

INSTRUCTIONS FOR USE

GORE[®] VIABAHN[®] VBX

Balloon Expandable Endoprosthesis

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English

INSTRUCTIONS FOR USE

GORE® VIABAHN® VBX BALLOON EXPANDABLE ENDOPROSTHESIS

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DESCRIPTION

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Device) final product is comprised of two main components, the implantable endoprosthesis (also referred to as the stent graft) and a balloon catheter delivery system. The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis consists of two structural elements and a coating on the luminal surface: stainless steel rings, a fluoropolymer film that is attached to the stainless steel rings, and the CBAS® Heparin Surface. The CBAS® Heparin Surface on the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis consists of stable, covalent, end-point attached heparin of porcine origin. The endoprosthesis is pre-mounted on a balloon designed for deploying the stent graft via balloon inflation. This balloon is covered with a thin layer of film to maximize retention of the endoprosthesis during introducer sheath insertion, tracking to the implant site, and balloon inflation/device deployment. The delivery system has two radiopaque balloon markers embedded in the shaft (denoting the effective balloon length) to aid in the placement of the endoprosthesis. The delivery system is compatible with 0.035" (0.89 mm) guidewires. The premounted stent system is available in a variety of endoprosthesis lengths from 15 to 79 mm and in a variety of diameters from 5 to 11 mm (See **Table 1**). The premounted endoprosthesis system balloon catheter is also offered in two shaft lengths with effective lengths of 80 cm or 135 cm. Multiple GORE® VIABAHN® VBX Balloon Expandable Endoprostheses may be implanted in an overlapping configuration within the approved indications.

This product is supplied sterile. It should not be resterilized.

The VBX should be used with branched or fenestrated aortic endografts indicated for use with bridging stents wherein safety and effectiveness of the device system (i.e., aortic component and bridging stent) has been demonstrated. Data to support the safety and effectiveness of the device system may be provided in the aortic endograft and/or bridging stent Instructions for Use.

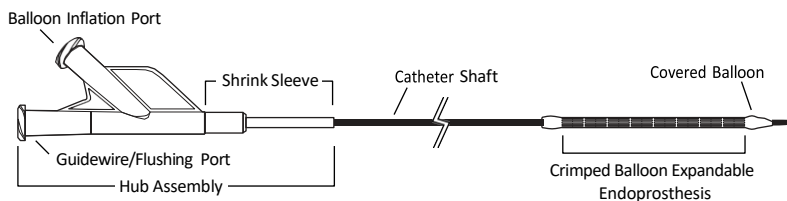
Note: VBX has been studied as a bridging stent with multiple aortic endografts – refer to the clinical section below and/or the labeling of approved branched and fenestrated aortic endografts. Compatibility with other aortic stent grafts has not been evaluated.

Note: The diameter of the endoprosthesis may be increased post-placement beyond the nominal diameter by expanding with a larger diameter balloon. Refer to **Table 1** and **Table 2**.

Figure 1. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis



Figure 2. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis Delivery System



INTENDED USE/INDICATIONS

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated for the treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5 mm-13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation.

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated to maintain visceral artery perfusion as a bridging stent in:

- fenestrated endovascular aortic aneurysm repair with 6-8 mm diameter fenestrations.
- branched endovascular aortic aneurysm repair with 6-8 mm diameter branches (e.g., portals, cuffs, or directional branches) that are at least 10 mm in length.

Bridging stent use is limited to aortic endovascular graft systems wherein safety and effectiveness has been demonstrated.

CONTRAINDICATIONS

- Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II.

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- Patients with known sensitivities or allergies to the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis materials including expanded polytetrafluoroethylene (ePTFE), fluorinated ethylene propylene (FEP), stainless steel, and heparin.

RECOMMENDED DEVICE SIZING

Note: 15 mm length and 8L diameter configurations are not indicated for use as bridging stents in fenestrated or branches endovascular aortic aneurysm repair

Table 1. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis Sizes

Stent Labeled/ Nominal Diameter (mm)	Crimped Stent Length ^{4,5} (mm)	Introducer Sheath Size (Fr)	Guidewire Diameter	Max. Post- Dilated Stent Diameter ¹ (mm)	Catheter Length (cm)	RBP ³ (atm / kPa)
5	15, 19, 29, 39, 59, 79	7	0.035" (0.89 mm)	8	80, 135	15/1520
6	15, 19, 29, 39, 59, 79	7	0.035" (0.89 mm)	8	80, 135	15/1520
7	15, 19, 29, 39, 59, 79	7	0.035" (0.89 mm)	11	80, 135	15/1520
8	29, 39, 59	7	0.035" (0.89 mm)	11	80, 135	13/1317
	79	8				
8L	29, 39	7	0.035" (0.89 mm)	16 ²	80, 135	13/1317
	59, 79	8	0.035" (0.89 mm)			
9	29, 39, 59, 79	8	0.035" (0.89 mm)	13	80, 135	13/1317
10	29, 39, 59, 79	8	0.035" (0.89 mm)	13	80, 135	13/1317
11	29, 39, 59, 79	8	0.035" (0.89 mm)	16 ²	80, 135	12/1216

¹ Secondary balloon required to post-dilate the stent beyond its nominal deployed diameter (secondary balloon not included).

² Technical limit of the device as determined by *in-vitro* testing for the indicated use; device expansion beyond 13 mm was not studied as part of the VBX FLEX clinical study. Within the EMBRACE Registry maximum measured device expansion was 12.6 mm and flaring was performed with balloons up to 14 mm in diameter.

³ RBP is Rated Burst Pressure.

⁴ The 19 mm length configuration is the minimum length for use as a bridging stent in fenestrated endovascular aortic repair (FEVAR)

⁵ The 29 mm length configuration is the minimum length for use as a bridging stent in branched endovascular aortic repair (BEVAR)

Table 2. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis Sizing Table

Stent Labeled/ Nominal Diameter (mm)	Crimped Stent Length (mm) ^{4,5}	At Nominal Pressure			At Rated Burst Pressure			At Max. Post-Dilated Stent Diameter ¹	
		Nominal Inflation Pressure (atm/ kPa)	Final Stent ID (mm)	Stent Length ³ (mm)	Rated Burst Pressure (atm/kPa)	Final Stent ID (mm)	Stent Length ³ (mm)	Max. Post- Dilated Diameter (mm)	Stent Length at Max. Post- Dilated Stent Diameter ³ (mm)
5	15	14/1418	5.0	13.6	15/1520	5.1	13.5	8	10.5
	19	12/1216	5.0	18.2	15/1520	5.3	18.0	8	13.8
	29	12/1216	5.0	27.6	15/1520	5.3	27.3	8	22.3
	39	11/1114	5.0	37.8	15/1520	5.4	37.5	8	32.0
	59	11/1114	5.0	57.7	15/1520	5.3	57.3	8	51.2
	79	12/1216	5.0	77.3	15/1520	5.3	76.9	8	72.1
6	15	15/1520	6.0	13.1	15/1520	6.0	13.1	8	10.5
	19	15/1520	6.0	17.4	15/1520	6.0	17.4	8	14.6
	29	13/1317	6.0	27.5	15/1520	6.2	27.3	8	24.3
	39	14/1418	6.0	37.4	15/1520	6.1	37.3	8	33.3

	59	14/1418	6.0	57.5	15/1520	6.1	57.4	8	52.3
	79	12/1216	6.0	77.0	15/1520	6.3	76.7	8	73.6

Stent Labeled/ Nominal Diameter (mm)	Crimped Stent Length (mm)	At Nominal Pressure			At Rated Burst Pressure			At Max. Post-Dilated Stent Diameter ¹	
		Nominal Inflation Pressure (atm/kPa)	Final Stent ID (mm)	Stent Length ³ (mm)	Rated Burst Pressure (atm/kPa)	Final Stent ID (mm)	Stent Length ³ (mm)	Max. Post-Dilated Diameter (mm)	Stent Length at Max. Post-Dilated Stent Diameter ³ (mm)
7	15	15/1520	6.9	13.4	15/1520	6.9	13.4	11	9.5
	19	11/1114	6.9	17.7	15/1520	7.4	17.3	11	12.6
	29	11/1114	7.0	27.3	15/1520	7.4	26.8	11	19.4
	39	12/1216	7.0	37.0	15/1520	7.3	36.5	11	26.6
	59	12/1216	7.0	57.1	15/1520	7.3	56.7	11	46.9
	79	14/1418	7.0	77.3	15/1520	7.1	77.2	11	68.1
8	29	12/1216	8.0	26.9	13/1317	8.1	26.8	11	23.7
	39	12/1216	8.0	36.2	13/1317	8.1	36.1	11	30.0
	59	12/1216	8.0	56.1	13/1317	8.1	56.0	11	47.3
	79	11/1114	8.0	76.6	13/1317	8.3	76.4	11	69.6
8L	29	12/1216	8.0	29.0	13/1317	8.1	29.0	16 ²	21.8
	39	11/1114	8.0	39.0	13/1317	8.3	39.2	16 ²	26.8
	59	11/1114	8.0	59.4	13/1317	8.3	59.7	16 ²	44.1
	79	12/1216	8.0	79.3	13/1317	8.1	79.4	16 ²	58.6
9	29	11/1114	9.0	26.7	13/1317	9.3	26.4	13	20.4
	39	12/1216	9.0	36.3	13/1317	9.1	36.2	13	23.2
	59	11/1114	8.9	56.0	13/1317	9.2	55.7	13	38.1
	79	10/1013	8.9	76.2	13/1317	9.4	75.8	13	62.7
10	29	10/1013	10.0	25.4	13/1317	10.4	25.2	13	19.1
	39	11/1114	9.9	35.4	13/1317	10.2	35.3	13	31.1
	59	11/1114	10.0	55.3	13/1317	10.3	55.2	13	44.6
	79	11/1114	10.0	76.1	13/1317	10.3	76.2	13	68.4
11	29	10/1013	10.9	25.7	12/1216	11.4	25.4	16 ²	17.8
	39	11/1114	11.0	34.7	12/1216	11.2	34.6	16 ²	25.8
	59	10/1013	11.0	54.9	12/1216	11.4	54.5	16 ²	42.8
	79	10/1013	11.0	73.9	12/1216	11.5	73.7	16 ²	60.6

¹ Secondary balloon required to post-dilate the stent beyond its nominal deployed diameter (secondary balloon not included).

² Technical limit of the device as determined by *in-vitro* testing for the indicated use; device expansion beyond 13 mm was not studied as part of the VBX FLEX clinical study. Within the EMBRACE Registry maximum measured device expansion was 12.6 mm and flaring was performed with balloons up to 14 mm in diameter.

³ Based on idealized *in-vitro* conditions and provided to be used as a general guide.

⁴ The 19 mm length configuration is the minimum length for use as a bridging stent in fenestrated endovascular aortic repair (FEVAR)

⁵ The 29 mm length configuration is the minimum length for use as a bridging stent in branched endovascular aortic repair (BEVAR)

PACKAGE HANDLING

Store in a cool, dry place. This product has an expiration date and should be used before the labeled “Use By” (expiration) date marked on the box. The foil pouch for the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is both a moisture barrier and a sterile barrier. DO NOT use or store the device if the foil pouch has been compromised.

WARNINGS

General Warnings (All Applications):

- Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis for the treatment of lesions that would not allow an operative salvage procedure.
- Do not use the GORE® VIABAHN® VBX Balloon Expandable 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.^{1,2} If symptoms persist, or the health of the patient appears compromised, alternative pharmaceutical or surgical procedures, including ligation or removal of the device, may be considered at the discretion of the attending physician.
- Do not exceed the maximum rated burst pressure. Exceeding this pressure increases the potential for balloon rupture and possible vessel damage.
- Do not exceed the max. post-dilated stent diameter as per **Table 1** and **Table 2**.
- Care should be taken to ensure the device is sufficiently apposed to the vessel wall between initial device deployment and post-dilatation (if performed). Failure to do so may result in device displacement, endoleak, or migration.
- Special care should be taken to ensure that the appropriate size endoprosthesis, compatible sheath and guidewire are selected prior to introduction.
- Use only diluted contrast medium for balloon inflation (typically a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium in the balloon.
- Do not remove the endoprosthesis from the balloon delivery system. The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should not be removed and placed on another balloon catheter for deployment. The endoprosthesis should only be deployed using the supplied delivery system.
- Do not use a kinked introducer sheath. A kinked introducer sheath may increase the force necessary to advance the endoprosthesis to the desired location.
- Do not attempt to deploy the endoprosthesis or manipulate the delivery system without an appropriately sized guidewire (**Table 1**) and fluoroscopic guidance.
- Prior to endoprosthesis deployment, utilize high-resolution fluoroscopy to verify that stent has not been damaged, partially deployed or dislodged during positioning. Do not deploy the endoprosthesis if damaged, partially deployed or dislodged.
- Do not attempt to withdraw or reposition the balloon catheter within the lumen of the deployed endoprosthesis unless the balloon is completely deflated.
- Do not withdraw the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis back into the introducer sheath once the endoprosthesis is fully introduced. Withdrawing the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis back into the sheath can cause dislocation and/or damage to the endoprosthesis, premature deployment, deployment failure, and/or catheter separation. If removal prior to deployment is necessary, withdraw the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis to a position close to but not into the introducer sheath. Both the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis and introducer sheath can then be removed in tandem. After removal, do not reuse the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis or introducer sheath.
- Inadvertent, partial, or failed deployment or migration of the endoprosthesis may require surgical intervention.
- As with any balloon expandable stent, placement of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in vessels susceptible to severe external compression may result in permanent compression of the device.
- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is not indicated for use in the coronary arteries, coronary bypass grafts, coronary sinus or carotid arteries.

Stenotic Indication Warnings:

- To reduce the potential for vessel damage, the final stent inner diameter (as indicated on the compliance chart) should approximate the diameter of the vessel just proximal and distal to the stenosis. Overstretching of the artery may result in rupture and life threatening bleeding.

Bridging Stent Indication Warnings:

- Native vessel and fenestration/branch dimensions must be accurately measured, not estimated, to ensure the appropriately sized endoprosthesis is selected as a bridging stent.
- The 10 mm and 11 mm diameter GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis have not been clinically evaluated for use as bridging stents in the renal arteries through the EMBRACE Registry or GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) Pivotal Study.
- The 19 mm device does not meet the minimum recommended overlap requirements for FEVAR bridging. In the EMBRACE Registry, use of the 19 mm device was limited. Target vessel overlap of 10–15 mm in FEVAR was not associated with increased rates of displacement, migration, or endoleak. However, the literature identifies these complications as potential risks of inadequate proximal or distal overlap. When using the 19 mm device, prioritize achieving the recommended protrusion into the aortic endograft to allow flaring. Close monitoring is strongly recommended when choosing a device size that does not meet the anatomical requirements specified in the Sizing Section of the IFU.

- When used as a bridging stent for fenestrated or branched repair, utilize the required overlap and landing zone lengths with branches, fenestrations, overlapping VBX Devices, and target vessels to avoid device displacement, endoleak, or migration.
- When used as a bridging stent, confirm the target visceral vessel associated with each branch or fenestration before cannulation and device selection. Use of an incorrectly sized device may result in occlusion, vessel injury, or endoleak.
- Bridging stent 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.
- Lower branch primary patency rates were observed in specific clinical evaluations for certain patient subsets with renal artery diameters ≤ 5 mm compared to larger diameter renal arteries. Appropriate patient selection, procedural planning, and post-procedural surveillance are important considerations when treating smaller target vessels.
- Crossing of bridging stents is not recommended. Compromise to device integrity, including bridging stent compression and Aortic Component wire fracture, has been identified in clinical follow up under these conditions. Crossing bridging stents may lead to bridging stent occlusion, vessel damage, or endoleak.
- Incomplete long-term imaging follow-up in clinical evaluations of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent limits the ability to fully characterize late device-related adverse events. Published clinical experience suggests that the rate of compression, loss of patency, endoleak, and other target vessel complications are more likely to occur during long-term follow-up. Continued imaging surveillance is strongly recommended throughout the life of the implant.

PRECAUTIONS

- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is designed for single use only. 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. Reuse may result in infection, serious injury, or patient death.

- Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if the sterile package is compromised or the endoprosthesis is damaged.
- Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis after the labeled “Use By” (expiration) date.
- Do not resterilize the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should only be used by physicians trained in endovascular techniques.
- Follow the Directions for Use supplied with all accessories used in conjunction with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
- Antiplatelet medication should be initiated prior to and after placement of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Effective anticoagulation therapy, if needed, should be maintained at a dosage deemed appropriate by the physician. The presence of heparin on the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is not intended to serve as an alternative to the surgeon’s chosen intraoperative or postoperative anticoagulation regimens.
- Prep premounted endoprosthesis system per instructions given in Directions For Use. Significant amounts of air in the balloon may cause difficulty in deploying the endoprosthesis and deflation of the balloon.
- Do not attempt to manually remove or adjust the endoprosthesis on the delivery balloon catheter.
- Always manipulate the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis delivery system under fluoroscopy when in the body. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is not designed for use with power injection systems. Inflation at a high rate can cause damage to the balloon catheter. Use of a pressure monitoring device is recommended to prevent over pressurization.

MRI SAFETY INFORMATION **MR Conditional**

MRI Safety Information



MR Conditional

A patient with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis may be safely scanned immediately after placement under the following conditions. Failure to follow these conditions may result in injury.

Device Name	GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis
Static Magnetic Field Strength (B ₀)	1.5T or 3.0T
Maximum Spatial Field Gradient	10 T/m (1000 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	2W/kg (Normal Operating Mode)
Scan Duration	2W/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, the artifact may extend up to 15mm from the implant and does obscure the lumen.

MRI Compatibility Information for Bridging Stents Use with Fenestrated and Branched Aortic Endovascular Grafts (Applicable Regions Only)

GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) device

- When the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is used with the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) device, use of the TAMBE label is appropriate for MRI scans.

Other Fenestrated and Branched Aortic Endovascular Grafts:

- Consult the Fenestrated and Branched Aortic Endovascular Graft's Instructions for Use for the appropriate MRI Safety Information for the Aortic Endovascular Graft component.
- Consult the MRI Safety Information above for the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis when used as bridging stent components.
- If the scan conditions differ between the Aortic Endovascular Graft and the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, utilize the more restrictive scan conditions of the devices. The largest artifact of the combined system is approximated as the sum of the component artifacts.

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

HAZARDS AND ADVERSE EVENTS

Procedure Related: As with all procedures that utilize techniques for introducing a catheter into a vessel, complications may be expected. These complications include, but are not limited to: access site infection; entry site bleeding and/or hematoma; vessel thrombosis, occlusion, pseudoaneurysm, and trauma to the vessel wall (including rupture or dissection); distal embolization; arteriovenous fistula formation; transient or permanent contrast induced renal failure; renal toxicity; sepsis; shock; radiation injury; myocardial infarction; fever; pain; malposition; malapposition; inflammation; and/or death. A possible complication which may occur in conjunction with the use of systemic heparin: HIT type II.

Device Related: Complications and adverse events can occur when using any endovascular device. These complications include, but are not limited to: hematoma; stenosis, thrombosis or occlusion; distal embolism; side branch occlusion; vessel wall trauma and/or rupture; false aneurysm; infection; inflammation; fever and/or pain in the absence of infection; deployment failure; migration; and device failure. A possible complication which may occur in conjunction with the use of any heparin-containing product: HIT type II (see *Warnings*).

DIRECTIONS FOR USE

Materials Required For Implantation

- GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis
- Marker guidewire or catheter (for calibrated measurement reference)

- Syringe filled with heparinized saline for prepping the endoprosthesis system
- Introducer sheath of appropriate size (**Table 1**)
- Stiff guidewire: diameter must be 0.035" (0.89 mm)
- Guidewire length should be at least twice the length of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis delivery catheter
- Appropriate diagnostic catheters and accessories
- Inflation device (20 cc or greater) and diluted contrast medium

Additional Material Required for Bridging Stent Implantation

- When using a GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for fenestrated or branched repair, refer to the directions for use of the aortic endovascular grafts used in the procedure to aid in sizing, alignment, and deployment of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis within the aortic endovascular grafts fenestrations or branches.
- PTA Balloon(s) from any supplier; diameter, length, and catheter working length as appropriate for bridging stent devices selected.

Accessory, auxiliary, and ancillary materials (equipment, tools, and devices) should be used in accordance with the manufacturer's instructions for use. 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 and devices.

Treatment of Vessel

A. Access

1. Using appropriate anesthesia, access is achieved using the appropriate vessel. When possible, a percutaneous Seldinger technique is preferred. A cutdown may be performed when indicated.
2. Using standard technique, insert the appropriately sized angiographic vascular introducer sheath into the vessel.

B. Imaging and Measurement

1. To achieve accurate measurement and ensure precise sizing and placement of the endoprosthesis, use image-centered, magnified-view contrast angiography, including a marker guidewire or catheter.
2. When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in fenestrated and branched aortic endovascular repair, base proximal landing zones on aortic endovascular graft fenestration and branch dimensions, and distal landing zones on measured target vessel diameters.

C. Percutaneous Transluminal Angioplasty (PTA)

1. It is recommended to pre-dilate the lesion to allow for easy passage of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
2. Refer to manufacturer's Directions for Use.
3. Inflate the angioplasty balloon to its nominal pressure according to manufacturer's Directions for Use. Ensure full expansion of the balloon within the lesion.
Note: Carefully mark the margins of the angioplasty treatment segment in order to ensure complete coverage with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
4. Following deflation of the angioplasty balloon, evaluate the results angiographically. For reference, measure the native vessel diameter, lesion length, and residual percent stenosis.

D. Sizing and Selection of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

1. Prior to opening the sterile package, check that the diameter and length of the endoprosthesis as well as the delivery catheter length are correct before removing from the packaging.
 - a. In selecting the appropriate size endoprosthesis, a careful assessment of the vessel is necessary.
Stenotic or occlusive lesions: To reduce the potential for vessel damage, the final stent inner diameter (as indicated on the compliance chart) should approximate the diameter of the vessel just proximal and distal to the stenosis. To prevent endoprosthesis migration, care should be taken to ensure the device is sufficiently apposed to the vessel wall between initial device deployment and post-dilatation (if performed).
 - b. The endoprosthesis lengths of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis listed in **Table 1** are nominal. Wherever appropriate, it is recommended that the endoprosthesis overlap the native vessel at least 1 cm beyond the proximal and distal margins of the lesion when treating stenotic or occlusive lesions. Endoprosthesis foreshortening should be taken into account to achieve the recommended lesion coverage.
 - c. Verify that there is sufficient catheter length to access the treatment site.

d. **Bridging Stent:**

Fenestrated Bridging Stent: When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for fenestrated endovascular aneurysm repair (FEVAR) the following is required to ensure adequate anchoring and seal:

- Fenestration:

- **Diameter:** The inflated diameter of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis within the fenestration should approximate the maximum inner diameter of the fenestration.
- **Length:** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should have 5-10 mm protrusion in the aortic endovascular graft lumen for flaring.
- **Flaring:** Utilize an angioplasty balloon with a diameter ≥ 2 mm larger than the fenestration diameter to flare the proximal portion of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis that extends into the lumen of the aortic endovascular graft.
- When flaring, do not expand the stent beyond the maximum post-dilated stent diameter shown in **Table 2**.

- Visceral Vessel:

- **Diameter:** The final stent inner diameter should approximate the diameter of the native healthy vessel, with a final stent diameter 10% greater than the diameter of the native artery being acceptable.
- **Length:** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should have ≥ 15 mm overlap into the landing zone of each visceral vessel (renal, celiac, and superior mesenteric arteries).

Branched Bridging Stent: When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for Branched Endovascular Aneurysm Repair (BEVAR) the following is required to ensure adequate anchoring and seal:

- Aortic Endovascular Graft Branch:

- **Diameter:** The final stent inner diameter of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis contained within the branch (portal, cuff, or directional branch) should approximate the diametric dimensions of the aortic endovascular graft branch.
- **Branches < 15 mm in Length:** Ensure length of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is sufficient to meet vessel overlap requirements and have 5-10 mm extension beyond the branches (portal, cuff or directional branch) inlet to be flared.
- **Flaring for Branches < 15 mm in Length:** Use an appropriately sized balloon catheter to flare the proximal end of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis outside the branch 1-2 mm greater than branch diameter.
- **Note:** Depending on desired diameter, the balloon on which the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is mounted may be used to flare the proximal end of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if it can reach the appropriate diameter (1-2 mm larger than the aortic endovascular graft branch diameter).
- **Branches ≥ 15 mm in Length:** Ensure complete apposition along the overlapping length between the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis and the aortic endovascular graft branch.

Note: The requirement not to flare in branches ≥ 15 mm in length is supported by literature, physician experience, and current clinical practice. Longer branch designs rely on full apposition along the branch for fixation and sealing, while shorter branch designs require proximal protrusion and flaring.

- Visceral Vessel:

- **Diameter:** The final stent inner diameter should approximate the diameter of the native healthy vessel, with a final stent diameter 10% greater than the diameter of the native artery being acceptable.
- **Length:** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should have ≥ 15 mm overlap into the landing zone of each visceral vessel (renal, celiac, and superior mesenteric arteries).

