INSTRUCTIONS FOR USE

GORE® EXCLUDER®

Thoracoabdominal Branch Endoprosthesis

en

English

DEVICE ILLUSTRATIONS

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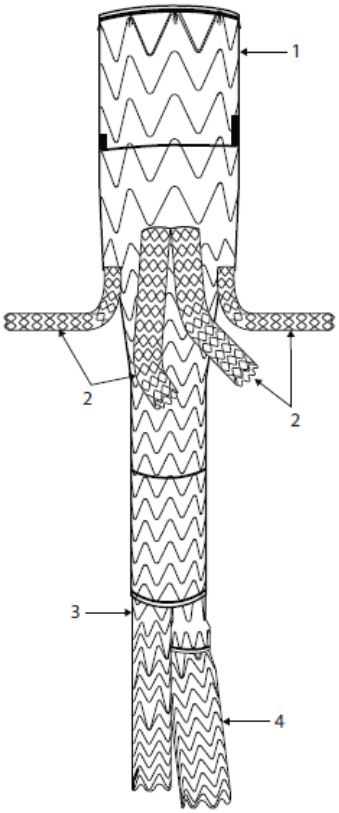

en Figure 1: Complete TAMBE Device

1. Aortic Component
2. Branch Components (GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis)
3. Distal Bifurcated Component (GORE® EXCLUDER® Iliac Branch Endoprosthesis - Iliac Branch Component)
4. Contralateral Leg Component (GORE® EXCLUDER® AAA Endoprosthesis - Contralateral Leg Endoprosthesis and/or GORE® EXCLUDER® AAA Endoprosthesis - Iliac Extender Endoprosthesis)

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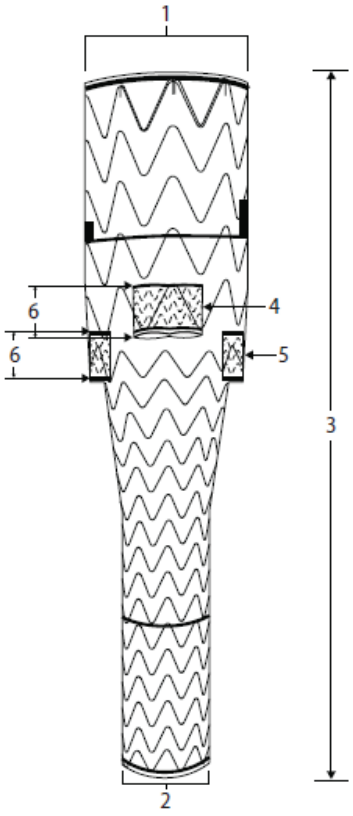

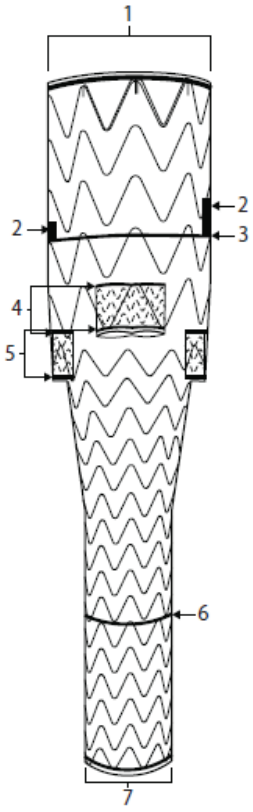

en Figure 2a: Aortic Component Dimensions:

1. Proximal diameters of 31 mm or 37 mm
2. Distal diameter of 20 mm
3. Total length of 160 mm
4. Proximal portals diameter of 8 mm
5. Distal portals diameter of 6 mm
6. Portal lengths of 10 mm

en Figure 2b: Aortic Component Radiopaque Markers:

1. One (1) Proximal radiopaque marker band
2. One (1) long and one (1) short rotational radiopaque marker in the proximal seal zone denotes portal orientation
3. One (1) radiopaque marker band located 3.5 cm from the proximal end of the device
4. Four (4) proximal portal radiopaque marker bands at proximal and distal end of each proximal portal
5. Four (4) distal portal radiopaque marker bands at proximal and distal end of each distal portal
6. One (1) radiopaque marker band 3.5 cm from the distal end of the device
7. One (1) distal radiopaque marker band

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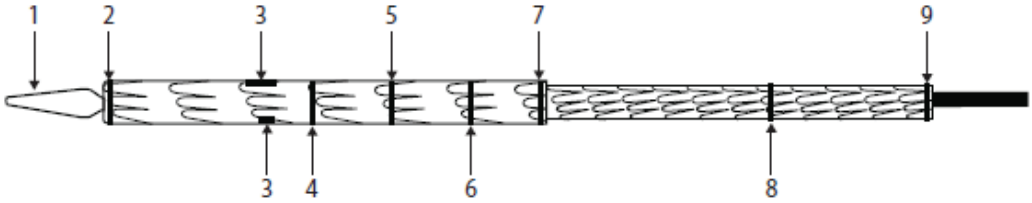

en Figure 3: Constrained Aortic Component on Delivery Catheter with Radiopaque Markers

1. Leading Tip
2. Proximal gold marker band
3. Long and one short rotational markers in the proximal seal zone denotes portal orientation
4. Marker band located 3.5 cm from the proximal end of the device
5. Proximal portal leading marker bands
6. Proximal portal trailing marker/distal portal leading marker bands
7. Distal portal trailing marker band
8. Marker band 3.5 cm from the distal end of the device
9. Distal marker band

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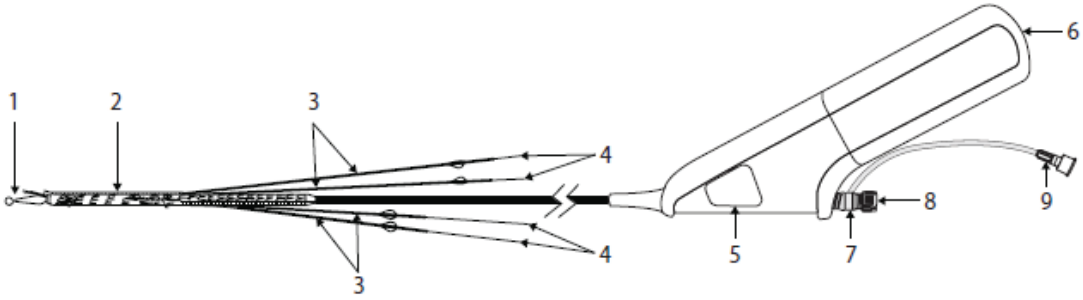

en Figure 4: Aortic Component Delivery System

1. Leading end of delivery catheter
2. Constrained endoprosthesis
3. Removable Guidewire Tubes (RGT)
4. RGT mandrels
5. Deployment Line Access Hatch
6. White Outer Deployment Knob
7. Tuohy-Borst Valve
8. Guidewire Lumen
9. Flushing Port

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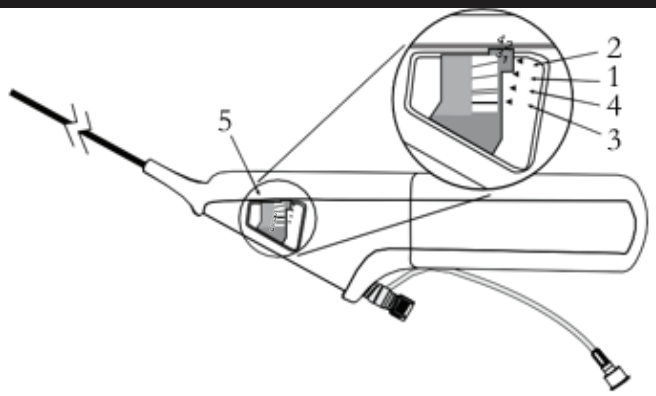

en Figure 5: Aortic Component Deployment Line Access Hatch

1. Proximal Deployment Line
2. Lock Pin
3. Constraining Loop
4. Proximal Secondary Sleeve Deployment Line and Distal Section Deployment Line
5. Deployment Line Access Hatch

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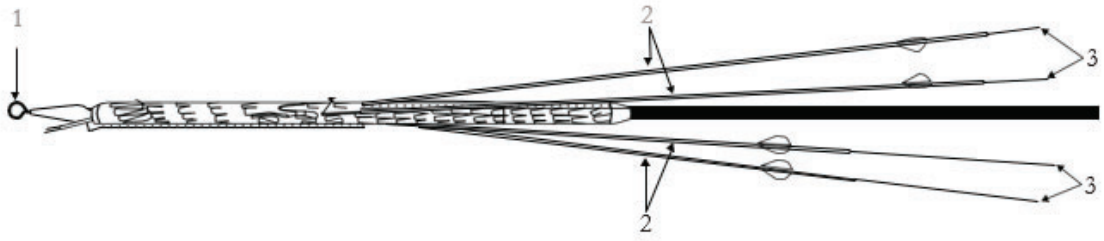

en Figure 6: Location of Aortic Component Packaging Mandrel, Removable Guidewire Tubes (RGT) and RGT Packaging Materials

1. Aortic Component Packaging Mandrel
2. Removable Guidewire Tubes (RGT)
3. RGT packaging mandrels

PROCEDURE ILLUSTRATIONS

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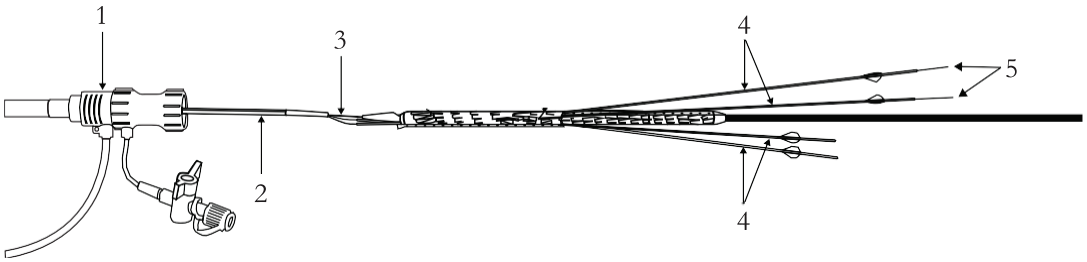

en Figure 7: Aortic Component Loaded onto the 0.035" Aortic Guidewire

1. 22 Fr GORE® DrySeal Introducer Sheath
2. Multi-lumen Catheter or Angiographic Catheter
3. 0.035" Aortic Guidewire
4. Removable Guidewire Tube (RGT)
5. RGT Packaging Mandrels

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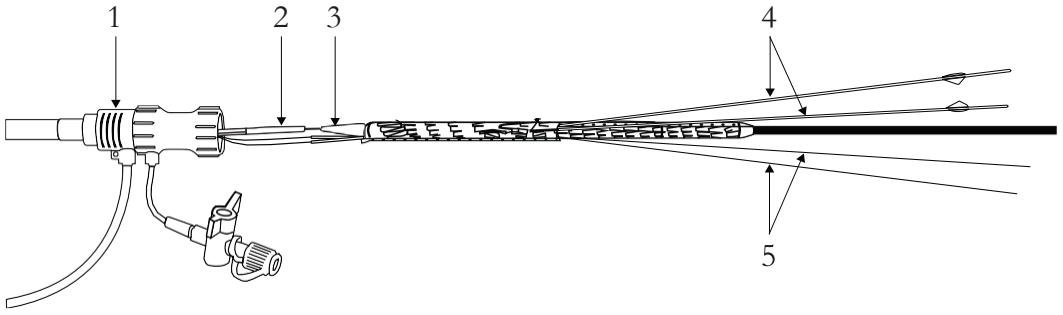

en Figure 8: Loading Through-and-Through Guidewires into Pre-cannulated Portals of Aortic Component

1. 22 Fr GORE® DrySeal Introducer Sheath
2. Multi-lumen Catheter or Angiographic Catheter
3. 0.035" Aortic Guidewire
4. Removable Guidewire Tube (RGT)
5. 0.014" or 0.018" Through-and-Through Guidewires

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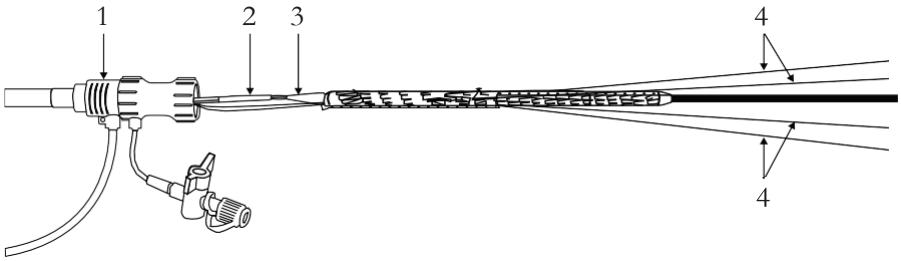

en Figure 9: Fully Prepared Aortic Component Prior to Insertion into Introducer Sheath

1. 22 Fr GORE® DrySeal Introducer Sheath
2. Multi-lumen Catheter or Angiographic Catheter
3. 0.035" Aortic Guidewire
4. 0.014" or 0.018" Through-and-Through Guidewires

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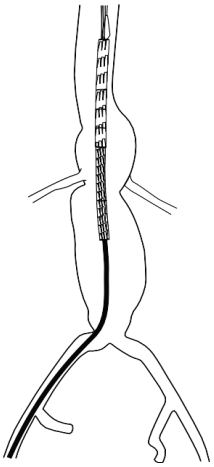

en Tracking the Aortic Component into the visceral segment of the aorta.

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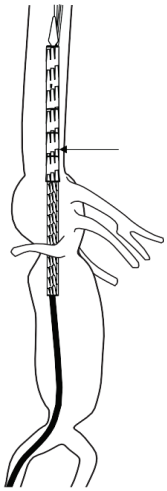

en Position the Aortic Component such that the outlet of the proximal portal is between 1-3 cm above the origin of the most proximal visceral artery.

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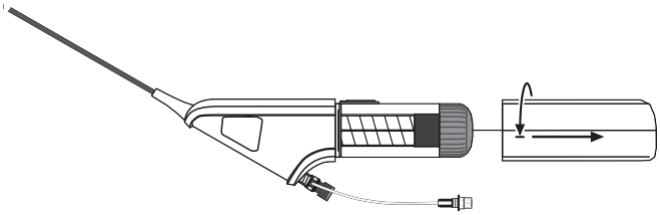

en Once Aortic Component positioning is confirmed, deploy proximal end by turning the White Outer Deployment Knob 90 degrees counterclockwise and using a steady and continuous pull to fully remove the deployment line.

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en The proximal end of the Aortic Component will open to a secondary diameter with the proximal fixation anchors constrained.

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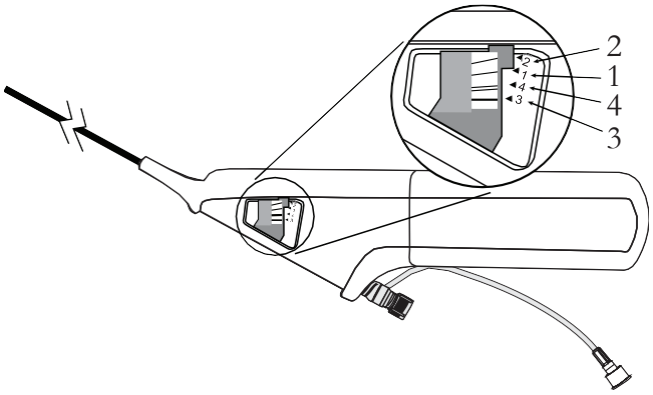

en In the event that removal of any of the deployment knobs does not initiate deployment, and the problem is suspected to have occurred in the handle, the Aortic Component Deployment Line Access Hatch may be accessed to complete deployment.

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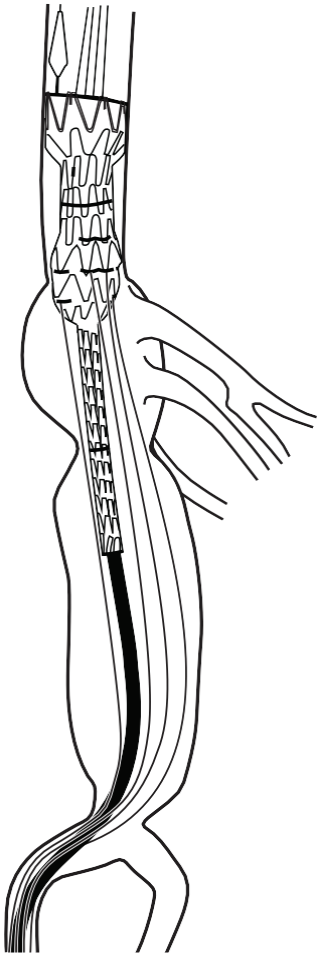

en Once the desired position of the Aortic Component is confirmed, unconstrain the proximal aspect to fix the anchors in place.

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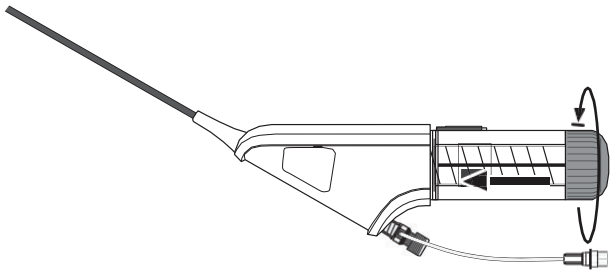

en To unconstrain the anchors, rotate the Gray Constraining Dial counterclockwise until it stops. The Black Nut within the Transparent Knob housing will move toward the leading end when the Aortic Component is fully opened.

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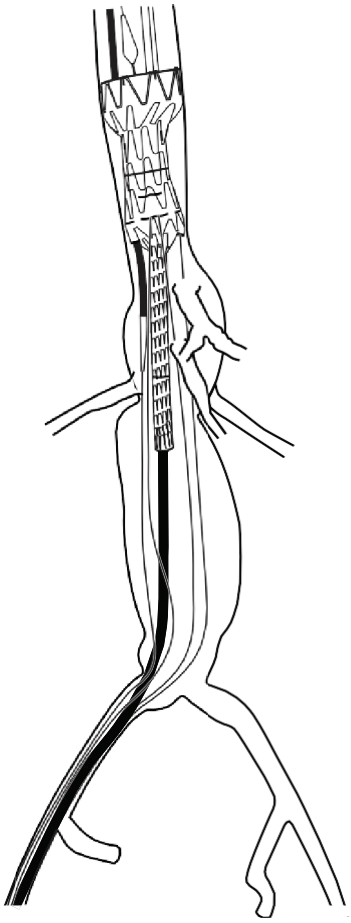

en From brachial/axillary access, advance an appropriate sheath or guide catheter over the pre-cannulated guidewire through the portal.

