6%)	0 (0%)	0 (0%)	11 (13.1%)
Subjects with Lesion-Related Mortality	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

[1]Column header counts and denominators are the number of Subjects at risk at the start of each interval.

Study period definitions: 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) Total(0-1826 days)

Table 35: Zone 2 Aneurysm Cohort Deaths

Study Day	Cause of Death (Associated Adverse Event)[1]	Adjudicated Adverse Event Relationship	Adjudicated as Lesion-Related Mortality?
1066	COVID-19	Unrelated to Device and Procedures	No
368	Small cell lung cancer	Unrelated to Device and Procedures	No
332	Urinary tract infection	Unrelated to Device and Procedures	No
97	Cardiac arrest	Unknown	No
729	ST segment elevation myocardial infarction	Unrelated to Device and Procedures	No
628	Myocardial infarction	Unrelated to Device and Procedures	No
79	Pulmonary sepsis	Unrelated to Device and Procedures	No
641	Dysphagia	Unrelated to Device and Procedures	No
816	Cardiac failure aggravated	Unrelated to Device and Procedures	No
901	Atherosclerotic cardiovascular disease	Unrelated to Device and Procedures	No
166	Anoxic brain damage	Unrelated to Device and Procedures	No

[1]Based on site-reported data. Associated Adverse Event is reported as MedDRA Lower Level term.

The Kaplan-Meier estimated 1-year (through day 365) freedom from all-cause mortality is 90.8% for the Zone 2 dissection cohort.

Table 36: Mortality for Zone 2 Dissection Cohort

	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	Total
Number of Enrolled Subjects[1]	132	126	118	109	67	28	1	132
Subjects with Mortality (All-Cause)	6 (4.5%)	5 (4.0%)	1 (0.8%)	6 (5.5%)	0 (0%)	0 (0%)	1 (100.0%)	19 (14.4%)
Subjects with Lesion-Related Mortality	2 (1.5%)	1 (0.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (2.3%)

[1]Column header counts and denominators are the number of Subjects at risk at the start of each interval.

Study period definitions: 30 days(0-30 days) 6 Months(31-182 days) 1 Year(183-365 days) 2 Years(366-731 days) 3 Years (731-1096 days) 4 Years(1097 -1461 days) 5 Years(1462 -1826 days)

Table 37: Zone 2 Dissection Cohort Deaths

Study Day	Cause of Death (Associated Adverse Event)[1]	Adjudicated Adverse Event Relationship	Adjudicated as Lesion-Related Mortality?

26	Myocardial infarction	Related to Endovascular Procedure	No[2]
124	Congestive heart failure	Unrelated to Device and Procedures	No
2	Hypoxic respiratory failure	Unknown	No
402	Gastrointestinal bleeding	Unrelated to Device and Procedures	No
593	Lung cancer	Unrelated to Device and Procedures	No
2	Embolic stroke	Related to Endovascular Procedure	No
692	Respiratory failure	Unrelated to Device and Procedures	No
25	Cardiac arrest	Unknown	Yes
176	Atrial fibrillation	Unrelated to Device and Procedures	No
639	Third degree burns	Unrelated to Device and Procedures	No
6	Aortic dissection rupture	Related to Device and Endovascular Procedure	Yes
2	Gastrointestinal bleed	Unknown	No
80	Cardiac arrest	Related to Device	Yes
363	Unknown cause of death	Unknown	No[2]
102	Cardiac arrest	Unknown	No
470	Unknown cause of death	Unknown	No
1522	Cardiac arrest	Unrelated to Device and Procedures	No
667	Sepsis	Unrelated to Device and Procedures	No
70	Hormone-refractory prostate cancer	Unrelated to Device and Procedures	No

[1]Based on site-reported data. Associated AE is reported as MedDRA Lower Level term.

[2]Although not adjudicated prior to PMA data export, it was later adjudicated and entered in the database.

There have been no deaths reported for the Zone 2 Traumatic Transection cohort at the time of data lock.

The Kaplan-Meier estimated 1-year (through day 365) freedom from all-cause mortality is 84.6% for the Zone 2 Other Isolated Lesion Cohort.

Table 38: Mortality for Zone 2 Other Isolated Lesion Cohort

	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	Total
Number of Enrolled Subjects[1]	13	13	11	8	3	1	0	13
Subjects with Mortality (All-Cause)	0 (0%)	2 (15.4%)	0 (0%)	1 (12.5%)	1 (33.3%)	0 (0%)	-	4 (30.8%)
Subjects with Lesion-Related Mortality	0 (0%)	0 (0%)	0 (0%)	1 (12.5%)	0 (0%)	0 (0%)	-	1 (7.7%)

[1] Column header counts and denominators are the number of Subjects at risk at the start of each interval.

Study period definitions: 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) 5Years(1462-1826 days) Total(0-1826 days)

Table 39: Zone 2 Other Isolated Lesion Cohort Deaths

Study Day	Cause of Death (Associated Adverse Event)[1]	Adjudicated Adverse Event Relationship	Adjudicated as Lesion-Related Mortality?
534	Aortic aneurysm rupture	Related to Device	Yes
129	Cerebral hemorrhage	Unrelated to Device and Procedures	No
167	Acute respiratory failure	Unrelated to Device and Procedures	No
875	Hypoxic respiratory failure	Unrelated to Device and Procedures	No

[1] Based on site-reported data. Associated Adverse Event is reported as MedDRA Lower Level term.

Learnings from Execution of study

Throughout the execution of the SSB11-02 pivotal there were learnings from reported outcomes (i.e., Type I and III Endoleak, New Dissections, Stroke, Deployment Events/Technical Success failures). Throughout the study, the IFU was updated to inform users of the risks identified and, if appropriate, implantation techniques to overcome or avoid the events from occurring. The learnings from the clinical study are reflected throughout the IFU in the appropriate sections (e.g., Warnings and Precautions, Implantation procedure sections).

Conclusion

Data from the pivotal clinical investigation demonstrate that the GORE® TAG® Thoracic Branch Endoprosthesis has met its primary safety and efficacy endpoints for the treatment oflesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients with appropriate anatomy.