2. **Overlapping Requirements for Overlapping Multiple GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis;** When overlapping (telescoping) multiple devices, the following are suggested:

- Endoprosthesis foreshortening should be taken into account to achieve the recommended overlap between devices. To ensure proper seating between devices, follow the suggested overlap requirements.
 - For occlusive disease at least 1 cm of overlap between devices is recommended.
 - When used as a bridging stent, at least 2 cm of overlap between devices is recommended.
- Overlapping devices should not differ by more than 1 mm in deployed diameter.
- If a bridging stent extension is planned with devices of differing deployed diameters, the smaller diameter device should be deployed first.
- When using multiple endoprostheses to treat multiple lesions, it is recommended, wherever appropriate, to first treat the lesion that would obviate the need to cross the first endoprosthesis when placing the second or

subsequent endoprosthesis. This would reduce the chance of disrupting or damaging the endoprotheses.

- e. Balloon touch-up (post-dilatation) should be performed at the overlap region.
- 3. When deploying into a tapered vessel, consider the following:
 - a. **Stenotic or occlusive lesions:** To reduce the potential for vessel damage, the final stent inner diameter should approximate both the proximal and distal reference vessel diameters. This is possible when the device is deployed in a tapered configuration.

Fenestrated and Branched Bridging Stent: The following is required to assure adequate anchoring and seal:

- Visceral Vessel:

- **Diameter:** The final stent inner diameter should approximate the diameter of the native healthy vessel, with a final stent diameter 10% greater than the diameter of the native artery being acceptable.

Note: For achievable diameters using the provided delivery system, refer to the compliance chart. For achievable diameters using a secondary balloon during post-dilatation, refer to **Table 1** and **Table 2** under the max. post-dilated stent diameter.

- Device tapering may be performed by first deploying the device to the smaller of the two reference vessel diameters and subsequently post-dilating the device in the region of the larger reference vessel diameter. To prevent endoprosthesis migration, care should be taken to ensure the device is sufficiently apposed to the vessel wall between initial device deployment and post-dilatation.
- When post-dilating with another balloon, choose a balloon length smaller than the deployed endoprosthesis length. Do not extend balloon dilatation beyond the ends of the endoprosthesis and into healthy vessel as this may also induce restenosis and subsequent failure. Do not expand any portion of the stent beyond the maximum post-dilated diameter as listed in **Table 1** and **Table 2**.
- When post-dilating the 8L device with a larger diameter balloon, do not increase the device diameter by more than 4 mm with a single balloon inflation. For example, to obtain a final diameter >12 mm from the nominal 8 mm diameter, first post-dilate with a 12 mm diameter secondary balloon before post-dilating with a larger diameter (13-16 mm) secondary balloon.

E. Preparation of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

- Open the sterile package. Carefully inspect the packaging for damage to the sterile barrier. Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis after the “Use By” (expiration) date. Peel back the outer pouch and remove the sterile inner pouch and coil containing the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Beginning at one corner, peel back the edge of the inner pouch and gently remove the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
- Inspection Prior to Use:
 - Prior to using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, all materials and equipment to be used for the procedure should be carefully examined for bends, kinks, or other damage.
 - Do not use any damaged or defective equipment and materials.
 - Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if the sterile package is compromised or the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is damaged.
- The distal end of the delivery catheter with the crimped endoprosthesis may be shaped or formed gently around a radius of about 6 mm or greater, prior to loading the catheter on a guidewire, to assist with trackability of the delivery system. Care should be taken to ensure that the metal stent rings are not deformed, displaced or damaged while shaping or forming.
- Preparation of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis delivery catheter:
 - Flush the delivery catheter by attaching a syringe of heparinized saline to the guidewire lumen port on the catheter hub assembly (**Figure 2**). Continue flushing until a steady stream of fluid exits the tip of the catheter.
 - After flushing the catheter, remove the syringe.
 - Prepare inflation device/syringe with diluted contrast medium. The standard inflation medium is a 50/50 mixture of contrast medium and normal saline or as deemed appropriate by the physician.
 - Attach inflation device/syringe to stopcock (if needed). Attach to the endoprosthesis system inflation port.
 - Open stopcock to the endoprosthesis system. With the distal balloon tip pointing down and placed below the level of the inflation device/syringe, pull negative pressure for 20-30 seconds. Carefully release to neutral for contrast fill. Do not apply any positive pressure at this time as it may result in partial deployment.
 - Close stopcock to the endoprosthesis system; purge inflation device/syringe of all air.
 - Repeat the previous two steps until all air is expelled. If bubbles persist, do not use the endoprosthesis system.
 - If a syringe was used for preparation, attach a prepared inflation device to stopcock.
 - Open stopcock between the endoprosthesis system and the inflation device.

F. Introduction and Positioning of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

- Select the compatible size introducer sheath from **Table 1**. Always use an appropriately sized sheath for the implant procedure. It is advisable to use a sheath or guide catheter that is long enough to cross the lesion. Use of a guide sheath or guide catheter minimizes the risk of dislodging the endoprosthesis from the balloon during tracking. Use standard interventional techniques to introduce the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis to the target lesion or intended location.
- Ensure the stiff guidewire is 0.035" (0.89 mm).

3. Be sure to remove the balloon catheter while maintaining the position of the guidewire beyond the target lesion or intended location. It is strongly recommended that the guidewire remain across the lesion until the procedure is complete to avoid having to regain access.
4. With the delivery catheter as straight as possible, insert the guidewire into the tip of the delivery catheter while supporting the delivery catheter and the endoprosthesis. Carefully advance the endoprosthesis in small increments (approximately 0.5 cm) over the guidewire, through the hemostasis valve and introducer sheath, and into the access vessel. **Note:** If excessive resistance is felt as the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is introduced through the hemostasis valve, remove and inspect the delivery catheter for damage. Do not reuse the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if damaged or if the covered stent is fluoroscopically observed to be displaced relative to the radiopaque markers on the delivery catheter. Ensure a compatible introducer sheath size (Table 1) is used, and that the introducer sheath is free of kinks. Do not insert the shrink sleeve or the hub assembly into the introducer sheath.
5. Using fluoroscopic guidance, advance the delivery catheter over the guidewire via the angiographic sheath. Advance cautiously, especially if resistance is felt. If excessive resistance is felt, remove the delivery catheter and sheath together as a unit.
6. Position the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis across the target lesion or intended location under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers (denoting the effective balloon length) as well as the radiopaque endoprosthesis as reference points to position the endoprosthesis in the lesion or intended location.
Note: Upon deployment, the ends of the endoprosthesis will be located inside the effective length of the balloon, away from the radiopaque markers, due to longitudinal foreshortening. Endoprosthesis foreshortening should be taken into account to achieve the desired lesion coverage and overlap with targeted landing zones. During positioning, verify that the endoprosthesis is still centered within the marker bands and has not been dislodged. Do not deploy the endoprosthesis unless it is properly centered on the balloon and properly positioned within the target lesion or intended location. If the position of the endoprosthesis within the lesion or intended location is not optimal, it should be carefully repositioned or removed.
NOTE: If PTA is performed, the endoprosthesis length should cover the entire vessel segment treated with balloon angioplasty.

Stenotic or Occlusive Lesion Positioning: Wherever appropriate, it is recommended that the endoprosthesis extend at least 1 cm proximal and distal to the margins of the lesion.

Bridging Stent Positioning:

Fenestrated Bridging Stent:

- Fenestration:
 - **Protrusion:** When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for FEVAR ensure the device protrudes 5-10 mm inside the aortic endovascular graft lumen for flaring.
- Visceral Vessel:
 - **Overlap:** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should have ≥ 15 mm overlap into the landing zone of each visceral vessel (renal, celiac, and superior mesenteric arteries).

Branched Bridging Stent:

- Aortic Endovascular Graft Branch:
 - **Overlap for Branches < 15 mm in Length:** Ensure length is sufficient to meet vessel overlap requirements and have 5-10mm extension beyond the branch (portal, cuff, or directional branch) inlet to be flared.
 - **Overlap for Branches ≥ 15 mm in Length:** When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for BEVAR it is recommended to ensure complete apposition along the overlapping length within the aortic endovascular graft branch.
- Visceral Vessel:
 - **Overlap:** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should have ≥ 15 mm overlap into the landing zone of each visceral vessel (renal, celiac, and superior mesenteric arteries).

7. Once the optimal position is verified fluoroscopically, the endoprosthesis is ready to be deployed.
NOTE: Should it become necessary to remove either a partially expanded or non-deployed GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis from the vessel, do not withdraw the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis back into the introducer sheath after the endoprosthesis is fully introduced. To remove the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, it can be withdrawn to a position close to but not into the introducer sheath. Both the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis and introducer sheath can then be removed in tandem. After removal, neither the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis nor the introducer sheath should be reused. Do not attempt to pull an endoprosthesis system that has been either partially expanded or not expanded back into the sheath or guide catheter, as dislodgement of the endoprosthesis from the balloon may occur. Carefully observe the endoprosthesis for stent dislodgement or movement while attempting to withdraw the undeployed stent back through the sheath.

G. Deployment of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

1. Stabilize the delivery catheter at the hemostasis valve of the introducer sheath. It is also important to stabilize

the delivery catheter and introducer sheath relative to the patient. This will minimize catheter movement during deployment and ensure accurate endoprosthesis positioning.

2. Deployment Instructions by Indication:

Stenotic or occlusive lesions: To reduce the potential for vessel damage, the final stent inner diameter (as indicated on the compliance chart) should approximate the diameter of the vessel just proximal and distal to the stenosis.

Fenestrated Bridging Stent: When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for FEVAR, the following is required to ensure adequate anchoring and seal:

- **Fenestration:**

- **Diameter:** The inflated diameter of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis within the fenestration approximates the maximum inner diameter of the fenestration.
- **Flaring:** Proceed by flaring the proximal portion of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis that extends into the lumen of the aortic endovascular graft using an angioplasty balloon with a diameter ≥ 2 mm larger than the fenestration diameter.
- When Flaring, do not expand the stent beyond the maximum post-dilated stent diameter shown in **Table 1** and **Table 2**.

- **Visceral Vessel:**

- **Diameter:** The final stent inner diameter should approximate the diameter of the native healthy vessel, with a final stent diameter 10% greater than the diameter of the native artery being acceptable.

Branched Bridging Stent: When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for BEVAR, the following is required to ensure adequate anchoring and seal:

- **Aortic Endovascular Graft Branch:**

- **Diameter for all Branch Lengths:** The final stent inner diameter of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis contained within the branch approximates the diametric dimensions of the aortic endovascular graft branch.
- **Flaring for Branches < 15 mm in Length:** Use an appropriately sized balloon catheter to flare the proximal end of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis outside the branch 1-2 mm greater than branch diameter.
Note: Depending on desired diameter, the balloon on which the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is mounted may be used to flare the proximal end of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if it can reach the appropriate diameter (1-2 mm larger than the aortic endovascular graft branch diameter).

- **Visceral Vessel:**

- **Diameter:** The final stent inner diameter should approximate the diameter of the native healthy vessel, with a final stent diameter 10% greater than the diameter of the native artery being acceptable.

3. To deploy the endoprosthesis, use an inflation device to slowly inflate the endoprosthesis system to the pressure needed for the desired diameter. Maintain the inflation pressure for approximately 15 seconds. Higher pressure may be necessary to overcome any luminal loss due to the lesion, vessel, fenestration, or branch to overcome stent recoil. Balloon pressures must not exceed rated burst pressure (Refer to **Table 1**). Extreme oversizing of the endoprosthesis relative to the vessel diameter may cause vessel damage. Undersizing of the endoprosthesis relative to the vessel diameter may lead to endoprosthesis migration. The compliance charts, provided on the box label, are generated in idealized *in vitro* conditions that do not take into account *in vivo* characteristics of lesions, vessels and patient-to-patient variability. Therefore, the compliance chart should be used as a general guide and user should confirm stent diameter and length angiographically during and after balloon inflation and deflation.
4. After deploying the endoprosthesis, slowly deflate the balloon manually using the inflation device to ensure proper balloon rewrap/refold. Allow adequate time for the balloon to fully deflate prior to removal. Observe fluoroscopically that the balloon is fully deflated prior to removal.
5. Maintaining proper sheath or guide catheter support, very slowly withdraw the balloon. Observe under fluoroscopy to ensure that the balloon disengages from the stent. If resistance is encountered upon attempted removal, do not force removal, use fluoroscopy and conventional techniques to determine and remedy the cause of resistance before proceeding. The balloon needs to be fully deflated to ensure it disengages fully from the endoprosthesis.
6. Confirm endoprosthesis position and deployment using angiographic techniques. For optimal results, the entire lesion should be covered by the stent. For bridging stent applications, the device should have a minimum landing zone of 15 mm into the target vessel. Fluoroscopic visualization should be used in order to properly judge the optimum expanded endoprosthesis diameter as compared to the proximal and distal reference vessel, fenestration, or branch diameters.
7. If re-sizing is necessary, re-advance the delivery catheter, or another balloon catheter of appropriate size, to the stented area using standard interventional techniques.

8. While observing under fluoroscopy, inflate the balloon to the desired pressure; do not exceed the rated burst pressure. Do not expand the stent beyond maximum post-dilated stent diameter as shown in **Table 1** and **Table 2**. The maximum post-dilated stent diameter of 16 mm listed in **Table 1** and **Table 2** indicates the technical limit of the device as determined by in vitro testing for the indicated use. Device expansion beyond the diameter noted in the indication statement (13 mm) was not studied as part of the VBX FLEX clinical study. Within the EMBRACE Registry, maximum measured device expansion was 12.6 mm and flaring was performed with balloons up to 14 mm in diameter. When using another balloon to post-dilate, choose a balloon length smaller than the deployed endoprosthesis length. Do not extend balloon dilatation beyond the ends of the endoprosthesis and into healthy vessel as this may also induce restenosis and subsequent failure. Deflate the balloon and follow the instructions as outlined previously.
9. Reconfirm endoprosthesis position and angiographic result. Repeat inflations until the desired result is achieved.
10. While maintaining negative pressure in the balloon and the guidewire position across the treated lesion, carefully remove the delivery catheter from the body through the sheath or guide catheter. Moderate resistance may be felt when the balloon is withdrawn through the introducer sheath.
NOTE: If, during catheter removal, the balloon catches on the leading edge of the introducer sheath, a slight “back and forth” motion of the catheter may aid in release. If needed, the delivery catheter and the sheath or guide catheter may be removed together as a unit. Excessive or abrupt force during catheter removal may damage the delivery catheter, or introducer sheath.
11. A final angiographic run to evaluate vessel patency is recommended.
12. When clinically appropriate, remove the introducer sheath or guide catheter and achieve hemostasis of the puncture site.
13. Deployment of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in the kissing stent configuration/technique is recommended when proximal common iliac disease (unilateral or bilateral) cannot be adequately covered without extending into the aortic bifurcation, or when the disease involves the aortic bifurcation. Device selection should be made to ensure that the final stented length properly covers the lesion. The two devices are advanced to the target location and the stent-grafts are deployed simultaneously. Additional devices may be deployed in an overlapping configuration to achieve proper lesion coverage. Any post-dilation in the kissing stent region should be conducted bilaterally and simultaneously to avoid crushing either device.

SUMMARY OF CLINICAL STUDIES

Clinical Evidence Supporting Use in Stenotic/Occlusive Disease:

The VBX FLEX clinical study was a prospective, multicenter, single-arm clinical study to evaluate the safety and efficacy of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis for the treatment of arterial occlusive disease in patients with de novo or restenotic lesions in the common and/or external iliac arteries. The primary study endpoint was a composite of major adverse events defined as device- or procedure-related death within 30 days; myocardial infarction (MI) within 30 days; amputation above the metatarsals in the treated leg, resulting from a vascular event, within 9 months; or target lesion revascularization (TLR) within 9 months. The statistical analysis plan prospectively specified that subjects meeting all of the eligibility criteria would be used for analysis of study endpoints. A sensitivity analysis was performed for testing the primary hypothesis in the intent-to-treat (ITT) population, which included all enrolled subjects, as well as the per-protocol (PP) population which included only those subjects who met the study inclusion criteria. The performance goal was met in both analyses with p-values <0.001, providing evidence for similarity of the results between the two populations. All endpoint data reported is based on the PP population, unless otherwise specified.

A. Study Design

The study population included symptomatic (Rutherford Category 2-4) patients with angiographic confirmation of either de novo or restenotic unilateral or bilateral occlusive disease in the common and/or external iliac arteries, with a total treated lesion length of ≤110 mm and vessel diameters between approximately 5 mm and 13 mm. Patients were included who presented with up to two discrete lesions requiring treatment, either one lesion per side for patients presenting with bilateral disease, or two lesions on the same side. All subjects could be treated with up to three GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Eligible patients in the study included those presenting with tortuous iliac arteries, severe lesion calcification, total occlusions, and those determined to need direct stenting (pre-dilatation optional) and/or kissing stent treatment at the aortic bifurcation. 134 subjects meeting all eligibility criteria were enrolled across 26 sites in U.S. and 1 site in New Zealand.

B. Clinical Endpoints

1. **Primary Endpoint**
The primary study endpoint was a composite of major adverse events (MAE) defined as device- or procedure-related death within 30 days; MI within 30 days; amputation above the metatarsals in the treated leg, resulting from a vascular event, within 9 months; or TLR within 9 months. The objective of the VBX FLEX clinical study was to demonstrate that the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is safe and effective for treatment of iliac artery disease by comparing the composite primary endpoint result to a pre-specified Performance Goal of 17.0%.
2. **Secondary Endpoints**
The secondary endpoints in this study included acute procedural success, 30-day clinical success, primary patency, primary assisted patency, secondary patency, freedom from TLR, freedom from clinically-driven TLR, freedom from target vessel revascularization (TVR), freedom from clinically-driven TVR, change in Rutherford category, change in ankle-brachial index (ABI), and change in functional status (based on subject questionnaires). All of these secondary outcomes were evaluated descriptively without any pre-specified performance criteria.

C. Demographics and Clinical Characteristics

Table 3 reports the baseline demographics and clinical characteristics for all 134 subjects.

Table 3. Baseline Demographics and Clinical Characteristics

	N=134 subjects
Gender at Birth	
Male	79 (59.0%)
Age	
Mean (Std Dev)	66 (9.5)
Race	
American Indian or Alaskan Native	3 (2.2%)
Asian	2 (1.5%)
Black or African American	4 (3.0%)
Native Hawaiian or Pacific Islander	0 (0.0%)
White	123 (91.8%)
Other Race	3 (2.2%)
Medical History and Risk Factors	
Smoking History	
Never Smoked	7 (5.2%)
Quit ≤ 1 Year Ago	18 (13.4%)
Quit 1-5 Years Ago	8 (6.0%)
Quit > 5 Years Ago	43 (32.1%)
Current User	58 (43.3%)
Diabetes	38 (28.4%)
Hypertension	113 (84.3%)
Hyperlipidemia	104 (77.6%)
Hypercholesterolemia	64 (47.8%)
Coronary Artery Disease	56 (41.8%)
Previous Myocardial Infarction	25 (18.7%)
Prior Treatment on Study Limb	22 (16.4%)
Prior Treatment on Non-Study Limb	13 (9.7%)
Rutherford	
Category 2 - Moderate Claudication	26 (19.4%)
Category 3 - Severe Claudication	101 (75.4%)
Category 4 - Ischemic Rest Pain	7 (5.2%)
TASC II Classification	
Type A	50 (37.3%)
Type B	41 (30.6%)
Type C	32 (23.9%)
Type D	11 (8.2%)

Table 4 reports the baseline anatomic and lesion characteristics for all 134 subjects.

Table 4. Baseline Anatomic and Lesion Characteristics

By Subject	
Access Approach¹	N=134
Ipsilateral	27 (20.1%)
Contralateral	24 (17.9%)
Bilateral	83 (61.9%)
Treated Segments¹	N=134
1	59 (44.0%)
2	71 (53.0%)
3	4 (3.0%)
Treated Limb(s)¹	N=134
Right	29 (21.6%)
Left	38 (28.4%)
Bilateral	67 (50.0%)

Kissing Stent Procedure	57 (42.5%)
Total Lesion Length per Subject (mm)²	N=132
Mean (Std Dev)	42.08 (23.98)
Total Stented Length per Subject (mm)²	N=133
Mean (Std Dev)	72.09 (29.39)
Number of Devices per Subject²	N=134
1	51 (38.1%)
2	69 (51.5%)
3	12 (9.0%)
4	1 (0.7%)
5	1 (0.7%)
By Limb	
Resting ABI¹	N=199
Mean (Std Dev)	0.77 (0.22)
Treated Vessel(s)¹	N=201
CIA	154 (76.6%)
EIA	31 (15.4%)
CIA and EIA	16 (8.0%)
Device(s) Successfully Delivered¹	N=201 100%
Max Post-Procedure Residual Stenosis ≤ 30%¹	N=201 100%
By Lesion	
Disease Characterization²	N=210
Stenosis	182 (86.7%)
Occlusion	28 (13.3%)
Maximum Stenosis (%)²	N=182
Mean (Std Dev)	62.1 (15.9)
Lesion Length (mm)²	N=209
Mean (Std Dev)	26.6 (16.3)
Stented Length (mm)²	N=212
Mean (Std Dev)	45.2 (14.4)

¹ Site reported.

² Core lab determination.

D. Methods

Following enrollment at the index procedure, all evaluable subjects were assessed at 1 month (± 7 days) and 9 months (± 30 days) post-index procedure. The severity of adverse events was determined by the site investigator based on the ISO 14155 definition of serious and non-serious adverse events. All adverse events were reviewed and adjudicated by the Clinical Events Committee. The Clinical Events Committee determined the final relationship of each adverse event and categorized each adverse event as device-related, index procedure-related, disease-related, unrelated to device, procedure, or disease, or unknown relationship. The Data Safety and Monitoring Board provided oversight of safety trends and reviewed site reported protocol deviations and source data related to subject eligibility. Independent core laboratories evaluated angiographic and ultrasound imaging obtained during the study procedure and at follow-up visits.

E. Safety and Effectiveness Results

1. Primary Endpoint

The primary endpoint result consisted of a composite of Major Adverse Events (**Table 5**). No device- or procedure-related deaths and no myocardial infarctions for any subjects were reported within 30 days of the study procedure. No major amputations for any subjects were reported within 9 months of the study procedure. TLR was reported for 3 subjects within the 9 month follow-up interval. The GORE[®] VIABAHN[®] VBX Balloon Expandable Endoprosthesis demonstrated safety and effectiveness since the composite MAE of 2.3%, with the upper limit of the 95% confidence interval at 6.5%, was less than the performance goal of 17.0% (p<0.001).

Table 5. Primary Endpoint

Primary Endpoint	Number (Fraction) [95% CI]
Subjects Available for Assessment	N=132
Composite MAE	3 (2.3%) [0.5%, 6.5%]
P-Value	<0.001
Device or Procedure Related Death Within 30 Days	0 (0.0%) [0%, 2.3%]
MI Within 30 Days	0 (0.0%) [0%, 2.3%]
TLR Within 9 Months	3 (2.3%) [0.5%, 6.5%]
Major Amputation Within 9 Months	0 (0.0%) [0%, 2.3%]

2. Secondary Endpoints and additional analyses

Acute Procedural Success was defined as $\leq 30\%$ residual stenosis prior to procedure completion and no device- or procedure-related serious adverse events (SAEs) before discharge. Thirty-day Clinical Success was defined as an improvement of at least one Rutherford Category at the 30-day visit as compared to pre-procedure and no device- or procedure-related SAEs within 30 days of the index procedure. Primary patency was defined as blood flow in the treated segment(s), without reintervention. Acute procedural success was 97.0% (N=134 subjects). Results of all other secondary endpoints at the pre-determined follow-up are summarized in **Table 6**. Kaplan-Meier estimates of survival probability at 1 month and 9 months are shown for primary patency, primary assisted patency, secondary patency, freedom from TLR, freedom from clinically-driven TLR, freedom from TVR, and freedom from clinically-driven TVR. Upon discharge, there were no instances of residual stenosis greater than 30% (**Table 4**). Four subjects experienced 5 SAEs before discharge, resulting in a 97.0% acute procedural success rate. One subject did not show evidence of blood flow through the treated segment at 1 month follow-up yet no treatment was attempted, therefore resulting in 99.2% primary patency, primary assisted patency, and secondary patency at 30 days but 100% freedom from TLR at 30 days.