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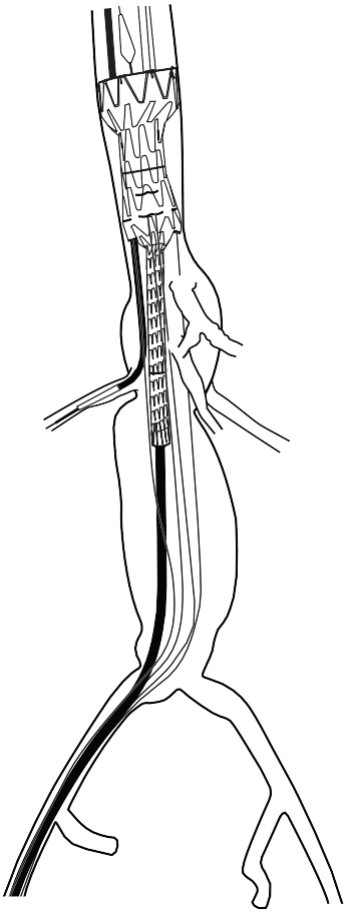

en Using appropriate accessories, cannulate the target vessel and advance the appropriate guidewire into the artery. Repeat for all portals and all target arteries.

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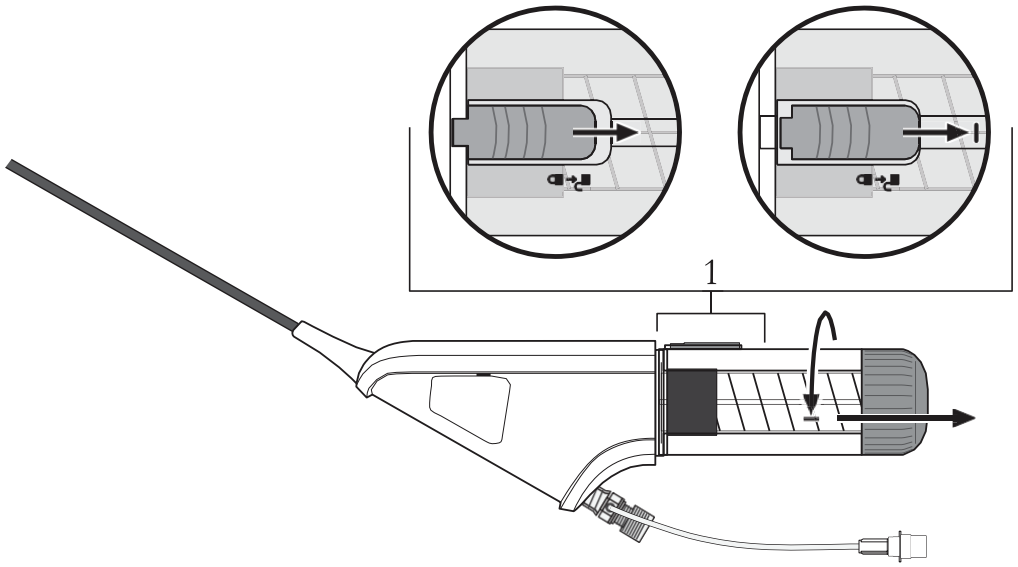

en After cannulating all visceral vessels and verifying the Aortic Component is in the desired final position, disengage the constraining mechanism by sliding the Red Safety Lock back while rotating the entire Transparent Knob 90 degrees counterclockwise.

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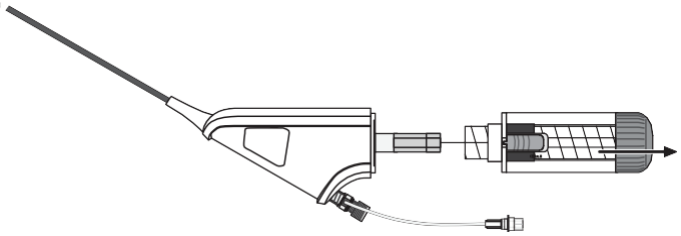

en Remove the constraining mechanism using a steady and continuous pull to fully disengage the constraining mechanism and Secondary Sleeve Deployment Line of the Aortic Component.

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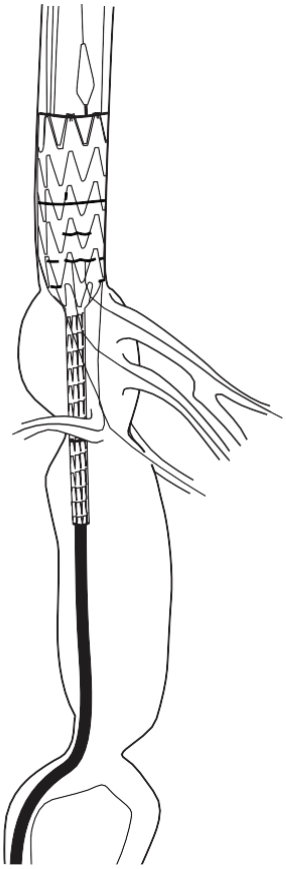

en Removing the constraining mechanism will fully open the proximal end of the Aortic Component.

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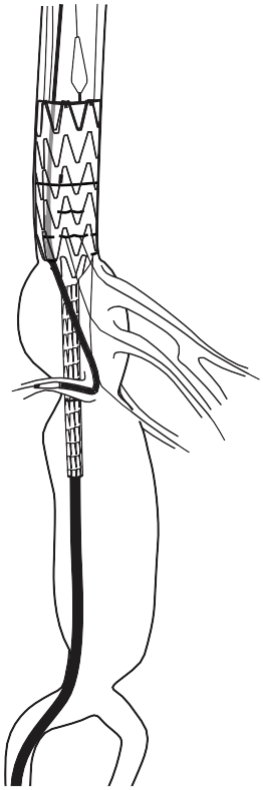

en Branch Components may be delivered now that the proximal Aortic Component is fully opened. Branch Components may be delivered with or without an introducer sheath. Ensure a minimum of 3 stent rows (15 mm) is in the seal zone of the target vessel, as well as 1-2 stent rows (5-10 mm) above the portal inlet.

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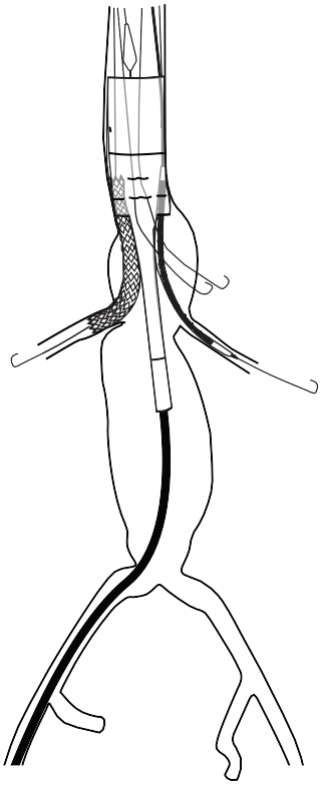

en Continue delivering and deploying Branch Components. Branch Component guidewires may be removed once branches are deployed or left in place.

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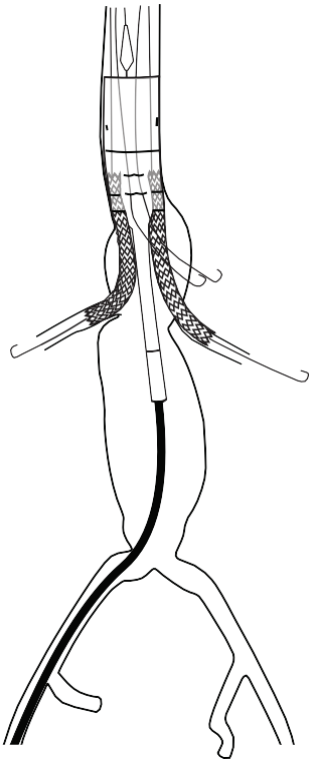

en Continue delivering and deploying Branch Components. Branch Component guidewires may be removed once branches are deployed or left in place.

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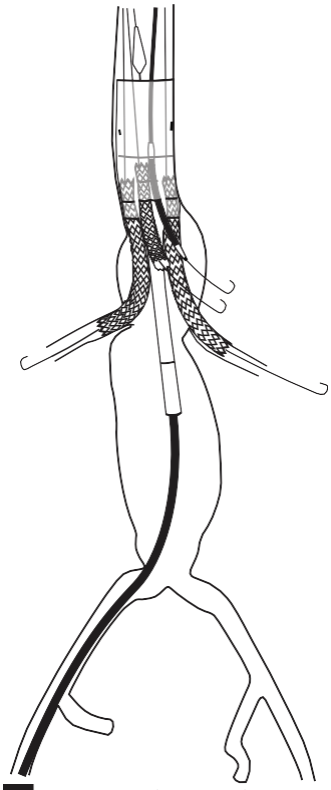

en Introduce the fourth and final Branch Component, but **do not deploy** it until the distal section of the Aortic Component is fully deployed.

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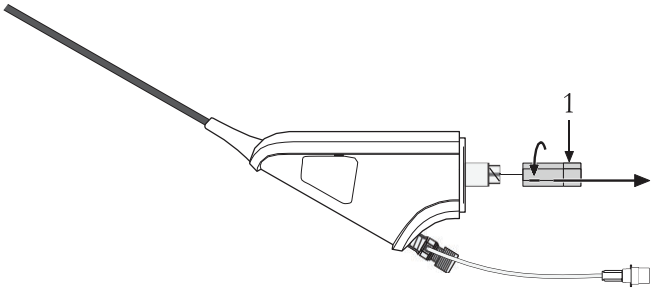

en To deploy the distal section of the Aortic Component, rotate the Gray Deployment Knob by turning it counterclockwise. Remove using a steady and continuous pull to fully remove the deployment line. The distal section of the Aortic Component is now open, and the delivery system can be removed.

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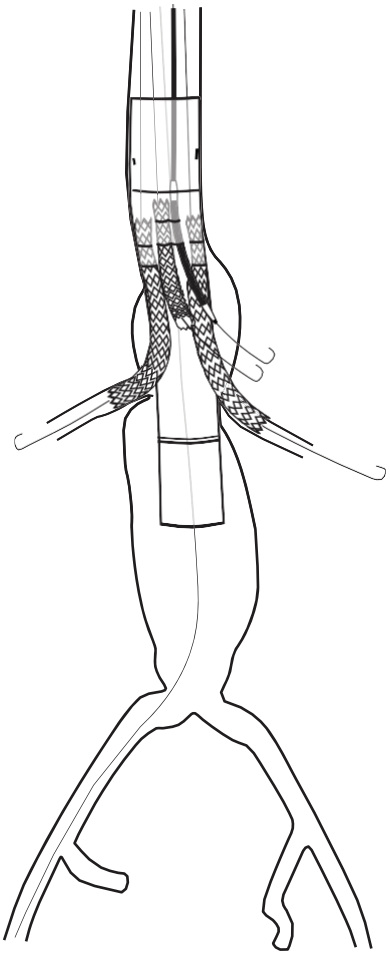

en Deploy the final Branch Component. Introduce the Distal Bifurcated Component into the distal end of the Aortic Component. Align the proximal radiopaque markers on the Distal Bifurcated Component with the circumferential radiopaque marker band distal to the renal portals (3.5 cm from the distal end of the Aortic Component).

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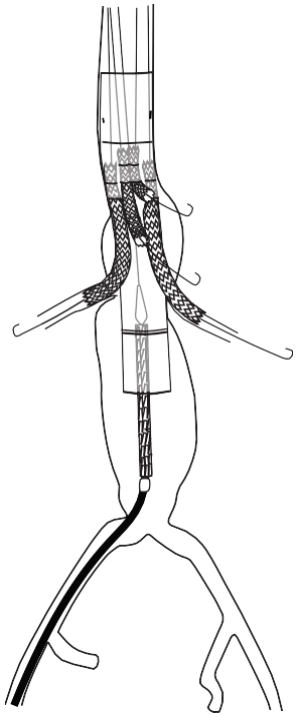

en Once the Distal Bifurcated Component is in position, deploy the proximal section by rotating the White Outer Knob counterclockwise and remove using a steady and continuous pull (the trailing end of the Distal Bifurcated Component delivery catheter is not shown).

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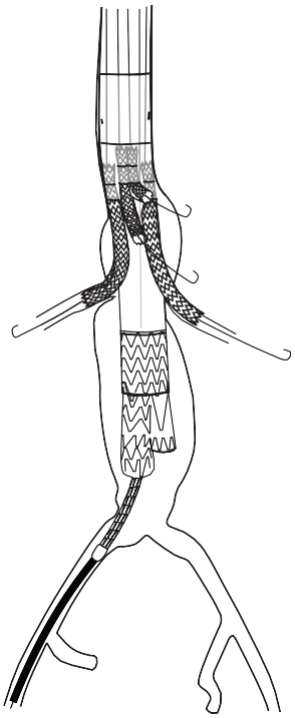

en Once the Distal Bifurcated Component is partially deployed, cannulate the contralateral leg hole. Advance the Contralateral Leg Component until the proximal radiopaque marker aligns with the long radiopaque marker on the Distal Bifurcated Component.

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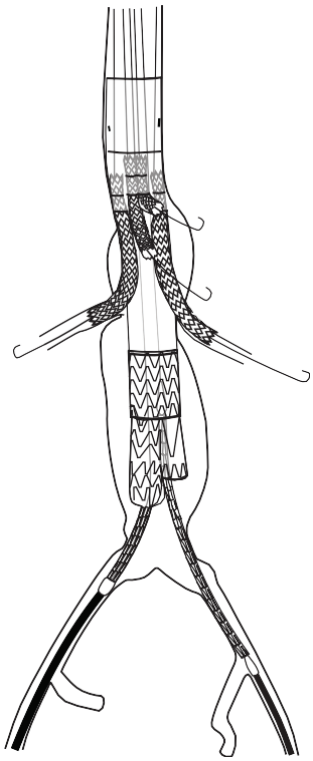

en Verify position of the Contralateral Leg Component then deploy by rotating the knob counterclockwise and remove with a steady and continuous pull.

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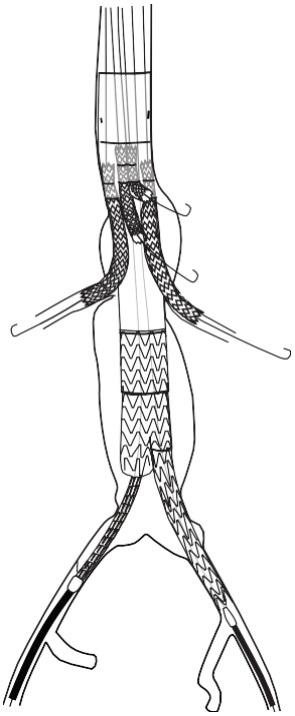

en Deploy the ipsilateral leg of the Distal Bifurcated Component by loosening the Gray Inner Deployment Knob by turning counterclockwise and removing using a steady continuous pull. The ipsilateral limb of the Distal Bifurcated Component may be extended with an appropriately sized Contralateral Leg Component to achieve seal in the iliac artery.

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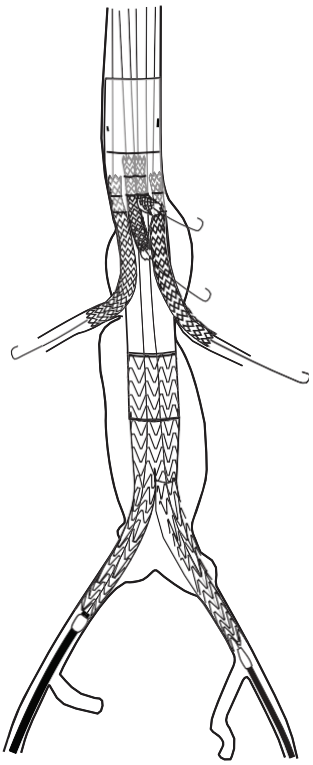

en At the completion of the procedure, verify all components are patent and the aneurysm has successfully been excluded.

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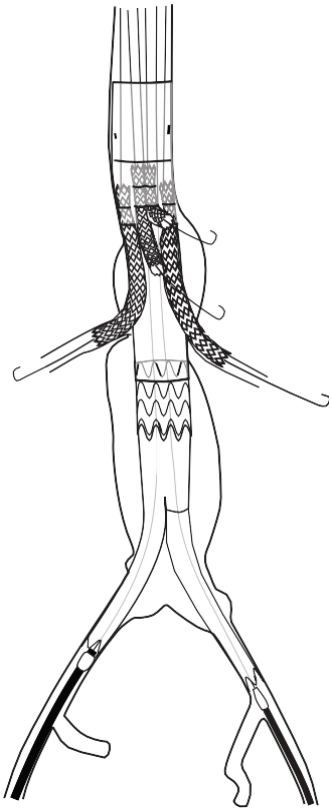

en (Optional) Distal Bifurcated Component Extender (DBC Extender) Component Positioning and Deployment

If an optional DBC Extender Component is desired for additional sealing at the junction between the Aortic Component and the Distal Bifurcated Component, specific instructions on the deployment of the DBC Extender Component are provided in the IFU for the GORE® EXCLUDER® AAA Endoprosthesis - Aortic Extender.

TABLE OF CONTENTS

- **Carefully read all instructions prior to use. Observe all indications, instructions, warnings, and precautions noted throughout. Failure to do so may result in complications. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) should only be used by physicians experienced in endovascular procedures involving the visceral arteries, and who have successfully completed the appropriate physician training program.**

INSTRUCTIONS FOR USE
GORE® EXCLUDER® THORACOABDOMINAL BRANCH ENDOPROSTHESIS

This Instructions for Use (IFU) for the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) is specific to how the components of the TAMBE Device, including the Aortic Component, are utilized in the endovascular repair of patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy (see INDICATIONS FOR USE).

Information regarding the overall TAMBE Device in terms of required materials, patient selection, recommended device sizing, anatomical requirements, and implant procedure are provided in this IFU.

Information regarding the Aortic Component of the TAMBE Device in terms of recommended device sizing, anatomical requirements, device preparation and implant procedure are provided in this IFU.