PATIENT COUNSELING INFORMATION

The physician and patient should review the risks and benefits when discussing this endovascular device and procedure including:

- Risk and benefit differences between open surgical repair, medical management, branched thoracic endovascular repair (TEVAR) and non-branched thoracic endovascular aortic repair (TEVAR) including potential emergencyconversion to open surgical repair
- Potential advantages and disadvantages of non-branched TEVAR
- Potential advantages and disadvantages of branched TEVAR
- The possibility that subsequent interventional or open surgical repair may be required after initial endovascular repair

In addition to the risks and benefits of an endovascular repair, the physician should assess the patient's commitment and compliance to post-operative follow-up as necessary to ensurecontinuing safe and effective results. Listed below are additional topics to discuss with the patient as to expectations after an endovascular repair:

- The long-term safety and effectiveness of endovascular repair has not been established. Physicians should advise all patients that this treatment modality requires long-term, regularfollow-up to assess patients' health status and stent graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging lesions) should receive enhanced follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms, e.g., pain, numbness, weakness (see IMAGING GUIDELINES AND POST- OPERATIVE FOLLOW-UP).
- Regular follow-up including imaging of the device should be performed at least every 12 months for all patients and at least every 6 to 12 months for patients with known endoleaksor lesion enlargement for the duration of the implant (see IMAGING GUIDELINES AND POST- OPERATIVE FOLLOW-UP).
- Physicians must advise all patients that it is important to seek prompt medical attention if they experience signs of device occlusion, lesion enlargement or rupture. Signs of device occlusion include stroke; pain in the left arm, chest, abdomen or hip(s) or leg(s) during but may not be limited to activity. Rupture may be asymptomatic, but usually presents as pain,numbness, weakness in the legs, back, chest, abdominal, or groin pain, dizziness, fainting, rapid heartbeat, or sudden weakness.

Physicians are encouraged to refer the patient to the Patient Brochure regarding risks occurring during or after implantation of the device. Procedure related risks include cardiac, pulmonary, neurologic, bowel, and bleeding complications. Device related risks include occlusion, endoleak, lesion enlargement or progression, pseudoaneurysm formation, fracture, potential for reintervention and open surgical conversion, rupture and death (See Potential Device or Procedure Related Adverse Events in the WARNINGS AND PRECAUTIONS section). Physicians are encouraged to complete the Patient Wallet Card and give it to the patient so that they can carry it with them at all times. The patient should refer to the wallet card anytimethey visit additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

PATIENT SELECTION AND TREATMENT (SEE WARNINGS AND PRECAUTIONS)

During the execution of the clinical study, the adverse event rates, shown in Table 40, were reported and may be higher than corresponding rates reported for non-branched TEVAR. These outcomes need to be considered by physician users and guide decision-making regarding the benefit-risk profile of the TBE device in individual patients. High risk patients conditions include but are not limited to morbid obesity, potential for duct/nerve injury, and carotid stenosis. Please consider these rates when determining appropriate treatment decisions.

Table 40: Rates of AEs reported in TBE Pivotal Study that may be higher than corresponding reported rates for non-branched devices.

	Aneurysm (N = 84)	Dissection (N = 132)	Trauma (N =9)	Other Isolated Lesions (N = 13)	Total (N = 238)
Events through 12-Months					
Stroke	7 (8.3%)	6 (4.6%)	0%	1 (7.7%)	14 (5.9%)
- Disabling Stroke	4 (4.8%)	3 (2.3%)	-	1 (7.7%)	8 (3.4%)
- WHO Stroke	7 (8.3%)	6 (4.6%)	-	1 (7.7%)	14 (5.9%)
Branch New Dissection	1 (1.2%)	6 (4.5%)	0%	0%	7 (2.9%)
- open surgical repair	0%	0%	-	-	0%
- untreated resulting death	0%	0%	-	-	0%
Distal Aorta New Dissection	5 (6.0%)	0%	0%	2 (15.4%)	7 (2.9%)
- open surgical repair	0%	-	-	0%	0%
- untreated resulting death	0%	-	-	1 (7.7%)	1 (0.4%)
Proximal Aorta New Dissection	1 (1.2%)	8 (6.1%)	0%	0%	9 (3.8%)
- open surgical repair	1 (1.2%)	6 (4.5%)	-	-	7 (2.9%)
- untreated resulting death	0%	1 (0.8%)	-	-	1 (0.4%)
Core Lab Type I/III Endoleak	8/82 (9.8%)	5/121 (4.1%)	0%	0%	13/225 (5.8%)
- Type I	3/82 (3.7%)	3/121 (2.5%)	-	-	6/225 (2.7%)
- Type III	5/82 (6.1%)	2/121 (1.6%)	-	-	7/225 (3.1%)
- Reintervention	1 (1.2%)	0%	-	-	1/225 (0.4%)

The GORE® TAG® Thoracic Branch Endoprosthesis is designed to treat patients whose anatomies are compatible with the device sizing requirements specified in **Tables 2 – 4**.

- Proximal aortic neck inner diameters between 16 and 42 mm.
- Proximal aortic neck outer curvature length, including the left subclavian artery ostium and distal to a proximal branch vessel ostium, greater than or equal to the Proximal CoveredLength of the selected Aortic Component (see **Table 2**). The Partially Uncovered Stent Length may extend over no more than half of a more proximal branch vessel ostium.
- For patients with prior replacement of the ascending aorta and/or aortic arch by a surgical graft, there must be at least 2 cm of landing zone proximal to the most distal anastomosissite.

- For dissections, the primary entry tear must be distal to the left subclavian artery and the proximal extent of the intended landing zone must not be dissected.
- Left subclavian artery dimensions as follows:
  - With the use of an Aortic Component with an 8 mm portal diameter:
    - Left subclavian artery diameters between 6 and 15 mm
    - Left subclavian artery length ≥ 3 cm
  - With the use of an Aortic Component with a 12 mm portal diameter:
    - Left subclavian artery diameters between 11 and 18 mm
    - Left subclavian artery length ≥ 2.5 cm
- For Isolated lesions, distal aortic neck length ≥ 2 cm proximal to the celiac artery.
  - If the lesion segment being treated is longer than can be treated with a single GORE® TAG® Thoracic Branch Endoprosthesis, distal extensions with the GORE® TAG® ConformableThoracic Stent Graft are required.
- Differing proximal and distal aortic neck diameters (aortic taper) outside the intended aortic diameter requirements for a single Aortic Component diameter (**Table 2**) requires the useof distal extensions using the GORE® TAG® Conformable Thoracic Stent Graft. The GORE® TAG® Conformable Thoracic Stent Graft should be used according to its Instructions for Use.
- Use of distal extensions with the GORE® TAG® Thoracic Conformable Thoracic Stent Graft requires sufficient treatment length for positioning at least 1 cm distal to the deployed SideBranch (SB) Component. This length varies according to the dimensions of the Aortic Component selected for treatment and the final positioning of the SB Component within the Aortic Component internal portal. Generally, the SB Component will extend approximately 2 cm distal to the native ostium of the left subclavian artery.