Table 6. Secondary Endpoints, by Subject¹

Endpoint	1 Month	9 Months
30-Day Clinical Success	90.8% (N=119)	N/A
Primary Patency	99.2% (N=128)	96.7% (N=98)
Primary Assisted Patency	99.2% (N=128)	99.2% (N=101)
Secondary Patency	99.2% (N=128)	99.2% (N=101)
fTLR	100% (N=133)	97.7% (N=109)
fCD-TLR	100% (N=133)	98.4% (N=110)
fTVR	100% (N=133)	97.7% (N=109)
fCD-TVR	100% (N=133)	97.7% (N=109)
Change in Rutherford From Pre-Procedure	Worsened / Maintained / Improved 0.8% / 5.1% / 94.1% (N=118)	Worsened / Maintained / Improved 0.0% / 5.4% / 94.6% (N=112)
Change in ABI From Pre-Procedure¹ Mean (Std Dev)	0.19 (0.22) (N=172)	0.19 (0.22) (N=168)
Change in Functional Status From Pre-Procedure		
EQ-5D	Worsened / Maintained / Improved	Worsened / Maintained / Improved
Mobility	6.1% / 49.6% / 44.3% (N=115)	3.5% / 54.4% / 42.1% (N=114)
Self-Care	1.7% / 93.9% / 4.3% (N=115)	2.6% / 92.1% / 5.3% (N=114)
Usual Activities	7.0% / 47.8% / 45.2% (N=115)	3.5% / 50.0% / 46.5% (N=114)
Pain / Discomfort	8.7% / 42.6% / 48.7% (N=115)	8.8% / 48.2% / 43.0% (N=114)
Anxiety / Depression	5.2% / 71.3% / 23.5% (N=115)	6.1% / 69.3% / 24.6% (N=114)
Own Health State (1 - 100)	7.0% / 73.7% / 19.3% (N=114)	15.0% / 64.6% / 20.4% (N=113)
WIQ	Median (IQR)²	Median (IQR)²
Differential Diagnosis	2 (0, 4) (N=115)	1 (0, 4) (N=114)
Walking Distance	10 (3, 19) (N=115)	10 (3, 18) (N=114)
Walking Speed	5 (1, 8) (N=114)	5 (0, 9) (N=114)
Stair Climbing	4 (1, 8) (N=107)	4 (0, 7) (N=110)

¹ ABI reported on per-limb basis.

² Higher scores indicate a healthier state.

Since a significant fraction of the overall population received kissing stents (42.5%, **Table 4**), additional analysis of the composite primary endpoint was conducted for this subgroup (**Table 7**).

Table 7. Primary Endpoint for the Kissing Stent Subgroup

Primary Endpoint - Kissing Stent Subgroup	Number (Fraction) [95% CI]
Subjects Available for Assessment	N=57
Composite MAE	2 (3.5%) [0.4%, 12.1%]
Device or Procedure Related Death Within 30 Days	0 (0.0%) [0%, 5.3%]
MI Within 30 Days	0 (0.0%) [0%, 5.3%]
TLR Within 9 Months	2 (3.5%) [0.4%, 12.1%]
Major Amputation Within 9 Months	0 (0.0%) [0%, 5.3%]

A description of all adjudicated/unrefuted SAEs through 9 months is provided in **Table 8**. Two (2) patients were censored from the primary endpoint analysis. The reasons for discontinuation (missing data) were lost to follow-up and death. This death occurred on Day 187 and was not associated with the study device or procedure. This death was related to subject co-morbidities that resulted in cardiac arrest. No subjects experienced a SAE related to the study device within 9 months. There were no unanticipated device-related events reported in the study within 9 months.

Table 8. Description of Serious Adverse Events Through 9 Months

Subjects Enrolled	134
Subjects Experiencing Serious Adverse Events	30 (22.4%) [43]
Blood and Lymphatic System Disorders	1 (0.7%) [1]
Haemorrhagic Anaemia	1 (0.7%) [1]
Cardiac Disorders	4 (3.0%) [4]
Acute Myocardial Infarction	1 (0.7%) [1]
Angina Pectoris	1 (0.7%) [1]
Cardiac Failure Congestive	1 (0.7%) [1]
Coronary Artery Disease	1 (0.7%) [1]
Gastrointestinal Disorders	3 (2.2%) [3]
Gastrointestinal Haemorrhage	1 (0.7%) [1]
Rectal Haemorrhage	1 (0.7%) [1]
Umbilical Hernia	1 (0.7%) [1]
General Disorders and Administration Site Conditions	2 (1.5%) [2]
Non-Cardiac Chest Pain	1 (0.7%) [1]
Vascular Stent Occlusion	1 (0.7%) [1]
Infections and Infestations	4 (3.0%) [4]
Clostridium Difficile Infection	1 (0.7%) [1]
Pneumonia	1 (0.7%) [1]
Postoperative Wound Infection	1 (0.7%) [1]
Urinary Tract Infection	1 (0.7%) [1]
Injury, Poisoning, and Procedural Complications	8 (6.0%) [10]
Arterial Restenosis	1 (0.7%) [1]
Humerus Fracture	1 (0.7%) [1]
Incisional Hernia	1 (0.7%) [1]
Joint Dislocation	1 (0.7%) [1]
Post Procedural Haematoma	1 (0.7%) [1]
Postoperative Ileus	1 (0.7%) [1]
Vascular Pseudoaneurysm	2 (1.5%) [2]
Wound Dehiscence	2 (1.5%) [2]
Metabolism and Nutrition Disorders	1 (0.7%) [1]
Hyperkalaemia	1 (0.7%) [1]
Neoplasms Benign, Malignant and Unspecified (including cysts and polyps)	2 (1.5%) [2]
Lung Adenocarcinoma	1 (0.7%) [1]
Prostate Cancer	1 (0.7%) [1]
Nervous System Disorders	2 (1.5%) [2]
Carotid Artery Stenosis	1 (0.7%) [1]
Vascular Dementia	1 (0.7%) [1]
Renal and Urinary Disorders	1 (0.7%) [1]
Acute Kidney Injury	1 (0.7%) [1]

Respiratory, Thoracic, and Mediastinal Disorders	1 (0.7%) [1]
Chronic Obstructive Pulmonary Disease	1 (0.7%) [1]
Vascular Disorders	8 (6.0%) [11]
Femoral Artery Dissection	1 (0.7%) [1]
Haematoma	1 (0.7%) [1]
Hypovolaemic Shock	1 (0.7%) [1]
Intermittent Claudication	2 (1.5%) [3]
Lymphocele	1 (0.7%) [1]
Peripheral Arterial Occlusive Disease	1 (0.7%) [1]
Peripheral Artery Stenosis	1 (0.7%) [1]
Peripheral Ischaemia	1 (0.7%) [1]
Poor Peripheral Circulation	1 (0.7%) [1]

- Results by Gender
No statistically significant difference in the primary endpoint was observed based on gender.
- Applicability to Pediatric Population
Peripheral artery disease is not typically found in pediatric populations. The VBX FLEX clinical study did not evaluate the safety and effectiveness of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in the pediatric population.
- Summary of Results
The primary endpoint for the VBX FLEX clinical study consisted of a composite of major adverse events to evaluate the safety and effectiveness of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis through 9 months. The composite MAE of 2.3%, with the upper limit of the 95% confidence interval at 6.5%, was less than the performance goal of 17.0% (p<0.001). Within 9 months, no subjects experienced a SAE related to the study device and there were no unanticipated device-related events reported. Additionally, secondary endpoints including Rutherford status and functional status improved through 9 months follow-up, providing evidence of relief from clinical symptoms and a corresponding increase in quality of life. In conclusion, the VBX FLEX clinical study demonstrated that the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is safe and effective in treating subjects with de novo or restenotic lesions found in iliac arteries.

POST-APPROVAL STUDY

As a condition of US FDA pre-market approval of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, W. L. Gore & Associates continued to collect long-term follow-up data in the form of a Post-Approval study.

SUMMARY OF GORE® VIABAHN® VBX BALLOON EXPANDABLE ENDOPROSTHESIS
POST-APPROVAL STUDY METHODS

The objective of the post-approval study was to evaluate the long terms safety and effectiveness of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Prospective, multicenter subject follow-up data from 27 clinical sites was collected from active pivotal study subjects up to 36 months post-treatment. The post-approval study endpoints were the following:

Table 9. Post-Approval Study Primary Endpoint

Post-Approval Primary Endpoint
Freedom from target lesion revascularization (TLR) at 36 months

Table 10. Post-Approval Study Secondary Endpoints

Post-Approval Study Secondary Endpoints		
Freedom from target vessel revascularization (TVR), annually, up to 36 months	Freedom from target lesion revascularization (TLR) at 12, 24 months	Patency at 12 months -Primary -Primary assisted -Secondary
Change in Rutherford category from pre-procedure, annually, up to 36 months	Change in Ankle-Brachial Index (ABI) and Toe Brachial Index (TBI) from pre-procedure, annually, up to 36 months	Change in functional status based on EQ-5D from pre-procedure, annually, up to 36 months
Change in functional status based on Walking Impairment Questionnaire (WIQ) from pre-procedure, annually, up to 36 months	Serious adverse events, annually, up to 36 months	

Between 17-DEC-2013 and 12-AUG-2015, 140 study subjects were enrolled at 27 sites for the prospective, multi-center, non-randomized, single-arm IDE clinical study. One-hundred and thirty-four (134) subjects met all eligibility criteria and reflect the per protocol population. Tables used in this report reflect the results of the PP population unless otherwise stated.

Subjects available for each annual follow-up evaluation are described in **Table 11**.

Table 11. Subject Availability for Annual Follow-Up Evaluations

Number of Subjects Enrolled (134)	Reached the visit ¹	Available for visit ²	Data available ³
12 Months	134	130 (97.0%)	120 (92.3%)
24 Months	134	125 (93.3%)	117 (93.6%)
36 Months	134	115 (85.8%)	102 (88.7%)

¹ Subjects reached the beginning of the corresponding visit window.

² Subjects not discontinued prior to the corresponding visit, % of Reached.

³ Subjects completed the corresponding visit and the data is available in the system, % of Available.

SUMMARY OF THE POST-APPROVAL STUDY RESULTS

Post-Approval Study Primary Endpoint

Target Lesion Revascularization was defined as revascularization occurring within the treated segment(s) by means of a percutaneous vascular intervention, surgical bypass, thrombolysis, or other invasive means. Estimate of freedom from TLR (survival probability) is 91.4% at 36 months.

Table 12. Kaplan-Meier Estimates of Freedom from TLR by Subject

Time Post Treatment (days)	# at Risk Interval Start	Events Number (Cumulative)*	Censored Number (Cumulative)*	Survival Probability	95% C.I.
GORE [®] VIABAHN [®] VBX Balloon Expandable Endoprosthesis (N=134)					
[731-1095]	113	2 (11)	60 (72)	91.4%	(84.9%, 95.1%)

* Number in parenthesis represents cumulative events or censored observations through the end of interval.

Table 13. Post-Approval Study Secondary Endpoints

Endpoint	12 Months	24 Months	36 Months
Primary Patency	94.4% (N=124)	N/A	N/A
Primary Assisted Patency	98.4% (N=127)	N/A	N/A
Secondary Patency	99.2% (N=127)	N/A	N/A
fTLR	95.4% (N=129)	93.1% (N=124)	91.4% (N=113)
fCD-TLR	97.7% (N=130)	97.7% (N=127)	97.7% (N=119)
fTVR	95.4% (N=129)	92.3% (N=124)	90.6% (N=112)
fCD-TVR	97.7% (N=129)	96.9% (N=127)	96.1% (N=118)
Change in Rutherford from Pre-Procedure	Worsened / Maintained / Improved 0.0% / 5.3% / 94.7% (N=114)	Worsened / Maintained / Improved 1.0% / 4.9% / 94.1% (N=102)	Worsened / Maintained / Improved 0.0% / 7.9% / 92.1% (N=89)

Endpoint	12 Months	24 Months	36 Months
Change in ABI from Pre-Procedure ^a Mean (Std Dev)	0.19 (0.24) (N=165)	0.17 (0.24) (N=148)	0.17 (0.26) (N=123)
Change in TBI from Pre-Procedure ^a Mean (Std Dev)	0.08 (0.15) (N=5)	0.06 (0.16) (N=9)	0.08 (0.19) (N=9)
Change in Functional Status from Pre-Procedure			
ED-5D	Worsened / Maintained / Improved	Worsened / Maintained / Improved	Worsened / Maintained / Improved
Mobility	4.3% / 57.4% / 38.3% (N=115)	4.9% / 51.5% / 43.7% (N=103)	4.4% / 47.8% / 47.8% (N=90)
Self-Care	2.6% / 92.2% / 5.2% (N=115)	4.9% / 90.3% / 4.9% (N=103)	2.2% / 93.3% / 4.4% (N=90)
Usual Activities	7.8% / 47.8% / 44.3% (N=115)	7.8% / 49.5% / 42.7% (N=103)	4.4% / 46.7% / 48.9% (N=90)
Pain / Discomfort	10.4% / 38.3% / 51.3% (N=115)	12.6% / 39.8% / 47.6% (N=103)	7.8% / 48.9% / 43.3% (N=90)
Anxiety / Depression	7.0% / 71.3% / 21.7% (N=115)	6.8% / 68.9% / 24.3% (N=103)	5.6% / 64.4% / 30.0% (N=90)
Own Health State (1-100)	12.3% / 67.5% / 20.2% (N=114)	12.9% / 68.3% / 18.8% (N=101)	13.5% / 62.9% / 23.6% (N=89)
WIQ	Median (IQR) ²	Median (IQR) ²	Median (IQR) ²
Differential Diagnosis	1 (0, 4) (N=115)	2 (-1, 4) (N=104)	1 (-1, 4) (N=90)
Walking Distance	9 (3, 18) (N=115)	11 (1, 17) (N=104)	9 (4, 18) (N=90)
Walking Speed	5 (1, 9) (N=115)	5 (1, 9) (N=104)	5 (1, 9) (N=90)
Stair Climbing	3 (1, 7) (N=109)	3 (0, 7) (N=99)	4 (0, 7) (N=87)

Table 14. Description of Serious Adverse Events Through 12 Months

Subjects Enrolled	134
Subjects Experiencing Serious Adverse Events	40 (29.9%) [67]
Blood and lymphatic system disorders	2 (1.5%) [2]
Anaemia	1 (0.7%) [1]
Haemorrhagic anaemia	1 (0.7%) [1]
Cardiac disorders	7 (5.2%) [8]
Acute myocardial infarction	2 (1.5%) [2]
Angina pectoris	1 (0.7%) [1]
Cardiac failure congestive	2 (1.5%) [2]
Coronary artery disease	1 (0.7%) [1]
Myocardial infarction	1 (0.7%) [1]
Myocardial ischaemia	1 (0.7%) [1]
Gastrointestinal disorders	5 (3.7%) [6]
Abdominal pain	1 (0.7%) [1]
Gastrointestinal haemorrhage	1 (0.7%) [2]
Haematemesis	1 (0.7%) [1]
Rectal haemorrhage	1 (0.7%) [1]
Umbilical hernia	1 (0.7%) [1]
General disorders and administration site conditions	3 (2.2%) [3]
Non-cardiac chest pain	1 (0.7%) [1]
Vascular stent occlusion	2 (1.5%) [2]
Infections and infestations	4 (3.0%) [5]

Subjects Enrolled	134
Clostridium difficile infection	1 (0.7%) [1]
Diverticulitis	1 (0.7%) [1]
Pneumonia	1 (0.7%) [1]
Postoperative wound infection	1 (0.7%) [1]
Urinary tract infection	1 (0.7%) [1]
Injury, poisoning and procedural complications	8 (6.0%) [10]
Arterial restenosis	1 (0.7%) [1]
Humerus fracture	1 (0.7%) [1]
Incisional hernia	1 (0.7%) [1]
Joint dislocation	1 (0.7%) [1]
Post procedural haematoma	1 (0.7%) [1]
Postoperative ileus	1 (0.7%) [1]
Vascular pseudoaneurysm	2 (1.5%) [2]
Wound dehiscence	2 (1.5%) [2]
Metabolism and nutrition disorders	1 (0.7%) [1]
Hyperkalaemia	1 (0.7%) [1]
Musculoskeletal and connective tissue disorders	1 (0.7%) [1]
Pain in extremity	1 (0.7%) [1]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (3.0%) [4]
Lung adenocarcinoma	1 (0.7%) [1]
Prostate cancer	1 (0.7%) [1]
Renal cell carcinoma	1 (0.7%) [1]
Squamous cell carcinoma	1 (0.7%) [1]
Nervous system disorders	3 (2.2%) [5]
Carotid artery stenosis	2 (1.5%) [3]
Transient ischaemic attack	1 (0.7%) [1]
Vascular dementia	1 (0.7%) [1]
Renal and urinary disorders	2 (1.5%) [2]
Acute kidney injury	2 (1.5%) [2]
Respiratory, thoracic and mediastinal disorders	2 (1.5%) [2]
Chronic obstructive pulmonary disease	1 (0.7%) [1]
Pulmonary embolism	1 (0.7%) [1]
Vascular disorders	11 (8.2%) [18]
Arterial occlusive disease	1 (0.7%) [1]
Femoral artery dissection	1 (0.7%) [1]
Haematoma	1 (0.7%) [1]
Hypovolaemic shock	1 (0.7%) [1]
Intermittent claudication	4 (3.0%) [6]
Lymphocele	1 (0.7%) [1]
Peripheral arterial occlusive disease	1 (0.7%) [1]

Subjects Enrolled	134
Peripheral artery occlusion	1 (0.7%) [1]
Peripheral artery stenosis	2 (1.5%) [2]
Peripheral ischaemia	1 (0.7%) [1]
Poor peripheral circulation	1 (0.7%) [1]
Vena cava thrombosis	1 (0.7%) [1]

Table 15. Description of Serious Adverse Events Through 24 Months

Subjects Enrolled	134
Subjects Experiencing Serious Adverse Events	54 (40.3%) [110]
Blood and lymphatic system disorders	3 (2.2%) [3]
Anaemia	2 (1.5%) [2]
Haemorrhagic anaemia	1 (0.7%) [1]
Cardiac disorders	9 (6.7%) [11]
Acute myocardial infarction	2 (1.5%) [2]
Angina pectoris	1 (0.7%) [1]
Atrial fibrillation	1 (0.7%) [1]
Cardiac failure congestive	2 (1.5%) [2]
Coronary artery disease	2 (1.5%) [2]
Myocardial infarction	1 (0.7%) [1]
Myocardial ischaemia	1 (0.7%) [2]
Gastrointestinal disorders	7 (5.2%) [8]
Abdominal pain	1 (0.7%) [1]
Colitis	1 (0.7%) [1]
Gastrointestinal haemorrhage	2 (1.5%) [3]
Haematemesis	1 (0.7%) [1]
Rectal haemorrhage	1 (0.7%) [1]
Umbilical hernia	1 (0.7%) [1]
General disorders and administration site conditions	8 (6.0%) [8]
Non-cardiac chest pain	2 (1.5%) [2]
Systemic inflammatory response syndrome	1 (0.7%) [1]
Vascular stent occlusion	3 (2.2%) [3]
Vascular stent stenosis	1 (0.7%) [1]
Vascular stent thrombosis	1 (0.7%) [1]
Infections and infestations	8 (6.0%) [10]
Clostridium difficile infection	1 (0.7%) [1]
Diverticulitis	1 (0.7%) [1]
Lower respiratory tract infection	1 (0.7%) [1]
Pneumonia	3 (2.2%) [3]
Postoperative wound infection	1 (0.7%) [1]
Scrotal abscess	1 (0.7%) [1]
Urinary tract infection	2 (1.5%) [2]
Injury, poisoning and procedural complications	9 (6.7%) [11]
Arterial restenosis	1 (0.7%) [1]
Femoral neck fracture	1 (0.7%) [1]
Humerus fracture	1 (0.7%) [1]
Incisional hernia	1 (0.7%) [1]
Joint dislocation	1 (0.7%) [1]
Post procedural haematoma	1 (0.7%) [1]
Postoperative ileus	1 (0.7%) [1]
Vascular pseudoaneurysm	2 (1.5%) [2]
Wound dehiscence	2 (1.5%) [2]
Metabolism and nutrition disorders	1 (0.7%) [1]

Hyperkalaemia	1 (0.7%) [1]
Musculoskeletal and connective tissue disorders	1 (0.7%) [1]
Pain in extremity	1 (0.7%) [1]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (4.5%) [7]
Lung adenocarcinoma	1 (0.7%) [1]
Lung cancer metastatic	1 (0.7%) [1]
Malignant respiratory tract neoplasm	1 (0.7%) [1]
Metastases to bone	1 (0.7%) [1]
Prostate cancer	1 (0.7%) [1]
Renal cell carcinoma	1 (0.7%) [1]
Squamous cell carcinoma	1 (0.7%) [1]
Nervous system disorders	7 (5.2%) [11]
Carotid artery disease	1 (0.7%) [1]
Carotid artery stenosis	4 (3.0%) [5]
Cerebellar infarction	1 (0.7%) [1]
Cerebral hypoperfusion	1 (0.7%) [1]
Syncope	1 (0.7%) [1]
Transient ischaemic attack	1 (0.7%) [1]
Vascular dementia	1 (0.7%) [1]
Renal and urinary disorders	4 (3.0%) [4]
Acute kidney injury	3 (2.2%) [3]
Ureterolithiasis	1 (0.7%) [1]
Respiratory, thoracic and mediastinal disorders	6 (4.5%) [7]
Chronic obstructive pulmonary disease	3 (2.2%) [3]
Hypoxia	1 (0.7%) [1]
Pneumothorax	1 (0.7%) [1]
Pulmonary embolism	1 (0.7%) [1]
Pulmonary mass	1 (0.7%) [1]
Vascular disorders	18 (13.4%) [28]
Accelerated hypertension	1 (0.7%) [1]
Aortic stenosis	1 (0.7%) [1]
Arterial occlusive disease	1 (0.7%) [1]
Femoral artery dissection	1 (0.7%) [1]
Haematoma	1 (0.7%) [1]
Hypovolaemic shock	1 (0.7%) [1]
Iliac artery occlusion	1 (0.7%) [1]
Intermittent claudication	4 (3.0%) [6]
Lymphocele	1 (0.7%) [1]
Orthostatic hypotension	1 (0.7%) [1]
Peripheral arterial occlusive disease	2 (1.5%) [2]
Peripheral artery occlusion	1 (0.7%) [1]
Peripheral artery stenosis	4 (3.0%) [4]
Peripheral ischaemia	1 (0.7%) [1]
Peripheral vascular disorder	2 (1.5%) [3]
Poor peripheral circulation	1 (0.7%) [1]
Vena cava thrombosis	1 (0.7%) [1]

Table 16. Description of Serious Adverse Events Through 36 Months

Subjects Enrolled	134
Subjects Experiencing Serious Adverse Events	72 (53.7%) [172]
Blood and lymphatic system disorders	3 (2.2%) [3]
Anaemia	2 (1.5%) [2]
Haemorrhagic anaemia	1 (0.7%) [1]
Cardiac disorders	18 (13.4%) [29]

Acute myocardial infarction	4 (3.0%) [6]
Angina pectoris	1 (0.7%) [1]
Angina unstable	1 (0.7%) [1]
Atrial fibrillation	2 (1.5%) [2]
Bradycardia	1 (0.7%) [2]
Cardiac failure chronic	1 (0.7%) [1]
Cardiac failure congestive	6 (4.5%) [7]
Cardiogenic shock	1 (0.7%) [1]
Chronic left ventricular failure	1 (0.7%) [1]
Coronary artery disease	3 (2.2%) [3]
Myocardial infarction	2 (1.5%) [2]
Myocardial ischaemia	1 (0.7%) [2]
Gastrointestinal disorders	12 (9.0%) [13]
Abdominal pain	1 (0.7%) [1]
Abdominal pain upper	1 (0.7%) [1]
Colitis	1 (0.7%) [1]
Gastrointestinal haemorrhage	2 (1.5%) [3]
Haematemesis	1 (0.7%) [1]
Inguinal hernia	1 (0.7%) [1]
Rectal haemorrhage	1 (0.7%) [1]
Salivary gland calculus	1 (0.7%) [1]
Small intestinal obstruction	1 (0.7%) [1]
Stomach mass	1 (0.7%) [1]
Umbilical hernia	1 (0.7%) [1]
General disorders and administration site conditions	10 (7.5%) [10]
Non-cardiac chest pain	3 (2.2%) [3]
Systemic inflammatory response syndrome	1 (0.7%) [1]
Vascular stent occlusion	3 (2.2%) [3]
Vascular stent stenosis	2 (1.5%) [2]
Vascular stent thrombosis	1 (0.7%) [1]
Hepatobiliary disorders	1 (0.7%) [1]
Cholecystitis	1 (0.7%) [1]
Infections and infestations	12 (9.0%) [17]
Arthritis infective	1 (0.7%) [1]
Clostridium difficile infection	1 (0.7%) [1]
Diverticulitis	1 (0.7%) [1]
Influenza	1 (0.7%) [1]
Lower respiratory tract infection	1 (0.7%) [1]
Pneumonia	5 (3.7%) [5]
Postoperative wound infection	1 (0.7%) [1]
Pyelonephritis	1 (0.7%) [1]
Scrotal abscess	1 (0.7%) [1]
Sepsis	1 (0.7%) [1]
Skin infection	1 (0.7%) [1]
Urinary tract infection	2 (1.5%) [2]
Injury, poisoning and procedural complications	11 (8.2%) [17]
Arterial restenosis	1 (0.7%) [1]
Cervical vertebral fracture	1 (0.7%) [2]
Craniocerebral injury	1 (0.7%) [1]
Femoral neck fracture	1 (0.7%) [1]
Humerus fracture	1 (0.7%) [1]
Incisional hernia	1 (0.7%) [1]
Joint dislocation	1 (0.7%) [1]
Post procedural haematoma	1 (0.7%) [1]

Postoperative ileus	1 (0.7%) [1]
Splenic rupture	1 (0.7%) [1]
Subdural haematoma	1 (0.7%) [1]
Traumatic renal injury	1 (0.7%) [1]
Vascular pseudoaneurysm	2 (1.5%) [2]
Wound dehiscence	2 (1.5%) [2]
Metabolism and nutrition disorders	4 (3.0%) [4]
Dehydration	1 (0.7%) [1]
Hyperkalaemia	1 (0.7%) [1]
Hyponatraemia	2 (1.5%) [2]
Musculoskeletal and connective tissue disorders	2 (1.5%) [2]
Lumbar spinal stenosis	1 (0.7%) [1]
Pain in extremity	1 (0.7%) [1]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (5.2%) [8]
Lung adenocarcinoma	1 (0.7%) [1]
Lung cancer metastatic	1 (0.7%) [1]
Malignant respiratory tract neoplasm	1 (0.7%) [1]
Metastases to bone	1 (0.7%) [1]
Metastatic neoplasm	1 (0.7%) [1]
Prostate cancer	1 (0.7%) [1]
Renal cell carcinoma	1 (0.7%) [1]
Squamous cell carcinoma	1 (0.7%) [1]
Nervous system disorders	10 (7.5%) [14]
Carotid artery disease	1 (0.7%) [1]
Carotid artery stenosis	4 (3.0%) [5]
Cerebellar infarction	1 (0.7%) [1]
Cerebral hypoperfusion	1 (0.7%) [1]
Cerebral infarction	1 (0.7%) [1]
Cerebrovascular accident	1 (0.7%) [1]
Sciatica	1 (0.7%) [1]
Syncope	1 (0.7%) [1]
Transient ischaemic attack	1 (0.7%) [1]
Vascular dementia	1 (0.7%) [1]
Renal and urinary disorders	7 (5.2%) [8]
Acute kidney injury	5 (3.7%) [6]
Nephropathy	1 (0.7%) [1]
Ureterolithiasis	1 (0.7%) [1]
Respiratory, thoracic and mediastinal disorders	10 (7.5%) [12]
Acute respiratory failure	1 (0.7%) [1]
Chronic obstructive pulmonary disease	4 (3.0%) [4]
Dyspnoea	2 (1.5%) [2]
Hypoxia	1 (0.7%) [1]
Pneumothorax	1 (0.7%) [1]
Pulmonary embolism	1 (0.7%) [1]
Pulmonary mass	1 (0.7%) [1]
Respiratory failure	1 (0.7%) [1]
Vascular disorders	20 (14.9%) [34]
Accelerated hypertension	1 (0.7%) [1]
Aortic stenosis	1 (0.7%) [1]
Arterial occlusive disease	1 (0.7%) [1]
Femoral artery dissection	1 (0.7%) [1]
Haematoma	1 (0.7%) [1]
Hypertension	1 (0.7%) [1]
Hypertensive emergency	1 (0.7%) [1]

Hypotension	1 (0.7%) [1]
Hypovolaemic shock	1 (0.7%) [1]
Iliac artery occlusion	1 (0.7%) [1]
Intermittent claudication	4 (3.0%) [6]
Lymphocele	1 (0.7%) [1]
Orthostatic hypotension	1 (0.7%) [1]
Peripheral arterial occlusive disease	2 (1.5%) [3]
Peripheral artery occlusion	2 (1.5%) [2]
Peripheral artery stenosis	5 (3.7%) [5]
Peripheral ischaemia	1 (0.7%) [1]
Peripheral vascular disorder	2 (1.5%) [3]
Poor peripheral circulation	1 (0.7%) [1]
Vena cava thrombosis	1 (0.7%) [1]

POST APPROVAL STUDY STRENGTH AND WEAKNESSES

A major strength of the VBX FLEX STUDY was that it was a prospective, multicenter study focused exclusively on understanding the safety and performance of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in the treatment of arterial occlusive disease in patients with de novo or restenotic lesions in the common and/or external iliac arteries. Additionally, the 36 month follow-up allowed for long-term evaluation of safety and effectiveness. Limitations of the study were the participation of only sites in US and New Zealand and that it was not randomized to a control arm.