For details regarding the other components of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis, please see the IFU for the following:
- Branch Components - GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis IFU
- Distal Bifurcated Component - GORE® EXCLUDER® Iliac Branch Endoprosthesis IFU
- Contralateral Leg Component - GORE® EXCLUDER® AAA Endoprosthesis IFU

Details regarding the optional TAMBE Device components in terms of device preparation and implantation instructions are provided in the following IFUs:
- Distal Bifurcated Component Extender (DBC Extender) Component - GORE® EXCLUDER® AAA Endoprosthesis IFU

PRODUCT DESCRIPTION

GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) provides endovascular treatment of aneurysms extending into the visceral segment of the aorta. The TAMBE Device is comprised of multiple required components (**Figure 1**):
- The Aortic Component is implanted in the visceral segment of the aorta and has four portals to position the Branch Components. The Aortic Component is designed to provide proximal (supra celiac) sealing and anchoring within the aorta and is placed proximal to the Distal Bifurcated Component. The superior mesenteric artery (SMA), celiac artery, and renal arteries are perfused via four antegrade portals in the Aortic Component.
- Branch Components (GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis) are deployed in the Aortic Component portals, extending into the SMA, celiac artery, and renal arteries.
- The Distal Bifurcated Component (GORE® EXCLUDER® Iliac Branch Endoprosthesis - Iliac Branch Component) is used to bifurcate from the Aortic Component to facilitate extension of the aneurysmal repair into the aortic bifurcation.
- The Contralateral Leg Component (GORE® EXCLUDER® AAA Endoprosthesis - Contralateral Leg Endoprosthesis and/or GORE® EXCLUDER® AAA Endoprosthesis - Iliac Extender Endoprosthesis) is used to extend the repair distally into the iliac arteries. More than one Contralateral Leg Component may be used.

In addition to the required components, the DBC Extender Component (GORE® EXCLUDER® AAA Endoprosthesis - Aortic Extender) is used as an optional component for additional sealing at the junction between the Aortic Component and the Distal Bifurcated Component (**Figure 33**).

The Aortic Component is advanced into the visceral segment of the aorta. The Aortic Component has radiopaque markers which are visible when it is deployed (**Figure 2**) and constrained on the catheter (**Figure 3**), to aid in positioning the TAMBE Device components. The Aortic Component is available in proximal diameters of 31 mm and 37 mm with a distal diameter of 20 mm and a total length of 160 mm. The Aortic Component is comprised of expanded polytetrafluoroethylene (ePTFE), fluorinated ethylene propylene (FEP) that is supported over the entire length by nickel titanium alloy (Nitinol) wire along its external surface. The stent is attached to the external surface of the graft by laminated ePTFE/FEP bonding tape. Radiopaque gold bands are embedded in the graft material for device imaging.

The Aortic Component delivery system has a working length of 66 cm and consists of the constrained endoprosthesis mounted on the delivery catheter (**Figure 4**). The Aortic Component has four removable guidewire tubes (RGTs) to facilitate pre-cannulation of guidewires through the portals. Three ePTFE/FEP sleeves are used to constrain the endoprosthesis on the leading end of the delivery catheter. Deployment of all three sleeves initiates from the leading (aortic) end and proceeds toward the trailing (iliac) end of the delivery catheter. The ePTFE/FEP sleeve remains in situ between the endoprosthesis and the vessel wall.

The Aortic Component is placed in the aorta at a level where the outlet of the proximal portals is 1-3 cm above the origin of the most proximal branch vessel, placing the Aortic Component proximal gold marker band 6.5-8.5 cm above the origin of the most proximal branch vessel. Deployment of the Aortic Component initiates from the leading end and proceeds toward the trailing end of the delivery catheter.

INDICATIONS FOR USE

The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is indicated for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy as described below:
1. Adequate iliac/femoral access and brachial/axillary access
2. Proximal (supraceliac) aortic neck treatment diameter range over 2 cm seal zone of 22-34 mm for aneurysms extending up to 6.5 cm or less above the origin of the most proximal branch vessel
3. Aortic neck angle ≤ 60° at the Aortic Component proximal seal zone
4. Iliac artery treatment diameter range of 8-25 mm and iliac artery seal zone length of at least 10 mm
5. Renal artery seal zone diameters between 4.0-10.0 mm
6. Celiac and superior mesenteric artery seal zone diameters between 5.0-12.0 mm
7. ≥ 15 mm seal zone length in renal arteries, superior mesenteric artery, and celiac artery
8. Visceral segment of aorta (3 cm proximal through 9.5 cm distal to the most proximal visceral artery) must be ≥ 20 mm in diameter

CONTRAINDICATIONS

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

- Patients with known sensitivities or allergies to the TAMBE Device materials including ePTFE, FEP, nickel titanium alloy (Nitinol), stainless steel, and gold.
- Patients who have a condition that threatens to infect the graft.
- Patients with known hypersensitivity to heparin, including patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II and cannot receive the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.

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).

WARNINGS

- 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 could occur including infection.
- Reuse may result in infection and related serious potential patient harms. See HOW SUPPLIED.
- Choose devices based on sizing tables (**Tables 4-9**). Excessive oversizing of the endoprosthesis relative to the vessel diameter may cause vessel damage and may increase the risk of wire fracture. Under-sizing of the endoprosthesis relative to the vessel diameter may lead to endoprosthesis migration and endoleak.
- When preparing the Aortic Component, do not withdraw the removable guidewire tubes (RGTs) from the constrained device prior to achieving pre-cannulation through each internal portal. Removable guidewire tubes (RGTs) serve to facilitate passage of the pre-cannulated branch guidewires through the internal portals of the Aortic Component. Removing the RGTs will result in loss of portal pre-cannulation and may increase procedure time. After guidewire pre-cannulation has been achieved, remove all RGTs prior to inserting devices into the introducer sheath. Failure to do so could cause embolization of the RGT.
- Do not attempt to advance through smaller introducer sheath than is recommended. Device damage may occur resulting in an inaccurate deployment and possible surgical conversion.
- Compatibility of the Aortic Component has not been assessed with pinch valve sheaths. Failure to use GORE® DrySeal Introducer Sheaths could lead to endoprosthesis damage and increased procedural blood loss.
- Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel and/or catheter damage may occur.
- Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheaths. The sheath and undeployed device must be removed together. Attempting to withdraw the undeployed endoprosthesis through the introducer sheath may cause an inadvertent deployment.
- Do not rotate any delivery catheters while the endoprosthesis is inside the introducer sheath. Catheter breakage or premature deployment may occur.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- Follow positioning sequence of the Aortic Component as instructed in the DIRECTIONS FOR USE section. Failure to position in the correct sequence may result in Type I endoleak, aneurysm growth, reintervention, vessel ischemia, spinal cord ischemia, lower limb ischemia, or aortic rupture post procedure.
- Ensure the Aortic Component is fully out of the sheath before deploying. Failure to pull down the sheath could result in being unable to complete the procedure, partial deployment, inaccurate deployment, or vessel damage. This may result in the need for reintervention or introducer sheath removal causing potential vessel damage, surgical conversion, intervention, and blood loss.
- Do not rotate the Aortic Component delivery catheter beyond 180 degrees to avoid delivery system damage and/or premature deployment as well as entanglement of the pre-cannulated wires.
- Aortic Component should be positioned to minimize aortic coverage. Increased coverage of the aorta increases the risk of spinal cord ischemia leading to paraplegia/paraparesis.
- A two-person deployment should always be utilized at every deployment step to prevent unintentional device movement. Failure to use a two-person deployment may result in inaccurate device deployment resulting in endoleak and open surgical conversion reintervention.
- Fully unconstrain proximal anchors before attempting to cannulate branch vessels. Failure to unconstrain the proximal portion of the Aortic Component prior to branch vessel cannulation may result in being unable to complete the procedure which may result in the need for reintervention.
- Verify identity of the portal before cannulating branch vessel. Cannulating the incorrect vessel from the corresponding portal has resulted in Branch Component occlusion and may result in being unable to complete the procedure, increased branch length, branch ischemia, unplanned guidewire removal from the portal or endoleak. This could also result in increased procedure time, increased follow-up, surgical conversion, reintervention, mesenteric ischemia, renal injury, renal ischemia, and renal failure. Misidentification of portal-branch alignment could also result in a Type I or III endoleak which may result in aneurysm growth, which may require reintervention, surgical conversion, or surgical intervention.
- If, during branch cannulation or Branch Component delivery, the angiographic catheter or sheath catches on the portal, do not continue pushing. Stop and assess cause of resistance. Pushing against the portal may cause downward migration of the Aortic Component. Pulling tension on the wire may help pass the catheter or sheath through the portal.
- Do not attempt to reposition the Aortic Component more than two times. Repositioning more than two times may result in device and/or catheter damage.
- Fully unconstrain the endoprosthesis prior to removing the transparent knob. Failure to do so may cause device migration or vessel trauma which could lead to surgical intervention, surgical conversion, or reintervention.
- Verify the final Aortic Component position before sliding the red safety lock on the delivery system back. Sliding the red safety lock back disengages the constraining mechanism and prevents repositioning which may result in reintervention and surgical conversion.
- Do not attempt to reposition the device once the constraining system has been removed. Vessel damage or device misplacement may result.
- Ensure the Branch Component delivered is sized appropriately for both the portal and the vessel. Failure to do so could lead to a Type I or Type III endoleak and device migration.
- If an introducer sheath is used to deliver a Branch Component, verify sheath is fully withdrawn before deployment of Branch Components. Failure to withdraw the sheath could result in an inaccurate Branch Component deployment leading to Type I or III endoleak.
- Crossing of Branch Components is not recommended. Compromise to device integrity, including Branch Component compression and Aortic Component wire fracture, has been identified in clinical follow up under these conditions.
- Verify location of the gold target markers on Aortic Component prior to deployment of branches. If branches are aligned too far proximally the superior mesenteric artery or celiac artery could be partially occluded by ballooning resulting in surgical intervention, surgical conversion, increased follow-up, or reintervention. If branches are aligned too far distally there may be a Type III endoleak with increased follow-up, or the procedure may not be able to be

completed resulting in aneurysm growth, and may result in mesenteric ischemia, acute multi-organ failure, and renal injury, renal ischemia and renal failure, and may require reintervention and/or hemodialysis.

- Do not remove the Branch Component delivery catheter until it is ensured that the balloon is fully deflated. Removing the balloon prior to full deflation could cause branch migration.
- Prior to deploying the 4th and final Branch Component, deploy the distal sleeve of the Aortic Component to restore blood flow to the aorta. Deploying the 4th branch before the Aortic Component may result in an inability to complete the procedure due to device migration, and may result in mesenteric ischemia, acute multi-organ failure, and renal injury, renal ischemia and renal failure, and may require reintervention and/or hemodialysis.
- Do not continue to withdraw any delivery catheters if resistance is felt during removal through the introducer sheath. Forcibly withdrawing the delivery catheter through the introducer sheath when resistance is encountered may result in catheter separation and may require reintervention.
- Each Branch Component must be flared by 1-2 mm proximal to the portal. Insufficient flaring may result in a Type III endoleak which may cause increased follow-up, aneurysm growth or reintervention. Ensure 1-2 stent rings of the Branch Component extends beyond the proximal portal marker band and is flared 1-2 mm larger in diameter ≥ 7 mm for renal portals, ≥ 9 mm for celiac/SMA portals).
- For the Aortic Component, if the deployment line access hatch is utilized, be sure to remove the lines in numerical order and to completely and fully remove each line. Failure to do so could result in device migration which could result in kinked branches, endoleak or surgical conversion.
- Remove the removable guidewire tube from the Distal Bifurcated Component prior to introduction into the introducer sheath. Pre-cannulation of this RGT is not needed for the TAMBE Device procedure. Failure to remove the RGT could result in embolization leading to lower limb ischemia.
- Carefully align the proximal gold marker band of the Distal Bifurcated Component to the target marker 3.5 cm from the distal end of the Aortic Component. Deploying the Distal Bifurcated Component too far distally could result in a Type III endoleak resulting in increased follow-up, aneurysm growth and may require reintervention.
- Do not attempt to remove the Distal Bifurcated Component after the first deployment. The Distal Bifurcated Component is a two-stage deployment and attempting to remove the catheter after the first deployment has resulted in procedural Type III endoleak requiring intervention and may result in post-operative Type III endoleak resulting in aneurysm growth and may require reintervention.
- When ballooning the proximal seal zone of the aorta, carefully align the balloon gold markers between the Proximal gold marker band of the Aortic Component and the marker band 3.5 cm distal to the proximal gold marker band. Ballooning the Aortic Component too high could cause traumatic device interaction with the vessel wall resulting in aortic rupture, dissection, and reintervention. Ballooning the Aortic Component too low may compromise branch blood flow resulting in mesenteric ischemia, acute multi-organ failure, renal injury, renal ischemia, and renal failure, and may require reintervention or surgical conversion.
- When ballooning or inserting delivery systems for any TAMBE Device component(s), use care to ensure that the integrity of all Branch Components is not compromised. Compromised Branch Component integrity may lead to mesenteric ischemia, acute multi-organ failure, renal injury, renal ischemia, and renal failure and may require reintervention or surgical conversion. If Branch Component integrity is compromised, use one or more appropriate-sized PTA balloons to ensure each Branch Component is appropriately dilated and not compressed during ballooning or inserting delivery systems for any TAMBE Device component(s).
- When ballooning, adhere to the balloon catheter manufacturer's IFU and do not over inflate molding balloons or PTA balloons in relation to the diameter of the device components or the applicable seal zones. Over inflation of the balloon has led to aortic rupture and may lead to new dissection and vessel rupture and may require emergent reintervention in clinical use.
- Do not inflate molding balloons or PTA balloons in areas of significant calcified plaque. Balloon rupture and/or vessel damage may occur.
- 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 or surgical procedure may be required to re-establish flow if clinically necessary.
- Compatibility with Branch Components other than GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis has not been established. Use of other devices other than the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as Branch Components may jeopardize safety or performance.
- Risks were identified in the TAMBE Pivotal Study including Branch Component occlusions and compression. Mesenteric ischemia or the need for hemodialysis was reported among the Subjects with these events. Reintervention may be indicated to restore patency or resolve clinical sequelae.
- The safety and effectiveness of the TAMBE Device has not been established for patients with Thoracoabdominal Aortic Aneurysms extending more than 6.5 cm above the origin of the most proximal branch vessel.

PRECAUTIONS

The following cautions should be considered to ensure the safe and effective use of the device and protect the safety of the patient.

- The safety and effectiveness of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms was determined based on 30 day and 1 year follow-up data. 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 stent graft performance (see IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms and/or persistent endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing branch stenosis or occlusion, as this may lead to ischemia and/or death.
- Always have appropriate anesthesia and surgical teams available during implantation or reintervention procedures in the event that conversion to open surgical repair and/or placement of a lumbar drain is necessary.

GENERAL

- The presence of heparin on the Branch Components of the GORE® EXCLUDER® Thoracoabdominal Endoprosthesis is not intended to serve as an alternative to the physician's chosen intraoperative or postoperative anticoagulation and/or antiplatelet regimens.
- The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.
- The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is not recommended in patients unable to undergo, or who will not be compliant with, the necessary pre- and post-operative imaging and follow-up described in IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP.
- Consider use of cerebrospinal fluid drainage or other spinal protection measures when treating a patient with increased risk of paraplegia/paraparesis.

PATIENT SELECTION

- The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is indicated for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms extending up to 6.5 cm or less above the origin of the most proximal branch vessel in native aorta who have appropriate anatomy. Patient risk level should be assessed by a qualified medical professional based on the patient's clinical comorbidities.
- Successful patient selection requires specific imaging and accurate measurements (see IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW UP).
- Use of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis outside of the recommended anatomical sizing guidelines (**Tables 4-9**) may result in potentially serious device-related events (e.g., endoleak, wire fracture, migration).
- Exercise caution when treating patients with small visceral arteries. Smaller diameter visceral arteries have been identified as a risk factor for branch instability following branched EVAR.[1]
- Do not use the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in patients unable to undergo, or who will not be compliant with, the necessary pre- and post-operative imaging, medication, and follow-up described in IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP.
- 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, enlarging aneurysms) should receive enhanced follow-up (see IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
- Do not use the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in patients with known sensitivities or allergies to the device materials, including ePTFE, FEP, nickel titanium alloy (Nitinol), stainless steel, and gold. 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® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in patients who have a condition that threatens to infect the graft.
- Do not use the GORE® EXCLUDER® Thoracoabdominal 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 HIT type II is diagnosed, established procedures for the treatment of this condition, including immediate cessation of systemic heparin administration, should be followed.[2,3] 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.

BEFORE THE IMPLANT PROCEDURE

- Consider patient anatomical length when choosing access site for brachial/axillary access. Increasing length limits the accessory catheters and sheaths available potentially increasing procedure time.
- Carefully inspect the packaging for damage or defects prior to 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 could occur including infection.
- Do not bend, kink, or otherwise alter the delivery system prior to implantation because it may cause deployment difficulties.

PROCEDURE

- Systemic anticoagulation based on hospital and physician preferred protocol should be used during the implantation procedure to prevent thrombotic complications.
- If using a multi-lumen catheter or angiographic catheter to facilitate guidewire introduction, take care when removing the catheter to prevent unplanned guidewire removal from the portals which may increase procedure time.
- When preparing the Aortic Component, take care to not kink guidewires when inserting into the RGTs. Kinking the guidewires may result in unplanned guidewire removal, which may increase the procedure time.
- Do not damage the RGTs when removing them from the Aortic Component. Damaged RGTs that prevent the device from being prepared or introduced may increase procedure time.
- Carefully position the Aortic Component prior to deployment. Deploying too far proximal may cause Type I endoleak resulting in increased frequency of follow-up and increased procedure time. Deploying too far distal may cause Type I endoleak which may result in increased frequency of follow-up and increased procedure time.
- Verify the Aortic Component is entirely out of the introducer sheath before deploying. Failure to do so may result in unplanned introducer sheath removal, which may increase procedure time.
- Monitor and maintain wire positioning within the visceral arteries and aorta throughout the procedure to minimize the risk of iatrogenic complications due to wire manipulation.
- Do not attempt to remove the Distal Bifurcated Component after the first deployment. The Distal Bifurcated Component is a two-stage deployment and attempting to remove the catheter after the first deployment may result in a Type III endoleak resulting in increased frequency of follow-up and increased procedure time.

AFTER THE IMPLANT PROCEDURE

- All patients with GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis should undergo periodic imaging to evaluate aneurysm exclusion, device location, device patency, and durability.
- Current best practices and physician discretion for the anti-thrombotic regimen post implantation should be applied to prevent thrombus formation in the device. Long-term anticoagulation or anti-platelet therapy is not required for the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis but may be considered in patients at an increased risk of thrombosis or thromboembolism.

MR SAFETY

Non-clinical testing has demonstrated the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is MR Conditional. A patient with this device can be safely scanned under the conditions detailed in the MR SAFETY INFORMATION section.