Additional considerations for patient selection include, but are not limited to:

- Patient's age and life expectancy
- Comorbidities (e.g., cardiac, pulmonary, renal)
- Patient's suitability for open surgical repair
- Patient's anatomical suitability for endovascular repair
- Risk of aortic rupture versus the risk of treatment with the GORE® TAG® Thoracic Branch Endoprosthesis as listed in the WARNINGS AND PRECAUTIONS section
- Ability to tolerate general, regional or local anesthesia
- Iliofemoral access vessel size and morphology (minimal thrombus, calcium and/or tortuosity) should be compatible with vascular access techniques and accessories
- The final treatment decision is at the discretion of the physician and patient
- Presence of thrombus, calcium, and/or atherosclerotic plaque in the aorta, especially the aortic arch

HOW SUPPLIED

STERILITY

- The GORE® TAG® Thoracic Branch Endoprosthesis is provided STERILE and non-pyrogenic, and is sterilized by ethylene oxide. Do not resterilize.
- Do not use after the "Use By" (expiration) date printed on the label.
- The GORE® TAG® Thoracic Branch Endoprosthesis is designed for single use only; do not reuse device. Gore does not have data regarding reuse of this device. Reuse may cause devicefailure or procedural complications including device damage, compromised device biocompatibility, and device contamination which may lead to patient harms.

STORAGE AND HANDLING

- Keep dry and store in a cool place.
- Do not resterilize; for single use only.
- Do not use the GORE® TAG® Thoracic Branch Endoprosthesis if damaged or if sterile barrier has been compromised.
- The foil pouch of the Side Branch Component packaging is both a moisture barrier and a sterile barrier. Do not use or store the graft if the foil pouch has been compromised.
- Use clean sterile gloves or atraumatic sterile instruments when handling the GORE® TAG® Thoracic Branch Endoprosthesis.
- Handle and dispose of the device and packaging, taking into account any infectious or microbial hazard risks, with the necessary precautionary measures in accordance withacceptable medical practice and with applicable local, state, and federal laws and regulations.

See WARNINGS AND PRECAUTIONS for additional considerations specific to storage and

handling.For additional Storage and Handling information, see HOW SUPPLIED.

CLINICAL USE INFORMATION

WARNING: Always have a surgical team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

WARNING: The GORE® TAG® Thoracic Branch Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program which requires case planning/sizing and device training which includes positioning and deployment of the device. Physicians may be assisted in device preparation, delivery, and deployment by surgical team members trained in these steps.

The recommended skill/knowledge requirements for physicians using the GORE® TAG® Thoracic Branch Endoprosthesis including patient selection knowledge, materials required for device placement knowledge and skills, and sizing knowledge, are outlined below:

Patient Selection

- Knowledge of the natural history of thoracic aortic disease and co-morbidities associated with endovascular repair of the thoracic aorta.
- Knowledge of radiographic image interpretation, device selection and

sizing.A multi-disciplinary team that has combined procedural experience

with:

- Vascular access techniques
- Guidewire and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Appropriate use of contrast agents
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities
- Conventional open surgery and surgical conversion

Materials Required for Device Placement

- Aortic Component of the GORE® TAG® Thoracic Branch Endoprosthesis in the appropriate diameter and length (**Table 2**)
- Side Branch Component of the GORE® TAG® Thoracic Branch Endoprosthesis with a portal segment diameter the same as the internal portal diameter of the selected Aortic Componentand with the appropriate device diameter for the left subclavian artery (**Table 3**)
- (optional) Aortic Extender of the GORE® TAG® Thoracic Branch Endoprosthesis in the appropriate diameter (**Table 4**)
- (optional) GORE® TAG® Conformable Thoracic Stent Graft in the appropriate diameter.
- GORE® DrySeal Sheath (family of devices) of appropriate French size for the Aortic Component selected (**Table 2**)
- GORE® Tri-Lobe Balloon Catheter of appropriate size
- Compliant or non-compliant balloon catheter of appropriate diameter and length for the left subclavian artery
- Heparin and heparinized saline solution
- Contrast agents
- Sterile syringes
- 3-way stopcock
- Appropriate diagnostic catheters and accessories
- 0.035" super-stiff guidewire (e.g., Cook® Lunderquist® DC wire guide or equivalent)
- 0.035" stiff guidewire (e.g., EV3® Nitrex® guidewire, Cook® Rosen wire guide, or equivalent)

Sizing

Tables 2 - 4 indicate the appropriate endoprosthesis components for the intended vessel diameters and lengths. The aortic neck and left subclavian artery should be measured from orthogonal views of reconstructed CTA films. Diameter measurements should consist only of the flow lumen and not the vessel wall. Three diameter measurements are required for theproximal and distal aortic landing zones as well as for the left subclavian artery (**Figure 5**). All measurements for each landing zone must be within the Intended Vessel Inner Diameter range for each endoprosthesis component, as listed in **Tables 2 - 4**. The Side Branch Component should be selected such that the portal segment diameter is the same as the internal portal diameter of the selected Aortic Component. Appropriate oversizing is built into the recommended sizes and, as such, additional oversizing should not be incorporated in the selection of the endoprosthesis components.

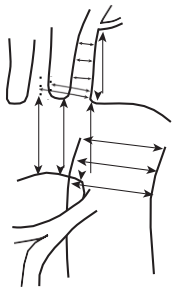
DIRECTIONS FOR USE

Anatomical Requirements - Isolated Lesion

Measurements to be taken during the pre-treatment assessment are described in **Figures 5 and 6**.

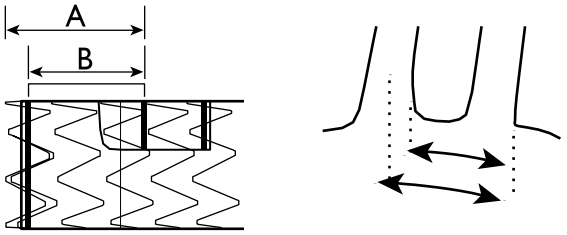
Figure 5. Isolated Lesion Screening Measurements

Proximal Landing Zone



Distal Landing Zone

Figure 6. Proximal Aortic Component device dimensions and corresponding anatomic measurements (A) Proximal Segment Length (B) Proximal Covered Length (refer to Table 2 for device dimensions)



Proximal Landing Zone (Isolated Lesions[1]):

Aortic Requirements:

- **Figure 6, measurement A**: Available proximal outer curvature length greater than or equal to the proximal segment length of the selected Aortic Component (**Table 2**). The proximalouter curvature length includes the ostium of the left subclavian artery and up to half of the ostium of a more proximal branch vessel (e. g., the left common carotid artery). Only the partially uncovered stent should be allowed to extend into a proximal branch vessel ostium.
- **Figure 6, measurement B**: Available proximal aortic neck outer curvature length greater than or equal to the proximal covered length of the selected Aortic Component (**Table 2**). The proximal aortic neck outer curvature length includes the ostium of the left subclavian artery and must not extend to include a more proximal branch vessel (e.g., the left commoncarotid artery). The proximal covered length of the Aortic Component does not include the length of the partially uncovered stent.
- Proximal aortic landing zone inner diameters (ID) between 16 and 42 mm or 24 and 42 mm for Aortic Components having a portal segment diameter of 8 mm or 12 mm, respectively.The proximal aortic landing zone inner diameters (ID) must not include taper outside the treatment range for a single Aortic Component (**Table 2**).