POST APPROVAL STUDY CONCLUSIONS

The results of the post-approval evaluation suggest that the long-term performance of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in the primary treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5 mm-13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation continues to be a safe and effective treatment option. Furthermore, the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis had low rates of MAEs and device-related adverse events through end of study at 36 months, with clinical improvements in Rutherford Classification, the Quality of Life Questionnaires (WIQ and EQ-5D), and Ankle Brachial Index(ABI) / Toe Brachial Index (TBI) measurements.

Clinical Evidence Supporting Use as a Bridging Stent:

SUMMARY OF EMBRACE REGISTRY METHODS

The EMBRACE Registry is a multicenter, retrospective and prospective registry initiated at 14 European clinical sites designed to evaluate use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in conjunction with a fenestrated or branched aortic stent graft. Site staff performed a search of the hospital database to identify patients treated using a GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in conjunction with a fenestrated or branched aortic stent graft; the search interval was January 1, 2017 to December 30, 2021. Sites reviewed potential patients in their database in sequential order and patients who met eligibility criteria and signed the informed consent form (ICF) were enrolled. Patients were categorized into FEVAR or BEVAR cohorts. Enrollment was monitored regularly to ensure broad participation across sites and countries, thereby promoting population heterogeneity and avoiding overrepresentation of any single site. No individual site contributed more than 30% of the study subjects. The registry data collection is ongoing with planned follow-up through 5 years. Follow-up data through 3 years has been reviewed and fully adjudicated by a core laboratory (Core Lab) and Clinical Events Committee (CEC). The site performed patient screening consecutively in reverse chronological order, beginning with the most recent procedure date, against the registry eligibility criteria. This order of patient screening allowed for enrollment of contemporary cases that reflected current clinical practice. A waiver of informed consent for any deceased patient was requested and approved based on local ethics committee regulations. Informed consent was obtained from all living study subjects at the time of enrollment; the only exception was for patients in Sweden, where local ethics committee regulations allowed for a full waiver given the observational and partially retrospective nature of the study.

A prospective analysis plan of the registry data was designed to statistically test the hypothesis of the Target Vessel Patency (at patient level) at 12 months (Primary Endpoint) in FEVAR and BEVAR cohorts separately. The results were evaluated against a Performance Goal of 77%. The performance goal was derived from an assumed 1-year target vessel patency of 87% derived from published literature on complex endovascular aortic aneurysm repair available at the time of protocol development [7] and a margin of 10%. An exact binomial exact test was used with a one-sided 97.5% confidence level ($\alpha = 0.025$) to test the null hypothesis.

Imaging components were analyzed based on core laboratory review (Core Lab). The core laboratory, Gore Imaging Services, performed independent assessment of computed tomographic angiography (CTA) studies submitted by registry sites. Primary and secondary endpoints were reviewed and adjudicated by an independent CEC.

Inclusion and Exclusion Criteria:

Enrollment in the EMBRACE Registry was limited to patients who met the following inclusion and exclusion criteria.

Inclusion Criteria:

- Patients treated with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a Bridging Stent in conjunction with a

branched/fenestrated stent graft to allow endovascular aneurysm repair from 31 December 2021 until 01 January 2017

- Age ≥ 18 years at the time of implant
- Informed consent by the patient or next of kin/legal representative (or waiver for deceased patients), according to local regulations.

Exclusion Criteria

- Patient treated for ruptured aneurysm or who were otherwise hemodynamically unstable at the time of the procedure
- Patient treated for acute or sub-acute dissection, <90 days from onset of symptoms
- Patient treated using physician-modified endovascular grafts
- Patient intended to be treated with parallel graft (e.g., chimney, periscope, sandwich) or octopus (use of an off-the-shelf bifurcated aortic endografts and peripheral stent grafts to revascularize mesenteric and renal arteries) technique per the pre-treatment case plan.
- At the time of treatment, patient had known coagulation disorders including hypercoagulability that were not amenable to treatment
- Patient was pregnant at the time of treatment.
- Participation in another drug or device investigational registry within one year of device implant, that can confound the registry endpoints.
- Patient had known or suspected systemic infection (including treatment for mycotic aneurysm) at the time of implant.

Follow up Schedule

The registry was designed to include both retrospective and prospective follow-up. The retrospective phase incorporates all available data from the pre-procedure date through the date of enrollment (date of informed consent signature or waiver of informed consent). The prospective phase incorporates data collected from the date of enrollment through 5-year follow-up. Follow-up is in accordance with standard of care with expectations of at least annual follow-up, based on guidelines and site physician feedback received during site qualification discussions. Imaging data is collected (if available) at baseline, treatment, post-op, and all follow-up visits (including any unplanned visits) throughout the 5-year duration of the study. Table 17 provides an outline of the registry follow-up phases along with the schedule of events.

Table 17. Schedule of Events

	Retrospective phase			Prospective phase ⁴	
	Baseline	Treatment	First post-operative visit (within 30 days)	Follow-up visits up to 5 years after treatment (annually)	Unplanned follow-up visit
Informed Consent or consent is waived	X				
Inclusion / Exclusion criteria	X				
Physical Examination	X				
Demographics & Medical History	X				
Case Planning ¹	X				
Procedure Details and Discharge		X			
Imaging ²	X	X	X	X	X
Medication ³	X	X	X	X	X
Adverse Events		X	X	X	X
Reinterventions ⁵		X	X	X	X
Lab results ⁶	X	X	X	X	X
¹ Available information used in case planning (e.g. diagrams, imaging) will be requested as part of registry documentation. ² Available imaging performed per the site standard of care for complex EVAR procedures and follow-up. This may include angiography, echocardiography, X-Ray, computed tomography and /or magnetic resonance. Any available imaging performed (fully anonymized) can be requested as part of registry documentation. ³ Medication collected: Antiplatelet and anticoagulant therapy. ⁴ The start of the prospective phase may change from subject to subject depending on the treatment date. ⁵ Data on any reintervention occurring during study follow-up was collected and included in study assessments. ⁶ Lab result will be collected, if available, and can include, RBC, WBC, platelet, Creatinine, eGFR.					

EMBRACE Registry Endpoints:

The EMBRACE Registry endpoints were designed to evaluate the performance and safety of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis when used as a Bridging Stent with Branched and Fenestrated Endografts in the Treatment of Aortic Aneurysms Involving the visceral arteries (i.e., superior mesenteric, celiac trunk, and renal arteries). Reference **Table 18** and **Table 19** for the primary and secondary endpoints of the EMBRACE Registry.

Table 18. Primary Endpoints

EMBRACE Primary Endpoint	
Target vessel patency (patient level) at 12 months	- Uninterrupted patency with no occlusion or procedure performed to maintain patency on the VBX Stent Graft or native target vessel.

Table 19. Secondary Endpoints

EMBRACE Secondary Endpoints	
Secondary Performance Outcomes	Primary Technical Success (Total Endovascular Procedure) - Placement of bridging stents, patency of all components (including modular aortic components and bridging stents), and freedom from Type I or Type III Endoleaks at completion angiography.
	Target Vessel Technical Success - Catheterization and VBX Device placement in all intended target vessels.
	Target vessel instability at 12 months and annually through 5 years post-implant - A composite endpoint of any branch related complication leading to aneurysm rupture, death, occlusion, component separation or reintervention to maintain branch patency or to treat a branch related component separation or endoleaks.
	Target vessel patency, patient level, annually from 2-5 years post-implant
	Target vessel patency, vessel level analysis, annually from procedure to 5 years post-implant
	Reintervention (total and reintervention that can be attributed to branches originally treated with the VBX Stent Graft) at 12 months and annually through 5 years post-implant - Any repeat vascular or nonvascular procedure (e.g. wound debridement, hernia or laparotomy-related interventions) related to the index procedure.
Secondary Safety Outcomes	Aneurysm-related mortality at 12 months and annually through 5 years post-implant - All-cause death within 30 days or any death related to rupture, aortic complication, or complication from a secondary intervention.
	Major Adverse Events at 30 days - All-cause mortality, respiratory failure, renal deterioration, bowel ischemia, permanent paraplegia or major stroke.

EMBRACE Registry Follow Up:

A total of 300 patients were screened for the registry with 41 patients failing to meet eligibility criteria. The primary reasons for non-enrollment were refusal to sign the informed consent form (20/41, 48.8%), failure to meet eligibility criteria (14/41, 34.1%), and other reasons (7/41, 17.1%). The most frequently reported eligibility criteria were ruptured aneurysm/hemodynamic instability (n=6), not treated with VBX bridging stent (n=5), and acute or subacute dissection within 90 days (n=3).

Data lock for the primary analysis was completed on October 14, 2025, with 12 centers contributing data on 259 patients.

The primary analysis was performed following the data export based on complete one-year follow-up. The study evaluated 92 subjects with 194 VBX-treated vessels in the FEVAR cohort and 136 subjects with 401 VBX-treated vessels in the BEVAR cohort. The registry data collection is ongoing with planned follow-up through 5 years. Follow-up data through 3 years has been reviewed and fully adjudicated by Core Lab and CEC for all available patients. Reference **Table 20** and **Table 21** for the number of subjects in each follow-up window.

Table 20 Subject Availability for Annual Follow-Up Evaluations FEVAR

	Eligible for Follow-up	Subject with Any Visit in Window	Subject with CT Imaging in Window*	Follow-up Pending	Subjects with Interpretable Imaging ³	Subject Status		
						Death	Lost to Follow-up ¹	Not Due for Next Window ²
Procedure	92	-	-	-	-	0	-	0
1 Year	92	87(94.6%)	89(96.7%)	0 (0.0%)	89(96.7%)	7	2	9
2 Year	83	69(83.1%)	64(77.1%)	0 (0.0%)	62(74.7%)	2	1	3
3 Year	80	59(73.8%)	52(65.0%)	0 (0.0%)	51(63.8%)	6	2	8
4 Year	72	41(56.9%)	35(48.6%)	0 (0.0%)	34(47.2%)	10	1	20
5 Year	52	28(53.8%)	23(44.2%)	9(17.3%)	23(44.2%)	0	0	37

Procedure Day (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)

¹Lost to follow, subject withdrawal, investigator decision to withdraw subject or other reason.

²Numbers reflect the sum of deaths, lost-to-follow up, and pending visits.

³Core Laboratory determined imaging was of sufficient quality to allow assessment of vessel-level characteristics or device integrity outcomes (e.g., wire fracture, separation, migration, and endoleak).

Table 21 Subject Availability for Annual Follow-Up Evaluations BEVAR

	Eligible for Follow-up	Subject with Any Visit in Window	Subject with CT Imaging in Window*	Follow-up Pending	Subjects with Interpretable Imaging ³	Subject Status		
						Death	Lost to Follow-up ¹	Not Due for Next Window ²
Procedure	136	-	-	-	-	3	-	3
1 Year	133	120(90.2%)	122(91.7%)	0 (0.0%)	121(91.0%)	32	5	37
2 Year	96	69(71.9%)	64(66.7%)	0 (0.0%)	63(65.6%)	10	0	10
3 Year	86	57(66.3%)	50(58.1%)	0 (0.0%)	50(58.1%)	7	0	7
4 Year	79	47(59.5%)	41(51.9%)	0 (0.0%)	40(50.6%)	12	1	22
5 Year	57	20(35.1%)	15(26.3%)	9(15.8%)	15(26.3%)	2	4	46

Procedure Day (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)

¹Lost to follow, subject withdrawal, investigator decision to withdraw subject or other reason.

²Numbers reflect the sum of deaths, lost-to-follow up, and pending visits.

³Core Laboratory determined imaging was of sufficient quality to allow assessment of vessel-level characteristics or device integrity outcomes (e.g., wire fracture, separation, migration, and endoleak).

Subject Demographics:

The baseline demographics and baseline medical history of the patients studied in the EMBRACE registry are provided in **Table 22**. Although the study population was enrolled from European centers, relevant co-variants (e.g., smoking history, diabetes, chronic kidney disease, hypertension, SVS Risk) are consistent with similar studies comprised of U.S. patients [3, 4, 5]. The majority of subjects treated within the EMBRACE Registry were male with a mean age of approximately 73 years reference **Table 22**.

Table 22. Subject Demographics

	FEVAR	BEVAR
Number of Subjects Enrolled	92	136
Gender	92	136
Male	80 (87.0%)	99 (72.8%)
Female	12 (13.0%)	37 (27.2%)
Age (years)		
n	92	136
Mean (Std Dev)	72.7 (8.1)	73.0 (8.9)
Median	74	74
(Min, Max)	(45, 87)	(28, 89)
Smoking History	92	131
Never	15 (16.3%)	30 (22.9%)
Current	19 (20.7%)	26 (19.8%)
Former	58 (63.0%)	75 (57.3%)
Classification For Chronic Kidney Disease	89	131
No chronic kidney disease	61 (68.5%)	94 (71.8%)
Stage 1	3 (3.4%)	4 (3.1%)
Stage 2	3 (3.4%)	5 (3.8%)
Stage 3	19 (21.3%)	22 (16.8%)
Stage 4	2 (2.2%)	5 (3.8%)
Stage 5	1 (1.1%)	1 (0.8%)
Diabetes	92	134
Yes	14 (15.2%)	22 (16.4%)
Chronic Obstructive Pulmonary Disease (COPD)	91	135
Yes	31 (34.1%)	45 (33.3%)
Myocardial Infarction	92	134
Yes	29 (31.5%)	31 (23.1%)
SVS: Hypertension Score	92	136
None	20 (21.7%)	22 (16.2%)
Easily controlled with Single Drug	30 (32.6%)	51 (37.5%)
Controlled with 2 Drugs	30 (32.6%)	46 (33.8%)
Requires more than 2 drugs or Uncontrolled	12 (13.0%)	17 (12.5%)

	FEVAR	BEVAR
SVS: Total Score		
n	83	111
Mean (Std Dev)	6.8 (4.2)	7.6 (4.7)
Median	7.0	7.0
(Min, Max)	(0.0, 17.0)	(0.0, 19.0)
SVS: Total Score Category	83	111
None	67 (80.7%)	75 (67.6%)
Mild	16 (19.3%)	36 (32.4%)
Moderate	0 (0%)	0 (0%)
Severe	0 (0%)	0 (0%)

*SVS, Society for Vascular Surgery. Total SVS score = (4 × cardiac) + (2 × pulmonary) + (2 × renal) + hypertension + age; component scores range from 0 to 3, and the weighted total ranges from 0 to 30. The normalized category score equals the total score divided by 10. Chaikof EL, Fillinger MF, Matsumura JS, et al. Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair. *Journal of Vascular Surgery*. 2002;35:1061-1066. doi:10.1067/mva.2002.123991.

Summary of Disease and Procedure Characteristics:

Table 23–Table 27 summarize the characteristics of the disease states treated (obtained from case planning documentation, procedural data, and the summary of implanted devices).

Table 23. Case Planning Data

	FEVAR	BEVAR
Number of Subjects Enrolled	92	136
Pre-Procedure Contrast CT		
Yes	90 (97.8%)	125 (91.9%)
Aneurysm Type		
Thoracoabdominal aneurysm	27 (29.3%)	103 (75.7%)
I	6 (6.5%)	11 (8.1%)
II	6 (6.5%)	21 (15.4%)
III	4 (4.3%)	33 (24.3%)
IV	11 (12.0%)	33 (24.3%)
Pararenal aneurysm	20 (21.7%)	18 (13.2%)
Infrarenal aneurysm	24 (26.1%)	0 (0.0%)
Juxtarenal aneurysm	18 (19.6%)	6 (4.4%)
Unknown	3 (3.3%)	9 (6.6%)
Dissection Present		
Yes	10 (10.9%)	13 (9.6%)
No	71 (77.2%)	87 (64.0%)
Indeterminate	7 (7.6%)	20 (14.7%)
Unknown	4 (4.3%)	16 (11.8%)
Etiology		
Degenerative	81 (88.0%)	123 (90.4%)
Dissection	6 (6.5%)	9 (6.6%)
Congenital	1 (1.1%)	0 (0%)
Other	4 (4.3%) ¹	4 (2.9%) ²

¹ FEVAR: Pseudoaneurysm (1), Type 1A Endoleak following EVAR (2), Chronic Type B Aortic Dissection (1)

² BEVAR: Penetrating Aortic Ulcer (1), TAAA Type 5 (1), Type 1A Endoleak following EVAR (1), Proximal Saccular/Seam Aneurysm (1)

Table 24. Procedural Data (Patient Level)

	FEVAR	BEVAR
Number of Subjects Enrolled	92	136
Type of Fenestrated Branched Graft	92	134 ¹
COOK Custom	82 (89.1%)	42 (31.3%)
Zenith® Fenestrated AAA Endovascular Graft	7 (7.6%)	0 (0%)
Zenith® t-Branch® Thoracoabdominal Endovascular Graft	0 (0%)	73 (54.5%)
Terumo Anaconda™ Fenestrated	1 (1.1%)	0 (0%)
Jotec E-nside	0 (0%)	9 (6.7%)
Jotec Custom	0 (0%)	7 (5.2%)
Other	2 (2.2%)	3 (2.2%)
Total Procedure Duration (Hours)		
n	82	121
Mean (Std Dev)	4.2 (1.6)	4.7 (1.6)
Median	4	4
(Min, Max)	(2, 10)	(1, 10)
Devices Successfully Navigated to Intended Location²		
Yes	90 (97.8%)	135 (99.3%)
Devices Deployed as Intended²		
Yes	91 (98.9%)	136 (100.0%)
Devices Delivery Catheters Successfully Removed²		
Yes	92 (100.0%)	136 (100.0%)
Devices Patent at End of Procedure²		
Yes	92 (100.0%)	136 (100.0%)

¹ The type of aortic device was not available from the medical record for two subjects.

² All components including the VBX Device

Table 25. Treated Artery Data (Vessel Level) FEVAR

Number of Subjects Enrolled	92			
	Celiac Trunk	Superior Mesenteric Artery (SMA)	Left Renal	Right Renal
Number of Subjects with Artery Treated	45 (48.9%)	61 (66.3%)	47 (51.1%)	41 (44.6%)
Status of Artery Prior To Procedure				
Patent	37 (82.2%)	58 (95.1%)	39 (83.0%)	39 (95.1%)
Stenosis > 50%	3 (6.7%)	1 (1.6%)	2 (4.3%)	0 (0%)
25% < Stenosis <= 50%	4 (8.9%)	2 (3.3%)	6 (12.8%)	1 (2.4%)
<= 25% Stenosis	1 (2.2%)	0 (0%)	0 (0%)	1 (2.4%)
Fenestration Diameter (mm) ¹				
6x6	0 (0%)	0 (0%)	16 (34.0%)	14 (34.1%)
6x8	5 (11.1%)	6 (9.8%)	24 (55.1%)	21 (51.2%)
8x8	36 (80.0%)	50 (81.9%)	3 (6.4%)	0 (0%)
Access Site				
Femoral artery	42 (93.3%)	58 (95.1%)	45 (95.7%)	40 (97.6%)
Iliac artery	0 (0%)	1 (1.6%)	0 (0%)	0 (0%)
Axillary	3 (6.7%)	1 (1.6%)	1 (2.1%)	0 (0%)
Brachial	0 (0%)	0 (0%)	0 (0%)	1 (2.4%)
Other	0 (0%)	1 (1.6%)	1 (2.1%)	0 (0%)

¹Total number does not add up to 100% as fenestration diameter was not documented in the medical record for all patients.

Table 26. Treated Artery Data (Vessel Level) BEVAR

Number of Subjects Enrolled	136			
	Celiac Trunk	Superior Mesenteric Artery (SMA)	Left Renal	Right Renal
Number of Subjects with treated artery	96 (70.6%)	108 (79.4%)	96 (70.6%)	101 (74.3%)
Status of Artery Prior To Procedure				
Patent	82 (85.4%)	105 (97.2%)	89 (92.7%)	96 (95.0%)
Stenosis > 50%	5 (5.2%)	0 (0%)	3 (3.1%)	3 (3.0%)
25% < Stenosis <= 50%	7 (7.3%)	1 (0.9%)	3 (3.1%)	2 (2.0%)
<= 25% Stenosis	2 (2.1%)	2 (1.9%)	1 (1.0%)	0 (0%)
Portal/Branch Configuration				
External branch	79 (82.3%)	90 (83.3%)	77 (80.2%)	81 (80.2%)
Internal branch	17 (17.7%)	18 (16.7%)	19 (19.8%)	20 (19.8%)
Portal/Branch Orientation ¹				
Cranial	27 (28.4%)	30 (27.8%)	26 (27.1%)	29 (28.7%)
Caudal	68 (71.6%)	78 (72.2%)	70 (72.9%)	72 (71.3%)
Access Site				
Femoral artery	42 (43.8%)	47 (43.5%)	43 (44.8%)	45 (44.6%)
Iliac artery	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Axillary	45 (46.9%)	51 (47.2%)	46 (47.9%)	49 (48.5%)
Brachial	8 (8.3%)	9 (8.3%)	6 (6.3%)	6 (5.9%)
Other ²	1 (1.0%)	1 (0.9%)	1 (1.0%)	1 (1.0%)

¹ The portal/branch orientation was not documented in the medical record for one subject.

² The site reported "Access Site" as "common femoral artery [AFC] and brachial artery" for 1 subject.