ADVERSE EVENTS

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

POTENTIAL DEVICE AND PROCEDURE-RELATED ADVERSE EVENTS

Possible adverse events and complications that may occur with the use of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis or in any endovascular repair procedure, which may or may not require intervention include, but are not limited to:

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

CLINICAL AND DEVICE ADVERSE EVENT REPORTING

Any adverse event involving the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis should be reported to the manufacturer and the country specific regulatory authority immediately. To report an event to W. L. Gore & Associates, email: medcomplaints@wlgore.com or contact by phone at +1 800 528 1866 or +1 928 864 4922.

HOW SUPPLIED

The information detailed in the HOW SUPPLIED section is in reference to the Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis.

CONTENTS

The Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is preloaded on a delivery catheter.

STERILITY

- The Aortic Component of the GORE® EXCLUDER® Thoracoabdominal 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 Aortic Component of the GORE® EXCLUDER® Thoracoabdominal 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 device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination which may lead to patient harms. (See WARNINGS and PRECAUTIONS)
- Prohibited to reprocess.

STORAGE AND HANDLING

- Store in a dry place. Avoid exposing the package or device to extreme hot or cold temperatures.
- Do not use the Aortic Component of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis if the sterile pouch is compromised or if the device is damaged.
- To open the package, remove pouch from cardboard carton. Peel single pouch at the chevron but do not touch the tray to maintain sterility. The tray should be removed by an individual in the sterile field.
- Handle and dispose of the device and packaging, taking into account any infectious or microbial hazard risks, with the necessary precautionary measures in accordance with acceptable 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 INVESTIGATIONS

AAA 17-01 PIVOTAL CLINICAL INVESTIGATION

An Investigational Device Exemption (IDE) clinical study was conducted to evaluate the safety and effectiveness of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) in treating thoracoabdominal (TAAA) and pararenal aortic aneurysms (PAAA) in patients requiring treatment with appropriate anatomy (AAA 17-01). A summary of the study for subjects matching the appropriate anatomy outlined in the Indications for Use is provided below that includes study information and clinical data. Clinical data reported is current as of March 8, 2023, and included 102 patients.

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

Patients were treated between July 8, 2019, and November 28, 2022. There were 44 investigational sites (42 in the U.S. and 2 in the U.K.). The study design includes assessment of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in the repair of aneurysms with a proximal extent that originate in Zones 5-8 (as defined by Society of Vascular Surgery [SVS]) and that involved at least one visceral vessel.

PATIENT POPULATION(S)

Enrollment in AAA 17-01 was limited to patients who met the following inclusion criteria:

- Aortic aneurysm involving the visceral vessel(s) requiring treatment defined as at least one of the following:
  a. Fusiform aneurysm diameter ≥ 5 cm
  b. Saccular aneurysm (no diameter requirement)
  c. Rapid aneurysm growth ≥ 5 mm in one year)
- Aortic aneurysm that involves the abdominal aorta, with:
  a. Involvement of at least one visceral vessel and aneurysmal extension as far as 65 mm proximal to the celiac artery, and/or
  b. No normal aorta between the upper extent of aneurysm and renal artery(s)
- Adequate access for TAMBE Device components (femoral, axillary, and/or brachial arteries as required)
- Age ≥ 19 years at the time of informed consent signature
- Male or infertile female
- Subject assessment favors an endovascular approach when compared to open surgical repair, as deemed by the treating physician
- Capable of complying with protocol requirements, including follow-up
- An Informed Consent Form signed by Subject or legal representative
- Sufficient distal landing zones in both iliac arteries, with at least one patent internal iliac artery and without planned placement of a branched iliac device, or planned coverage/occlusion/embolization of any patent internal iliac artery
- Appropriate aortic anatomy to receive the TAMBE Device defined as all of the following:
  a. For the TAMBE Aortic Component, proximal aortic landing zone diameters between 22-34 mm
  b. Proximal seal zone ≥ 20 mm in length
  c. Aortic neck angle ≤ 60°
  d. Distal landing zone (iliac arteries) 8-25 mm
  e. Distal seal zone in iliac arteries of at least 10 mm in length
  f. Renal artery landing zone diameters between 4-10 mm
  g. Celiac and superior mesenteric artery landing zone diameters between 5-12 mm
  h. 15 mm landing zone in each branch vessel
  i. Visceral segment of aorta must be ≥ 20 mm in diameter
  j. Landing zones in the proximal and distal aorta and all branch vessels cannot be aneurysmal, heavily calcified, or heavily thrombosed
  k. Patent left subclavian artery

Patients were not permitted to enroll in AAA 17-01 if they met any of the following exclusion criteria:

- Prior open, aortic surgery of the ascending aorta or aortic arch
- Ruptured or leaking aortic aneurysm
- Aneurysmal dilatation due to chronic aortic dissection
- Infected aorta

- Mycotic aneurysm
- Life expectancy < 2 years
- Myocardial infarction or stroke within 1 year of treatment (staged or index procedure)
- Systemic infection which may increase risk of endovascular graft infection
- Degenerative connective tissue disease, e.g., Marfan's or Ehlers-Danlos Syndrome
- Participation in an investigational drug study (within 30 days of last administration) or investigational medical device study (within 1 year of implant) from the time of study screening
- History of drug abuse, e.g., cocaine or amphetamine or alcohol, within 1 year of treatment
- Tortuous or stenotic iliac and/or femoral arteries and the inability to use a conduit for vascular access
- A branch vessel(s) that is dissected or has significant calcification, tortuosity, thrombus formation that would interfere with device delivery or ability to exclude from blood flow
- Known sensitivities or allergies to the device materials
- Previous instance of Heparin Induced Thrombocytopenia type 2 (HIT-2) or known hypersensitivity to heparin
- Subject has body habitus or other medical condition which prevents adequate fluoroscopic and CT visualization of the aorta
- Renal Insufficiency (creatinine value > 1.8 mg/dL, glomerular filtration rate (GFR) < 30, or subject undergoing dialysis)
- Known concomitant aneurysm of the ascending aorta or aortic arch anticipated to require surgical intervention within one year of study treatment

Table 1 provides the disposition and Imaging Assessments for subjects.

At the time of database lock, 102 Subjects meeting the above inclusion and exclusion criteria were eligible and included for analysis. Information regarding Subject disposition and imaging assessment by analysis window is provided in **Table 1**.

Table 1: Subject Disposition and Imaging Assessments by Analysis Windows

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

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

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

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

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

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

Subject Characteristics

Table 2 shows a summary of Subject baseline demographics for the AAA 17-01 study.

The demographics of the study population are typical for an endovascular graft study performed in the U.S. for the treatment of complex aneurysms involving the visceral aorta. The majority of Subjects were male (84/102; 82.4%). The majority of Subjects were Not Hispanic or Latino (92/99; 92.9%). The majority of Subjects were White (86/99; 86.9%). The median age was 73.0 years old (range 58-89 years). Median Body Mass Index (BMI) was 27.6 kg/m^2.

Table 2: Summary of Baseline Demographic Characteristics of Implanted Subjects

	Subjects
Number of Subjects	102
Sex at Birth	102
Male	84 (82.4%)
Female	18 (17.6%)
Ethnicity (U.S. Only)[1]	99
Not Hispanic or Latino	92 (92.9%)
Hispanic or Latino	2 (2.0%)
Unknown or Not Reported	5 (5.1%)
Race (U.S. Only)[1]	99
White	86 (86.9%)
Black or African American	4 (4.0%)
Asian	2 (2.0%)
American Indian or Alaska Native	2 (2.0%)

	Subjects
Hawaiian or Pacific Islander	1 (1.0%)
Other	5 (5.1%)
Age (years)	
n	102
Mean (Std Dev)	73.3 (6.39)
Median	73.0
Range	(58.0,89.0)
Weight (kg)	
n	102
Mean (Std Dev)	88.1 (18.37)
Median	86.7
Range	(42.0,142.9)
Height (cm)	
n	102
Mean (Std Dev)	176.2 (9.18)
Median	177.4
Range	(149.9,193.0)
BMI (kg/m2)	
n	102
Mean (Std Dev)	28.3 (5.01)
Median	27.6
Range	(17.0,46.5)

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

A summary of the Subject baseline medical history is displayed in **Table 3**.

Table 3: Summary of Subject Baseline Medical History

	Subjects
Number of Subjects	102
Atrial Fibrillation	18 (17.6%)
Cancer	29 (28.4%)
Cardiac Arrhythmia	16 (15.7%)
Chronic Obstructive Pulmonary Disease	27 (26.5%)
Congestive Heart Failure	8 (7.8%)
Coronary Artery Bypass Graft	23 (22.5%)
Coronary Artery Disease	50 (49.0%)
Diabetes Mellitus	24 (23.5%)
Erectile Dysfunction (% of Male)	10 (11.9%)
Familial History of Aneurysms	17 (16.7%)
Familial History of Atherosclerosis	16 (15.7%)
Hypercholesterolemia	86 (84.3%)
Hypertension	94 (92.2%)
Myocardial Infarction	26 (25.5%)
Other Vascular Intervention	9 (8.8%)
Paraplegia	0 (0.0%)
Percutaneous Coronary Intervention	22 (21.6%)
Peripheral Vascular Disease	13 (12.7%)
Renal Dialysis	0 (0.0%)
Renal Insufficiency	11 (10.8%)

	Subjects
Stroke	5 (4.9%)
Thrombocytopenia	1 (1.0%)
Thromboembolic Event	3 (2.9%)
Transient Ischemic Attack (TIA)	2 (2.0%)
Valvular Heart Disease	6 (5.9%)
Visceral Artery Stenosis	2 (2.0%)
Previous Aortic Surgery	5 (4.9%)
Ascending Aorta	0 (0.0%)
Aortic Arch	0 (0.0%)
Descending Thoracic Aorta (DTA) (not involving proximal landing zone)	0 (0.0%)
Abdominal Aorta	5 (4.9%)[1]
Other	0 (0.0%)

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

A summary of pre-treatment risk factors is displayed in **Table 4**.

Table 4: Summary of Baseline Risk Factors[1]

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

	Subjects
Transient or Temporary Stroke	2 (2.0%)
Complete Stroke with Permanent Neurologic Deficit	0 (0.0%)
Renal Status	
Creatinine less than 1.5mg/dl, Clearance >50ml/min	96 (94.1%)
1.5-3.0 mg/dl Creatinine, Clearance 30-50 ml/min	6 (5.9%)
3.0-6.0 mg/dl Creatinine, Clearance 15-30 ml/min	0 (0.0%)
Creatinine greater than 6.0 ml/dl, Clearance <15 ml/min	0 (0.0%)
Pulmonary Status	
0 - Asymptomatic, normal chest x-ray	81 (79.4%)
1 - Asymptomatic or mild dyspnea or exertion, mild x-ray parenchymal changes, PFTs 65%-80% of predicted	18 (17.6%)
2 - Between 1 and 3	3 (2.9%)
3 - Vital capacity <1.85L, Forced Expiratory Volume (FEV_1) less than 1.2L or less than 35% of predicted, Maximal Voluntary Ventilation less than 50% of predicted, pCO_2 greater than 45 mm/Hg. Supplemental oxygen use medically necessary, or Pulmonary Hypertension (HTN)	0 (0.0%)

[1] Categorization per Society of Vascular Surgery (SVS) Reporting Standards[4].

A summary of pre-treatment aneurysm size and type is displayed in **Table 5**. Aneurysm size represents site-reported data and aneurysm type represents the joint assessment by Gore Imaging Services and a Screening Committee comprised of consulting physicians.

Table 5: Breakdown of Pre-Index Procedure Aneurysm Size and Type

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

[1] Pre-index procedure aneurysm size was determined by the Site's baseline measurement.

[2] Aneurysm type was determined via centralized review consisting of Gore Imaging Sciences and physician(s) with prior TAMBE Device experience.

[3] Saccular aneurysm. Per Principal Investigator (PI), urgent repair was needed due to unpredictability of the natural history of saccular aneurysms.

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

Table 6: Summary of Implanted Devices

	Index Procedure
Number of Subjects with Devices Implanted	102
Subjects with TAMBE Aortic Component	102 (100.0%)
1 Device	102 (100.0%)
TAMBE Aortic Component Proximal Diameter (mm) x Distal Diameter (mm) x Length (mm)	
31 x 20 x 160	47 (46.1%)
37 x 20 x 160	55 (53.9%)
Subjects with Branch Component(s)	102 (100.0%)
Celiac	102 (100.0%)
1 Device	59 (57.8%)
2 Devices	42 (41.2%)
3 Devices	1 (1.0%)
SMA	102 (100.0%)
1 Device	50 (49.0%)
2 Devices	50 (49.0%)
3 Devices	2 (2.0%)
Left Renal	102 (100.0%)
1 Device	30 (29.4%)
2 Devices	60 (58.8%)
3 Devices	11 (10.8%)
4 Devices	1 (1.0%)
Right Renal	102 (100.0%)
1 Device	38 (37.3%)
2 Devices	64 (62.7%)
Other[1]	1 (1.0%)
1 Device	1 (1.0%)
Subjects with Distal Bifurcated Component	102 (100.0%)
1 Device	102 (100.0%)
Subjects with Contralateral Leg Endoprosthesis/Iliac Extender	102 (100.0%)
2 Devices	53 (52.0%)
3 Devices	36 (35.3%)
4 Devices	11 (10.8%)
5 Devices[2]	1 (1.0%)
6 Devices[3]	1 (1.0%)

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

[1] Subject received one Branch Component in the left hepatic artery for treatment of a focal dissection.
[2] One Subject received 5 contralateral leg endoprosthesis/iliac extenders during the index procedure to achieve adequate coverage and overlap. Completion angiogram revealed the presence of a dissection of the left common iliac artery from the aortic bifurcation to the iliac bifurcation. This dissection was completely covered by the contralateral leg endoprosthesis/iliac extenders.
[3] One Subject received 6 contralateral leg endoprosthesis/iliac extenders in total during the index procedure to allow for appropriate bridging of devices to resolve a Type III endoleak detected after the completion aortogram was performed. The additional two iliac limbs implanted resolved the endoleak.
[4] GORE® TAG® Conformable Thoracic Endoprosthesis were successfully implanted during the index treatment procedure in four Subjects as proximal extensions to treat intraoperative Type I endoleak or iatrogenic dissection. Use of these devices was not planned.
[5] Other devices successfully implanted during the index treatment procedure included aortic extenders, bare metal stents, embolization coils, one self-expanding stent graft and one bovine pericardial patch.

Procedure Characteristics

A summary of procedure data collected at the time of the index treatment procedure is provided in **Table 7**. All Subjects (100%) survived the index procedure. The median procedure time was 302.5 minutes (range 163-944 min) with a median anesthesia time of 419.5 minutes (range 250-1175 min). Median procedural blood loss was 250 ml (range 10-2000 ml). Four Subjects experienced ≥ 1000ml of procedural blood loss, three of whom received a transfusion. Procedural time for these Subjects ranged from 287-531 minutes. Of the neurological protection strategies tracked within the study database, 90 Subjects (90/102; 88.2%) had at least one strategy used during the TAMBE Device index procedure. Elevated mean arterial pressure was the most common protection strategy used (49/102; 48%), and electromyography (EMG) the least used protection strategy, (2/102; 2.0%). A prophylactic Cerebrospinal fluid (CSF) drain was placed in 9.8% of Subjects (10/102).

Table 7: Summary of TAMBE Device Index Procedure

	Index Procedure
Number of Subjects	102
Procedure Time (minutes)	
Mean (Std Dev)	315.3 (103.3)
Median	302.5
Range	(163,944[1])
Anesthesia Type	
General	102 (100.0%)
Anesthesia Time (minutes)	
Mean (Std Dev)	438.4 (117.0)
Median	419.5
Range	(250,1175)

	Index Procedure
Access Method - Right Femoral	
Percutaneous	90 (88.2%)
Cut-down	9 (8.8%)
Cut-down and conduit	3 (2.9%)
Not Used	0 (0.0%)
Access Method - Left Femoral	
Percutaneous	90 (88.2%)
Cut-down	11 (10.8%)
Cut-down and conduit	1 (1.0%)
Not Used	0 (0.0%)
Access Method - Right Arm	
Percutaneous	2 (2.0%)
Cut-down	40 (39.2%)
Cut-down and conduit	1 (1.0%)
Not Used	59 (57.8%)
Access Method - Left Arm	
Percutaneous	5 (4.9%)
Cut-down	49 (48.0%)
Cut-down and conduit	5 (4.9%)
Not Used	43 (42.2%)
Side Aortic Component Delivered	
Left	26 (25.5%)
Right	76 (74.5%)
Time Between Aortic Component (AC) Insertion to Final Completion Angiogram (minutes)	
n	98[2]
Mean (Std Dev)	189.2 (81.18)
Median	173.0
Range	(59, 690)
Neurological Protection Strategies Used[3]	90 (88.2%)
CSF Drain	10 (9.8%)
MEP/SSEP	29 (28.4%)
NIRS	22 (21.6%)
Steroid	15 (14.7%)
Elevated Mean Arterial Pressure	49 (48.0%)
Hypothermia	4 (3.9%)
ECG	46 (45.1%)
EMG	2 (2.0%)
Total Fluoroscopic Time (minutes)	
Mean (Std Dev)	80.8 (35.85)
Median	74.5
Range	(29,249)

	Index Procedure
Contrast Used During Procedure (mL)	
Mean (Std Dev)	153.6 (73.56)
Median	143.0
Range	(16,420)
Total Radiation Dose (Gy cm²)	
n	95[4]
Median	250.0
Interquartile Range (IQR)	150.0, 626.0
Estimated Blood Loss During Procedure (mL)	
Mean (Std Dev)	299.9 (295.5)
Median	250.0
Range	(10,2000)
Transfusion Required	14 (13.7%)
Heparin Administered	102 (100.0%)
Additional Procedures Performed	32 (31.4%)[5]
Planned Additional Procedures	6 (5.9%)
Unplanned Additional Procedures	28 (27.5%)
Subject Survived Procedure	102 (100.0%)

[1] One Subject had a prolonged procedure time due to challenges with cannulation of visceral vessels and additional time spent for observation of renal outflow.
[2] Missing three Subjects due to time values for completion angiogram not being provided. Missing one subject who has a negative time value and was not counted and considered a data entry error.
[3] The neurological protection strategies in the table are not an exhaustive list, but only includes those captured in the study database; Cerebrospinal fluid (CSF) drain, motor/somatosensory-evoked potential (MEP / SSEP) monitoring, Near-infrared spectroscopy (NIRS) monitoring, Steroid, Elevated Mean Arterial Pressure (MAP), Hypothermia, Electrocardiogram (ECG), and Electromyography (EMG).
[4] Data was based on site's calculation. Total Radiation Dose was not collected for six Subjects. For one subject, data entry field would not accept decimal; therefore, the value was rounded down to 0 and this was excluded from this analysis.
[5] This was done on a per-subject level. Two Subjects had both a planned and an unplanned procedure. These included placement of a self-expanding GORE® VIABAHN® Endoprosthesis in the left subclavian artery after extravasation of contrast visualized, prophylactic coil embolization, use of Aortic Extender to treat Type III endoleaks at the junction of Distal Bifurcated Component and the Aortic Component, use of CTAG for treatment of intraoperative Type I endoleak and iatrogenic dissections, use of bare metal stents to address iatrogenic dissection and smoothing a transition zone, use of bovine pericardial patch to treat focal dissection, and other procedures that did not require device implantation (e.g., thrombectomy, Percutaneous Transluminal Angioplasty).