[1] Isolated lesions includes aneurysms and other pathologies with non-diseased proximal and distal landing zones (e.g., Penetrating Aortic Ulcers, IMH, Aneruysm, Traumatic Transection, etc.)

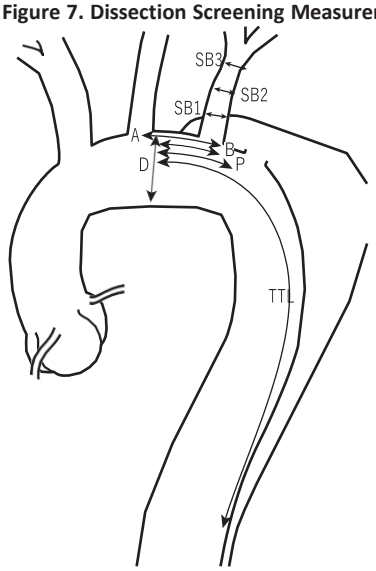
Distal Landing Zone (Isolated Lesions):

- Distal aortic neck outer curvature length of ≥ 2 cm proximal of the celiac artery.
- Distal aortic landing zone inner diameters (ID) within the range of intended aortic diameters for the selected Aortic Component (**Table 2**) or as required by the GORE® TAG® Conformable Thoracic Stent Graft Instructions for Use when distal extension(s) are used. See USING MULTIPLE DEVICES section below.

Anatomical Requirements- Dissection

Measurements to be taken during the pre-treatment assessment are described in **Figure 7**.

Figure 7. Dissection Screening Measurements



Proximal Landing Zone (Dissections):

Aortic Requirements:

- **Figure 7, measurement A:** Available proximal outer curvature length greater than or equal to the proximal segment length of the selected Aortic Component (**Table 2**). The proximalouter curvature length includes the ostium of the left subclavian artery and up to half of the ostium of a more proximal branch vessel (e.g., the left common carotid artery). Only the partially uncovered stent should be allowed to extend into a proximal branch vessel ostium.
- **Figure 7, measurement B:** Available proximal aortic neck outer curvature length greater than or equal to the proximal covered length of the selected Aortic Component (**Table 2**). The proximal aortic neck outer curvature length includes the ostium of the left subclavian artery and must not extend to include a more proximal branch vessel (e.g., the left commoncarotid artery). The proximal covered length of the Aortic Component does not include the length of the partially uncovered stent.
- **Figure 7, measurement D:** Diameter at proximal extent of proximal landing zone (must be in non-dissected aorta)
- Proximal aortic landing zone inner diameter (ID) between 16 and 42 mm or 24 and 42 mm for Aortic Components having a portal segment diameter of 8 mm or 12 mm,

respectively.

- **Figure 7, measurement P:** Length from proximal extent of proximal landing zone to primary entry tear
- The primary entry tear must be distal to the left subclavian artery and the proximal extent of the intended landing zone must not be dissected.
- **Figure 7, measurement TTL:** Total treatment length from proximal extent of the intended landing zone
- Total treatment length should include a minimum of 10 cm distal to the primary entry tear where the distal end of the device terminates in a straight segment of the aorta. It isrecommended to cover a longer length when treating ruptured dissections.

Additional Anatomical Measurements - Isolated Lesions and Dissections

Left Subclavian Artery Requirements:

- Left subclavian artery diameters (ID) between 6 and 15 mm or 11 and 18 mm for SB Components having a portal segment diameter of 8 mm or 12 mm, respectively. The treatedsegment of the left subclavian artery must be in the range of the intended vessel diameters for a single SB Component (**Table 3**).
- Left subclavian artery outer curvature length greater than or equal to 3 cm or 2.5 cm for SB Components having a portal segment diameter of 8 mm or 12 mm, respectively.
- The SB Component must be selected such that the portal segment diameter is the same as the internal portal diameter of the selected Aortic

Component.Vascular Access

- Iliofemoral access vessels should be of sufficient diameter to allow passage of the GORE® DrySeal Sheath (family of devices) required for the selected Aortic Component (see **Table 2**).
- Iliofemoral access vessel morphology should be compatible with vascular access techniques and accessories (minimal thrombus, calcium and/or tortuosity).
- Iliofemoral access vessels of insufficient diameter or significant disease and/or tortuosity may require the use of a surgical conduit from the common iliac artery or the abdominalaorta.
- If brachial access is obtained, vessel size and morphology should be adequate for side branch wire manipulation. If brachial access is inadequate, proximal upper extremity access(e.g. axillary artery) may be obtained.

Using Multiple Devices

When a distal GORE® TAG® Conformable Thoracic Stent Graft is used as a distal extension to accommodate aortic taper or for additional treatment length, adhere to the GORE® TAG® Conformable Thoracic Stent Graft IFU in conjunction with the recommended guidelines below:

- Always deploy the larger diameter endoprosthesis into the smaller diameter endoprosthesis.
- If overlapping devices of the same diameter, overlap by at least 5 cm. When possible, the distal device should be deployed first.
- Distal extensions that overlap with the Aortic Component in an aneurysmal section should be one to two sizes different in diameter with an overlap of at least 3 cm (gold band to goldband).
- Distal extensions deployed after the Aortic Component should be deployed following deployment of the SB Component and at least 1 cm distal to the trailing end of the SBComponent. Care should be taken to ensure adequate treatment length is available for the selected distal extension(s).

Arterial Access (see Procedure Illustrations, Step 1)

1. Obtain appropriate vascular access, according to standard practice.
2. Administer heparin, according to standard practice.
3. Perform angiography to identify the target anatomy, according to standard practice.
4. Advance the appropriate size GORE® DrySeal Sheath (family of devices) through the vasculature, according to standard practice.
5. Branch Guidewire: If through and through wire access is required, advance a 260 cm x 0.035" stiff guidewire (e.g. Cook® Rosen wire guide) from the upper extremity access site (e.g. left brachial artery) through the left subclavian artery and into the descending thoracic aorta. Snare the branch wire in the descending thoracic aorta. Establish through andthrough wire access according to standard practice.

   NOTE: Use of a stiff guidewire (e.g., Boston Scientific Amplatz Super Stiff) in anatomies with acute left subclavian artery angulation has led to difficultly in advancing the AorticComponent to target location.

   NOTE: Use of a catheter or sheath from upper extremity access (e.g. brachial access) to protect the left subclavian artery during the procedure (including snaring) may prevent newdissections in the left subclavian artery.
6. Branch Guidewire: If through and through is not required, advance a 260 cm x 0.035" stiff guidewire (e.g., EV3® Nitrex® guidewire, Cook® Rosen wire guide) through the GORE® DrySeal Sheath (family of devices) to the left subclavian artery.