Table 27. VBX Device Details by Treated Artery by Cohort

	FEVAR (N=92)	BEVAR (N=136)
Number of Subjects Enrolled	92	136
Total number of arteries treated with VBX devices	196	467
Average number of VBX devices used per subject (Std. Dev)	2.1 (1.1)	3.4 (1.5)
Subjects with Branch Components		
Celiac Treated	45 (48.9%)	96 (70.6%)
1 Device	44 (47.8%)	86 (63.2%)
2 Devices	1 (1.1%)	10 (7.4%)
3 Devices	0	0
SMA Treated	61 (66.3%)	108 (79.4%)
1 Device	61 (66.3%)	88 (64.7%)
2 Devices	0	20 (14.7%)
3 Devices	0	0
Left Renal Treated	47 (51.1%)	96 (70.6%)
1 Device	47 (51.1%)	75 (55.1%)
2 Devices	0	19 (14.0%)
3 Devices	0	2 (1.5%)
Right Renal Treated	41 (44.6%)	101 (74.3%)
1 Device	40 (43.5%)	88 (64.7%)
2 Devices	1 (1.1%)	13 (9.6%)
3 Devices	0	0
VBX Device Size (Subjects [Devices])		
VBX Device Diameter (mm)	89 [193]	136 [458]
5	1 (1.1%) [1]	8 (5.9%) [10]
6	34 (37.0%) [51]	84 (61.8%) [145]
7	34 (37.0%) [50]	61 (44.9%) [99]
8	45 (48.9%) [60]	68 (50.0%) [96]
9	5 (5.4%) [6]	34 (25.0%) [47]
10	4 (4.3%) [5]	19 (14.0%) [24]
11	4 (4.3%) [4]	7 (5.1%) [7]
8L	14 (15.2%) [16]	24 (17.6%) [30]
VBX Device Length (mm)	89 [193]	136 [458]
15	0 (0%) [0]	0 (0%) [0]
19	3 (3.3%) [3]	1 (0.7%) [1]
29	68 (73.9%) [124]	7 (5.1%) [7]
39	38 (41.3%) [55]	34 (25.0%) [51]
59	5 (5.4%) [7]	94 (69.1%) [164]
79	3 (3.3%) [4]	105 (77.2%) [235]

Header row represents number of non-missing CRF fields, where applicable

SUMMARY OF EMBRACE REGISTRY Results

EMBRACE Registry Primary Endpoint:

The primary endpoint for the EMBRACE Registry was target vessel primary patency (patient level) at 12 months. In the FEVAR and BEVAR arms, target vessel primary patency at 12 months was 98.8% and 92.2% respectively, and hence the Performance Goal of 77% was met for both cohorts. Reference Table 28. Subjects without a reported event who were discontinued prior to the 1-year follow-up window, or those missing 1-year imaging were excluded from the analysis. The remaining 80 and 90 subjects were evaluated for target vessel primary patency in the FEVAR and BEVAR cohorts, respectively.

- One (1) subject in the FEVAR cohort experienced a right renal artery stent occlusion at Day 110 resulting in a loss of target vessel patency. The right renal artery stent occlusion was left untreated.

-In the BEVAR cohort, 5 subjects experienced a VBX branch occlusion (Day 43 to 383; most occurring late in the 1-year follow-up window), and 2 subjects exhibited stenosis in the VBX branch that required reintervention (i.e., ballooning which was noted as effective).

Table 28. Primary Endpoint for FEVAR and BEVAR Arms

	FEVAR		BEVAR	
	Total	P-value ²	Total	P-value ²
Number of Subjects Enrolled	92	-	136	-
Discontinued at beginning of 1 Year Window ¹	7	-	33	-
Deceased	5	-	28	-
LTF	2	-	5	-
Withdrew Consent	0	-	0	-
Other	0	-	0	-
Missing 1 Year Imaging	5	-	13	-
Number of Subjects Eligible for Analysis²	80	-	90	-
Subjects Free From Patency Loss at 12 Months	79 (98.8%)	<.0001	83 (92.2%)	0.0001
95% Lower Confidence Limit ³	92.3%	-	83.5%	-

¹ Subjects that did not lose patency and discontinued study prior to beginning of 1 Year Window

² Subjects with event of interest by end of 1 year window (post procedure day 455), or event-free and still in study at beginning of 1 year window (post procedure day 275)

³ Based on one-sided Clopper-Pearson (Exact) binomial confidence interval

A tipping point analysis using a best-case-to-worst case approach was performed to evaluate the robustness of the primary endpoint results for each cohort. For the FEVAR cohort, if all 12 subjects (those discontinued or missing 1 year imaging) were assumed to be endpoint failures, the Performance Goal (PG) would still be met. For the BEVAR cohort, if 15 of the 46 subjects were endpoint failures, then the PG would still be met; if 16 or more of the subjects with missing data were failures, the PG would not be met.

EMBRACE REGISTRY SECONDARY ENDPOINTS FOR FEVAR AND BEVAR COHORTS

Technical Success:

Primary Technical success was defined as catheterization and placement of all components during the index procedure to exclude the target lesion. Target Vessel Technical success was defined as catheterization and VBX stent graft placement in all intended target vessels. Target Vessel Technical success in the FEVAR and BEVAR arms was 100% and 98.5%, respectively. Reference Table 29 for a summary of additional outcomes. In the BEVAR cohort, two (2) subjects did not achieve target vessel technical success for the following reasons: failure to navigate and deploy VBX stent graft (1), and failure to gain target vessel access (1). Since data collection was initiated in EMBRACE registry, updated SVS Reporting Standards [6] have been published. As defined in the standard, the following must be met for primary technical success: 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 that extends beyond 30 days by confirmatory imaging (CTA, magnetic resonance angiography [MRA], or duplex ultrasound), and patency of all aortic modular stent graft components and intended side branch components. While the specific definition from the SVS reporting standard was not used in the technical success analysis, all elements of the SVS definition are captured in the study based on variables available from the EMBRACE registry database.

Table 29. Technical Success

	FEVAR	BEVAR
Number of Subjects Enrolled	92	136
Primary Technical Success¹	88/92 (95.7%)	130/135 (96.3%)
Target Vessel Technical Success (VBX)²	92/92 (100.0%)	134/136 (98.5%)
¹ Complete endovascular system implantation in the index procedure to treat lesion		
² VBX implantation in target visceral arteries (site reported retained)		

Major Adverse Events:

Major Adverse Events were defined as all-cause mortality, myocardial infarction, respiratory failure, renal function deterioration, bowel ischemia, permanent paraplegia, or major stroke. The Major Adverse Event endpoint was based on CEC adjudicated data and reported at 30 days. **Table 30** and **Table 31** list all Major Adverse Events at 30 days as well as through available five-year follow-up.

None of the all-cause mortality events through 30 days were adjudicated as VBX-related. In the FEVAR cohort, the all-cause mortality events (2) were adjudicated as procedure-related. The all-cause mortality events (13 subjects) in the BEVAR cohort were adjudicated as procedure-related (9), disease-related (1) and unknown relationship (3). In the FEVAR cohort, 2 (2.2%) subjects experienced renal deterioration within 30 days of the procedure. None of these events were CEC adjudicated as VBX-related. Thirteen (9.6%) subjects in the BEVAR cohort experienced renal deterioration within 30 days of the procedure. None of these events were CEC adjudicated as VBX-related.

In the FEVAR cohort, bowel ischemia was reported in 1 subject (1.1%) within 30 days of the procedure. In the BEVAR cohort, bowel ischemia was reported for 1 subject (0.7%) within 30 days of the procedure. None of these events were CEC adjudicated as VBX-related.

In the FEVAR cohort, permanent paraplegia was reported for 1 subject (1.1%) within 30 days of the procedure. No major stroke events were reported within 30 days of the procedure in the FEVAR cohort. In the BEVAR cohort, permanent paraplegia and major stroke rates were 4.4% (6 subjects) and 2.2% (3 subjects), respectively. None of these events were CEC adjudicated as VBX-related.

Table 30. Major Adverse Events FEVAR

	30Day	1 Year	2 Year	3 Year	4 Year	5 Year	Total ²
Number of Subjects at Risk¹	92	89	84	80	74	59	92
Any Major Adverse Event (MAE)	3 (3.3%)	4 (4.5%)	4 (4.8%)	5 (6.3%)	10 (13.5%)	1 (1.7%)	26 (28.3%)
All-cause mortality	2 (2.2%)	4 (4.5%)	3 (3.6%)	5 (6.3%)	10 (13.5%)	1 (1.7%)	25 (27.2%)
Myocardial infarction (MI): MI resulting in severe hemodynamic dysfunction necessitating resuscitation, cardiac arrest, or fatal outcome	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Respiratory failure requiring prolonged (>24 hours from anticipated) mechanical ventilation or reintubation	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	1 (1.1%)
Any renal function deterioration according to the RIFLE classification system	2 (2.2%)	0 (0%)	2 (2.4%)	0 (0%)	0 (0%)	0 (0%)	4 (4.3%)
Bowel ischemia requiring surgical resection or not resolving with medical therapy	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Permanent paraplegia (any grade 3 A-C spinal cord injury) in a patient who is not ambulatory	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Any major stroke defined according to National Institutes of Health Stroke Scale (NIHSS) or equivalent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
¹ Numbers represent subjects remaining in the study during or beyond the specified window. Follow-up begins at the end of the previous window and continues until the start of the subsequent window. Only the first occurrence of each adverse event type is counted for a subject. Windows: 30 Day (0-30 days), 1 Year (31-365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)							
² Events may be underestimated as study follow-up is ongoing.							

Table 31. Major Adverse Events BEVAR

	30Day	1 Year	2 Year	3 Year	4 Year	5 Year	Total ²
Number of Subjects at Risk¹	136	123	98	88	83	64	136
Any Major Adverse Event (MAE)	23 (16.9%)	22 (17.9%)	10 (10.2%)	8 (9.1%)	14 (16.9%)	4 (6.3%)	71 (52.2%)
All-cause mortality	13 (9.6%)	20 (16.3%)	10 (10.2%)	5 (5.7%)	14 (16.9%)	4 (6.3%)	66 (48.5%)
Myocardial infarction (MI): MI resulting in severe hemodynamic dysfunction necessitating resuscitation, cardiac arrest, or fatal outcome	0 (0%)	2 (1.6%)	1 (1.0%)	0 (0%)	0 (0%)	1 (1.6%)	4 (2.9%)

	30Day	1 Year	2 Year	3 Year	4 Year	5 Year	Total ²
Respiratory failure requiring prolonged (>24 hours from anticipated) mechanical ventilation or reintubation	3 (2.2%)	0 (0%)	0 (0%)	1 (1.1%)	0 (0%)	0 (0%)	4 (2.9%)
Any renal function deterioration according to the RIFLE classification system	13 (9.6%)	3 (2.4%)	0 (0%)	2 (2.3%)	1 (1.2%)	0 (0%)	19 (14.0%)
Bowel ischemia requiring surgical resection or not resolving with medical therapy	1 (0.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)
Permanent paraplegia (any grade 3 A-C spinal cord injury) in a patient who is not ambulatory	6 (4.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (4.4%)
Any major stroke defined according to National Institutes of Health Stroke Scale (NIHSS) or equivalent	3 (2.2%)	0 (0%)	1 (1.0%)	0 (0%)	2 (2.4%)	0 (0%)	6 (4.4%)
¹ Numbers represent subjects remaining in the study during or beyond the specified window. Follow-up begins at the end of the previous window and continues until the start of the subsequent window. Only the first occurrence of each adverse event type is counted for a subject. Windows: 30 Day (0-30 days), 1 Year (31-365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)							
² Events may be underestimated as study follow-up is ongoing.							

Target Vessel Instability:

Target vessel instability is a composite end point of any branch-related complication leading to aneurysm rupture, death, occlusion, component separation, or reintervention to maintain branch patency or to treat a branch-related component separation or endoleaks. Target Vessel Instability endpoint was based on the CEC and Core Lab adjudicated data and reflects complete data through 3-year follow-up.

In the FEVAR cohort, five (5) subjects have experienced a Target Vessel Instability event through 5-year follow-up. The events include 3 occlusion events (2 with reinterventions) and 3 endoleak reinterventions (2 Type IIc, 1 Type 1c).

In the BEVAR cohort, 27 subjects experienced Target Vessel Instability through available 5-year follow-up, including 13 subjects with vessel occlusion and 16 subjects with endoleak requiring a reintervention (12 Type Ic, 2 Type IIc, 1 Type Ib, and 1 Type Ia).

Table 32 and **Table 33** summarize the target vessel instability events for the FEVAR and BEVAR cohort, respectively through available 5-year follow-up.

Table 32. Target Vessel Instability Events FEVAR

	Procedure ¹	1 Year ¹	2 Year ¹	3 Year ¹	4 Year ¹	5 Year ¹	Total ³
Number of Subjects ²	92	92	84	80	74	59	92
Evaluable Subjects	92	87	80	76	70	56	92
Target Vessel Instability	0 (0%)	4 (4.6%)	2 (2.5%)	0 (0%)	0 (0%)	0 (0%)	5 (5.4%)
Vessel Occlusion	0 (0%)	1 (1.1%)	2 (2.5%)	0 (0%)	0 (0%)	0 (0%)	2 (2.2%)
Aneurysm Related Death	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Rupture of Treated Segment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reintervention Reason							
Endoleak	0 (0%)	3 (3.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (3.3%)
Occlusion	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)

¹Beginning at end of previous window and continuing to beginning of subsequent window: Procedure Day (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732- 1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)

²Numbers represent subjects in or past window

³ Total represents number of subjects experiencing a TVI event. Subjects may experience an event in multiple time windows Events may be underestimated as study follow-up is ongoing.

Table 33. Target Vessel Instability Events BEVAR

	Procedure ¹	1 Year ¹	2 Year ¹	3 Year ¹	4 Year ¹	5 Year ¹	Total ³
Number of Subjects ²	136	133	98	88	83	64	136
Evaluable Subjects	133	117	88	75	65	49	133
Target Vessel Instability	0 (0%)	14 (12.0%)	7 (8.0%)	7 (9.3%)	1 (1.5%)	1 (2.0%)	27 (20.3%)
Vessel Occlusion	0 (0%)	2 (1.7%)	5 (5.7%)	6 (8.0%)	1 (1.5%)	0 (0%)	13 (9.8%)
Aneurysm Related Death	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Rupture of Treated Segment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reintervention Reason							
Endoleak	0 (0%)	12 (10.3%)	2 (2.3%)	1 (1.3%)	0 (0%)	1 (2.0%)	16 (12.0%)
Disconnection	0 (0%)	1 (0.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.8%)
Kink	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	1 (0.8%)
Stenosis	0 (0%)	2 (1.7%)	2 (2.3%)	0 (0%)	0 (0%)	0 (0%)	4 (3.0%)
Occlusion	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	1 (0.8%)

¹Beginning at end of previous window and continuing to beginning of subsequent window: Procedure Day (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732- 1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)

²Numbers represent subjects in or past window

³ Total represents number of subjects experiencing a TVI event. Subjects may experience an event in multiple time windows Events may be underestimated as study follow-up is ongoing.

Reference **Table 34** and **Table 35** for Kaplan-Maier estimates of Freedom from Target Vessel Instability in the FEVAR and BEVAR arms, respectively, at the individual vessel level for timepoints with adjudicated data. Freedom from Target Vessel Instability for all vessels at 1, 2, and 3 years in the FEVAR cohort was 97.5%, 97.5%, and 94.7%, respectively. In the BEVAR cohort, the Freedom from Target Vessel Instability at 1, 2, and 3 years was 94.3%, 91.8%, and 87.2%, respectively.

Table 34. Kaplan- Meier Estimates of Freedom from Target Vessel Instability FEVAR

FEVAR						
Vessel	Time Post Treatment (Years**)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	Vessels Free from Instability (%)	95% C.I.
All Vessels	Procedure Day	194	0 (0)	5 (5)	100%	(100.0%, 100.0%)
	1 Year	189	4 (4)	33 (38)	97.5%	(93.6%, 99.1%)
	2 Year	152	3 (7)	13 (51)	95.5%	(90.7%, 97.8%)
	3 Year	136	1 (8)	33 (84)	94.7%	(89.6%, 97.3%)
Celiac Trunk	Procedure Day	45	0 (0)	2 (2)	100%	(100.0%, 100.0%)
	1 Year	43	1 (1)	5 (7)	97.4%	(83.2%, 99.6%)
	2 Year	37	0 (1)	3 (10)	97.4%	(83.2%, 99.6%)
	3 Year	34	0 (1)	7 (17)	97.4%	(83.2%, 99.6%)
Left Renal Artery	Procedure Day	47	0 (0)	0 (0)	100%	(100.0%, 100.0%)
	1 Year	47	1 (1)	10 (10)	97.4%	(83.2%, 99.6%)
	2 Year	36	1 (2)	2 (12)	94.6%	(79.9%, 98.6%)
	3 Year	33	1 (3)	9 (21)	91.4%	(75.6%, 97.2%)
Right Renal Artery	Procedure Day	41	0 (0)	0 (0)	100%	(100.0%, 100.0%)
	1 Year	41	1 (1)	8 (8)	97.1%	(81.4%, 99.6%)
	2 Year	32	1 (2)	4 (12)	93.8%	(77.3%, 98.4%)
	3 Year	27	0 (2)	6 (18)	93.8%	(77.3%, 98.4%)
Superior Mesenteric Artery	Procedure Day	61	0 (0)	3 (3)	100%	(100.0%, 100.0%)
	1 Year	58	1 (1)	10 (13)	98.0%	(86.6%, 99.7%)
	2 Year	47	1 (2)	4 (17)	95.7%	(83.9%, 98.9%)
	3 Year	42	0 (2)	11 (28)	95.7%	(83.9%, 98.9%)
Number in Parenthesis represents cumulative events or censored observations through end of interval.						

Table 35. Kaplan- Meier Estimates of Freedom from Target Vessel Instability FEVAR

BEVAR						
Vessel	Time Post Treatment (Years**)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	Vessels Free Instability (%)	95% C.I.
All Vessels	Procedure Day	401	0 (0)	31 (31)	100%	(100.0%, 100.0%)
	1 Year	370	18 (18)	103 (134)	94.3%	(91.1%, 96.4%)
	2 Year	249	6 (24)	33 (167)	91.8%	(88.0%, 94.5%)
	3 Year	210	10 (34)	23 (190)	87.2%	(82.4%, 90.7%)
Celiac Trunk	Procedure Day	96	0 (0)	4 (4)	100%	(100.0%, 100.0%)
	1 Year	92	4 (4)	27 (31)	94.8%	(86.8%, 98.0%)

BEVAR						
Vessel	Time Post Treatment (Years**)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	Vessels Free Instability (%)	95% C.I.
	2 Year	61	1 (5)	10 (41)	93.1%	(84.0%, 97.1%)
	3 Year	50	2 (7)	8 (49)	89.3%	(78.5%, 94.8%)
Left Renal Artery	Procedure Day	96	0 (0)	8 (8)	100%	(100.0%, 100.0%)
	1 Year	88	3 (3)	24 (32)	95.9%	(87.9%, 98.7%)
	2 Year	61	4 (7)	8 (40)	89.1%	(78.4%, 94.7%)
	3 Year	49	2 (9)	4 (44)	85.2%	(73.3%, 92.1%)
	Procedure Day	101	0 (0)	9 (9)	100%	(100.0%, 100.0%)
Right Renal Artery	1 Year	92	6 (6)	26 (35)	92.4%	(83.9%, 96.5%)
	2 Year	60	1 (7)	8 (43)	90.7%	(81.2%, 95.5%)
	3 Year	51	3 (10)	3 (46)	85.2%	(73.8%, 91.9%)
	Procedure Day	108	0 (0)	10 (10)	100%	(100.0%, 100.0%)
Superior Mesenteric Artery	1 Year	98	5 (5)	26 (36)	94.1%	(86.3%, 97.5%)
	2 Year	67	0 (5)	7 (43)	94.1%	(86.3%, 97.5%)
	3 Year	60	3 (8)	8 (51)	88.8%	(78.5%, 94.3%)
	Procedure Day	108	0 (0)	10 (10)	100%	(100.0%, 100.0%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Target Vessel Primary Patency Through 3 Years:

The Target vessel primary patency endpoint was based on Core Lab adjudicated data. Patient-level target vessel primary patency at 3 years for the FEVAR and BEVAR arms are estimated at 97.4% and 81.3% respectively. Reference **Table 36** and **Table 37** for additional timepoints.

Table 36. Kaplan-Meier Estimates of Target Vessel Primary Patency (Patient Level) for FEVAR

FEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects with Primary Patency	95% C.I.
Procedure Day	92	0 (0)	3 (3)	100%	(100.0%, 100.0%)
1 Year	89	1 (1)	12 (15)	98.8%	(91.6%, 99.8%)
2 Year	76	1 (2)	7 (22)	97.4%	(89.8%, 99.3%)
3 Year	68	0 (2)	14 (36)	97.4%	(89.8%, 99.3%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Table 37. Kaplan-Meier Estimates of Target Vessel Primary Patency (Patient Level) for BEVAR

BEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects with Primary Patency	95% C.I.
Procedure Day	136	0 (0)	12 (12)	100%	(100.0%, 100.0%)
1 Year	124	3 (3)	37 (49)	97.1%	(91.2%, 99.0%)
2 Year	84	6 (9)	10 (59)	89.8%	(81.2%, 94.6%)
3 Year	68	6 (15)	8 (67)	81.3%	(70.6%, 88.4%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Primary Patency by Vessel:

A summary of the estimates for target vessel primary patency (vessel level analysis) at all available timepoints for the FEVAR and BEVAR arms are shown in **Table 38** and **Table 39**.

Table 38. Kaplan-Meier Estimates Primary Patency by Vessel FEVAR

FEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects with Primary Patency	95% C.I.
Group: Celiac Trunk					
Procedure Day	45	0 (0)	2 (2)	100%	(100.0%, 100.0%)
1 Year	43	0 (0)	5 (7)	100%	(100.0%, 100.0%)
2 Year	38	0 (0)	3 (10)	100%	(100.0%, 100.0%)
3 Year	35	0 (0)	7 (17)	100%	(100.0%, 100.0%)
Group: Left Renal Artery					
Procedure Day	47	0 (0)	0 (0)	100%	(100.0%, 100.0%)
1 Year	47	0 (0)	10 (10)	100%	(100.0%, 100.0%)
2 Year	37	1 (1)	2 (12)	97.1%	(81.4%, 99.6%)
3 Year	34	0 (1)	9 (21)	97.1%	(81.4%, 99.6%)
Group: Right Renal Artery					
Procedure Day	41	0 (0)	0 (0)	100%	(100.0%, 100.0%)
1 Year	41	1 (1)	8 (8)	97.1%	(81.4%, 99.6%)
2 Year	32	1 (2)	4 (12)	93.8%	(77.3%, 98.4%)
3 Year	27	0 (2)	6 (18)	93.8%	(77.3%, 98.4%)
Group: Superior Mesenteric Artery					
Procedure Day	61	0 (0)	3 (3)	100%	(100.0%, 100.0%)
1 Year	58	0 (0)	10 (13)	100%	(100.0%, 100.0%)
2 Year	48	1 (1)	4 (17)	97.7%	(84.9%, 99.7%)
3 Year	43	0 (1)	11 (28)	97.7%	(84.9%, 99.7%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Table 39. Kaplan-Meier Estimates Primary Patency by Vessel BEVAR

BEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects with Primary Patency	95% C.I.
Group: Celiac Trunk					
Procedure Day	96	0 (0)	4 (4)	100%	(100.0%, 100.0%)
1 Year	92	1 (1)	28 (32)	98.7%	(91.2%, 99.8%)
2 Year	63	1 (2)	10 (42)	97.0%	(88.2%, 99.2%)
3 Year	52	2 (4)	9 (51)	93.1%	(82.6%, 97.4%)
Group: Left Renal Artery					
Procedure Day	96	0 (0)	8 (8)	100%	(100.0%, 100.0%)
1 Year	88	1 (1)	25 (33)	98.6%	(90.5%, 99.8%)
2 Year	62	4 (5)	8 (41)	91.9%	(81.6%, 96.6%)
3 Year	50	1 (6)	4 (45)	89.9%	(78.8%, 95.4%)
Group: Right Renal Artery					
Procedure Day	101	0 (0)	9 (9)	100%	(100.0%, 100.0%)
1 Year	92	1 (1)	28 (37)	98.7%	(91.4%, 99.8%)
2 Year	63	2 (3)	8 (45)	95.4%	(86.2%, 98.5%)
3 Year	53	4 (7)	4 (49)	87.9%	(76.1%, 94.1%)
Group: Superior Mesenteric Artery					
Procedure Day	108	0 (0)	10 (10)	100%	(100.0%, 100.0%)
1 Year	98	1 (1)	28 (38)	98.8%	(91.6%, 99.8%)
2 Year	69	0 (1)	7 (45)	98.8%	(91.6%, 99.8%)
3 Year	62	1 (2)	8 (53)	96.9%	(88.0%, 99.2%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Freedom from Reinterventions:

Reinterventions were defined as any repeat vascular or nonvascular procedure related to the index procedure.

Reinterventions were further categorized as Major and Minor as follows:

- Major reinterventions included the deployment of proximal or distal aortic or iliac extensions, removal of the device, use of thrombectomy or thrombolysis, and any major open surgical procedure.
- Minor reinterventions included endovascular procedures (percutaneous transluminal angioplasty, atherectomy, stenting) without thrombectomy or thrombolysis, interventions to treat branch stenosis, Type II or branch-related endoleaks, and minor surgical procedures (patch angioplasty) for access vessels.