Table 8 summarizes hospital discharge details. The median length of hospital stay after the index procedure was four days with a range of 1-19 days. Ninety-one Subjects (91/102; 89.2%) were discharged home. No Subject required long-term rehabilitation.

Table 8: Summary of Index Treatment Procedure Discharge Details

Number of Subjects	102
Time in ICU (hours)	83
Mean (Std Dev)	58.7 (52.72)
Median	48.0
Range	(1, 288)
Length of Stay for TAMBE Device Procedure (days)	102
Mean (Std Dev)	4.9 (3.45)

Median	4.0
Range	(1, 19)
Time on Ventilator (hours)	102
Mean (Std Dev)	8.9 (11.43)
Median	7.0
Range	(2, 99)
Post Procedure Location	102
Post Anesthesia Recovery Unit	21 (20.6%)
ICU	69 (67.6%)
Step Down Unit	1 (1.0%)
Floor	10 (9.8%)
Other	1 (1.0%)
Discharge Location	102
Home	91 (89.2%)
Skilled Nursing	4 (3.9%)
Short Term Rehab	6 (5.9%)
Long Term Rehab	0
Other	1 (1.0%)

RESULTS

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

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

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

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

Co-Primary Endpoint #1 was compared to a Performance Goal (PG) of 80%, derived from open surgical repair literature available and experience from past Gore studies at the time of protocol development.

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

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

Co-Primary Endpoint #2 was compared to a PG of 68%, derived from experience of branched or fenestrated thoracoabdominal device published literature available at the time of protocol development.

Co-Primary Endpoint #1: 30 Day Safety and Effectiveness Endpoint

Table 9 displays the Composite 30 Day Safety and Effectiveness Primary Endpoint and 90% confidence interval (CI). Subgroup analysis for the endpoint results was performed by Subject's sex, aneurysm type, aneurysm size, age, and race. No statistically significant differences were identified in any of the subgroup analyses.

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Table 9: Uncomplicated Technical Success and Procedural Safety

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

Table 10 displays the Uncomplicated Technical Success and Procedural Safety event rates for each element of the endpoint from the time of the TAMBE Device index treatment procedure through 30-Days post-index treatment procedure.

Table 10: Summary of Composite 30 Day Primary Safety and Effectiveness Endpoints

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

[1] TAMBE Device components included the Aortic Component, Distal Bifurcated Component, Contralateral Leg Components, and Branch Components.
[2] Devices implanted that were not considered to be TAMBE Device components were bare metal stents in the visceral arteries of six Subjects (to address branch device deformity and smooth transition from the Branch Component to the uncovered branch vessel in one Subject and to address visceral artery dissection in five Subjects), a GORE® TAG® Conformable Thoracic Endoprosthesis in four Subjects (to mitigate concerns for Type Ia endoleak in two Subjects and to mitigate an aortic dissection in two Subjects), and the use of the GORE® EXCLUDER® AAA Endoprosthesis Aortic Extender in eight Subjects. The GORE® EXCLUDER® AAA Endoprosthesis Aortic Extender has since been added as an optional component of the TAMBE Device (DBC Extender Component).
[3] Use of non-TAMBE Device components to correct iatrogenic complications in the treated aorta or branch vessels would be considered technical failures. Adjudicated by the CEC.
[4] Adjudicated by the CEC.

Uncomplicated Technical Success

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

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

- Four Type B aortic dissections have been reported in the TAMBE Pivotal Study, two of which were identified and treated during the index procedure via proximal extension with a GORE® TAG® Conformable Thoracic Endoprosthesis. The other two were identified on post operative day (POD) #1 and 3 and did not require intervention to mitigate the Type B aortic dissections. No aneurysm growth or rupture has been reported in any of the four Subjects, and three of the four Subjects experienced freedom from 30-day procedure safety endpoints. A definite root cause of the Type B aortic dissections has not been confirmed.
- Visceral vessel iatrogenic events (including dissection or perforation of a renal, superior mesenteric or celiac artery, or distal branches thereof) have occurred in 8 (2.0%) target visceral arteries. Treatment of these iatrogenic events included placement of a bare metal stent in five impacted target arteries, placement of embolization coils in one Subject (in addition to a bare metal stent), and placement of a Branch Component in two Subjects, one of whom additionally underwent surgical abdominal exploration and evacuation of a hematoma. A splenic artery dissection was left untreated in one Subject. All impacted target arteries were patent at the conclusion of the index procedure. Further, none of the iatrogenic events that occurred in the renal arteries have resulted in acute kidney injury requiring dialysis, nor has the one in a superior mesenteric artery resulted in severe bowel ischemia. No singular, definitive root cause of visceral vessel iatrogenic events has been identified; however, the rate of visceral vessel iatrogenic complications decreased throughout the course of the TAMBE Pivotal Study enrollment following an increased emphasis on potential associated risks conveyed during training and case planning.

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Since the time of protocol development in 2016, updated reporting standards have been published (2021).[4] These updated standards clearly outline primary technical success can include the use of additional modular components, stents, or angioplasty and adjunctive surgical procedures at the time of the primary procedure. **Table 11** provides outcomes for both the protocol defined Uncomplicated Technical Success and Technical Success as defined in reporting standards. Applying Technical Success as defined in the reporting standards yields 99% Technical Success (100 of 101 Subjects).

Table 11: Summary of Technical Success Measurements - TAMBE Pivotal Study Compared with SVS Standard[4]

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

* Requires the following be met:

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

Procedural Safety

All 102 Subjects (100%) were free from lesion related mortality events and severe bowel ischemia in the first 30-days post-index treatment procedure. As shown in Table 10 above and reiterated in Table 12, nine procedural safety events, as adjudicated by CEC, occurred in a total of 8 Subjects (8/102; 7.8%).

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

Table 12: Summary of Procedural Safety Events in 30 Days

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

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

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

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

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

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

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

Table 13 displays the composite 12 month primary safety and effectiveness endpoint and 90% confidence interval. Subgroup analysis for the endpoint results was performed by Subject's sex, aneurysm type, aneurysm size, age, and race. No statistically significant differences were identified in any of the subgroup analyses. The denominator for several events that comprise this co-primary endpoint is less than 102 because a follow up visit was not completed and/or Core Laboratory did not have adequate imaging available for their assessment.

Table 13: Clinically Significant Reintervention and Freedom from Lesion Related Mortality

	Subjects Available for Assessment	Subjects with Success on the Endpoint	% (90% CI)
All Subjects	102		
Freedom from Clinically Significant Reintervention and Freedom from Lesion Related Mortality Through 12 Months	85	60	70.6% (61.4, 78.7)

Table 14 displays the individual elements of clinically significant reintervention and lesion related mortality following the TAMBE Device index treatment procedure through 12-months post-index treatment procedure.

Table 14: Composite 12 Month Primary Safety and Effectiveness Endpoint

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	Subjects Available for Assessment	Subjects with Events (%)
Freedom from Clinically Significant Reintervention and Freedom from Lesion Related Mortality Through 12 Months	85	60 (70.6%)
Clinically Significant Reintervention Through 12 Months	85	25 (29.4%)
Clinically-Indicated Condition	81	6 (7.4%)
Untreated Device Seal Zone Endoleak[1]	82	0 (0.0%)
Target-Lesion Growth >5 mm[1]	84	5 (6.0%)
Rupture[2]	94	1 (1.1%)
Failure of Device Effectiveness (Compromise Device Seal Zone/Integrity[2])	94	7 (7.4%)
Patient Safety Events (Total Occlusion of Device Component[2])	95	14 (14.7%)
Complicated Device System Prophylaxis (Reintervention requiring Hospitalization[2])	95	4 (4.2%)
Lesion Related Mortality Through 12 Months	94	0 (0.0%)

[1] Core Laboratory Assessment.

[2] Adjudicated by the CEC.

Clinically Indicated Condition

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

Clinically Significant Reintervention

Twenty-five Subjects (25/85; 29.4%) experienced one or more events.

- Seven Subjects (7/94; 7.4%;) experienced compromised device seal zone/integrity requiring placement of an additional stent or stent graft, with more noted in Type IV TAAA than PAAA anatomies.
- Fourteen Subjects (14/95; 14.7%;) experienced total occlusion of a device component, with more noted in PAAA than Type IV TAAA anatomies. Based on this observation and the higher percentage of PAAA subjects who experienced target-lesion growth >5mm, the indications for use are limited to PAAA in high-surgical-risk patients. The occlusions included 16 Branch Components, including one celiac and one superior mesenteric artery, six left renal arteries and eight right renal arteries; no occlusions were reported for any other TAMBE Device components. No surgical interventions were performed for treatment of any Branch Component occlusions, five Subjects underwent percutaneous reinterventions on six renal branches, with restoration of branch patency in four of the six targeted Branch Components. The remaining ten occluded Branch Components had no reintervention attempted. One Subject with a SMA Branch Component occlusion experienced mesenteric ischemia and three Subjects with renal Branch Component occlusions required hemodialysis treatment within 12 months. A root cause investigation for Branch Component occlusions did not identify a singular root cause; however, diameters in the landing zone of renal Branch Component with occlusions tended to be near the lower end of the treatment range (4 mm), disproportionately relative to the overall study population.
- Four Subjects (4/95 assessable; 4.2%;) had an early reintervention requiring an extension of index hospital stay 3 days or longer (complicated device system prophylaxis), with more noted in Type IV TAAA than PAAA anatomies. These included interventions for post operative Branch Component occlusion, Branch Component compression, paraparesis, and/or paraplegia.

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

Lesion Related Mortality

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

Major Adverse Events

The SVS Reporting Standard[4] definition for major adverse events (MAEs) was not available at the time of protocol development; however, an analysis of MAEs was performed and included respiratory failure, myocardial infarction, stroke, paraplegia, acute renal failure, bowel ischemia, and death. Where possible, the MAEs are consistent with the SVS Reporting Standards; however, it should be noted that the SVS Reporting Standard definitions for MAE components are not identical to the event definitions for some components of the Co-Primary Endpoints [e.g., new onset sustained renal failure requiring dialysis (SVS Reporting Standards) vs. acute renal failure (protocol)].

In addition to MAEs, there have been two access related serious adverse events (SAEs) reported. Follow-up in the study remains ongoing; however, a summary of cumulative MAEs and access related SAEs through all available follow-up are displayed in **Table 15**.

Table 15: Summary Cumulative Major Adverse Events and Access Related Serious Adverse Events

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

[1] Composite Event with the first occurrence of any of the following components.

[2] MedDRA (Medical Dictionary for Regulatory Activities) coded as Respiratory Failure with Ventilation or Intubation as description of treatment for an undetermined amount of time.

[3] MedDRA coded as Myocardial Infarction.

[4] MedDRA coded as Stroke with mRS of ≥2 And a difference of ≥1 from the Screening or adjudicated by the CEC as Disabling Stroke without Resolution at 90 Days Post-Procedure.

[5] MedDRA coded as Paraplegia or adjudicated by the CEC as Paraplegia in 30 days.

[6] MedDRA coded as Acute Kidney Injury/Acute Renal Failure with Dialysis or estimated Glomerular Filtration Rate (eGFR) drop of ≥50% at 1 month visit. Or adjudicated by the CEC as new onset of Renal Failure with Dialysis at 1 month post procedure.

[7] MedDRA coded as Bowel Ischemia with Resection or remained Unresolved, or adjudicated by the CEC as Severe Bowel Ischemia.

[8] All-Cause Mortality.

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

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

Deaths

Table 16 lists Subject deaths. At the time of data lock, there were 11 deaths reported (11/102; 10.8%). One Subject death was CEC adjudicated as being related to the study device, one Subject death adjudicated as study procedure related, and the remaining Subject deaths applicable for adjudication were not related or unknown. Three Subject deaths were not adjudicated since their deaths fell in the >546-day (12-month) analysis window.

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

Table 16: Listing of Subject Deaths

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

Adverse Event Treatments Involving the Study Device

Adverse event treatments involving the study device performed after the initial endovascular procedure were reported as reinterventions. Reinterventions were performed at the discretion of the Investigator. Follow-up in the study remains ongoing; however, **Table 17** below displays a cumulative overview of the site-reported reinterventions by follow-up period.

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

Table 17: Cumulative Reinterventions by Follow-up Period

	Procedure	1 Month	3 Month	6 Month	12 Month	24 Month	36 Month	48 Month	60 Month	Total[6]
Subjects at Risk[1]	102	102	102	98	96	87	56	32	0	102
Number of Subjects with any Reintervention[2]	2 (2.0%) [2]	3 (2.9%) [3]	11 (10.8%) [14]	11 (11.2%) [14]	15 (15.6%) [22]	22 (25.3%) [32]	26 (46.4%) [40]	26 (81.3%) [40]	-	26 (25.5%) [40]
Reintervention Reason/Type										
Stent Graft Stenosis	0 (0.0%) [0]	1 (33.3%) [1]	2 (18.2%) [3]	2 (18.2%) [3]	4 (26.7%) [7]	7 (31.8%) [10]	7 (26.9%) [10]	7 (26.9%) [10]	-	7 (26.9%) [10]
Balloon angioplasty with peripheral stent	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	3 (13.6%) [3]	3 (11.5%) [3]	3 (11.5%) [3]	-	3 (11.5%) [3]
Balloon angioplasty with peripheral stent graft	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [2]	1 (9.1%) [2]	1 (6.7%) [2]	1 (4.5%) [2]	1 (3.8%) [2]	1 (3.8%) [2]	-	1 (3.8%) [2]
Peripheral stent graft without balloon angioplasty	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Balloon angioplasty without stent or stent graft	0 (0.0%) [0]	1 (33.3%) [1]	1 (9.1%) [1]	1 (9.1%) [1]	2 (13.3%) [4]	2 (9.1%) [4]	2 (7.7%) [4]	2 (7.7%) [4]	-	2 (7.7%) [4]
Endoleak	0 (0.0%) [0]	0 (0.0%) [0]	4 (36.4%) [5]	4 (36.4%) [5]	5 (33.3%) [6]	8 (36.4%) [11]	12 (46.2%) [18]	12 (46.2%) [18]	-	12 (46.2%) [18]
Balloon angioplasty with peripheral stent	0 (0.0%) [0]	0 (0.0%) [0]	3 (27.3%) [3]	3 (27.3%) [3]	3 (20.0%) [3]	3 (13.6%) [3]	3 (11.5%) [3]	3 (11.5%) [3]	-	3 (11.5%) [3]
Balloon angioplasty with peripheral stent graft	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	2 (9.1%) [2]	2 (7.7%) [2]	2 (7.7%) [2]	-	2 (7.7%) [2]
Balloon angioplasty with aortic stent graft	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	2 (7.7%) [2]	2 (7.7%) [2]	-	2 (7.7%) [2]
Peripheral stent graft without balloon angioplasty	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Balloon angioplasty without stent or stent graft	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Embolization coils	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [1]	1 (9.1%) [1]	2 (13.3%) [2]	4 (18.2%) [4]	6 (23.1%) [6]	6 (23.1%) [6]	-	6 (23.1%) [6]
Other	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [1]	1 (9.1%) [1]	1 (6.7%) [1]	2 (9.1%) [2]	3 (11.5%) [3]	3 (11.5%) [3]	-	3 (11.5%) [3]
Target-lesion growth (>5mm in max diameter)[3]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	-	0 (0.0%) [0]
Post-Treatment TAAA rupture[4]	1 (50.0%) [1]	1 (33.3%) [1]	1 (9.1%) [1]	1 (9.1%) [1]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Other	1 (50.0%) [1]	1 (33.3%) [1]	1 (9.1%) [1]	1 (9.1%) [1]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Total occlusion of a device component	1 (50.0%) [1]	1 (33.3%) [1]	3 (27.3%) [4]	3 (27.3%) [4]	5 (33.3%) [6]	6 (27.3%) [7]	6 (23.1%) [7]	6 (23.1%) [7]	-	6 (23.1%) [7]
Balloon angioplasty with peripheral stent	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [1]	1 (9.1%) [1]	2 (13.3%) [2]	2 (9.1%) [2]	2 (7.7%) [2]	2 (7.7%) [2]	-	2 (7.7%) [2]
Balloon angioplasty with peripheral stent graft	1 (50.0%) [1]	1 (33.3%) [1]	1 (9.1%) [1]	1 (9.1%) [1]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Peripheral stent without balloon angioplasty	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Balloon angioplasty without stent or stent graft	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Other	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [2]	1 (9.1%) [2]	1 (6.7%) [2]	1 (4.5%) [2]	1 (3.8%) [2]	1 (3.8%) [2]	-	1 (3.8%) [2]
An open conversion[5]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	-	0 (0.0%) [0]
Other	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [1]	1 (9.1%) [1]	2 (13.3%) [2]	3 (13.6%) [3]	4 (15.4%) [4]	4 (15.4%) [4]	-	4 (15.4%) [4]

	Procedure	1 Month	3 Month	6 Month	12 Month	24 Month	36 Month	48 Month	60 Month	Total[6]
Balloon angioplasty with peripheral stent	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (6.7%) [1]	2 (9.1%) [2]	2 (7.7%) [2]	2 (7.7%) [2]	-	2 (7.7%) [2]
Peripheral stent without balloon angioplasty	0 (0.0%) [0]	0 (0.0%) [0]	1 (9.1%) [1]	1 (9.1%) [1]	1 (6.7%) [1]	1 (4.5%) [1]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]
Balloon angioplasty without stent or stent graft	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	0 (0.0%) [0]	1 (3.8%) [1]	1 (3.8%) [1]	-	1 (3.8%) [1]

[1] Subjects at risk is defined as any subject that has had a visit in the indicated window or has had a reintervention prior to the indicated window.