   NOTE: Use of a stiff guidewire (e.g., Boston Scientific Amplatz Super Stiff) in anatomies with acute left subclavian artery angulation has led to difficultly in advancing the Aortic Component to target location.
7. Aortic Guidewire: Advance a 260 cm x 0.035" super-stiff guidewire (e.g., Cook® Lunderquist® DC wire guide) through the GORE® DrySeal Sheath or GORE® DrySeal Flex Sheath to theascending aorta.

GORE® TAG® Thoracic Branch Endoprosthesis Deployment

Aortic Component Preparation and Delivery (see Procedure Illustrations, Step 2 - Step 5)

1. Following removal of the Aortic Component delivery catheter from the outer packaging, remove the packaging sheaths from the constrained device and examine for possibledamage.
2. Remove the packaging mandrel from the device olive and central guidewire lumen. Remove the packaging mandrel from the green removable guidewire tube. **Do not withdrawthe removable guidewire tube from the constrained device at this time. This tube serves to facilitate passage of the pre-cannulated Branch Guidewire through the internal portal of the Aortic Component.**
3. Flush heparinized saline through the flushing port in the hub of the delivery catheter.
4. Pass the Aortic Guidewire into the central lumen of the delivery catheter.
5. Pass the Branch Guidewire into the removable guidewire tube and through the constrained device. When the device is fully advanced over the Branch Guidewire, withdraw the removable guidewire tube. Retain the tube in case it becomes necessary to remove the constrained Aortic Component from the patient following insertion.

(See WARNINGS ANDPRECAUTIONS – IMPLANT PROCEDURE)

6. Insert the delivery catheter over both pre-positioned guidewires and into the valve of the GORE® DrySeal Sheath (family of devices) stopping when only the trailing end of theconstrained device is visible. Allow blood to flow back through the constrained device.
7. With the position of the Aortic and Branch Guidewires secure, and using fluoroscopic guidance, advance the delivery catheter to the proximal descending thoracic aorta, taking careto remove any twists between the two guidewires while advancing.
   - Remove guidewire twists in the straight descending thoracic aorta before advancing into the proximal descending thoracic aorta. Guidewire twists should be removed whileadvancing the device through the straight descending aorta.
   - **Caution: Over torqueing of the Aortic Component may loosen the deployment line which has been observed to cause premature partial deployment of the proximal end of the Aortic Component.**
8. **Ensure the image intensifier (C-arm) is positioned such that it is perpendicular to the proximal aortic neck and the origin of the left subclavian artery, as determined by 3-D CTA reconstructions of pre-operative CT imaging.** This angle is typically 45-75 degrees left anterior oblique (LAO). Additionally, cranial or caudal angulation of the C-arm may be necessary for accurate visualization of the origin of the left subclavian artery.
   - For patients with tortuous left subclavian arteries use of a stiff Branch wire (e.g. Nitrex) can straighten the left subclavian artery which results in difficulty visualizing the full length of the left subclavian artery (e.g. lack of contrast in the left subclavian artery). If there is no flow into the left subclavian artery, consider using a softer side Branch wire(e.g. Rosen) which is less likely to straighten the left subclavian artery and will allow for visualization of the full length of the left subclavian artery.
9. Advance the delivery catheter to the approximate target location using the radiopaque markers for guidance (**Figure 2**). The Aortic Component should be positioned as far proximallyas possible while ensuring that the following conditions are met:
   - The endoprosthesis should be advanced slightly beyond the target implant location and pulled back to release stored energy in the delivery catheter.
   - Ensure the device is positioned against the outer curve of the aorta by applying forward pressure on the Aortic Guidewire. **Caution: Excessive forward pressure or pressureapplied directly to the catheter shaft during deployment has resulted in inaccurate device positioning.**
   - The proximal radiopaque portal marker should not be positioned more distal than the distal edge of the left subclavian artery ostium.
   - The proximal radiopaque portal marker should not be more proximal than one portal diameter (8 mm or 12 mm) from the proximal edge of the left subclavian artery ostium.
   - The leading gold band of the Aortic Component should be positioned such that it is proximal of the left subclavian artery ostium.
   - The leading gold band of the Aortic Component should be distal of a more proximal branch vessel (the left common carotid artery).
   - The leading tip of the partially uncovered stent of the Aortic Component should be distal to the midpoint of the ostium of a more proximal branch vessel (e.g., the left commoncarotid artery).
   - The constrained device should be rotated such that the Branch Guidewire extends from the "edge" of the fluoroscopic projection of the delivery catheter, immediately adjacent tothe left subclavian artery.
   - An RAO projection looking down the length of the aorta may be desired to confirm rotational alignment of the Aortic Component.
10. Advance a marker pigtail angiographic catheter and perform angiography according to standard practice to confirm the position of the target anatomy, and the location of theconstrained endoprosthesis. A magnified view of the proximal landing zone may be desired for accurate positioning.
11. Using a two-person deployment and with the device at the desired location, one person should stabilize the introducer sheath at the patient and the delivery catheter at the introducer sheath to prevent introducer sheath or delivery catheter movement prior to or during deployment of the endoprosthesis. A second person should then loosen the luer lock on the deployment knob and, while maintaining the exposed delivery catheter as straight as possible, deploy the endoprosthesis by pulling the deployment knob in a steady,continuous motion. Deployment of the Aortic Component initiates from the portal opening and extends simultaneously to the proximal and distal ends.
    - **Caution: Slow deployment or non-continuous motion has resulted in the Aortic Component landing distal to the target location.**
12. Withdraw the delivery catheter using fluoroscopic guidance to ensure safe removal from the deployed endoprosthesis.

    NOTE: A small sleeve will remain attached to, and is withdrawn with the delivery catheter following deployment. No additional manipulations are required for catheter withdrawal.