Reintervention endpoints were based on CEC adjudicated data through 3-year follow-up. In the FEVAR cohort, 11 (12.0%) subjects experienced 13 major reinterventions. The most common reason for major reintervention was Type IB endoleak (7 events, 53.8%). One (1) subject underwent a major reintervention for a left renal stent occlusion which the CEC adjudicated as VBX-related. No other major reinterventions were adjudicated as VBX-related by the CEC.

For the BEVAR cohort, 23 (16.9%) subjects experienced 28 major reinterventions. The most common reasons for major reintervention were endoleak (11 events, 39.3%), thrombosis/occlusion (6 events, 21.4%), and rupture (4 events, 14.3%). No major reintervention were adjudicated by the CEC as VBX-related.

The estimates of freedom from VBX-related reintervention are presented in **Table 40** for FEVAR and **Table 41** for BEVAR.

Table 40. Kaplan-Meier Estimates of Freedom from Reintervention in FEVAR

FEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	%Subjects Free from Reintervention	95% C.I.
Group: Major					
Procedure Day	92	0 (0)	0 (0)	100%	(100.0%, 100.0%)
1 Year	92	0 (0)	11 (11)	100%	(100.0%, 100.0%)
2 Year	81	1 (1)	3 (14)	98.7%	(91.4%, 99.8%)

3 Year	77	0 (1)	7 (21)	98.7%	(91.4%, 99.8%)
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FEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects Free from Reintervention	95% C.I.
Group: Minor					
Procedure Day	92	0 (0)	0 (0)	100%	(100.0%, 100.0%)
1 Year	92	3 (3)	8 (8)	96.6%	(89.7%, 98.9%)
2 Year	81	0 (3)	4 (12)	96.6%	(89.7%, 98.9%)
3 Year	77	1 (4)	6 (18)	95.3%	(87.8%, 98.2%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Table 41. Kaplan-Meier Estimates of Freedom from Reintervention in BEVAR

BEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects Free from Reintervention	95% C.I.
Group: Major					
Procedure Day	136	0 (0)	3 (3)	100%	(100.0%, 100.0%)
1 Year	133	0 (0)	42 (45)	100%	(100.0%, 100.0%)
2 Year	91	0 (0)	12 (57)	100%	(100.0%, 100.0%)
3 Year	79	0 (0)	9 (66)	100%	(100.0%, 100.0%)
Group: Minor					
Procedure Day	136	0 (0)	3 (3)	100%	(100.0%, 100.0%)
1 Year	133	9 (9)	33 (36)	92.2%	(85.5%, 95.9%)
2 Year	91	3 (12)	9 (45)	89.0%	(81.3%, 93.6%)
3 Year	79	4 (16)	5 (50)	84.2%	(75.4%, 90.1%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Freedom from Aneurysm-Related Mortality:

Freedom from Aneurysm-related mortality endpoint was based on CEC adjudicated data. None of the events were adjudicated by the CEC as VBX-related. Freedom from Aneurysm-related mortality through 3 years for FEVAR and BEVAR is 96.6% and 88.9% respectively. Reference **Table 42** and **Table 43** for additional time points.

Table 42. Kaplan-Meier Estimates of Freedom from Aneurysm-related Mortality for FEVAR

FEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects Free from Aneurysm Related Mortality (%)	95% C.I.
Procedure Day	92	0 (0)	0 (0)	100%	(100.0%, 100.0%)
30 Day	92	2 (2)	1 (1)	97.8%	(91.6%, 99.5%)
1 Year	89	0 (2)	4 (5)	97.8%	(91.6%, 99.5%)
2 Year	85	0 (2)	5 (10)	97.8%	(91.6%, 99.5%)
3 Year	80	1 (3)	12 (22)	96.6%	(89.7%, 98.9%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Table 43. Kaplan-Meier Estimates of Freedom from Aneurysm-related Mortality for BEVAR

BEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects Free from Aneurysm Related Mortality (%)	95% C.I.
Procedure Day	136	3 (3)	0 (0)	97.8%	(93.3%, 99.3%)
30 Day	133	10 (13)	0 (0)	90.4%	(84.1%, 94.3%)
1 Year	123	2 (15)	21 (21)	88.9%	(82.2%, 93.1%)
2 Year	100	0 (15)	15 (36)	88.9%	(82.2%, 93.1%)
3 Year	85	0 (15)	12 (48)	88.9%	(82.2%, 93.1%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

All-Cause Mortality:

Reference **Table 44** and **Table 45** for a summary of all-cause mortality rates for FEVAR and BEVAR, respectively. Cause of death is listed below all-cause mortality numbers. For FEVAR, 1 all-cause mortality event was CEC adjudicated as VBX-related [i.e., left renal stent occlusion (POD 586), thrombolysis performed, related mortality]. For BEVAR, to date, no VBX-related death has been reported in the BEVAR cohort.

Table 44. All-Cause Mortality FEVAR

	Procedure ²	1 Year ²	2 Years ²	3 Years ²	4 Years ²	5 Years ²	Total
Number of Subjects ¹	92	92	84	80	74	59	92
Not Yet in Window	0	0	0	0	0	3	0
All-Cause Mortality ⁴	0 (0%)	6 (6.5%)	3 (3.6%)	5 (6.3%)	10 (13.5%)	1 (1.7%)	25 (27.2%)
Aneurysm Related Death ³	0 (0%)	2 (2.2%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	3 (3.3%)
Myocardial Infarction ³	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Respiratory Failure ³	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	1 (1.1%)
Renal Function Deterioration ³	0 (0%)	1 (1.1%)	1 (1.2%)	0 (0%)	1 (1.4%)	0 (0%)	3 (3.3%)
Bowel Ischemia ³	0 (0%)	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Permanent Paraplegia ³	0 (0%)	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Major Stroke ³	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Rupture of Treated Segment ³	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	1 (1.1%)
Reintervention as Part of Treatment ³	0 (0%)	1 (1.1%)	3 (3.6%)	1 (1.3%)	4 (5.4%)	1 (1.7%)	10 (10.9%)
Reason for Reintervention ³							
Endoleak	0 (0%)	0 (0%)	2 (2.4%)	1 (1.3%)	2 (2.7%)	1 (1.7%)	6 (6.5%)
Disconnection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Kink	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	1 (1.1%)
Stenosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	1 (1.1%)
Occlusion	0 (0%)	0 (0%)	1 (1.2%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Rupture	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Migration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reintervention Classification ³							
Major	0 (0%)	1 (1.1%)	2 (2.4%)	1 (1.3%)	2 (2.7%)	0 (0%)	6 (6.5%)
Minor	0 (0%)	1 (1.1%)	1 (1.2%)	0 (0%)	2 (2.7%)	1 (1.7%)	5 (5.4%)

¹Numbers represent subjects still in the study in or past window
²Beginning at end of previous window and continuing to beginning of subsequent window: Procedure (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)
³CEC adjudicated cause of death at time of data export
⁴Not all causes of death were known

Table 45. All-Cause Mortality BEVAR

	Procedure ²	1 Year ²	2 Years ²	3 Years ²	4 Years ²	5 Years ²	Total
Number of Subjects ¹	136	133	98	88	83	64	136

	Procedure ²	1 Year ²	2 Years ²	3 Years ²	4 Years ²	5 Years ²	Total
Not Yet in Window	0	0	0	0	0	4	0
All-Cause Mortality ⁴	3 (2.2%)	30 (22.6%)	10 (10.2%)	5 (5.7%)	14 (16.9%)	4 (6.3%)	66 (48.5%)
Aneurysm Related Death ³	2 (1.5%)	7 (5.3%)	0 (0%)	0 (0%)	1 (1.2%)	0 (0%)	10 (7.4%)
Myocardial Infarction ³	0 (0%)	2 (1.5%)	1 (1.0%)	0 (0%)	0 (0%)	1 (1.6%)	4 (2.9%)
Respiratory Failure ³	0 (0%)	3 (2.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (2.2%)
Renal Function Deterioration ³	0 (0%)	11 (8.3%)	0 (0%)	1 (1.1%)	3 (3.6%)	0 (0%)	15 (11.0%)
Bowel Ischemia ³	0 (0%)	1 (0.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)
Permanent Paraplegia ³	0 (0%)	6 (4.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (4.4%)
Major Stroke ³	0 (0%)	3 (2.3%)	1 (1.0%)	0 (0%)	2 (2.4%)	0 (0%)	6 (4.4%)
Rupture Of Treated Segment ³	0 (0%)	2 (1.5%)	0 (0%)	0 (0%)	1 (1.2%)	0 (0%)	3 (2.2%)
Reintervention as Part Of Treatment ³	0 (0%)	8 (6.0%)	2 (2.0%)	1 (1.1%)	5 (6.0%)	1 (1.6%)	17 (12.5%)
Reason for Reintervention ³							
Endoleak	0 (0%)	3 (2.3%)	1 (1.0%)	1 (1.1%)	2 (2.4%)	1 (1.6%)	8 (5.9%)
Disconnection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Kink	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Stenosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.2%)	0 (0%)	1 (0.7%)
Occlusion	0 (0%)	1 (0.8%)	0 (0%)	0 (0%)	3 (3.6%)	0 (0%)	4 (2.9%)
Rupture	0 (0%)	2 (1.5%)	1 (1.0%)	0 (0%)	1 (1.2%)	0 (0%)	4 (2.9%)
Migration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reintervention Classification ³							
Major	0 (0%)	3 (2.3%)	1 (1.0%)	1 (1.1%)	4 (4.8%)	0 (0%)	9 (6.6%)
Minor	0 (0%)	6 (4.5%)	1 (1.0%)	0 (0%)	2 (2.4%)	1 (1.6%)	10 (7.4%)

¹Numbers represent subjects still in the study in or past window
²Beginning at end of previous window and continuing to beginning of subsequent window: Procedure (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)
³CEC adjudicated cause of death at time of data export
⁴Not all causes of death were known

Summary of Core Lab Findings

Table 46 and **Table 47** summarize the Core Lab device event findings at the vessel-level for FEVAR and BEVAR through available five-year follow up, respectively.

The most commonly reported Core Lab finding was compression/invagination in VBX-treated vessels. Core Lab prospectively defined compression as evidence of the device being crushed or compressed by surrounding anatomy (e.g., calcium, thrombus, or vessel wall), resulting in a focal reduction in device diameter. Invagination was prospectively defined as evidence of the study device collapsing on itself in the absence of external anatomical compression. The Core Lab did not distinguish between compression and invagination during image adjudication or data reporting. Rather, any vessel meeting either definition was recorded as a single Core Lab imaging endpoint of compression/invagination. The majority of findings were not associated with reported clinical sequelae or the need for reintervention. The following is a subject-level summary of compression/invagination findings for each cohort:

- For FEVAR, of the 21 subjects with one or more Core Lab-adjudicated compression/invagination findings, 19 subjects had no associated VBX-related adverse event. Two subjects underwent three endovascular reinterventions for two device occlusions and one Type IIIC endoleak. Of the three adverse events, two resolved without sequelae, and one resulted in a fatal outcome following thrombolysis for left renal artery device occlusion. Overall, this resulted in a rate of 2.2% (95% CI: 0.3–7.6) for subjects with both a compression/invagination finding and a VBX-related adverse event.
- For BEVAR, of the 35 subjects with one or more Core Lab-adjudicated compression/invagination findings, 27 subjects with a compression/invagination event had no VBX-related adverse events. The remaining eight subjects experienced nine VBX-related adverse events. Four subjects were left untreated. Four (4) subjects underwent 5 endovascular reinterventions for stenosis (1), occlusion (2), and endoleaks (3). The outcome of the reinterventions was reported as follows: 3 resolved without further sequelae, 1 resolved with sequelae, and 1 with unknown resolution, resulting in an overall rate of 6.0% (95% CI: 2.6 – 11.5) for subjects with both a compression/invagination event and VBX-related adverse event.

Branch dissections were observed; however, the origin of the dissection (e.g. iatrogenic, degenerative) could not be identified by the Core Lab. Thus, the number of branch dissections included in the Core Lab Findings table includes all dissections.

Table 46. Summary of Core Lab Findings FEVAR

	1 Year ²	2 Year ²	3 Year ²	4 Year ²	5 Year ²	Total
Number of Subjects at Risk ¹	92	83	80	72	52	92
Subjects with CT in Window ³	89	62	51	35	23	89
VBX-Treated Vessels at Risk	195	170	165	151	111	195
VBX-Treated Vessels with Available Imaging ³	188	122	96	62	50	188

	1 Year ²	2 Year ²	3 Year ²	4 Year ²	5 Year ²	Total
Vessels with Adequate Imaging for Vessel-Level Assessment⁴	188	122	96	61	50	188
Stenosis Evaluable	188	121	94	57	50	188
Stenotic >50 %	1 (0.5%)	4 (3.3%)	0 (0%)	0 (0%)	1 (2.0%)	5 (2.7%)
Vessels with Adequate Imaging for Device Compression/Invagination⁶	188	120	94	60	50	188
Device Compression/Invagination	16 (8.5%)	13 (10.8%)	8 (8.5%)	3 (5.0%)	3 (6.0%)	23 (12.2%)
Vessels with Adequate Imaging for Dissection Present (Branch Vessel)⁶	188	118	94	57	48	188
Dissection Present (Branch Vessel)	10 (5.3%)	3 (2.5%)	1 (1.1%)	1 (1.8%)	1 (2.1%)	12 (6.4%)
Vessels with Adequate Imaging for Wire Fracture⁵	188	122	96	61	50	188
Wire Fracture	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Vessels with Adequate Imaging for Device Component Separation⁵	188	122	96	61	50	188
Device Component Separation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Vessels with Adequate Imaging for Migration⁵	188	122	96	61	50	188
Migration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Vessels with Adequate Imaging for Endoleak⁵	188	122	96	61	50	188
Endoleak	2 (1.1%)	2 (1.6%)	1 (1.0%)	0 (0%)	0 (0%)	3 (1.6%)
Endoleak Type	2	2	1	0	0	3
Type IA	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IB	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IC	1 (0.5%)	1 (0.8%)	0 (0%)	-	-	1 (0.5%)
Type II	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IIIA	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IIIB	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IIIC	1 (0.5%)	1 (0.8%)	1 (1.1%)	-	-	2 (1.1%)
Type III general	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IV	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Indeterminate	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Unknown	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)

¹Numbers represent subjects still in the study in or past window
²Beginning at end of previous window and continuing to start of subsequent window: 1 Year (1- 455 days), 2 Year (456-820 days), 3 Year (821-1185 days), 4 Year (1186-1550 days), 5 Year (after 1550 days); Note: Procedural/30 Day outcomes were not assessed by the Core Laboratory.
³CTs that have been reviewed by Core Lab imaging at time of table creation.
⁴Core Laboratory determined imaging was of sufficient quality to allow assessment of vessel-level characteristics.
⁵Core Laboratory determined imaging was of sufficient quality to allow assessment of device integrity outcomes (e.g., wire fracture, separation, migration, and endoleak).
⁶Of the imaging that was considered of sufficient quality to allow assessment of vessel-level characteristics or device integrity outcomes as presented in Table 20 and 21, a subset of imaging was determined by the Core Lab to be adequate quality for compression/invagination and dissection.

Table 47. Summary of Core Lab Findings BEVAR

	1 Year	2 Year	3 Year	4 Year	5 Year	Total
Number of Subjects at Risk^{1,2}	133	96	86	79	57	133
Subjects with CT in Window³	118	62	50	41	15	122
VBX-Treated Vessels at Risk	394	288	260	239	172	394
VBX-Treated Vessels with Available Imaging³	357	183	143	136	47	364
Vessels with Adequate Imaging for Vessel-Level Assessment⁴	357	183	143	134	47	364
Stenosis Evaluable (>50%)	353	180	143	131	43	360
Stenotic > 50%	8 (2.3%)	7 (3.9%)	2 (1.4%)	1 (0.8%)	2 (4.7%)	17 (4.7%)
Vessels with Adequate Imaging for Device Compression/Invagination⁶	353	183	142	134	45	360
Device Compression/Invagination	30 (8.5%)	12 (6.6%)	12 (8.5%)	8 (6.0%)	7 (15.6%)	43 (11.9%)
Vessels with Adequate Imaging for Dissection Present (Branch Vessel)⁶	357	173	142	127	40	364
Dissection Present (Branch Vessel)	17 (4.8%)	8 (4.6%)	5 (3.5%)	4 (3.1%)	1 (2.5%)	22 (6.0%)
Vessels with Adequate Imaging for Wire Fracture⁵	357	183	143	134	47	364
Wire Fracture	0 (0%)	0 (0%)	1 (0.7%)	3 (2.2%)	1 (2.1%)	3 (0.8%)
Vessels with Adequate Imaging for Device Component Separation⁵	357	183	143	134	47	364
Device Component Separation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.1%)	1 (0.3%)

	1 Year	2 Year	3 Year	4 Year	5 Year	Total
Vessels with Adequate Imaging for Migration⁵	357	183	143	134	47	364
Migration	1 (0.3%)	1 (0.5%)	1 (0.7%)	0 (0%)	1 (2.1%)	2 (0.5%)
Vessels with Adequate Imaging for Endoleak⁵	357	183	143	134	47	364
Endoleak	10 (2.8%)	4 (2.2%)	5 (3.5%)	2 (1.5%)	1 (2.1%)	16 (4.4%)
Endoleak Type	10	4	5	2	1	16
Type IA	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type IB	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type IC	10 (2.8%)	4 (2.2%)	2 (1.4%)	0 (0%)	0 (0%)	12 (3.3%)
Type II	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type IIIA	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type IIIB	0 (0%)	0 (0%)	1 (0.7%)	2 (1.5%)	1 (2.1%)	2 (0.5%)
Type IIIC	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type III general	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%)
Indeterminate	0 (0%)	0 (0%)	2 (1.4%)	0 (0%)	0 (0%)	2 (0.5%)
Unknown	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
¹ Numbers represent subjects still in the study in or past window						
² Beginning at end of previous window and continuing to start of subsequent window: 1 Year (1- 455 days), 2 Year (456-820 days), 3 Year (821-1185 days), 4 Year (1186-1550 days), 5 Year (after 1550 days); Note: Procedural/30 Day outcomes were not assessed by the Core Laboratory.						
³ CTs that have been reviewed by Core Lab imaging at time of table creation.						
⁴ Core Laboratory determined imaging was of sufficient quality to allow assessment of vessel-level characteristics.						
⁵ Core Laboratory determined imaging was of sufficient quality to allow assessment of device integrity outcomes (e.g., wire fracture, separation, migration, and endoleak).						
⁶ Of the imaging that was considered of sufficient quality to allow assessment of vessel-level characteristics or device integrity outcomes as presented in Table 20 and 21, a subset of imaging was determined by the Core Lab to be adequate quality for compression/invagination and dissection.						

EMBRACE Registry Conclusions:

The EMBRACE Registry provides multicenter, independently adjudicated, hypothesis tested clinical data that supports the safety and effectiveness of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in conjunction with fenestrated or branched aortic endovascular grafts. The primary outcome of the EMBRACE registry analysis was target vessel patency at 12 months. The 12 month target vessel patency rate reported was 98.8% and 92.2% in the FEVAR and BEVAR cohorts, respectively. For both cohorts, the pre-specified Performance Goal of 77% was met. Composite rate of MAEs through 30 days was 3.3% and 16.9 % for the FEVAR and BEVAR cohorts, respectively. None of the MAEs through 30 days were adjudicated as VBX device-related. Data are available on all evaluable patients through 3-year follow-up, with complete Core Laboratory review and CEC adjudication. At 3 years, imaging was of sufficient quality to allow assessment of vessel-level characteristics and device integrity outcomes for 51 of 80 FEVAR subjects (63.8%) and 50 of 86 BEVAR subjects (58.1%). Four- and five-year follow-up remain ongoing and are not yet fully reviewed or adjudicated.

It is noted that BEVAR cohort outcomes are less favorable than those reported for the FEVAR cohort, especially as it relates to outcomes such as target vessel instability, endoleaks and major adverse events such as mortality and renal deterioration. Additionally, the tipping point analysis suggested higher uncertainty for the BEVAR cohort related to target vessel patency at 1 year. Although FEVAR and BEVAR procedures may involve a similar number of visceral vessels, the difference in outcomes may be attributed to different underlying anatomical conditions. BEVAR typically requires longer bridging distances and treatment of more extensive lesions, resulting in greater procedural complexity.

It is important to acknowledge that the real-world evidence in EMBRACE registry was derived from retrospective data collected from outside the United States during routine clinical care. As a result, clinical practice, patient and device selection, procedural techniques, and the timing and availability of follow-up assessments were not prospectively standardized and may have varied across sites. Additionally, uncertainty exists regarding lack of a complete characterization of patient attrition across all eligibility criteria, methods used during the retrospective medical-record review, and given the extent of censored subjects in the endpoint analysis. Patient attrition and missing imaging beyond the 1-year timepoint has limited the availability of longer-term outcomes in the EMBRACE registry; however, supplemental clinical data sources provide additional longer term outcome data. Another major limitation of the dataset is representation of aortic endografts with which the VBX Device was evaluated as a bridging stent; these limitations informed the device labeling.

Overall, the results from the EMBRACE Registry, as well as supplemental data, support use of the VBX Device as a bridging stent in fenestrated and branched endovascular aortic repair in patients who have appropriate anatomy.

SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

EXPAND Registry:

The EXPAND Registry (NCT03720704) is a European, post-market clinical follow-up study initiated upon receipt of CE Mark for the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in 2017. The primary objective of this registry was to collect real-world post-market safety and performance data of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in peripheral vessels (inclusive of visceral vessels) in patients who required interventional treatment; the registry includes use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent with fenestrated and branched aortic main body components.

The registry evaluated 39 subjects with 102 treated vessels in the FEVAR cohort and 73 subjects with 222 treated vessels in the BEVAR cohort. The primary endpoint for the EXPAND Registry was a composite of Procedural Success and Freedom from VBX Device-related Serious Adverse Events through 30 days.

- For FEVAR, 39 (100%) subjects met the Procedural Success criteria, and 38 (97.4%) met the Freedom from VBX-related SAEs criteria. Therefore, 38 (97.4%) subjects met the composite primary endpoint (95% CI 86.5% - 99.9%).

- For BEVAR, 73 (100%) subjects met the Procedural Success criteria, and 71 subjects were available for VBX-related SAE assessment; of those, 70 (98.6%) were free from VBX-related SAEs. Therefore, 70 (98.6%) subjects met the composite primary endpoint (95% CI 92.4% - 100.0%).

The secondary endpoint of Target Vessel Technical Success (same endpoint definition as the EMBRACE registry) at the index procedure was achieved for all subjects in each cohort (100% FEVAR and 100% BEVAR). The Kaplan-Meier estimate for Primary Patency at 1-year and 3 years at the vessel level was 100% and 95.1%, respectively, for the FEVAR subgroup and 96.0% and 93.4%, respectively, for the BEVAR subgroup. The Kaplan-Meier estimate for Freedom from Target Vessel Instability at 1-year and 3 years was 100% and 98.7%, respectively, for the FEVAR subgroup and 96.5% and 94.1%, respectively, for the BEVAR subgroup. Limitations of this data include the observational design, lack of core lab adjudication, and a limited number of subjects with longer-term follow-up. Despite the limitations, the EXPAND Registry results supplement the EMBRACE data with additional longer-term safety and effectiveness outcomes for the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis when used as a bridging stent for FEVAR and BEVAR.

EMBRACE Registry Mixed Cohort:

In addition to the FEVAR and BEVAR cohorts, a separate cohort of patients with GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as bridging stents in aortic endovascular grafts containing a mix of branches and fenestrations (mixed cohort) was enrolled and analyzed descriptively, comprising of 31 subjects with 67 VBX-treated vessels. The Target Vessel Technical Success at the index procedure was achieved for all subjects (100%). Primary Technical Success was achieved in 83.9% of subjects. No subject experienced Type I or Type III endoleaks that extended beyond 30 days. The Kaplan-Meier estimate of primary patency at 1, 2, and 3 years is 100%. Three (3, 12%) VBX Stent Graft related adverse events occurred in three patients (Type 1C, Type IIIC and Type II endoleaks), and no VBX Stent Graft related deaths were reported. The outcomes observed in the combined FEVAR/BEVAR cohort were consistent with those observed in the FEVAR and BEVAR analyses, providing additional supportive evidence for the use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in FEVAR and BEVAR procedures.

GORE TAMBE PMA:

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis has been evaluated as a bridging stent with the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) Device. Reference the TAMBE Device SSED and IFU for information regarding clinical results.

U.S. Aortic Research Consortium:

The US-ARC is a multicenter collaborative research consortium established in 2018 with the primary objective of evaluating outcomes of custom-made fenestrated and branched endovascular devices for treating patients with complex abdominal, thoracoabdominal, and arch aneurysms. The consortium aggregates prospectively collected data from physician-sponsored investigational device exemption studies, and has published analyses including pooled patient- and vessel-level outcomes from FEVAR/BEVAR procedures. Published US-ARC analyses [3,4] include clinical experience with GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis used in fenestrations and branches. The US-ARC data provide additional supportive evidence regarding use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in FEVAR/BEVAR.