[2] The number in [ ] denotes total number of reinterventions. N (%) [N]; denominator denotes the Subjects with at least one reintervention.

[3] Target=lesion growth (>5mm in max diameter) was not reported as the reason for reintervention for any subject in the EDC.

[4] One Subject experienced a rupture during the index procedure; however, site selected Post-Treatment TAAA rupture from the dropdown options on the Reintervention Case Report Form (CRF) in the EDC.

[5] One Subject underwent surgical abdominal exploration and evacuation of a hematoma, without TAMBE Device explant.

[6] Subjects with at least one repeat intervention during the study, total number of repeat interventions are shown in [ ]. Percentages in this column may be an underestimation as 5 year follow-up is not complete.

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

Endoleaks

Follow-up in the study remains ongoing; however, **Table 18** summarizes site-reported endoleaks by follow-up period. At the 12-month follow-up visit, 19 Subjects (19/88 assessable; 21.6%) had one or more endoleak ongoing. A total of 69 Subjects (69/88; 78.4%) were free from any type of site-reported ongoing endoleak in the 12- month window. Through all available follow-up, there have been 62 Subjects (62/102; 60.8%) with one or more Type I, II or III endoleak ongoing in window. There have been no Type IV or Indeterminate endoleaks.

Table 18: Summary of Site Reported Endoleaks by Follow-up Period

	Post Treatment Follow-up Period										
	Procedure	Post-Procedure[1]	1 Month	3 Months1	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total[2]
Number of Subjects	102	102	102	101	96	94	50	17	0	0	102
Evaluable Subjects	102	29	96	23	76	88	42	13	-	-	102
Subjects With One or More Endoleak Ongoing in Window	8(7.8%)	12(41.4%)	44(45.8%)	14(60.9%)	16(21.1%)	19(21.6%)	9(21.4%)	4(30.8%)	-	-	62(60.8%)

	Post Treatment Follow-up Period										
	Procedure	Post-Procedure[1]	1 Month	3 Months1	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total
New	8(7.8%)	9(31.0%)	37(38.5%)	1(4.3%)	5(6.6%)	10(11.4%)	5(11.9%)	1(7.7%)	-	-	-
Ongoing	-	3(10.3%)	8(8.3%)	13(56.5%)	11(14.5%)	10(11.4%)	5(11.9%)	3(23.1%)	-	-	-
Type I	1(1.0%)	0(0.0%)	3(3.1%)	1(4.3%)	1(1.3%)	2(2.3%)	3(7.1%)	1(7.7%)	-	-	7(6.9%)
New	1(1.0%)	0(0.0%)	3(3.1%)	0(0.0%)	0(0.0%)	1(1.1%)	3(7.1%)	0(0.0%)	-	-	-
Ongoing	-	0(0.0%)	0(0.0%)	1(4.3%)	1(1.3%)	1(1.1%)	0(0.0%)	1(7.7%)	-	-	-
Type II	7(6.9%)	12(41.4%)	40(41.7%)	13(56.5%)	15(19.7%)	17(19.3%)	7(16.7%)	2(15.4%)	-	-	60(58.8%)
New	7(6.9%)	9(31.0%)	33(34.4%)	1(4.3%)	5(6.6%)	8(9.1%)	2(4.8%)	0(0.0%)	-	-	-
Ongoing	-	3(10.3%)	8(8.3%)	12(52.2%)	10(13.2%)	9(10.2%)	5(11.9%)	2(15.4%)	-	-	-
Type III	0(0.0%)	0(0.0%)	2(2.1%)	0(0.0%)	0(0.0%)	1(1.1%)	0(0.0%)	0(0.0%)	-	-	3(2.9%)
New	0(0.0%)	0(0.0%)	2(2.1%)	0(0.0%)	0(0.0%)	1(1.1%)	0(0.0%)	0(0.0%)	-	-	-
Ongoing	-	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	-	-	-
Type IV	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	-	-	0(0.0%)
New	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	-	-	-
Ongoing	-	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	-	-	-
Indeterminate	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	-	-	0(0.0%)
New	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	-	-	-
Ongoing	-	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	-	-	-

[1] Contrast CT is not required.

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

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

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

Follow-up in the study remains ongoing; however, **Table 19** summarizes Core Laboratory reported endoleaks by Follow-Up period.
From post-index treatment procedure through available follow up, the Core Laboratory identified 65 (65/99; 65.7%) Type II endoleaks and 20 (20/99; 20.2%) Indeterminate endoleaks. There have been zero Type I or Type III endoleaks reported by the Core Laboratory.

Table 19: Summary of Core Laboratory Reported Endoleaks by Follow-up Period

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

[1] Evaluable Subjects = Subjects with adequate imaging.

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

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

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

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Keeping consistent with previous Gore and competitor aortic clinical studies, Core Laboratory evaluation of imaging data was used for primary endpoint evaluation for its objectivity and perceived benefit in the increased sensitivity and proceduralized methodology in making imaging observations. However, complete agreement between two types of image evaluators, such as a site and a Core Laboratory, may be unrealistic in a practical setting for multiple reasons. Endoleak determination by the Core Laboratory requires the ability to identify the origin of the endoleak to make a conclusive determination. Submitted imagery is reviewed by multiple Core Laboratory readers with a pre-defined process where differences between device issue events are internally adjudicated for the purpose of final reporting. Endoleak determinations are done by the Core Laboratory on a per image basis and independent of previous scans. Physicians, by contrast, may be more likely to assess and report clinically significant observations which were reported as adverse events. Physicians may determine both the presence and type of endoleak, based on their best medical judgement, through the evaluation across multiple images sets and image modalities. In the clinical study, for several cases, the type of endoleak reported from the Core Laboratory analysis was not in accordance with the site reported data, with Type II and/or indeterminate endoleaks reported by the Core Laboratory in Subjects reported by sites as having a Type I or III endoleak. It should be noted that the Core lab assessed component separation as an additional assessment only if device migration was noted (device migration assessed longitudinal movement of all or part of the device). Since no device migration was observed by the Core lab, no subjects were listed as evaluable for component separation (as shown within **Table 20** below).

Core Laboratory Device Findings

The imaging performed at each protocolized follow-up visit was evaluated by an independent Core Laboratory for the occurrence of critical events such as endoleaks, device/ vessel patency, wire fractures, and device migration/separation/compression/kinking (**Table 20**). Please note that follow-up in the study remains ongoing.

- Endoleaks: The Core Laboratory reported zero Type I, III and IV endoleaks. At 12 Months, Type II endoleaks were identified for 64/92 evaluable Subjects (69.6%) and Indeterminate endoleaks identified for 14/92 (15.2%). In total, Type II endoleaks were identified for 65/99 evaluable Subjects (65.7%) from 1-Month through 36-Months post-treatment procedure and Indeterminate endoleaks were identified for 20/99 evaluable Subjects (20.2%) during the same time period. The overall rate of Subjects identified as having a Type II endoleak is likely driven by the extent of coverage across the thoracoabdominal aorta and the associated presence of multiple potential sources of Type II endoleak, including the lumbar and intercostal arteries, the inferior mesenteric artery, and in some cases, accessory renal arteries.
- Patency: At 12-Months, the Core Laboratory reported 14/88 evaluable Subjects (15.9%) as having non-patent side branch component/vessel.
- Device Integrity Events: At 12-Months, the Core Laboratory reported 3/83 evaluable (3.6%) Subjects with wire fracture. Each wire fracture was subsequently reported by sites as a device deficiency [as defined in International Organization for Standardization (ISO) 14155]; no clinical sequelae were reported as a result of any reported wire fracture. A root cause investigation concluded that one of the wire fractures was the result of the increased strain imparted on the Aortic Component from the orientation of the Branch Components between the TAMBE Aortic Component and the arcuate ligament, combined with the radial inward pressure created from a pressurized endoleak and dissection-induced false lumen. Accordingly, a warning was added to the TAMBE Device IFU stating it is not recommended to cross Branch Components within a narrow visceral aortic lumen. A step in the manufacturing process was identified as the root cause for the other two reported wire fractures, and associated manufacturing process improvements were implemented for TAMBE Aortic Components used in all TAMBE Device procedures beginning in June 2022. No wire fractures attributable to this root cause have been reported in TAMBE Aortic Components manufactured after implementation of the manufacturing process improvements.
- Device Compression, Migration, and Kink: At 12-Months, 11/90 evaluable Subjects (12.2%) with device compression. Compressions occurred in one Contralateral Leg Component which did not necessitate reintervention and did not result in loss of patency and one Aortic Component compression secondary to a Type A aortic dissection. The remaining nine reported compressions occurred in Branch Components; three compressed Branch Component required reintervention and seven were patent at 12 months. No Subjects with reported Branch Compression have experienced mesenteric ischemia or acute kidney injury requiring dialysis, per site-reported adverse events; however, four Subjects with reported renal Branch Component compression subsequently exhibited renal function deterioration (a sustained >25% decrease in eGFR over two consecutive study visits compared to baseline). Half of the compressed Branch Components occluded with patency successfully restored in two instances. Branch Compressions were identified at the time of the first follow up CT in seven out of the ten instances; therefore, diligence to ensure that all TAMBE Device components are appropriately dilated and free from compression at the completion of the index procedure is warranted, as is routine follow-up imaging as outlined in the TAMBE Device IFU. Additionally, a warning was added to the TAMBE Device IFU stating it is not recommended to cross Branch Components within a narrow visceral aortic lumen. There were no evaluable Subjects with reported device migration or kink.
- Component Separation: There were no evaluable Subjects with reported component separation.
- Aortic Enlargement: Aortic enlargement was noted for 5/84 Subjects that had an aneurysm measurement (6.0%) through 12-months. The Core Laboratory reported these Subjects as having either Type II or Indeterminate endoleaks. Four of the subjects had Site reported adverse events of endoleak that were treated with coil embolization or balloon angioplasty at some timepoint after the aneurysm growth was reported by the Core Laboratory. One Subject did not require treatment. There was no post-operative aneurysm rupture, and no CEC adjudicated lesion related mortality through 12-month follow-up in any Subject.

Table 20: Summary of Cumulative Core Laboratory Device Findings by Follow-up Period

	Post-Treatment Follow-up Period								
	1 Month	3 Months[1]	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total[3]
Number of Subjects	102	101	96	94	50	17	0	0	102
Number of Subjects with CT Scan in Window	96	14	75	88	42	11	0	0	101
Number of Subjects with DUS in Window	94	76	77	81	37	12	0	0	99
Number of Subjects with X-Ray in Window	94	10	70	80	38	12	0	0	100

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

[1] CT not required.

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

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

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

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

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

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

As shown in **Table 21**, five Subjects (5/84; 6.0%) were reported by the Core Laboratory as having aneurysm growth >5 mm through 12 months. Among these five Subjects, one was reported by the site to have a Type III endoleak which was successfully resolved via percutaneous transluminal angioplasty of a branch component. The other four Subjects had only Type II endoleaks reported, three of which had been resolved via coil embolization and one of which had not been treated as of the date of data lock. In addition, through 12 months, twenty Subjects (20/84; 23.8%) were reported as having >5 mm of shrinkage in aneurysm size and 59 Subjects (59/84; 70.2%) were reported as having a stable aneurysm that was within 5 mm of the baseline measurement.

Table 21: Summary of Core Laboratory Aneurysm Growth/Shrinkage By Follow-up

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

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

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

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

CONCLUSION

The totality of data from the pivotal clinical investigation indicates that the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is a safe and effective option for endovascular repair in patients with thoracoabdominal aortic aneurysms extending up to 6.5 cm proximal to the most proximal visceral artery, and high surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy.

PATIENT SELECTION

The safety and effectiveness of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis has not been evaluated in the following patient populations:

- traumatic aortic or iliac injury
- leaking aneurysms: pending rupture or ruptured aneurysms
- mycotic aneurysms
- pseudoaneurysms resulting from previous graft placement
- revision of previously placed stent grafts
- genetic connective tissue disease (e.g., Marfan or Ehlers-Danlos Syndromes)
- concomitant thoracic aortic or thoracoabdominal aneurysms
- inflammatory aneurysms
- patients with active systemic infections
- pregnant or nursing females
- patients less than 21 years old
- patients with bilateral internal iliac artery occlusions
- Ilio-femoral access vessel size and morphology (minimal thrombus, calcium and/or tortuosity) should be compatible with vascular access techniques and the vascular introducer sheaths and accessories necessary to deliver the endoprostheses.
- Successful exclusion of the aneurysm(s) may be affected by significant thrombus and/or calcium at the distal iliac artery interfaces. Irregular calcium and/or plaque may compromise the fixation and sealing of the implantation sites.
- The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and post-operative follow-up imaging.
- The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is not recommended in patients exceeding weight and/or size limits which compromise or prevent the necessary imaging requirements.
- The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is not recommended in patients with known sensitivities or allergies to the device materials.

PATIENT COUNSELING INFORMATION

Based on the specific patient condition and comorbidities, the healthcare provider determines the risks and benefits specific to the patient and suggests the most appropriate course of action. The healthcare provider should counsel the patient on the prescribed endovascular device and procedure including:

- Risks and differences between endovascular repair and open surgical repair.
- Potential advantages of traditional open surgical repair.
- Potential advantages of endovascular repair.
- The possibility that subsequent interventional or open surgical repair of the aneurysm may be required after initial endovascular repair.
- Potential benefits of preservation of blood flow in the aorta and/or branch vessels of the aorta.
- The Patient Implant Card, which is provided with the device for you to give to the patient, and the Patient Information Leaflet (PIL), (for implantable devices as required), which is available to the patient through: eifu.goremedical.com.

Follow-Up

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 ensure continuing 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, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, unexpected decline in renal function) should receive additional 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 FOLLOW-UP AND IMAGING GUIDELINES).
- Regular follow-up including imaging of the device should be performed at least every 12 months for all patients and additional imaging for patients with known endoleaks or aneurysm enlargement for the duration of the implant (see FOLLOW-UP AND IMAGING GUIDELINES).

- Physicians must advise all patients that it is important to seek prompt medical attention if he/she experiences signs or symptoms of renal or visceral branch occlusion, limb occlusion, aneurysm enlargement or rupture. Signs of renal branch occlusion include impaired renal function and flank pain. Signs of visceral branch occlusion include abdominal pain or evidence of visceral ischemia. Signs of graft limb occlusion include pain in the hip(s) or leg(s) during walking, or discoloration or coolness of the leg. Aneurysm rupture may be asymptomatic, but usually presents as pain, numbness, weakness in the legs; any back, chest, abdominal, or groin pain, dizziness, fainting, rapid heartbeat, or sudden weakness.
- Procedure related risks include cardiac, renal, pulmonary, neurologic, bowel, and bleeding complications. Device related risks include occlusion, endoleak, aneurysm enlargement, fracture, potential for reintervention and open surgical conversion, rupture and death (see ADVERSE EVENTS).
-

Physicians are encouraged to complete the Patient Implant Card and give it to the patient so that he/she can carry it with them at all times, and to refer the patient to the Patient Information Leaflet that is available to the patient through: eifu.goremedical.com.

IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

GENERAL

The long-term safety and effectiveness of endovascular repair of thoracoabdominal aortic aneurysms and pararenal aortic aneurysms has not been established. 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., aneurysm enlargement, endoleaks, stenosis) should receive additional follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms.

Regular and consistent follow-up is a critical part of ensuring continuing safety and efficacy of aortic endovascular repair. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient. At least one annual physician visit and the patient imaging schedule (**Table 22**) is recommended.

Follow-up modalities include CT/CTA, multi-view abdominal X-ray, MRI/MRA, and ultrasound. Data from these modalities is acquired and used to compare baseline and subsequent exams to review devices and morphological changes over time and their effects on exclusion of the aneurysm.

1. CT/CTA imaging provides information on aneurysm size, vascular morphological changes, proximal device-Trunk fixation and migration, endoleak and patency/stent graft occlusion.
2. Multi-view device X-ray imaging provides information on device wire form integrity (e.g., fracture, kinking) and relative component migration.
3. MRI/MRA imaging provides information similar to CT/CTA and is often used as a surrogate for CT/CTA if patients are CT contrast intolerant.
4. Ultrasound may be used to assess for endoleak and aneurysm size status but not for device integrity, specifically the wire form. Ultrasound is a less reliable and sensitive diagnostic method compared to CT.
5. Cone-beam CT imaging is recommended during the treatment procedure post-deployment to evaluate device orientation and integrity.

Alternative imaging recommendations for patients with CT or angiography contrast intolerance issues include CO_2 angiography, MRI/MRA with or without contrast, and ultrasound. These imaging and surveillance modalities may be less sensitive and difficult to compare with diagnostic findings from previous or subsequent follow-up exams.

ANGIOGRAPHIC IMAGING

Angiographic images are recommended pre-treatment to evaluate the length and tortuosity of the abdominal aorta, iliac and common femoral arteries. Angiographic images are recommended during the treatment procedure both pre- and post-deployment to evaluate device placement and orientation. Selective angiography during subsequent follow-up exams may provide useful device position and device integrity information.

CT/CTA IMAGES

Non-contrast and contrast enhanced baseline and follow-up exams are important for optimal patient surveillance.

1. Film sets should include all sequential images at lowest possible slice thickness ≤ 2 mm). Do NOT perform large slice thickness (> 3 mm) and/or omission of CT images/film sets (non-consecutive) as it prevents precise anatomical and device comparisons over time.
2. If an endoleak is suspected or there is aneurysm enlargement, it is recommended that pre-contrast and contrast runs be performed.
3. Pre-contrast and contrast run slice thickness and interval must match.
4. DO NOT change patient orientation or re-landmark patient between non contrast and contrast runs.

X-RAY

If there is any concern regarding device integrity (e.g., kinking, stent-wire breaks, relative component migration), an abdominal X-ray film series may be acquired and evaluated by the attending physician. The following abdominal 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.

MR SAFETY INFORMATION

MR Conditional

A patient with the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) may be safely scanned immediately after placement under the following conditions. Failure to follow these conditions may result in injury.

Device Name	GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)
Static Magnetic Field Strength (B_0)	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 may extend up to 10mm from the implant. The lumen of the central aortic and iliac components (i.e., Aortic Component, Distal Bifurcated Component, Contralateral Leg Components, and optional DBC Extender Component) could be visualized using gradient echo and spin echo pulse sequences, while the lumens of the GORE® VIABAHN® VBX Balloon Expandable Endoprostheses (i.e., Branch Components) could not be visualized using gradient echo and spin echo pulse sequences.