Side Branch Component Preparation and Delivery (see Procedure Illustrations, Step 7-8)

1. Remove the Side Branch (SB) Component delivery catheter from the packaging. Remove the packaging sheath and mandrel and examine for possible damage.
2. Flush heparinized saline through the flushing port.
3. Over the Branch Guidewire, insert the SB Component into the valve of the GORE® DrySeal Sheath (family of devices) stopping when only the trailing end of the constrained device isvisible. Allow blood to flow back through the constrained device.
4. Using fluoroscopic guidance, advance the delivery catheter to the target implant location. Ensure that the tip of the SB Component delivery catheter does not catch on the internalportal while advancing the SB Component. **Caution: Do not rotate the SB Component delivery catheter. Catheter breakage or inadvertent deployment has occurred.**
   - In some cases it may be necessary to exchange a stiffer Branch Guidewire for a softer Branch Guidewire or obtain brachial access for through and through wire manipulation toease introduction of the SB Component through the internal portal and into the left subclavian artery.
   - **Caution: Excessive side branch wire manipulation during this step has been shown to cause the branch guidewire to prolapse and loop around the proximal uncovered apex of the Aortic Component.**
   - To prevent prolapsing of the side branch guide wire, advance a sheath or catheter from the brachial or axillary access site. Advance the catheter or sheath from the brachialaccess site to engage the tip of the SB Component to ease introduction of the SB Component through the internal portal and into the left subclavian artery.
   - **Note:** Catheter or sheath must be > 4 Fr to prevent tip from sliding under SB Component olive.
   - If the side branch wire loops around the proximal uncovered apex of the Aortic Component, the loop must be removed by re-establishing side branch wire access through theportal and directly into the left subclavian artery.
5. Finalize the position of the delivery catheter. The following conditions should be met during positioning of the SB Component:
   - The inner radiopaque marker of the constrained device should be aligned with the trailing gold marker on the Aortic Component internal portal (**Figure 8**). Note: It is necessaryfor the trailing 5 mm of the SB Component (denoted by the two trailing radiopaque markers) to be deployed distal to the internal portal. This ensures that the

SB Component flared apices are deployed outside of the internal portal.

- Ensure that no major branches of the left subclavian artery will be covered by the SB Component upon deployment. Ensure the SB Component leading end terminates in astraight segment of the target. **Note:** If necessary, the SB Component may be positioned up to 5 mm more distal (within the aorta) than indicated above to allow for less extension into the left subclavian artery.
- The endoprosthesis should be advanced slightly beyond the target implant location and pulled back to release stored energy in the delivery catheter.

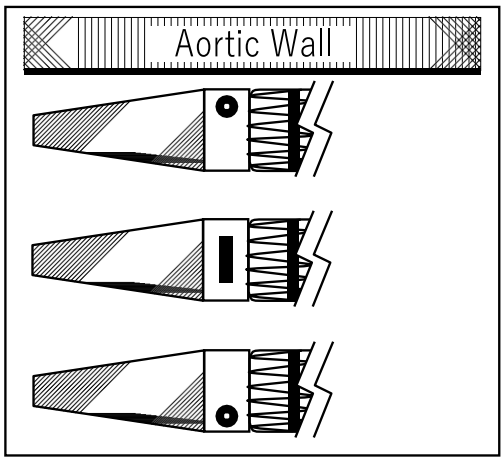
6. (Optional) Perform angiography according to standard practice to confirm the position of the target anatomy, and the location of the constrained endoprosthesis.
7. Using a two-person deployment and with the device at the desired location, one person should stabilize the introducer sheath at the patient and the delivery catheter at the introducer sheath to prevent movement prior to or during deployment of the endoprosthesis. A second person should then loosen the luer lock on the deployment knob and, whilemaintaining the exposed delivery catheter as straight as possible, deploy the endoprosthesis by pulling the deployment knob in a steady, continuous motion. Deployment of the SB Component initiates at the trailing end and extends to the leading end of the device.
8. Withdraw the delivery catheter using fluoroscopic guidance to ensure safe removal from the deployed endoprostheses.
9. If an additional SB Component is required, the additional SB Component can be deployed with up to 20 mm extension, (4cm of overlap in the previously place SB component) in the left subclavian artery.

Figure 8. Alignment of the inner radiopaque marker on the constrained SB Component with the trailing internal portal marker of the deployed Aortic Component

Aortic Extender Component Preparation and Delivery (Optional)

1. The Aortic Extender is an optional component and should be implanted only after the implantation of both the Aortic and SB Components.
2. Remove the Aortic Extender delivery catheter from the packaging. Remove the packaging sheath and mandrel and examine for possible damage.
3. Flush heparinized saline through the flushing port.
4. Insert the endoprosthesis delivery catheter over the Aortic Guidewire and into the valve of the introducer sheath, stopping when only the trailing end of the constrained device isvisible. Allow blood to flow back through the constrained device.
5. **Ensure the image intensifier (C-arm) is positioned such that it is perpendicular to the proximal extent of the target landing zone, as determined by 3-D CTA reconstructions of pre-operative CT imaging.** This angle is typically 45-75 degrees left anterior oblique (LAO). Additionally, cranial or caudal angulation of the C-arm may benecessary for accurate visualization of the target landing zone.
6. Advance the delivery catheter to the target implant location within the deployed Aortic Component. The following conditions should be met during positioning of the Aortic Extender:
   - The endoprosthesis should be advanced slightly beyond the target implant location and pulled back to release stored energy in the delivery catheter.
   - Rotate the delivery catheter such that the leading olive radiopaque marker appears as a dot adjacent to the aortic wall (**Figure 9**). The marker on the leading olive SHOULD NOT appear to be a line perpendicular to the catheter or a dot opposite the wall of the aorta. **Caution: Do not rotate the delivery catheter while the device is inside theintroducer sheath. Catheter breakage or inadvertent deployment may occur.**
   - Ensure the device is positioned against the outer curve of the aorta by applying forward pressure on the Aortic Guidewire. **Caution: Excessive forward pressure or pressureapplied directly to the catheter shaft during deployment may result in inaccurate device positioning.**
     Note: If there is difficulty in positioning the Aortic Extender on the outer curve of the superior aspect of the aorta, it is possible that the aortic wire is trapped beneath the portal.Deployment of the Aortic Extender with a trapped wire may result in deployment inaccuracy. Retract aortic wire and advance so that the aortic wire is positioned against the outer curve of the superior aspect of the aorta.
   - The Aortic Extender must extend minimally outside of the Aortic Component such that the leading gold marker of the Aortic Extender is aligned with the bare apices of the AorticComponent. Deployment of the Aortic Extender without this amount of extension has been shown to be associated with fractures of the proximal uncovered apices on the Aortic Extender/Component in benchtop testing. **Note:** When deployed within the Aortic Component, the Aortic Extender may be allowed to override the internal portal. **Caution: In no case should the Aortic Extender be deployed in such a way that the trailing gold band extends distally beyond the trailing end of the SB Component. This may result in branch occlusion.**
   - The leading radiopaque marker of the Aortic Extender should be distal of a more proximal branch vessel (e.g., the left common carotid artery).
   - The leading tip of the proximal partially uncovered stent of the Aortic Extender should be distal to the midpoint of the ostium of a more proximal branch vessel (e.g., the leftcommon carotid artery).
7. Advance a marker pigtail angiographic catheter and perform angiography according to standard practice to confirm the position of the target anatomy, and the location of theconstrained endoprosthesis. A magnified view of the proximal landing zone may be desired for accurate positioning.
8. Using a two-person deployment and with the device at the desired location, one person should stabilize the introducer sheath at the patient and the delivery catheter at the introducer sheath to prevent introducer sheath or delivery catheter movement prior to or during deployment of the endoprosthesis. A second person should then loosen the luerlock on the deployment knob and, while maintaining the exposed delivery catheter as straight as possible, deploy the endoprosthesis by pulling the deployment knob in a rapid, continuous motion. Deployment of the Aortic Extender initiates from both the leading end and the middle of the device and extends to the trailing end.
9. Following deployment, withdraw the delivery catheter using fluoroscopic guidance to ensure safe removal from the deployed endoprosthesis. Note: The constraining sleeve of theAortic Extender Component remains attached to, and is withdrawn with, the delivery catheter following deployment. As such, care should be taken during catheter withdrawal
   to avoid dislocation of the deployed Aortic Extender. A longitudinal radiopaque marker (approximately 1 cm in length) is provided to help identify the constraining sleeve duringretraction (see **Figure 4**).
   - **Caution: Upon initial deployment, do not advance the Aortic Extender catheter. The Aortic Extender may be pushed forward by the constraining sleeve attached to the delivery catheter.**
   - Pull on the wire and catheter to move device from outer wall to withdraw the proximal olive past the partially uncovered stents. Once the olive is past the partially uncoveredstents, continue pulling on the catheter while maintaining wire position on the outer curve by pushing on the wire until the sleeve is removed from the deployed devices.
   - **Note:** If unable to remove deployment line, the following techniques may be used to disengage the deployment line from the Aortic Extender. Rotate the catheter one full revolution to release the deployment line from the Aortic Extender before initiating Aortic Extender catheter withdrawal. If distal movement occurs during Aortic Extender catheter withdrawal, rotate the catheter one full revolution to release the deployment line while pushing forward. If the deployment line is still engaged, continue Aortic Extender catheter withdrawal by rotating the Aortic Extender catheter another full revolution which should disengage the deployment line from the Aortic Extender. It is not recommended to rotate more than three full revolutions in the same direction at one time while pushing or pulling the Aortic Extender catheter. If the Aortic Extender moves toan undesired location (e.g. coverage of a branch vessel), surgical conversion or intervention may be required.
   - **Note:** If there is difficulty in moving the device from the outer curve during initial withdrawal, it may be helpful to exchange to a softer guidewire for Aortic Extender catheterwithdrawal.
   - **Note:** Once the olive is past the partially uncovered stents, the trailing end of the Aortic Extender sleeve may engage with a SB Component flared apex leading to resistance during Aortic Extender delivery catheter withdrawal. If this occurs, push forward slightly on the catheter to disengage the Aortic Extender sleeve from the SB Component flared apex. If the Aortic Extender sleeve is still engaged, rotate slightly (180° or less) while pulling the catheter to disengage the Aortic Extender sleeve from the SB Component flaredapex.
   - **Caution: Do not over torque catheter. This may result in the sleeve wrapping around the Aortic Extender and/or Aortic Extender catheter.**