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DEFINITIONS

EC **REP** Authorised Representative in the European Community

REF Catalogue Number

 Caution

Rx 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

 Contains a Medicinal Substance

 Contains Biological Material of Animal Origin

 Date of Manufacture

 Do Not Resterilize

 Do Not Reuse

 Do Not Use if Package is Damaged

 Importer into the European Community

 Keep Dry

 Manufacturer

MD Medical Device

 MR Conditional

SN Serial Number

 Single Sterile Barrier System

STERILE **EO** Sterilized using Ethylene Oxide

 Store at 15°C - 30°C

UDI Unique Device Identifier

 Use By

 Catheter Working Length

 Final Stent ID

 Guidewire Compatibility

 Inflation Pressure

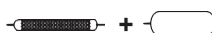
 Introducer Sheath

 Max Post-Dilated Stent Diameter

NP Nominal Pressure

 Nominal Stent Diameter

RBP Rated Burst Pressure

 Second Balloon Required, Not Included

 Stent Length



Manufacturer

W. L. GORE & ASSOCIATES, INC.

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Flagstaff, Arizona 86004

UNITED STATES

Order Information: Tel.: +1 928 526 3030 • Tel.: +1 800 528 8763

Technical Information: Tel.: +1 928 779 2771 • Tel.: +1 800 437 8181

For international contact and additional product information,
visit **goremedical.com**

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Printed on recyclable paper

JANUARY 2026

GORE® VIABAHN® VBX

Balloon Expandable
Endoprosthesis

INSTRUCTIONS FOR USE

Reduced Profile

en

English

INSTRUCTIONS FOR USE

GORE® VIABAHN® VBX BALLOON EXPANDABLE ENDOPROSTHESIS

Carefully read all instructions prior to use. Observe all instructions, warnings, and precautions noted throughout these instructions and only use as indicated. Failure to do so may result in complications.

PRODUCT DESCRIPTION

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Device) final product is comprised of two main components, the implantable endoprosthesis (also referred to as the stent graft) and a balloon catheter delivery system. The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis consists of two structural elements and a coating on the luminal surface: stainless steel rings, a fluoropolymer film that is attached to the stainless steel rings, and the CBAS® Heparin Surface (see **Figure 1**). The CBAS® Heparin Surface on the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis consists of covalent, end-point attached heparin of porcine origin. The endoprosthesis is premounted on a balloon designed for deploying the stent graft via balloon inflation. This balloon is covered with a thin layer of film to maximize retention of the endoprosthesis during introducer sheath insertion, tracking to the implant site, and balloon inflation/device deployment. The delivery system has two radiopaque balloon markers embedded in the shaft (denoting the effective balloon length) to aid in the placement of the endoprosthesis (see **Figure 2**). The delivery system is compatible with 0.035" (0.89 mm) guidewires. The premounted stent system is available in a variety of endoprosthesis lengths from 15 to 79 mm and in a variety of diameters from 5 to 11 mm (see **Table 1**). The premounted endoprosthesis system balloon catheter is also offered in two shaft lengths with effective lengths of 80 cm or 135 cm. Multiple GORE® VIABAHN® VBX Balloon Expandable Endoprostheses may be implanted in an overlapping configuration within the approved indications. This product is supplied sterile. It should not be resterilized.

The VBX should be used with branched or fenestrated aortic endografts indicated for use with bridging stents wherein safety and effectiveness of the device system (i.e., aortic component and bridging stent) has been demonstrated. Data to support the safety and effectiveness of the device system may be provided in the aortic endograft and/or bridging stent Instructions for Use.

Note: VBX has been studied as a bridging stent with multiple aortic endografts – refer to the clinical section below and/or the labeling of approved branched and fenestrated aortic endografts. Compatibility with other aortic stent grafts has not been evaluated.

NOTE: The diameter of the endoprosthesis may be increased post-placement beyond the nominal diameter by expanding with a larger diameter balloon. Refer to **Table 1** and **Table 2**.

Figure 1. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

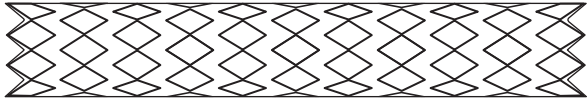
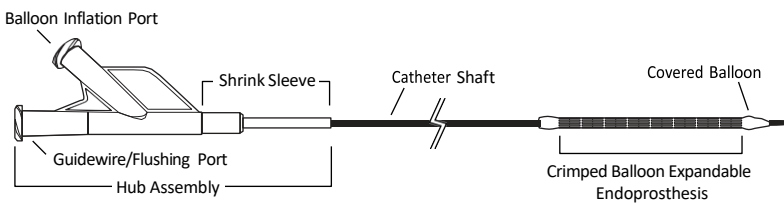


Figure 2. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis Delivery System



INDICATIONS FOR USE

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated for the treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5 mm-13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation.

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated to maintain visceral artery perfusion as a bridging stent in:

- fenestrated endovascular aortic aneurysm repair with 6-8 mm diameter fenestrations.
- branched endovascular aortic aneurysm repair with 6-8 mm diameter branches (e.g., portals, cuffs, or directional branches) that are at least 10 mm in length.

Bridging stent use is limited to aortic endovascular graft systems wherein safety and effectiveness has been demonstrated.

CONTRAINDICATIONS

Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II.

Patients with known sensitivities or allergies to the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis materials including expanded polytetrafluoroethylene (ePTFE), fluorinated ethylene propylene (FEP), stainless steel, and heparin.

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

General Warnings (All Applications):

- Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis for the treatment of lesions that would not allow an operative salvage procedure.
- Do not use the GORE® VIABAHN® VBX Balloon Expandable 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.^{1,2} If symptoms persist, or the health of the patient appears compromised, alternative pharmaceutical or surgical procedures, including ligation or removal of the device, may be considered at the discretion of the attending physician.
- Do not use if the package (i.e., foil pouch) 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.

- Reuse may result in infection and related serious potential patient harms. See *HOW SUPPLIED*.
- Use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis may not preclude the need for future surgical bypass, with attendant risks and harms.
- Use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in lesions involving a major side branch that may be covered by the endoprosthesis may result in ischemia, occlusion, and/or related serious harms, potentially necessitating surgical intervention.
- Special care should be taken to ensure that the appropriate size endoprosthesis is selected prior to introduction. Native vessel and fenestration/branch dimensions must be accurately measured, not estimated. Failure to follow the appropriate device sizing recommendations or failure to ensure proper device placement, including overlap conditions, prior to deployment can result in ischemia, vessel damage/rupture, and related serious harms, potentially necessitating additional endovascular procedures or surgical intervention.
- Special care should be taken to ensure that compatible introducer sheath(s) and guidewire(s) are selected prior to endoprosthesis introduction. Failure to do so may result in damage to the endoprosthesis, endoprosthesis dislodgement from the delivery system, partial or inaccurate deployment, vessel damage, and/or ischemia, potentially requiring surgical intervention.
- Do not exceed the maximum rated burst pressure. Exceeding this pressure increases the potential for balloon rupture and possible vessel damage.
- Care should be taken to ensure the device is sufficiently apposed to the vessel wall between initial device deployment and post-dilatation (if performed). Failure to do so may result in device displacement or migration.
- Use only diluted contrast medium for balloon inflation (typically a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium in the balloon.
- Do not exceed the max. post-dilated stent diameter as per **Table 1** and **Table 2**. Exceeding this diameter may result in damage to the endoprosthesis leading to possible ischemia, vessel damage/rupture, and related serious harms, potentially necessitating additional endovascular procedures or surgical intervention.
- Do not remove the endoprosthesis from the balloon delivery system. The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should not be removed and placed on another balloon catheter for deployment. The endoprosthesis should only be deployed using the supplied delivery system. Altering the endoprosthesis or delivery system may result in endoprosthesis dislodgement from the delivery system, inaccurate placement, vessel damage, or compromised performance of the device, potentially necessitating additional endovascular procedures or surgical intervention.
- Do not use a kinked introducer sheath or catheter shaft. A kinked introducer sheath or catheter shaft may increase the force necessary to advance the endoprosthesis to the desired location and may cause catheter breakage.
- Do not attempt to deploy the endoprosthesis or manipulate the delivery system without an appropriately sized guidewire (**Table 1**) and fluoroscopic guidance.
- Use high-resolution fluoroscopy to avoid inaccurate device placement and related serious patient harms leading to ischemia, potentially necessitating additional endovascular procedures or surgical intervention.
- Prior to endoprosthesis deployment, utilize high-resolution fluoroscopy to verify that stent has not been damaged, partially deployed or dislodged during positioning. Do not deploy the endoprosthesis if damaged, partially deployed or dislodged.
- Do not withdraw the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis back into the introducer sheath once the endoprosthesis is fully introduced. Withdrawing the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis back into the introducer sheath can cause dislocation and/or dislodgement and damage to the endoprosthesis, premature deployment, deployment failure, and/or catheter separation which may result in vessel damage and/or ischemia, potentially requiring surgical intervention. If removal prior to deployment is necessary, withdraw the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis to a position close to but not into the introducer sheath. Both the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis and introducer sheath can then be removed in tandem. After removal, do not reuse the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis or introducer sheath.
- Inadvertent, partial, or failed deployment or migration of the endoprosthesis may require additional endovascular procedures or surgical intervention.
- Do not attempt to withdraw or reposition the balloon catheter within the lumen of the deployed endoprosthesis unless the balloon is completely deflated. Failure to do so could lead to endoprosthesis displacement, vessel damage, and/or ischemia, potentially requiring additional endovascular procedures or surgical intervention.
- Forcefully removing the delivery system after deployment may cause the endoprosthesis to migrate, and/or cause inaccurate placement or delivery system damage which may require additional endovascular procedures or surgical intervention.
- As with any balloon expandable stent, use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in anatomy and procedures where the device is susceptible to severe external compression may result in permanent compression of the device (see *DIRECTIONS FOR USE, TREATMENT OF VESSEL* section, G.12). This can cause partial or complete device occlusion which may result in ischemia and related serious harms, potentially necessitating additional endovascular procedures or surgical intervention.
- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is not indicated for use in the coronary arteries, coronary bypass grafts, coronary sinus or carotid arteries.

Stenotic Indication Warnings:

- To reduce the potential for vessel damage, the final stent inner diameter (as indicated on the compliance chart) should approximate the diameter of the vessel just proximal and distal to the stenosis. Overstretching of the artery may result in rupture and life-threatening bleeding.

Bridging Stent Indication Warnings:

- Native vessel and fenestration/branch dimensions must be accurately measured, not estimated, to ensure the appropriately sized endoprosthesis is selected as a bridging stent.
- The 10 mm and 11 mm diameter GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis have not been clinically evaluated for use as bridging stents in the renal arteries through the EMBRACE Registry or GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) Pivotal Study.
- The 19 mm device does not meet the minimum recommended overlap requirements for FEVAR bridging. In the EMBRACE Registry, use of the 19 mm device was limited. Target vessel overlap of 10–15 mm in the EMBRACE FEVAR cohort was not associated with increased rates of displacement, migration, or endoleak. However, the literature identifies these complications as potential risks of inadequate proximal or distal overlap. When using the 19 mm device, prioritize achieving the recommended protrusion into the aortic endograft to allow flaring. Close monitoring is strongly recommended when choosing a device size that does not meet the anatomical requirements specified in the Sizing Section of the IFU.
- When used as a bridging stent for fenestrated or branched repair, utilize the required overlap and landing zone lengths with branches, fenestrations, overlapping GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, and target vessel to avoid device displacement, endoleak, or migration.
- When used as a bridging stent, confirm the target visceral vessel associated with each branch or fenestration before cannulation and device selection. Use of an incorrectly sized device may result in branch occlusion, vessel injury, or endoleak.
- Bridging stent 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.
- Lower branch primary patency rates were observed in specific clinical evaluations for certain patient subsets with renal artery diameters ≤5 mm compared to larger diameter renal arteries. Appropriate patient selection, procedural planning, and post-procedural surveillance are important considerations when treating smaller target vessels.

- Crossing of bridging stents is not recommended. Compromise to device integrity, including bridging stent compression and Aortic Component wire fracture, has been identified in clinical follow up under these conditions. Crossing bridging stents may lead to bridging stent occlusion, vessel damage, or endoleak.
- Incomplete long-term imaging follow-up in clinical evaluations of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent limits the ability to fully characterize late device-related adverse events. Published clinical experience suggests that the rate of compression, loss of patency, endoleak, and other target vessel complications are more likely to occur during long-term follow-up. Continued imaging surveillance is strongly recommended throughout the life of the implant.
-

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® VIABAHN® VBX Balloon Expandable Endoprosthesis has not been established in patients less than 18 years of age.
- Patients should receive an anticoagulant and/or antiplatelet regimen pre-, peri-, and post-procedure as deemed appropriate by the treating physician. The presence of heparin on the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is not intended to serve as an alternative to the physician's chosen intraoperative or postoperative anticoagulant and/or antiplatelet regimens.
- Follow the Directions for Use supplied with all accessories used in conjunction with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
- Prepare the premounted endoprosthesis system per the instructions given in the Directions For Use section. Significant amounts of air in the balloon may cause difficulty in deploying the endoprosthesis and deflation of the balloon.
- Do not attempt to manually remove or adjust the endoprosthesis on the delivery balloon catheter.
- Always manipulate the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis delivery system under fluoroscopy when in the body. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
- Avoid post-dilation outside the endoprosthesis to avoid vessel injury that can lead to partial or complete device occlusion.
- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is not designed for use with power injection systems. Inflation at a high rate can cause damage to the balloon catheter. Use of a pressure monitoring device is recommended to prevent over-pressurization.
- Non-clinical testing has demonstrated that the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is MR Conditional. A patient with this device can be safely scanned in an MR system under the conditions detailed in the *MRI SAFETY INFORMATION* section.

ADVERSE EVENTS

POTENTIAL CLINICAL AND DEVICE ADVERSE EVENTS

Possible adverse events and complications that may occur with the use of this device or in any endovascular procedure and require intervention include, but are not limited to (shown in English alphabetical order):

- access site complications
- allergic reaction and/or anaphylactoid response to x-ray contrast dye anti-platelet therapy
- arteriovenous fistula formation
- bleeding and/or hematoma
- death
- deployment failure
- device failure
- embolism
- endoleak and/or endotension
- fever and/or pain in the absence of infection
- infection
- inflammation
- ischemia
- malapposition
- malposition
- migration
- multi-organ failure
- myocardial infarction
- occlusion (thrombosis and/or stenosis) of endoprosthesis or vessel
- pseudoaneurysm
- radiation injury
- sepsis
- shock
- stroke
- tissue necrosis
- transient or permanent renal failure
- trauma to the vessel wall (including rupture or dissection)

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

Refer to IFU sections *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.

CLINICAL AND DEVICE ADVERSE EVENT REPORTING

Any adverse event involving the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should be reported to the manufacturer and the country specific regulatory authorities immediately. To report an event to W. L. Gore & Associates, email: medcomplaints@wlgore.com or contact (as applicable):

US: Phone: +1 800 528 1866, or +1 928 864 4922

China: Phone: +86 21 5172 8299

Japan: Phone: +81 3 6746 2562

Brazil: Phone: +55 11 5502-7953

EMEA: Phone: +49 89 4612 3440

For patients in Australia: Report any serious incident in relation to this device to the Therapeutic Goods Administration: <https://www.tga.gov.au/reporting-problems>.

To report an adverse event to W. L. Gore & Associates in all other markets, please use the email above (medcomplaints@wlgore.com) or call the US phone number (+1 800 528 1866 or +1 928 864 4922).

HOW SUPPLIED

CONTENTS

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is preloaded on a delivery catheter.

STERILITY

- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is provided STERILE and non-pyrogenic and is sterilized by Ethylene Oxide. Do not resterilize.
- Do not use after the “use by” (expiration) date printed on the label.
- The GORE® VIABAHN® VBX Balloon Expandable 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**).

STORAGE AND HANDLING

- Keep dry and store at 15°C - 30°C.
- Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if the foil pouch has been compromised or if the device is damaged.
- 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**.

DIRECTIONS FOR USE

PHYSICIAN TRAINING REQUIREMENTS

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should only be used by physicians trained in endovascular techniques.

REQUIRED MATERIALS

- GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis
- Marker guidewire or catheter (for calibrated measurement reference)
- Syringe filled with heparinized saline for prepping the endoprosthesis system
- Introducer sheath of appropriate size (**Table 1**)
- Stiff guidewire: diameter must be 0.035" (0.89 mm)
- Guidewire length should be at least twice the length of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis delivery catheter
- Appropriate diagnostic catheters and accessories
- Inflation device (20 cc or greater) and diluted contrast medium

Additional Materials Required For Bridging Stent Implantation

- When using a GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for fenestrated or branched repair, refer to the directions for use of the aortic endovascular grafts used in the procedure to aid in sizing, alignment, and deployment of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis within the aortic endovascular grafts fenestrations or branches.
- PTA Balloon(s) from any supplier; diameter, length, and catheter working length as appropriate for bridging stent devices selected.

Accessory, auxiliary, and ancillary materials (equipment, tools, and devices) should be used in accordance with the manufacturer’s instructions for use. 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 and devices.

RECOMMENDED DEVICE SIZING

Note: 15 mm length and 8L diameter configurations are not indicated for use as bridging stents in fenestrated or branches endovascular aortic aneurysm repair

Table 1. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis Sizes

Stent Labeled/Nominal Diameter (mm)	Crimped Stent Length ^{3, 4} (mm)	Introducer Sheath Size (Fr)	Guidewire Diameter	Max. Post-Dilated Stent Diameter ¹ (mm)	Catheter Length (cm)
5	15, 19, 29, 39, 59, 79	6	0.035" (0.89 mm)	8	80, 135
6	15, 19, 29, 39, 59, 79	6	0.035" (0.89 mm)	8	80, 135
7	15, 19, 29, 39, 59, 79	6	0.035" (0.89 mm)	11	80, 135
8	29, 39, 59, 79	7	0.035" (0.89 mm)	11	80, 135
8L	29, 39	7	0.035" (0.89 mm)	16 ²	80, 135
	59, 79	8	0.035" (0.89 mm)		80, 135

Stent Labeled/Nominal Diameter (mm)	Crimped Stent Length (mm)	Introducer Sheath Size (Fr)	Guidewire Diameter	Max. Post-Dilated Stent Diameter ¹ (mm)	Catheter Length (cm)
9	29, 39, 59, 79	7	0.035" (0.89 mm)	13	80, 135
10	29, 39, 59, 79	7	0.035" (0.89 mm)	13	80, 135
11	29, 39, 59, 79	8	0.035" (0.89 mm)	16 ²	80, 135

¹ Secondary balloon required to post-dilate the stent beyond its nominal deployed diameter (secondary balloon not included).

² Technical limit of the device as determined by *in-vitro* testing for the indicated use; device expansion beyond 13 mm was not studied as part of the VBX FLEX clinical study. Within the EMBRACE Registry maximum measured device expansion was 12.6 mm and flaring was performed with balloons up to 14 mm in diameter.

³ The 19 mm length configuration is the minimum length for use as a bridging stent in fenestrated endovascular aortic repair (FEVAR)

⁴ The 29 mm length configuration is the minimum length for use as a bridging stent in branched endovascular aortic repair (BEVAR)

Table 2. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis Sizing Table

Stent Labeled/ Nominal Diameter (mm)	Crimped Stent Length ^{4,5} (mm)	At Nominal Pressure			At Rated Burst Pressure			At Max. Post-Dilated Stent Diameter ¹	
		Nominal Inflation Pressure (atm/kPa)	Final Stent ID (mm)	Stent Length ³ (mm)	Rated Burst Pressure (atm/kPa)	Final Stent ID (mm)	Stent Length ³ (mm)	Max. Post-Dilated Diameter (mm)	Stent Length at Max. Post-Dilated Stent Diameter ³ (mm)
5	15	13/1317	5	14.1	16/1621	5.3	14.0	8	10.5
	19	11/1115	5	18.6	16/1621	5.4	18.2	8	13.8
	29	12/1216	5	28.3	16/1621	5.4	28.0	8	22.3
	39	11/1115	5	38.5	16/1621	5.5	38.1	8	32.0
	59	12/1216	5	58.6	16/1621	5.4	58.4	8	51.2
	79	14/1419	5	78.9	17/1723	5.3	78.9	8	72.1
6	15	18/1824	6	13.5	18/1824	6	13.5	8	10.5
	19	16/1621	6	18.4	17/1723	6.1	18.3	8	14.6
	29	15/1520	6	28.3	17/1723	6.1	28.2	8	24.3
	39	14/1419	6	38.1	17/1723	6.3	38.0	8	33.3
	59	15/1520	6	58.6	17/1723	6.1	58.6	8	52.3
	79	14/1419	6	79.4	17/1723	6.2	79.6	8	73.6
7	15	9/912	7	13.8	11/1115	7.2	13.7	11	9.5
	19	8/811	7	18.1	11/1115	7.4	17.7	11	12.6
	29	8/811	7	27.9	11/1115	7.4	27.7	11	19.4
	39	8/811	6.9	37.7	11/1115	7.4	37.4	11	26.6
	59	7/709	6.9	58.7	11/1115	7.4	58.5	11	46.9
	79	8/811	6.9	78.6	11/1115	7.4	78.5	11	68.1
8	29	11/1115	7.9	27.1	15/1520	8.4	27.0	11	23.7
	39	12/1216	8	37.7	15/1520	8.4	37.5	11	30.0
	59	12/1216	8	57.8	15/1520	8.4	57.7	11	47.3
	79	12/1216	7.9	78.3	15/1520	8.4	78.5	11	69.6
8L	29	12/1216	8	28.8	16/1621	8.6	28.7	16 ²	21.8
	39	12/1216	8	39.4	16/1621	8.5	39.5	16 ²	26.8
	59	11/1115	7.9	58.7	16/1621	8.7	58.4	16 ²	44.1
	79	12/1216	8	79.4	16/1621	8.6	79.7	16 ²	58.6

Stent Labeled/ Nominal Diameter (mm)	Crimped Stent Length ^{4,5} (mm)	At Nominal Pressure			At Rated Burst Pressure			At Max. Post-Dilated Stent Diameter ¹	
		Nominal Inflation Pressure (atm/kPa)	Final Stent ID (mm)	Stent Length ³ (mm)	Rated Burst Pressure (atm/kPa)	Final Stent ID (mm)	Stent Length ³ (mm)	Max. Post-Dilated Diameter (mm)	Stent Length at Max. Post-Dilated Stent Diameter ³ (mm)
9	29	13/1317	9	26.6	15/1520	9.3	26.4	13	20.4
	39	12/1216	9	36.5	15/1520	9.5	36.0	13	23.2
	59	11/1115	9	57.9	15/1520	9.6	57.7	13	38.1
	79	11/1115	9	76.9	15/1520	9.6	76.6	13	62.7
10	29	14/1419	10.0	26.3	15/1520	10.1	26.2	13	19.1
	39	12/1216	10.0	36.6	15/1520	10.4	36.3	13	31.1
	59	12/1216	10.0	57.2	12/1216	10.0	57.2	13	44.6
	79	12/1216	10.0	77.1	12/1216	10.0	77.1	13	68.4
11	29	10/1013	11.0	26.0	11/1115	11.2	25.8	16 ²	17.8
	39	10/1013	11.1	35.4	11/1115	11.4	35.1	16 ²	25.8
	59	9/912	11.0	55.9	11/1115	11.5	55.4	16 ²	42.8
	79	9/912	10.9	77.2	11/1115	11.4	76.9	16 ²	60.6

¹ Secondary balloon required to post-dilate the stent beyond its nominal deployed diameter (secondary balloon not included).

² Technical limit of the device as determined by *in-vitro* testing for the indicated use; device expansion beyond 13 mm was not studied as part of the VBX FLEX clinical study. Within the EMBRACE Registry maximum measured device expansion was 12.6 mm and flaring was performed with balloons up to 14 mm in diameter.

³ Based on idealized *in-vitro* conditions and provided to be used as a general guide.

⁴The 19 mm length configuration is the minimum length for use as a bridging stent in fenestrated endovascular aortic repair (FEVAR)

⁵The 29 mm length configuration is the minimum length for use as a bridging stent in branched endovascular aortic repair (BEVAR)

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

TREATMENT OF VESSEL

A. Access

- Using appropriate anesthesia, access is achieved using the appropriate vessel. When possible, a percutaneous Seldinger technique is preferred. A cutdown may be performed when indicated.
- Using standard technique, insert the appropriately sized introducer sheath into the vessel.
- Gain guidewire access across the target lesion.

B. Imaging and Measurement

- Use appropriate imaging modalities and accessories (e.g., marking guidewires or catheters) to:
 - accurately identify healthy proximal and distal landing zones
 - ensure precise vessel measurements (i.e., diameters and length)
 - When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in fenestrated and branched aortic endovascular repair, base proximal landing zones on aortic endovascular graft fenestration and branch dimensions, and distal landing zones on measured target vessel diameters.

C. Percutaneous Transluminal Angioplasty (PTA)

- It is recommended to pre-dilate the lesion to allow for easy passage of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
- Refer to angioplasty balloon's manufacturer's Directions for Use.
- Inflate the angioplasty balloon to its nominal pressure according to manufacturer's Directions for Use. Ensure full expansion of the balloon within the lesion.
Note: Carefully mark the margins of the angioplasty treatment segment in order to ensure complete coverage with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
- Following deflation of the angioplasty balloon, evaluate the results angiographically. For reference, measure the native vessel diameter and lesion length.