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

PATIENT IMAGING FOLLOW UP

Table 22: Recommended Schedule for Patient Follow-Up

	Pre-Treatment	Treatment	Hospital Discharge	One Month	Three Months	Six Months	Annually
Physical Examination	X		X	X	X	X	X
Spiral CT	X[1]			X	X[2]	X	X[3]
Non-Contrast CT	X[1]			X		X	X[3]
Angiogram		X					
Creatinine Concentration	X		X	X	X	X	X
Abdominal Ultrasound	X		X	X	X	X	X
Multi-planar X-Ray				X		X	X

[1] Imaging should be performed ≤ six months prior to the procedure.
[2] Recommended if endoleak reported at one month.
[3] Consider additional follow up imaging for patients with known endoleaks or aneurysm enlargement.

HOSPITAL/PATIENT TRACKING STATEMENT

The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is packaged with a Device Tracking Form which U.S. hospital staff are required to complete and forward to W. L. Gore & Associates, Inc. for the purposes of tracking all patients who receive a GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis product implant (as required by U.S. Federal Regulation).

DIRECTIONS FOR USE

PHYSICIAN TRAINING REQUIREMENTS

The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis should only be used by physicians experienced in endovascular interventional techniques, and who have successfully completed the physician training program. Physicians should implant the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis at hospitals with institutional capability to support open surgical intervention and surgical conversion as well as the capability for immediate emergent lumbar drain placement. In addition to standard physician training and experience, the following are specialized skills recommended for physicians using the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis.

- Radiographic, fluoroscopic, and angiographic image interpretation
- Arterial cutdown, arteriotomy, and repair or percutaneous access and closure techniques
- Nonselective and selective guidewire and catheter techniques
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Techniques to minimize radiation exposure
- Device selection and sizing
- Branch vessel cannulation

REQUIRED MATERIALS

The following are required accessories for use with GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis:

- **0.035" 'Super Stiff' Guidewire (≥ 260 cm)** (Cook® Lunderquist® DC wire guide or equivalent)
- **0.035" 'Super Stiff' Guidewire (180 cm)** (Cook® Lunderquist® DC wire guide or equivalent)
- **0.014" Guidewire (≥ 260 cm) x 2 - 4** (Abbott® Hi-Torque® Command™ or equivalent), or
- **0.018" Guidewire (≥ 260 cm) x 2 - 4** (Abbott® Hi-Torque® Steelcore™ or equivalent)
- **0.035" 'Stiff' Guidewire (260 cm) x 4** (Cook® Rosen or equivalent)
- **0.035" hydrophilic Guidewire (260 cm) x 2** (Terumo® Gluidewire® or equivalent)
- **GORE® DrySeal Introducer Sheaths for femoral access** (12 Fr, 14 Fr, 15 Fr, 16 Fr, 18 Fr, 22 Fr x 33 cm)
- **GORE® DrySeal Introducer Sheath for brachial/axillary access** (minimum 12 Fr x 33 - 45 cm)
- **Sheaths for Branch Components (6-8 Fr x 70 cm or more)** (Cook® Ansel, Terumo® Destination® or equivalent)
- **Diagnostic catheter(s)** Any supplier; 4-5 Fr / 110-150 cm / 0.035"
- **Marker Catheter** Any supplier; 5 Fr, 20 cm marker pigtail and straight
- **Snare** EN Snare® or equivalent
- **Molding Balloon** GORE® Tri-Lobe Balloon Catheter and/or GORE® Molding & Occlusion Balloon Catheter, or equivalent
- **PTA Balloon(s)** Any supplier; 0.035" guidewire compatible; 135 cm working length, diameter as appropriate for branch devices selected

Accessory, auxiliary, and ancillary materials (equipment and tools) should be used in accordance with the manufacturer's IFU. The physician should reference the manufacturer's instructions for use and any supporting clinical literature regarding any potential warnings, precautions, and adverse reactions related to the

accessories.

OPTIONAL MATERIALS

The following are optional accessories for use with GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis:

- Steerable or shaped sheath for branch vessel cannulation and/or delivery of Branch Components (6-8 Fr) (OSCOR Destino™ or equivalent)
- Introducer Sheath for accessing portals (5 Fr Sheath with 0.018" dilator, Cook® Flexor® Ansel or equivalent)
- Wire guide to facilitate guidewire management (Surge Cardiovascular Suture Guides or equivalent)
- 0.018" Catheter (0.035" Outer Diameter) to be used with 5-8 Fr Sheath and 0.035" Dilator for accessing portals (Medtronic® Trailblazer™ Angled Support Catheter, Cook® CXI® Support Catheter or equivalent)
- PTA Balloon(s) Any Supplier; 0.018" guidewire compatible; 135 cm working length, diameter as appropriate for portal access (4 mm, 6 mm, or 8 mm x 2 or 4 cm)
- Multiple colored 0.018" compatible guidewire torquers to label wires (Merit Medical or equivalent)
- Multi-lumen catheter to facilitate through wire access (GORE® Tri-Lumen Catheter or equivalent)
- Thoracic endovascular stent graft to treat intraoperative Type Ia endoleaks or iatrogenic aortic dissections (e.g., GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System)

Accessory, auxiliary, and ancillary materials (equipment and tools) should be used in accordance with the manufacturer's IFU. The physician should reference the manufacturer's instructions for use and any supporting clinical literature regarding any potential warnings, precautions, and adverse reactions related to the accessories.

PATIENT SELECTION AND RECOMMENDED DEVICE SIZING

A physician should determine if a particular patient and anatomy is suitable for proper use of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis. See WARNINGS AND PRECAUTIONS for additional considerations specific to the procedure.

The device should be properly sized by the physician to fit the patient's anatomy (see ANATOMICAL REQUIREMENTS). Failure to implant a device within the sizing matrix could lead to harms such as those listed in this IFU (see WARNINGS AND PRECAUTIONS).

ANATOMICAL REQUIREMENTS

Measurements should be taken using a CTA during the pre-treatment assessment to determine appropriate device sizing. IVUS and other imaging modalities should not be used to size grafts.

CT/CTA Imaging

- CT films should include all sequential images at the lowest possible slice thickness ≤ 2 mm, 1 mm preferred). Do NOT perform scans having large slice thickness (> 2 mm) and/or omission of CT images/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 vessel lengths for the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis. These reconstructions should be performed in sagittal, coronal, and varying oblique views depending upon individual patient anatomy.
- If an endoleak is suspected or there is aneurysm enlargement, both pre-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 pre-contrast and contrast runs.
- Pre- and Post-treatment CT/CTA imaging is recommended to be performed according to the guidelines listed in **Table 23**.
- Cone-beam CT and fusion overlay imaging is recommended during the treatment procedure to aid in target artery cannulation and to evaluate device orientation and integrity runs.

Table 23. Recommended Pre-treatment CTA Imaging Guidelines

Start Position	Pre-contrast: Top of the shoulders (to include both subclavian arteries) Arterial: Top of the shoulders (to include both subclavian arteries)
End Position	Pre-contrast: Femoral heads Arterial: Femoral heads
Scan Field	Large
Field of Vision (FOV)	350 mm or as appropriate for patient
Scan Type	Helical
Slice collimation/thickness	≤ 2 mm ≤ 1 mm preferred, for 4 row scanner as low as possible)
Reconstruction Interval	20% overlap (e.g., 0.8/1 mm, 0.4/.5 mm, or 1.6/2 mm)
Scan Delay (contrast	Smart prep or equivalent, 3-second delay (no delay for 4 row scanner)
Kilovoltage (KV)	120 or as appropriate
Contrast Medium (CM)	Recommendation: ≥ 350 mg/ml, 70-200 ml
Contrast Medium (CM) administration	Recommendation: ≥ 4 ml/s, via right cubital vein, 18 G, saline push ≥ 40 ml

Aortic Requirements:

1. Adequate iliac/femoral access and brachial/axillary access.
2. Proximal (supraceliac) aortic neck treatment diameter range over 2 cm seal zone of 22-34 mm for aneurysms extending up to 6.5 cm or less above the origin of the most proximal branch vessel.
3. The proximal seal zone (2 cm in total) is within the oversizing window for a single Aortic Component.
4. Aortic neck angle ≤ 60° at the Aortic Component proximal seal zone.
5. Visceral segment of aorta (3 cm proximal through 9.5 cm distal to the most proximal visceral artery) must be ≥ 20 mm in diameter.

Branch Vessel Requirements:

1. Renal artery seal zone diameters (ID) between 4.0 and 10.0 mm.
2. Celiac and superior mesenteric artery (SMA) seal zone diameters (ID) between 5.0 and 12.0 mm.
3. ≥ 15 mm seal zone length in each branch vessel (celiac artery, superior mesenteric artery, renal arteries).

4. The treated segment of each target branch vessel must be in the intended diameter range for the selected Branch Component (see GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis IFU).
5. When selecting and deploying Branch Components, the inflated diameter of the balloon at the portal end should approximate the inner diameter of the portal to which it is mated.
6. The Branch Components must be selected such that the length allows for a minimum 15 mm (3 stent rings) of seal in each target branch vessel, and approximately 5-10 mm (1-2 stent rings) overlap beyond the portal inlet.
7. If a Branch Component extension is needed, ensure a minimum overlap of 2 cm (4 stent rings) between the two Branch Components.
8. If a Branch Component extension is needed, the Branch Component extension must be deployed to a diameter greater than or equal to the Branch Component it is deployed inside.
9. When multiple Branch Components are needed for extension, start in the portal, and work distal unless the distal branch will be inflated to a smaller diameter, then work distal to proximal.

Iliac Artery Requirements:

1. Iliac artery inner diameters (ID) between 8-25 mm.
2. Iliac artery seal length of at least 10 mm.

Vascular Access:

1. Iliofemoral access vessels should be of sufficient diameter to allow passage of the GORE® DrySeal Introducer Sheath required for the selected Aortic Component (see **Table 24**).
2. Iliofemoral access vessel morphology should be compatible with vascular access techniques and accessories (minimal thrombus, calcium and/or tortuosity).
3. 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 abdominal aorta.
4. Brachial or axillary access vessels should be of sufficient diameter to allow passage of a minimum 12 Fr sheath.

Table 24: Aortic Component Sizing Guide

Device Dimensions[1] and Sizing Requirements						
Proximal Device Diameter (mm)	Distal Device Diameter (mm)	Intended proximal Aortic Diameters[2] (mm)	Proximal Portal Diameter (mm)	Distal Portal Diameter (mm)	Overall Device Length (mm)	GORE® DrySeal Introducer Sheath Size
37	20	22-29	8	6	160	22
31	20	27-34	8	6	160	22

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

The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is only compatible with the GORE® DrySeal Introducer Sheath. Compatibility with other sheaths has not been established. Please refer to specific sheath IFU for directions for use.

Table 25: Branch Component Vessel Sizing Guide

Branch Component Diameter[1,2,3], Sheath Size[4]	TAMBE Aortic Component Portal Compatibility (mm)	Lengths (mm)
5 mm, 6/7 Fr	6	39, 59, 79
6 mm, 6/7 Fr	6	39, 59, 79
7 mm, 6/7 Fr	6 & 8	39, 59, 79
8 mm, 7/8 Fr	8	39, 59, 79
9 mm, 7/8 Fr	8	39, 59, 79

[1] Device diameter is nominal. Larger diameters may be achieved by post-dilating with an appropriately sized balloon.
[2] Diameter ranges vary by stent length.
[3] Compatible vessel diameters depend on desired amount of oversizing.
[4] Refer to specific Branch Component IFU for sheath size compatibility.

Table 26: Distal Bifurcated Component Sizing Guide

Proximal Device Diameter[1] (mm)	Distal Device Diameter[1] (mm)	Overall Device Length (cm)	Length to Contralateral Leg Hole (cm)	Intended Iliac Vessel Diameter[2] (mm)	Recommended GORE® DrySeal Introducer Sheath Size[3] (Fr)
23	10	10	5.5	8-9	16
23	12	10	5.5	10-11	16
23	14.5	10	5.5	12-13.5	16

[1] All device dimensions are nominal.
[2] Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 7-25% in the iliac vessel.
[3] GORE® DrySeal Introducer Sheaths are recommended to accommodate multiple guidewires.

Table 27: Contralateral Leg Component Sizing Guide

Device Distal Diameter[1] (mm)	Intended Iliac Vessel Diameter[2] (mm)	Overall Device Lengths[3,4] (cm)	Recommended GORE® DrySeal Introducer Sheath Size[5] (Fr)
10	8-9	7	12
12	10-11	7	12
14.5	12-13.5	7	12
12	10-11	10, 12, 14	12

14.5	12-13.5	10, 12, 14	12
16	13.5-14.5	9.5, 11.5, 13.5	12
18	14.5-16.5	9.5, 11.5, 13.5	12
20	16.5-18.5	9.5, 11.5, 13.5	12
23	18.5-21.5	10, 12, 14	14
27	21.5-25	10, 12, 14	15

[1] All device dimensions are nominal.
[2] Recommended endoprosthesis oversizing relative to the vessel is approximately 7-25%.
[3] Labeled Contralateral Leg Component length includes 2.5 cm overlap with the Distal Bifurcated Component contralateral leg hole.
[4] All devices with 7 cm length are GORE® EXCLUDER® AAA Endoprosthesis - Iliac Extenders. All other components are GORE® EXCLUDER® AAA Endoprosthesis - Contralateral Legs.
[5] GORE® DrySeal Introducer Sheaths are recommended. Contralateral Leg Components are not compatible with introducer sheaths longer than 40 cm (total length including the hemostatic valve).

Table 28. DBC Extender[1] Component Sizing Guide

Device Diameter (mm)	Overall Device Length (cm)	Recommended GORE® DrySeal Introducer Sheath[2] (Fr)
23	3.3	16

[1] The DBC Extender Component may be used to provide additional seal at the junction of the Aortic Component and Distal Bifurcated Component.
[2] GORE® DrySeal Introducer Sheaths are recommended. DBC Extender Components are not compatible with introducer sheaths longer than 40 cm (total length including the hemostatic valve).

DEVICE PREPARATION

Aortic Component Preparation:

- Before use, inspect outer packaging for damage. Do not use if sterile barrier is compromised or there is damage to the device. Discard and select another device.
- Before use, verify device expiration date. Do not use if device is expired. Verify correct device size.
- To use, remove pouch from outer box. There is only one pouch. Open pouch and retrieve device while maintaining sterility. Discard if sterility is compromised.
- To remove device, open lid and withdrawal taking care to keep device in the sterile field.
- Prepare device by removing the packaging sheath and mandrel.
- Flush device by removing the end cap on the flush port and flushing with heparinized saline until it exits the leading tip. Replace the end cap.
- Do not remove RGTs or mandrels inside of RGTs until device is ready to be inserted (**Figure 6**).
  - WARNING: Do not withdraw the removable guidewire tubes (RGTs) from the constrained device at this time. These tubes serve to facilitate passage of the pre-cannulated branch guidewires through the internal portals of the Aortic Component. Removing the RGTs will result in loss of portal pre-cannulation and increased procedure time. (See WARNINGS AND PRECAUTIONS)
- Prepare all other components according to their respective IFUs (see OVERVIEW).

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

IMPLANT PROCEDURE

- *Adequate fluoroscopic visualization is required for implantation.*
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
- The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.

Arterial Access

- Obtain appropriate iliac/femoral vascular access, according to standard practice.
- Obtain appropriate brachial/axillary vascular access, according to standard practice.
- Administer heparin, according to standard practice.
- Perform angiography to identify the target anatomy, according to standard practice.
- Aortic Guidewire: Advance a 260 cm (or longer) x 0.035" hydrophilic guidewire via the access in the brachial/axillary vessel to the abdominal aorta.
- Snare the guidewire to make it through-and-through via the iliac/femoral access artery, according to standard practice.
- Exchange the hydrophilic guidewire for a super-stiff guidewire so it is through-and-through.
- If not already in place, advance the 22 Fr GORE® DrySeal Introducer Sheath through the vasculature over the super-stiff through-and-through guidewire via the iliac/femoral access, according to standard practice.
- Advance 12 Fr or larger GORE® DrySeal Introducer Sheath over through-and-through wire via brachial/axillary access into the descending thoracic aorta.
- Contralateral leg access should be obtained at this time. The appropriate size contralateral sheath may be advanced now or when the contralateral leg hole is being cannulated.

Aortic Component Preparation

- Using the brachial/axillary access, load the multi-lumen catheter over the 0.035" through-and-through wire using the 0.035" lumen. Advance the multi-lumen catheter over the through-and-through wire (through a minimum 12 Fr sheath) until the leading end exits the 22 Fr sheath. Application of slight tension to the 0.035" through-and- through wire may facilitate catheter advancement. Advance 0.014" or 0.018" guidewire(s) through the appropriate lumen(s). If necessary to establish a total of four 0.014" or 0.018" through-and-through guidewires, secure all wires at the iliac/femoral access and retract the multi-lumen catheter. Retract and re-advance the multi-lumen catheter over the 0.035" through-and-through wire and advance additional 0.014" or 0.018" guidewires through the 0.018" lumens.
  - Alternatively, four 0.014" or 0.018" wires may be introduced through a 5 Fr angiographic catheter to gain through-and-through access.
- At the 22 Fr femoral sheath access site, pass the aortic guidewire into the central lumen of the Aortic Component delivery catheter (**Figure 7**).
- One at a time, remove the packaging mandrels from each of the RGTs. Advancing the RGT slightly before removing the mandrel may help introduce the guidewire (**Figure 8**).
- Pass one 0.014"or 0.018" guidewire through each of the Aortic Component RGTs and through the constrained device, being careful to prevent twisting or entanglement. Label the guidewires as they are introduced to help with vessel selection and catheterization.
  - If desired, the 0.014" or 0.018" wires may be advanced through the Aortic Component RGTs as they are initially introduced through-and-through.
- When all 0.014" and 0.018" guidewires are fully advanced through the RGTs, withdraw the RGTs (toward the catheter handle) ensuring the four guidewires remain in place (see WARNINGS AND PRECAUTIONS) (**Figure 9**).