Figure 9. Correct rotation of the Aortic Extender delivery catheter (top image).



Completion of Procedure

1. After deployment, all device components should be ballooned sequentially if necessary. The Aortic Component may be ballooned first using the GORE® Tri-Lobe Balloon Catheter. This should be followed by balloon dilatation of the SB Component using either a non-compliant or compliant balloon catheter. If using a non-compliant balloon catheter, select the size of the aortic component portal, for portal overlap, and the size of the vessel for the landing zone ballooning. All balloons should bedelivered from the ilio-femoral access site only. Care should be taken to avoid balloon inflation outside of the endoprosthesis to avoid vessel injury or rupture.
   - For Aortic Component and Aortic Extender ballooning, an appropriately sized GORE® Tri-Lobe Balloon Catheter may be used to smooth and seat the endoprosthesis against theaortic wall in the proximal and distal aortic necks and areas of device overlap.
     - When treating isolated lesions, balloon the distal neck first, proximal neck second, then overlapped areas (if appropriate). Ballooning after device implant in aneurysms isnecessary to maximize seating of the endoprosthesis against the aortic wall.
     - Care should be taken when ballooning in patients with a history of aortic dissection. Over inflation of the balloon in dissection patients has led to aortic damage including retrograde dissection and damage to the septum. Ballooning should only be completed when necessary such as treatment of an endoleak. When ballooning in dissection patients, balloon the proximal neck first and then overlapped areas (if appropriate). Do not balloon the distal neck of dissections. Inadvertent pressurization of the false lumenmay result in retrograde dissection or damage to the septum.
   - Ballooning of the proximal or distal necks should be performed by centering the Tri-Lobe Balloon on the radiopaque gold band of the endoprosthesis. When the balloon is in the desired location it should be inflated to the recommended volume, according to its Instructions for Use. Deflate the balloon, rotate the balloon approximately 60° and repeat the inflation. **Warning: If resistance is felt, stop and assess the cause. Otherwise, device displacement may occur.**
   - For SB Component ballooning, the balloon catheter should be selected according to the left subclavian artery diameter and should have a balloon length no more than 2 cm. Ballooning should be performed first in the region of the portal overlap, followed by ballooning in the branch vessel per the balloon catheter's instructions for use. It isrecommended to balloon throughout the length of the SB Component.
   - It is recommended to balloon with a compliant balloon or hand inflate with a non-compliant balloon in the "curved" segment of the SB Component.
     - **Caution: Ballooning in the "curved" segment without hand inflation may result in device migration.**
     - **Note:** When ballooning within the region of the portal overlap, the balloon catheter should be inflated to profile only. In cases in which the selected balloon catheter hasa smaller maximum diameter than the portal diameter, a larger balloon must first be used in the region of the portal overlap, followed by the smaller balloon in the left subclavian artery.
2. Perform an aortogram in two views to assess exclusion of the lesion, luminal patency of the aorta and branch vessel, and endoprosthesis position.
3. Close the arterial access site(s), according to standard practice.

See WARNINGS AND PRECAUTIONS for additional considerations specific to the procedure.

IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

General

All patients should be advised this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, branch stenosis) should receive enhanced follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms(e.g., pain, numbness, weakness).

Regular and consistent follow-up is a critical part of ensuring continuing safety and effectiveness of aortic endovascular repair. Physicians should tailor patient follow-up to the needs and imaging findings (e.g., endoleaks, loss of patency) and circumstances of each individual patient. In the US clinical study, at least one annual physician visit and the imaging schedule(**Table 41**) were employed. Additional Surveillance and potential treatment is recommended for certain findings, see **Additional Surveillance and Potential Treatment** section below. Follow-up modalities include CT/CTA or MRA. Data from these modalities is acquired and used to compare changes over time and their effects on exclusion ofthe lesion.