Aortic Component Delivery

- Being careful not to displace the 0.014" and 0.018" guidewires, advance the Aortic Component delivery catheter over the 0.035" guidewire and advance until the leading end of the Aortic Component catheter abuts the leading end of the multi-lumen or angiographic catheter. Maintaining the relative position of all catheters, advance the Aortic Component delivery catheter into the valve of the 22 Fr GORE® DrySeal Introducer Sheath, while simultaneously withdrawing the multi-lumen catheter from the brachial/axillary access. Stop when only the trailing end of the constrained device is visible. Allow blood to flow back through the constrained device to flush any air that may be contained in the constrained endoprosthesis.
- Use fluoroscopic guidance to advance the Aortic Component delivery catheter to the intended landing zone, while simultaneously withdrawing the multi-lumen or angiographic catheter via the brachial/axillary access while making sure all guidewires are maintained (**Figure 10**). Use the radiopaque markers for guidance.
  - Pulling tension on all through wires will facilitate Aortic Component tracking into position.
- Ensure the image intensifier (C-Arm) is positioned such that it is perpendicular to the proximal aortic landing zone, as determined by 3-D CTA reconstructions of pre-operative CT imaging.
- While the C-Arm is in a straight anterior-posterior position, the constrained device should be rotated such that the SMA and Celiac side branch portals are facing the patient's anterior side. This can be achieved by making sure the long radiopaque marker is on the patient left and the short radiopaque marker is on the patient right.
- The Aortic Component should be positioned such that the outlets of each portal are located at least 1 cm proximal to the respective target branch vessels (celiac artery, SMA, left renal artery, right renal artery) (**Figure 11**), a lateral C-Arm position may be required for positioning.
- Before deploying, advance the endoprosthesis slightly beyond the target implant location and pulled back to release stored energy in the delivery catheter.
- Advance a marker angiographic catheter and perform angiography according to standard practice to confirm the position of the target anatomy, and the location of the constrained endoprosthesis. A magnified view of the proximal seal zone may be desired for accurate positioning.
- While maintaining the Aortic Component delivery catheter in position, retract the introducer sheath and visually verify that the leading end of the introducer sheath is below the distal Aortic Component radiopaque marker.
- Once the device is at the desired location, utilize a two-person deployment where one person should stabilize the iliac/femoral 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 deploy the first stage of the Aortic Component. Loosen the White Outer Deployment Knob by turning it 90 degrees counterclockwise. Confirm device position and orientation and deploy the first stage of the Aortic Component using a steady and continuous pull of the deployment knob (**Figure 12**). Pull the deployment knob straight out from the catheter handle. (Note: The proximal end of the Aortic Component will open to a secondary constrained diameter upon deployment of the first stage, **Figure 13**). Remove the multi-lumen catheter through the brachial access, being careful not to displace any of the through-and-through guidewires.
- **BACKUP DEPLOYMENT MECHANISM:** In the event that the removal of the White Outer Deployment Knob does not initiate the deployment of the proximal end of the TAMBE Aortic Component, and the problem is suspected to have occurred in the deployment handle, the deployment handle has a design feature that is intended to protect the patient against this problem becoming a hazard. Remove the Deployment Line Access Hatch Lid (**Figure 14**) and then pull the first deployment line (labeled "1") with an appropriate dull or blunt-edged tool. Fully remove the deployment line in a steady, continuous motion. This action will cause the proximal end of the Aortic Component to deploy to a secondary diameter. (**Figure 13**)
- The TAMBE Aortic Component deploys with the proximal fixation anchors constrained. Once desired position is confirmed, turn the Gray Constraining Dial counterclockwise until it stops to fully open the proximal end of the Aortic Component and allow for anchor engagement (**Figure 15**). The Black Nut within the Transparent Knob housing will move toward the leading end of the catheter when the proximal end of the Aortic Component is fully opened (**Figure 16**).

Optional Repositioning of Aortic Component

- To constrain the proximal end of the Aortic Component, turn the Gray Constraining Dial clockwise until it stops. The Black Nut within the Transparent Knob housing will move toward the trailing end of the handle when the proximal end of the device is constrained.
- Magnify and center the fluoroscopic image on the proximal end of the Aortic Component. Manually reposition and/or rotate the Aortic Component delivery catheter as necessary to properly position the device. Maximize the separation between the long and short radiopaque markers near the proximal end of the device to achieve optimal rotational positioning of the device. The long radiopaque marker should be positioned toward the patient's left side.
- Once desired positioning has been obtained, fully open the proximal end of the Aortic Component by turning the Gray Constraining Dial counter- clockwise until it stops. Remove the multi-lumen catheter and/or angiographic catheters through the brachial access, being careful not to displace any of the through-and-through guidewires.
- The Aortic Component may be repositioned up to two times.

Branch Vessel Cannulation

- From the brachial/axillary access, advance an appropriate sheath and/or guide catheter over one 0.014"/0.018" guidewire, and through the respective branch portal of the Aortic Component (applying slight tension to wire may aid in advancement). If a sheath catches on a portal, a 5 Fr catheter with 0.018" guidewire compatibility may be used (**Figure 17**).
  - WARNING: If a catheter/sheath catches on portal, do not continue pushing. Stop and assess cause of resistance. Pushing against the portal may cause downward migration of the Aortic Component (See WARNINGS).
- Using appropriate accessories, cannulate the target vessel. Advance an appropriate 0.035**"** stiff guidewire into the artery (**Figure 18**). Remove sheath and guide catheter via the brachial/axillary access while maintaining 0.035**"** stiff guidewire in target vessel.
- Repeat these branch vessel cannulation steps for all remaining 0.014"/0.018" guidewires and branch vessels.
  - WARNING: Crossing of Branch Components is not recommended. Compromise to device integrity, including Branch Component compression and Aortic Component wire fracture, has been identified in clinical follow up under these conditions (see WARNINGS).
- The Aortic Component may be constrained and rotated up to 90 degrees to facilitate branch vessel cannulation.

Aortic Component Proximal Secondary Sleeve Deployment

- Following cannulation of all branch vessels, verify the proximal end of the Aortic Component is in the desired position and fully open by turning the Gray Constraining Dial counterclockwise until it stops. The Black Nut within the Transparent Knob housing will move toward the leading end of the catheter when the proximal end of the Aortic Component is opened (**Figure 16**).
- Disengage the constraining mechanism by sliding the Red Safety Lock back while rotating the entire Transparent Knob 90 degrees counter-clockwise (**Figure 19**). Remove the constraining mechanism by pulling the Transparent Knob straight out from the catheter handle (**Figure 20**). Removing this handle will remove the constraining system and fully open the proximal end of the Aortic Component (Reference **Figure 21**).
  - Note: The Aortic Component is no longer repositionable after the transparent knob is removed.
- **BACKUP DEPLOYMENT MECHANISM:** In the event, that the removal of the Transparent Knob does not initiate the removal of the constraining mechanism or deploy the proximal secondary sleeve, and the problem is suspected to have occurred in the deployment handle, the deployment handle has a design feature that is intended to protect the patient against this problem becoming a hazard. Remove the Deployment Line Access Hatch Lid (**Figure 14**) and then grasp and cut the silver Lock Pin line (labeled "2") with an appropriate tool. Grasp, pull, and fully remove the silver Lock Pin line (labeled "2") in a steady, continuous

motion. Cut, grasp, pull, and fully remove the gray Constraining Loop line (labeled "3") in a steady, continuous motion. These actions will cause the constraining mechanism to be removed. To deploy the secondary sleeve, grasp, pull, and fully remove in a continuous motion the two remaining deployment lines (labeled "4"). One will deploy the secondary sleeve and the other will deploy the distal sleeve. It does not matter which is deployed first.

Introduction and Deployment of Branch Components

- See GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis IFU for specific instructions on deployment of the Branch Components.
- Verify guidewire in target vessel is 0.035" in diameter.
- Choose an appropriate length and diameter Branch Component and prepare according to the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis IFU. The length of the device(s) should allow them to extend from the intended distal landing zone in the branch vessel (at least 15 mm or 3 stent rings) to approximately 5-10 mm (1-2 stent rings) beyond the Aortic Component portal inlet (proximal landing zone). Multiple Branch Components may be used to reach the targets for each branch. Use the instructions below to extend the Branch Components.
- If use of a guiding sheath is desired, select appropriate size according to the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis IFU. Advance sheath through the 12 Fr or larger introducer sheath, through the Aortic Component portal, and into the target vessel.
- Advance the Branch Component over the 0.035" guidewire to its intended deployment location. If delivery sheath was used, make sure to withdraw past the branch component before deploying. Ensuring a minimum of 15 mm (3 stent rings) seal zone in the target vessel, as well as approximately 5-10 mm (1-2 stent rings) extension beyond the Aortic Component portal inlet, deploy the Branch Component according to the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis IFU (**Figure 22**).
- Use an appropriately sized balloon catheter to flare the proximal end of the Branch Component outside the portal to 1-2 mm greater than portal diameter.
  - Note: Depending on desired diameter, the balloon on which the Branch Component is mounted may be used to flare the proximal end of the Branch Component if it can reach the appropriate diameter (1-2 mm larger than the portal diameter).
- If necessary, use an appropriately sized balloon catheter to flare the Branch Component in the target vessel to the appropriate diameter, reference the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis IFU for sizing requirements.
- (Optional) Extension of Branch Component. If a Branch Component extension is needed, ensure a minimum overlap of 2 cm (4 stent rings) between the two Branch Components. If a Branch Component extension is needed, the Branch Component extension must be deployed to a diameter greater than or equal to the Branch Component it is deployed inside.
- If a branch extension is planned with devices of differing deployed diameters, the smaller diameter device should be deployed first. If the deployed diameters are equivalent, the proximal device (in the portal) should be deployed first.
- Withdraw Branch Component delivery catheter and sheath. Wire access may be maintained in the target artery, if desired.
- Repeat Branch Component deployment steps for two of the remaining three Branch Components (**Figure 23**).
  - WARNING: Crossing of Branch Components is not recommended. Compromise to device integrity, including Branch Component compression and Aortic Component wire fracture, has been identified in clinical follow up under these conditions (see WARNINGS).
- Introduce the fourth and final Branch Component, but do not deploy it until the distal section of the Aortic Component is fully deployed (**Figure 24**).
  - WARNING: When ballooning any TAMBE Device component(s), use care to ensure Branch Component integrity is not compromised. If necessary, use one or more appropriate-sized PTA balloons to ensure each Branch Component is appropriately dilated and not compressed during ballooning of other device components.

Aortic Component Distal Section Deployment

- Loosen the Gray Deployment Knob by turning counterclockwise. Deploy the distal section of the Aortic Component using a steady and continuous pull of the gray deployment knob to release the endoprosthesis. Pull the deployment line straight out from the catheter handle (**Figure 25**). This will fully remove the Aortic Component from the delivery catheter (**Figure 26**).
- **BACKUP DEPLOYMENT MECHANISM:** In the event that the removal of the Gray Deployment Knob does not initiate the deployment of the distal Aortic Component and the problem is suspected to have occurred in the deployment handle, the deployment handle has a design feature that is intended to protect the patient against this problem becoming a hazard. Remove the Deployment Line Access Hatch Lid (**Figure 14**) and then pull the third deployment line (labeled "4") with an appropriate dull or blunt-edged tool. Fully remove the deployment line in a steady, continuous motion. This action will cause the distal Aortic Component to deploy.

Deployment of Final Branch Component

- Follow instructions in the Introduction and Deployment of Branch Components section above for instructions on positioning, deploying, and flaring of the final Branch Component.
- Consider using a kissing balloon technique with appropriately sized balloon catheters in the Branch Components to maintain Branch Component integrity.

Removal of Aortic Component Delivery Catheter

- Using fluoroscopic guidance, withdraw and remove the Aortic Component delivery catheter via the iliofemoral access, being careful not to displace any components or accessories.
  - WARNING: If resistance is felt during removal of the delivery catheter through the introducer sheath, stop and assess cause of resistance. If necessary, withdraw delivery catheter and introducer sheath together.

Distal Bifurcated Component Positioning and First Stage Deployment

- All sizes of the Distal Bifurcated Component are compatible with the Aortic Component. The appropriate size should be selected based on inner diameter of the ipsilateral common iliac artery, if applicable (**Table 37**). Use fluoroscopic visualization for all guidewire, sheath, and device catheter manipulations.
- Prepare the Distal Bifurcated Component according to the GORE® EXCLUDER® Iliac Branch Endoprosthesis IFU with the following exception:
  - IMPORTANT: Once the device is prepped, remove and discard the Removable Guidewire Tube (RGT) from the Distal Bifurcated Component.
- Advance the Distal Bifurcated Component catheter over the femoral 0.035" 'super stiff' guidewire to the approximate level of intended landing zone within the Aortic Component. Align the proximal radiopaque markers on the Distal Bifurcated Component with the circumferential gold marker band distal to (below) the renal portals (**Figure 27**). This will provide an overlap of 3.5 cm between the two components.
- While maintaining the delivery catheter in position, withdraw the introducer sheath and visually verify that the leading end of the introducer sheath is not covering the Distal Bifurcated Component.
- Reposition and rotate the Distal Bifurcated Component delivery catheter as necessary to properly position the device in the correct orientation in regard to the anatomy. The long radiopaque marker indicates the proximal portion of the contralateral leg hole.
- Stabilize the Distal Bifurcated Component delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
- Loosen the White Outer Deployment Knob. Confirm final device position and orientation. Turn the knob counterclockwise and deploy the Distal Bifurcated Component using a steady and continuous pull of the deployment knob straight out and away from the catheter handle to release the proximal endoprosthesis

past the contralateral leg hole of the Distal Bifurcated Component. Deployment initiates from the leading (aortic) end toward the trailing (iliac) end. The ipsilateral iliac leg will remain constrained on the delivery catheter (**Figure 28**).

- WARNING: Do not attempt to remove the Distal Bifurcated Component after the first deployment. The Distal Bifurcated Component is a two-stage deployment.

Contralateral Leg Hole Guidewire Cannulation

- If not done already, advance the appropriate size GORE® DrySeal Introducer Sheath into the vasculature.
- Cannulate and advance a 0.035" guidewire into the contralateral leg hole of the Distal Bifurcated Component according to standard practice.
  1. Verify that the guidewire is within the contralateral leg hole of the Distal Bifurcated Component by standard practice used to verify guidewire location (e.g., catheter spinning).
  2. Change the 0.035" guidewire to a 0.035" 'super stiff' guidewire through the catheter.
  3. Advance the sheath over the guidewire and through the contralateral leg hole of the Distal Bifurcated Component.

Contralateral Leg Endoprosthesis Positioning and Deployment

- Advance the Contralateral Leg Component delivery catheter to the level of the long radiopaque marker on the contralateral side of the Distal Bifurcated Component (**Figure 29**). With the alignment of these markers, an approximate 2.5 cm overlap will be achieved.
- While maintaining the delivery catheter in position, withdraw the introducer sheath and visually verify that the leading end of the introducer sheath is not covering the Contralateral Leg Component.
- Following the GORE® EXCLUDER® AAA Endoprosthesis IFU, deploy the Contralateral Leg Component (**Figure 21**).
- Ensure that the Contralateral Leg Component achieves at least 3 cm of vessel engagement and 1 cm of seal in the vessel.

Distal Bifurcated Component Ipsilateral Leg Deployment

- Loosen the Gray Inner Deployment Knob by turning 90 degrees counterclockwise. Deploy the ipsilateral iliac leg of the Distal Bifurcated Component using a steady and continuous pull of the deployment knob straight out and away from the catheter handle to release the endoprosthesis (**Figure 22**).
- Use fluoroscopic guidance during withdrawal of the delivery catheter to assure safe removal from the patient. If resistance is felt during removal of the delivery catheter through the introducer sheath, stop and assess cause of resistance. If necessary, withdraw the delivery catheter and introducer sheath together.
- The ipsilateral limb of the Distal Bifurcated Component may be extended with an appropriately sized Contralateral Leg Component to achieve seal in the ipsilateral iliac artery. Refer to the GORE® EXCLUDER® Iliac Branch Endoprosthesis IFU when extension is needed.

COMPLETION OF PROCEDURE

- After deployment, the proximal end of the Aortic Component, the overlap of the Distal Bifurcated Component and Aortic Component, and the proximal overlap end and the distal end of all contralateral leg/Iliac extender junctions should be ballooned sequentially using appropriately sized PTA or compliant balloon catheters.
  - WARNING: When ballooning any TAMBE Device component(s), use care to ensure Branch Component integrity is not compromised. If necessary, use one or more appropriate-sized PTA balloons to ensure each Branch Component is appropriately dilated and not compressed during ballooning of other device components.
  - WARNING: When ballooning, adhere to the balloon catheter manufacturer's IFU. Over inflation of the balloon has led to aortic rupture and may lead to new dissection vessel rupture, with the potential need for emergent intervention in clinical use. Do not inflate molding balloons or PTA balloons in areas of significant calcified plaque. Balloon rupture and/or vessel damage may occur.
  - (Optional) The 23 mm DBC Extender Component may be used to provide additional seal at the junction of the Aortic Component and the Distal Bifurcated Component in the event of a Type III endoleak (Figure 35). Position the proximal and distal radiopaque markers of the DBC Extender Component such that approximately one-half of the device length (1.6 cm) is above the proximal end of the Distal Bifurcated Component, and one-half below the proximal end of the Distal Bifurcated Component. The proximal three (3) and distal one (1) markers are visible relative to host device pre- and post-deployment. Stabilize the DBC Extender Component delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site. Loosen the deployment knob. Using fluoroscopy, confirm final device position and deploy the DBC Extender Component using a steady and continuous pull of the deployment knob to release the endoprosthesis. Pull the deployment knob straight out from the catheter side-arm. Deployment initiates from the trailing end of the device toward the leading end of the device. Specific instructions on the deployment of the DBC Extender Component are provided in the IFU for the GORE® EXCLUDER® AAA Endoprosthesis.
- When ballooning the proximal Aortic Component, keep the balloon between the proximal gold marker band and the marker band 3.5 cm distal to avoid ballooning the aorta or compressing the branches.
  - CAUTION: If additional proximal extension is needed after the Aortic Component has been deployed (e.g., to treat Type la endoleaks or aortic dissections), ensure that the distal end of the deployed extension device does not exceed the 3.5 cm distal marker band of the proximal Aortic Component. Follow the manufacturer's IFU for specific deployment instructions.
- Perform an aortogram to assess exclusion of the aneurysmal segment, luminal patency of the aorta and branch vessels, and endoprosthesis position (**Figure 32**).
- Close the arterial access sites, according to standard practice.

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

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2. 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.
3. 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.
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DEFINITIONS

EC REP Authorised Representative in the European Community

REF Catalog 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 Expose to Extreme Hot or Cold Temperature

Do Not Resterilize

Do Not Reuse

Do Not Use if Package is Damaged

Keep Dry

Manufacturer

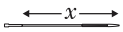
MR Conditional

SN Serial Number

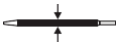
STERILE Sterile

STERILE EO Sterilized using Ethylene Oxide

Use By



Catheter Working Length


Delivery Profile


Guidewire Compatibility

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