Table 41. Recommended Schedule for Zone 2 Patient Follow-Up

Diagnostic Test	Pre-treatment	Treatment	Post-Procedure	1 month	6 months	One year and annually thereafter
Spiral CT (contrast) *	X			X	X	X
Spiral CT (non-contrast) *				X		
Angiogram		X				

*MRA may be used in follow-up if the subject is contraindicated for CTA. (see MRI conditional safety Section below)

Angiographic Imaging
Angiographic images are recommended pre-treatment to evaluate the length and tortuosity of the abdominal aorta, iliac and common femoral arteries. Additional angiographic imagesare required during the treatment procedure both pre and post-deployment to evaluate device placement and branch perfusion.

CT/CTA Imaging
- CT films should include all sequential images at the lowest possible slice thickness (≤ 2 mm). Do NOT perform scans having large slice thickness (> 2 mm) and/or omission of CTimages/film sets (non-consecutive) as it prevents precise anatomical and device comparisons over time.
- 3-D CTA reconstruction is the recommended imaging modality to accurately assess proximal and distal neck lengths for the GORE® TAG® Thoracic Branch Endoprosthesis. Thesereconstructions should be performed in sagittal, coronal and varying oblique views depending upon individual patient anatomy.
- **If an endoleak is suspected or there is lesion enlargement, both non-contrast and contrast runs should be performed.**
- Non-contrast and contrast run slice thickness and interval must match.
- DO NOT change patient orientation or re-landmark patient between non-contrast and contrast runs.
- Pre and Post-treatment CT/CTA imaging should be performed according to the guidelines listed in **Table 42** below.

Table 42. CT/CTA Imaging Guidelines

Start Position	Angle of the mandible with the head in neutral position
End Position	Pre-Treatment: Femoral heads Post-Treatment: Superior Mesenteric Artery
Scan Field	Large
Field Of Vision	240 mm or as appropriate for subject
Scan Type	Helical
Slice Collimation/Thickness	≤ 2 mm
Reconstruction Interval	20% overlap (e.g. 0.8/1 mm, 0.4/0.5 mm or 1.6/2 mm)
Scan Delay (Contrast)	Smart prep or equivalent, 3-second delay*
Kilovoltage	120 or as appropriate
Contrast Medium	Recommendation: ≥ 350 mg/ml, 70-200 ml
Contrast Medium Administration	Recommendation: ≥ 4 ml/s, via right cubital vein, 18G, saline push ≥ 40 ml
* Baseline Location: Thoracic Aorta; ROI: Ascending Aorta; mA: 40; Monitor Delay: 10s; Monitor ISD: 3s Scan; Enhance Threshold: 100 HU; Scan Phase: 3s	

Chest X-ray Film Series (plain film)
If there is any concern regarding device integrity (e.g., kinking, stent-wire breaks, relative component migration), a chest X-ray film series may be acquired and evaluated by the attendingphysician. The following chest X-ray views are recommended for optimal visualization of the endoprosthesis. Magnified views (2-4x) may aid in evaluation of device integrity.

- Supine – frontal (AP)
- Lateral
- 45° LPO
- 45° RPO
- Ensure the entire device is captured on each single image format.
- Set KvP to 75-85 to maximize device visualization.

MRI Safety Information **MR Conditional**
A patient with the GORE® TAG® Thoracic Branch Endoprosthesis may be safely scanned immediately after placement under the following conditions. Failure to follow these conditions mayresult in injury.

Device Name	GORE® TAG® Thoracic Branch Endoprosthesis
Static Magnetic Field Strength (B_o)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	There are no RF excitation restrictions
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body averaged SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact. With a gradient echo pulse sequence in a 3.0T MR System, the artifact mayextend up to 10mm from the implant. Under these conditions, the central portion of the lumen of the aortic component was visible.

A patient with the GORE® TAG® Thoracic Branch Endoprosthesis, including an Aortic Component, Side Branch Component, Aortic Extender, and up to four distally deployedGORE® TAG® Thoracic Endoprostheses can be scanned safely under the above conditions immediately after implantation.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Additional Surveillance and Treatment

Additional surveillance and possible treatment is recommended for:

- Branch vessel stenosis or occlusion
- Type I endoleak
- Type III endoleak
- Dissections with persistent false lumen perfusion
- Lesions enlargement ≥ 5 mm increase in maximum diameter (regardless of endoleak status) compared to any previous measurement

Consideration for reintervention or open surgical repair should include the attending physician's assessment of an individual patient's co-morbidities, life expectancy, and the patient'spersonal choices. Patients should be counseled as to the possibility of subsequent reinterventions including catheter-based and open surgical procedures, including conversion.

WARNING: Strict adherence to the GORE® TAG® Thoracic Branch Endoprosthesis IFU sizing guide (Tables 2-4) is required when selecting the appropriate device size. Oversizing for the GORE® TAG® Thoracic Branch Endoprosthesis has been incorporated into the IFU sizing guide. Use outside the IFU sizing guide can result in endoleak, fracture, migration, device infolding or compression. DO NOT treat patients with the GORE® TAG® Thoracic Branch Endoprosthesis if their anatomical measurements do not fall within the IFUsizing guide requirements.

REFERENCES

1. Linkins LA, Dans AL, Moores LK, Bona R, Davidson BL, Schulman S, Crowther M; American College of Chest Physicians. Treatment and prevention of heparin-induced thrombocytopenia: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141(2)Supplement:e495S-e530S.
2. Warkentin TE. Heparin-coated intravascular devices and heparin-induced thrombocytopenia. In: Warkentin TE, Greinacher A, eds. *Heparin-Induced Thrombocytopenia*. 5th ed. New York,NY: Informa Healthcare USA; 2012;(20):573-590.

PATIENT TRACKING INFORMATION

In addition to these Instructions for Use, the GORE® TAG® Thoracic Branch Endoprosthesis is packaged with a Device Tracking Form that US hospital staff are required to complete and forward to W. L. Gore & Associates for the purposes of tracking all patients who receive a GORE® TAG® Thoracic Branch Endoprosthesis product (as required by US Federal Regulation).

Device Identification Card.

This card must be completed by the hospital staff and provided to the patient. Patients should be instructed by their physician to keep this card with them at all times. Patients should refer to the card when visiting other healthcare practitioners, and especially when visiting MR imaging facilities since the card provides specific information on the safe imaging of the GORE® TAG® Thoracic Branch Endoprosthesis via MR.

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DEFINITIONS

EC REP Authorised Representative in the European Community

REF Catalogue Number

Caution

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

Consult Instructions for Use

Date of Manufacture

Do Not

Resterilize Do

Not Reuse

Do Not Use if Package is Damaged

Importer into the European

Community

Keep Dry

Manufacturer

MR Conditional

SN Serial Number

STERILE EO Sterilized using Ethylene Oxide

Store in a Cool Place

UDI Unique Device Identifier

Use By

Branched

Catheter Working Length

Delivery Profile

Guidewire Compatibility

Ⓟ Portal Diameter

Ⓥ Vessel Diameter

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