D. Sizing and Selection of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

- A careful assessment of the vessel is necessary to select the appropriate size(s) of and deployment positions for the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
 - Stenotic or occlusive lesions:** To reduce the potential for vessel damage, the final stent inner diameter (as indicated on the compliance chart) should approximate the diameter of the vessel just proximal and distal to the stenosis. To prevent endoprosthesis migration, care should be taken to ensure the device is sufficiently apposed to the vessel wall between initial device deployment and post- dilation (if performed).

- b. The endoprosthesis lengths of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis listed in **Table 1** are nominal. Wherever appropriate, it is recommended that the endoprosthesis overlap the healthy native vessel at least 1 cm beyond the proximal and distal margins of the lesion when treating stenotic or occlusive lesions. Endoprosthesis foreshortening should be taken into account to achieve the recommended lesion coverage.
- c. Verify that there is sufficient catheter length to access the treatment site.
- d. **Bridging Stent:**
Fenestrated Bridging Stent: When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for fenestrated endovascular aneurysm repair (FEVAR), the following is required to ensure adequate anchoring and seal:

- Fenestration:

- **Diameter:** The inflated diameter of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis within the fenestration should approximate the maximum inner diameter of the fenestration.
- **Length:** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should have 5-10 mm protrusion in the aortic endovascular graft lumen for flaring.
- **Flaring:** Utilize an angioplasty balloon with a diameter ≥ 2 mm larger than the fenestration diameter to flare the proximal portion of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis that extends into the lumen of the aortic endovascular graft.
- When flaring, do not expand the stent beyond the maximum post-dilated stent diameter shown in **Table 2**.

- Visceral Vessel:

- **Diameter:** The final stent inner diameter should approximate the diameter of the native healthy vessel, with a final stent diameter 10% greater than the diameter of the native artery being acceptable.
- **Length:** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should have ≥ 15 mm overlap into the landing zone of each visceral vessel (renal, celiac, and superior mesenteric arteries).

Branched Bridging Stent: When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for Branched Endovascular Aneurysm Repair (BEVAR), the following is required to ensure adequate anchoring and seal:

- Aortic Endovascular Graft Branch:

- **Diameter:** The final stent inner diameter of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis contained within the branch (portal, cuff, or directional branch) should approximate the diametric dimensions of the aortic endovascular graft branch.
- **Branches < 15 mm in Length:** Ensure length of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is sufficient to meet vessel overlap requirements and have 5-10 mm extension beyond the branches (portal, cuff or directional branch) inlet to be flared.
- **Flaring for Branches < 15 mm in Length:** Use an appropriately sized balloon catheter to flare the proximal end of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis outside the branch 1-2 mm greater than branch diameter.

Note: Depending on desired diameter, the balloon on which the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is mounted may be used to flare the proximal end of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if it can reach the appropriate diameter (1-2 mm larger than the aortic endovascular graft branch diameter).

- **Branches ≥ 15 mm in Length:** Ensure complete apposition along the overlapping length between the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis and the aortic endovascular graft branch.

Note: The requirement not to flare in branches ≥ 15 mm in length is supported by literature, physician experience, and current clinical practice. Longer branch designs rely on full apposition along the branch for fixation and sealing, while shorter branch designs require proximal protrusion and flaring.

- Visceral Vessel:

- **Diameter:** The final stent inner diameter should approximate the diameter of the native healthy vessel, with a final stent diameter 10% greater than the diameter of the native artery being acceptable.
- **Length:** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis has ≥ 15 mm overlap into the landing zone of each visceral vessel (renal, celiac, and superior mesenteric arteries).

2. **Overlapping Requirements for Overlapping Multiple GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis:** When overlapping (telescoping) multiple devices, the following are suggested:

- a. Endoprosthesis foreshortening should be taken into account to achieve the recommended overlap between devices. To ensure proper seating between devices, follow the suggested overlap requirements.
 - For occlusive disease, at least 1 cm of overlap between devices is recommended.
 - When used as a bridging stent, at least 2 cm of overlap between devices is recommended.
- b. Overlapping devices should not differ by more than 1 mm in deployed diameter.
- c. If a bridging stent extension is planned with devices of differing deployed diameters, the smaller diameter device should be deployed first.
- d. When using multiple endoprostheses to treat multiple lesions, it is recommended, wherever appropriate, to first treat the lesion that would obviate the need to cross the first endoprosthesis when placing the second or subsequent endoprosthesis. This would reduce the chance of disrupting or damaging the endoprostheses.
- e. Balloon touch-up (post-dilatation) should be performed at the overlap region.

3. When deploying into a tapered vessel, consider the following:

- a. **Stenotic or occlusive lesions:** To reduce the potential for vessel damage, the final stent inner diameter (as indicated on the compliance chart) should approximate the diameter of the vessel just proximal and distal to the stenosis.

Fenestrated and Branched Bridging Stent: The following is required to assure adequate anchoring and seal:

- Visceral Vessel:

- **Diameter:** The final stent inner diameter should approximate the diameter of the native healthy vessel, with a final stent diameter 10% greater than the diameter of the native artery being acceptable.

Note: For achievable diameters using the provided delivery system, refer to the compliance chart. For achievable diameters using a secondary balloon during post-

dilatation, refer to **Table 1** and **Table 2** under the max. post-dilated stent diameter.

- b. Device tapering may be performed by first deploying the device to the smaller of the two reference vessel diameters and subsequently post-dilating the device in the region of the larger reference vessel diameter. To prevent endoprosthesis migration, care should be taken to ensure the device is sufficiently apposed to the vessel wall between initial device deployment and post-dilatation.
- c. When post-dilating with another balloon, choose a balloon length smaller than the deployed endoprosthesis length. Do not extend balloon dilatation beyond the ends of the endoprosthesis and into healthy vessel as this may also induce restenosis and subsequent failure. Do not expand any portion of the stent beyond the maximum post-dilated diameter as listed in **Table 1** and **Table 2**.

- d. When post-dilating the 8L device with a larger diameter balloon, do not increase the device diameter by more than 4 mm with a single balloon inflation. For example, to obtain a final diameter >12 mm from the nominal 8 mm diameter, first post-dilate with a 12 mm diameter secondary balloon before post-dilating with a larger diameter (13-16 mm) secondary balloon.

E. Preparation of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

1. Prior to removing the device from the foil pouch, confirm that the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis has not expired. Do not use the GORE® VIABAHN® VBX Balloon Expandable after the "Use By" (expiration) date. Confirm the endoprosthesis diameter and length, delivery catheter length, and guidewire compatibility are correct before removing the device from the packaging.
2. Opening the Pouch:
 - a. Carefully inspect the foil pouch to ensure that it is not compromised. Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if the foil pouch is compromised.
 - b. Beginning at one corner, peel back the edge of the foil pouch and gently remove the coil containing the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
 - c. Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if the sterile pouch is compromised or the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is damaged.
3. Inspection Prior to Use:
 - a. Prior to using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, all materials and equipment to be used for the procedure should be carefully examined for bends, kinks, or other damage.
 - b. Do not use any damaged or defective equipment and materials.
4. The distal end of the delivery catheter with the crimped endoprosthesis may be shaped or formed gently prior to loading the catheter on a guidewire, to assist with trackability of the delivery system. Care should be taken to ensure that the metal stent rings are not deformed, displaced, or damaged while shaping or forming.
5. Preparation of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis delivery catheter:
 - a. Flush the delivery catheter by attaching a syringe of heparinized saline to the guidewire lumen port on the catheter hub assembly (**Figure 2**). Continue flushing until a steady stream of fluid exits the tip of the catheter.
 - b. After flushing the catheter, remove the syringe.
 - c. Prepare inflation device/syringe with diluted contrast medium. The standard inflation medium is a 50/50 mixture of contrast medium and normal saline or as deemed appropriate by the physician.
 - d. Attach inflation device/syringe to stopcock (if needed). Attach to the endoprosthesis system inflation port.
 - e. Open stopcock to the endoprosthesis system. With the distal balloon tip pointing down and placed below the level of the inflation device/syringe, pull negative pressure for 20-30 seconds. Carefully release to neutral for contrast fill. Do not apply any positive pressure at this time as it may result in partial deployment.
 - f. Close stopcock to the endoprosthesis system; purge inflation device/syringe of all air.
 - g. Repeat the previous two steps until all air is expelled. If bubbles persist, do not use the endoprosthesis system.
 - h. If a syringe was used for preparation, attach a prepared inflation device to stopcock.
 - i. Open stopcock between the endoprosthesis system and the inflation device.

F. Introduction and Positioning of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

1. Select the compatible size introducer sheath from **Table 1**. Always use an appropriately sized introducer sheath for the implant procedure. Ensure the introducer sheath is free of kinks. It is advisable to use an introducer sheath that is long enough to cross the lesion. Use of an introducer sheath minimizes the risk of dislodging the endoprosthesis from the balloon during tracking. Use standard interventional techniques to introduce the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis to the target lesion or intended location.
2. Ensure the stiff guidewire is 0.035" (0.89 mm).
3. Be sure to remove the balloon catheter while maintaining the position of the guidewire beyond the target lesion or intended location. It is strongly recommended that the guidewire remain across the lesion until the procedure is complete to avoid having to regain access.
4. With the delivery catheter as straight as possible, insert the guidewire into the tip of the delivery catheter while supporting the delivery catheter and the endoprosthesis. Carefully advance the endoprosthesis in small increments (approximately 0.5 cm) over the guidewire, through the hemostasis valve and introducer sheath, and into the access vessel. Do not insert the shrink sleeve or the hub assembly into the introducer sheath.

NOTE: If excessive resistance is felt as the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is introduced through the hemostasis valve, remove the device (Step 7; NOTE). Do not reuse the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis after removing from the introducer sheath.
5. Using high-resolution fluoroscopic guidance, advance the delivery catheter over the guidewire via the introducer sheath. Advance cautiously, especially if resistance is felt. If excessive resistance is felt, remove the delivery catheter and introducer sheath together as described below (Step 7; NOTE).
6. Position the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis across the target lesion or intended location under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers (denoting the effective balloon length) as well as the radiopaque endoprosthesis as reference points to position the endoprosthesis in the lesion or intended location.

Note: Upon deployment, the ends of the endoprosthesis will be located inside the effective length of the balloon, away from the radiopaque markers, due to longitudinal foreshortening. Endoprosthesis foreshortening should be taken into account to achieve the desired lesion coverage and overlap with targeted landing zones. During positioning, verify that the endoprosthesis is still centered within the radiopaque markers and has not been displaced. Do not deploy the endoprosthesis unless it is properly centered on the balloon and properly positioned within the target lesion or intended location. If the position of the endoprosthesis within the lesion or intended location is not optimal, it should be carefully repositioned or removed.

NOTE: If PTA is performed, the endoprosthesis length should cover the entire vessel segment treated with balloon angioplasty.

Stenotic or Occlusive Lesion Positioning: Wherever appropriate, it is recommended that the endoprosthesis extend at least 1 cm proximal and distal to the margins of the lesion.

Bridging Stent Positioning:
Fenestrated Bridging Stent:

- **Fenestration:**
 - **Protrusion:** When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for FEVAR ensure the device protrudes 5-10 mm inside the aortic endovascular graft lumen for flaring.
- **Visceral Vessel:**
 - **Overlap:** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should have ≥ 15 mm overlap into the landing zone of each visceral vessel (renal, celiac, and superior mesenteric arteries).

Branched Bridging Stent:

- **Aortic Endovascular Graft Branch:**
 - **Overlap for Branches < 15 mm in Length:** Ensure length is sufficient to meet vessel overlap requirements and have 5-10 mm extension beyond the branch (portal, cuff, or directional branch) inlet to be flared.
 - **Overlap for Branches ≥ 15 mm in Length:** When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for BEVAR ensure complete apposition along the overlapping length within the aortic endovascular graft branch.
 - **Visceral Vessel:**
 - **Overlap:** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should have ≥ 15 mm overlap into the landing zone of each visceral vessel (renals, celiac, and superior mesenteric arteries).
7. Once the optimal position is verified fluoroscopically, the endoprosthesis is ready to be deployed.
- NOTE:** Should it become necessary to remove either a partially expanded or non-deployed GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis from the vessel, do not withdraw the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis back into the introducer sheath after the endoprosthesis is fully introduced. To remove the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, it can be withdrawn to a position close to but not into the introducer sheath. Both the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis and introducer sheath can then be removed in tandem. After removal, neither the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis nor the introducer sheath should be reused. Do not attempt to pull an endoprosthesis system that has been either partially expanded or not expanded back into the introducer sheath, as dislodgement of the endoprosthesis from the balloon may occur.

G. Deployment of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

1. Stabilize the delivery catheter at the hemostasis valve of the introducer sheath. It is also important to stabilize the delivery catheter and introducer sheath relative to the patient. This will minimize catheter movement during deployment and ensure accurate endoprosthesis positioning.
2. Deployment Instructions by Indication

Stenotic or occlusive lesions: To reduce the potential for vessel damage, the final stent inner diameter (as indicated on the compliance chart) should approximate the diameter of the vessel just proximal and distal to the stenosis.

Fenestrated Bridging Stent: When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for FEVAR, the following is required to ensure adequate anchoring and seal:

- **Fenestration:**
 - **Diameter:** The inflated diameter of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis within the fenestration approximates the maximum inner diameter of the fenestration.
 - **Flaring:** Proceed by flaring the proximal portion of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis that extends into the lumen of the aortic endovascular graft using an angioplasty balloon with a diameter ≥ 2 mm larger than the fenestration diameter.
 - When Flaring, do not expand the stent beyond the maximum post-dilated stent diameter shown in **Table 1** and **Table 2**.
- **Visceral Vessel:**
 - **Diameter:** The final stent inner diameter should approximate the diameter of the native healthy vessel, with a final stent diameter 10% greater than the diameter of the native artery being acceptable.

Branched Bridging Stent: When using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent for BEVAR, the following is required to ensure adequate anchoring and seal:

- **Aortic Endovascular Graft Branch:**
 - **Diameter for all Branch Lengths:** The final stent inner diameter of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis contained within the branch approximates the diametric dimensions of the aortic endovascular graft branch.
 - **Flaring for Branches < 15 mm in Length:** Use an appropriately sized balloon catheter to flare the proximal end of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis outside the branch 1-2 mm greater than branch diameter.
 - Note: Depending on desired diameter, the balloon on which the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is mounted may be used to flare the proximal end of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if it can reach the appropriate diameter (1-2 mm larger than the aortic endovascular graft branch diameter).
 - **Visceral Vessel:**
 - **Diameter:** The final stent inner diameter should approximate the diameter of the native healthy vessel, with a final stent diameter 10% greater than the diameter of the native artery being acceptable.
3. To deploy the endoprosthesis, use an inflation device to slowly inflate the endoprosthesis system to the pressure needed for the desired diameter. Maintain the inflation pressure for approximately 15 seconds. Higher pressure may be necessary to overcome any luminal loss due to the lesion, vessel, fenestration or branch to overcome stent recoil. Balloon pressures must not exceed rated burst pressure (Refer to **Table 2**). Extreme oversizing of the endoprosthesis relative to the vessel diameter may cause vessel damage. Undersizing of the endoprosthesis relative to the vessel diameter may lead to endoprosthesis migration. The compliance charts, provided on the box label, are generated in idealized in vitro conditions that do not take into account in vivo characteristics of lesions, vessels and patient-to-patient variability. Therefore, the compliance chart should be used as a general guide and user should confirm stent diameter and length angiographically during and after balloon inflation and deflation.

4. After deploying the endoprosthesis, slowly deflate the balloon manually using the inflation device to ensure proper balloon rewrap/refold. Allow adequate time for the balloon to fully deflate prior to removal. Observe fluoroscopically that the balloon is fully deflated prior to removal.
5. Maintaining proper introducer sheath support, very slowly withdraw the balloon. Observe under fluoroscopy to ensure that the balloon disengages from the stent. If resistance is encountered upon attempted removal, do not force removal, use fluoroscopy and conventional techniques to determine and remedy the cause of resistance before proceeding. The balloon needs to be fully deflated to ensure it disengages fully from the endoprosthesis.
6. Confirm endoprosthesis position and deployment using angiographic techniques. For optimal results, the entire lesion should be covered by the stent. For bridging stent applications, the device should have a minimum landing zone of 15 mm into the target vessel. High-resolution fluoroscopic visualization should be used in order to properly judge the optimum expanded endoprosthesis diameter as compared to the proximal and distal reference vessel, fenestration, or branch diameters.
7. If re-sizing is necessary, re-advance the delivery catheter, or another balloon catheter of appropriate size, to the stented area using standard interventional techniques.
8. While observing under fluoroscopy, inflate the balloon to the desired pressure; do not exceed the rated burst pressure. Do not expand the stent beyond maximum post-dilated stent diameter as shown in **Table 1** and **Table 2**. The maximum post-dilated stent diameter of 16 mm listed in **Table 1** and **Table 2** indicates the technical limit of the device as determined by in vitro testing for the indicated use. Device expansion beyond the diameter noted in the indication statement (13 mm) was not studied as part of the VBX FLEX clinical study. Within the EMBRACE Registry, maximum measured device expansion was 12.6 mm and flaring was performed with balloons up to 14 mm in diameter. When using another balloon to post-dilate, choose a balloon length smaller than the deployed endoprosthesis length. Do not extend balloon dilatation beyond the ends of the endoprosthesis and into healthy vessel as this may also induce restenosis and subsequent failure. Deflate the balloon and follow the instructions as outlined previously.
9. Reconfirm endoprosthesis position and angiographic result. Repeat inflations until the desired result is achieved.
10. While maintaining negative pressure in the balloon and the guidewire position across the treated lesion, carefully remove the delivery catheter from the body through the sheath or guide catheter. Moderate resistance may be felt when the balloon is withdrawn through the introducer sheath.
NOTE: If, during catheter removal, the balloon catches on the leading edge of the introducer sheath, a slight “back and forth” motion of the catheter may aid in release. If needed, the delivery catheter and the introducer sheath may be removed together as a unit. Excessive or abrupt force during catheter removal may damage the delivery catheter or introducer sheath.
11. A final angiographic run to evaluate vessel patency is recommended.
12. When clinically appropriate, remove the introducer sheath and achieve hemostasis of the puncture site.
13. Deployment of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in the kissing stent configuration/technique is recommended when proximal common iliac disease (unilateral or bilateral) cannot be adequately covered without extending into the aortic bifurcation, or when the disease involves the aortic bifurcation. Device selection should be made to ensure that the final stented length properly covers the lesion. The two devices are advanced to the target location and the stent-grafts are deployed simultaneously. Additional devices may be deployed in an overlapping configuration to achieve proper lesion coverage. Any post-dilation in the kissing stent region should be conducted bilaterally and simultaneously to avoid crushing either device.

H. Post-operative Follow-up

Following endovascular treatment using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, anticoagulant and/or antiplatelet therapy is recommended at a dosage deemed appropriate by the physician. Additionally, duplex ultrasound or CTA is recommended to monitor flow through the endoprosthesis at regular intervals post-operatively.

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

MRI SAFETY INFORMATION

MRI Safety Information



MR Conditional

A patient with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis may be safely scanned immediately after placement under the following conditions. Failure to follow these conditions may result in injury.

Device Name	GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis
Static Magnetic Field Strength (B ₀)	1.5T or 3.0T
Maximum Spatial Field Gradient	10 T/m (1000 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	2W/kg (Normal Operating Mode)
Scan Duration	2W/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, the artifact may extend up to 15mm from the implant and does obscure the lumen.

MRI Compatibility Information for Bridging Stents Use with Fenestrated and Branched Aortic Endovascular Grafts (Applicable Regions Only)

GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) device

- When the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is used with the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) device, use of the TAMBE label is appropriate for MRI scans.

Other Fenestrated and Branched Aortic Endovascular Grafts:

- Consult the Fenestrated and Branched Aortic Endovascular Graft's Instructions for Use for the appropriate MRI Safety Information for the Aortic Endovascular Graft component.
- Consult the MRI Safety Information above for the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis when used as bridging stent components.
- If the scan conditions differ between the Aortic Endovascular Graft and the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, utilize the more restrictive scan conditions of the devices. The largest artifact of the combined system is approximated as the sum of the component artifacts.

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

SUMMARY OF CLINICAL STUDIES

Clinical Evidence Supporting Use in Stenotic/Occlusive Disease:

The VBX FLEX clinical study was a prospective, multicenter, single-arm clinical study to evaluate the safety and efficacy of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis for the treatment of arterial occlusive disease in patients with de novo or restenotic lesions in the common and/or external iliac arteries. The primary study endpoint was a composite of major adverse events defined as device- or procedure-related death within 30 days; myocardial infarction (MI) within 30 days; amputation above the metatarsals in the treated leg, resulting from a vascular event, within 9 months; or target lesion revascularization (TLR) within 9 months. The statistical analysis plan prospectively specified that subjects meeting all of the eligibility criteria would be used for analysis of study endpoints. A sensitivity analysis was performed for testing the primary hypothesis in the intent-to-treat (ITT) population, which included all enrolled subjects, as well as the per-protocol (PP) population which included only those subjects who met the study inclusion criteria. The performance goal was met in both analyses with p-values <0.001, providing evidence for similarity of the results between the two populations. All endpoint data reported is based on the PP population, unless otherwise specified.

A. Study Design

The study population included symptomatic (Rutherford Category 2-4) patients with angiographic confirmation of either de novo or restenotic unilateral or bilateral occlusive disease in the common and/or external iliac arteries, with a total treated lesion length of ≤110 mm and vessel diameters between approximately 5 mm and 13 mm. Patients were included who presented with up to two discrete lesions requiring treatment, either one lesion per side for patients presenting with bilateral disease, or two lesions on the same side. All subjects could be treated with up to three GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Eligible patients in the study included those presenting with tortuous iliac arteries, severe lesion calcification, total occlusions, and those determined to need direct stenting (pre-dilatation optional) and/or kissing stent treatment at the aortic bifurcation. 134 subjects meeting all eligibility criteria were enrolled across 26 sites in U.S. and 1 site in New Zealand.

B. Clinical Endpoints

1. Primary Endpoint

The primary study endpoint was a composite of major adverse events (MAE) defined as device- or procedure-related death within 30 days; MI within 30 days; amputation above the metatarsals in the treated leg, resulting from a vascular event, within 9 months; or TLR within 9 months. The objective of the VBX FLEX clinical study was to demonstrate that the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is safe and effective for treatment of iliac artery disease by comparing the composite primary endpoint result to a pre-specified Performance Goal of 17.0%.

2. Secondary Endpoints

The secondary endpoints in this study included acute procedural success, 30-day clinical success, primary patency, primary assisted patency, secondary patency, freedom from TLR, freedom from clinically-driven TLR, freedom from target vessel revascularization (TVR), freedom from clinically-driven TVR, change in Rutherford category, change in ankle-brachial index (ABI), and change in functional status (based on subject questionnaires). All of these secondary outcomes were evaluated descriptively without any pre-specified performance criteria.

C. Demographics and Clinical Characteristics

Table 3 reports the baseline demographics and clinical characteristics for all 134 subjects.

Table 3. Baseline Demographics and Clinical Characteristics

	N=134 subjects
Gender at Birth	
Male	79 (59.0%)
Age	
Mean (Std Dev)	66 (9.5)
Race	
American Indian or Alaskan Native	3 (2.2%)
Asian	2 (1.5%)
Black or African American	4 (3.0%)
Native Hawaiian or Pacific Islander	0 (0.0%)
White	123 (91.8%)
Other Race	3 (2.2%)
Medical History and Risk Factors	
Smoking History	
Never Smoked	7 (5.2%)
Quit ≤ 1 Year Ago	18 (13.4%)
Quit 1-5 Years Ago	8 (6.0%)
Quit > 5 Years Ago	43 (32.1%)
Current User	58 (43.3%)
Diabetes	38 (28.4%)
Hypertension	113 (84.3%)
Hyperlipidemia	104 (77.6%)
Hypercholesterolemia	64 (47.8%)
Coronary Artery Disease	56 (41.8%)
Previous Myocardial Infarction	25 (18.7%)
Prior Treatment on Study Limb	22 (16.4%)
Prior Treatment on Non-Study Limb	13 (9.7%)
Rutherford	

Category 2 - Moderate Claudication	26 (19.4%)
Category 3 - Severe Claudication	101 (75.4%)
Category 4 - Ischemic Rest Pain	7 (5.2%)
TASC II Classification	
Type A	50 (37.3%)
Type B	41 (30.6%)
Type C	32 (23.9%)
Type D	11 (8.2%)

Table 4 reports the baseline anatomic and lesion characteristics for all 134 subjects.

Table 4. Baseline Anatomic and Lesion Characteristics

By Subject	
Access Approach¹	N=134
Ipsilateral	27 (20.1%)
Contralateral	24 (17.9%)
Bilateral	83 (61.9%)
Treated Segments¹	N=134
1	59 (44.0%)
2	71 (53.0%)
3	4 (3.0%)
Treated Limb(s)¹	N=134
Right	29 (21.6%)
Left	38 (28.4%)
Bilateral	67 (50.0%)
Kissing Stent Procedure	57 (42.5%)
Total Lesion Length per Subject (mm)²	N=132
Mean (Std Dev)	42.08 (23.98)
Total Stented Length per Subject (mm)²	N=133
Mean (Std Dev)	72.09 (29.39)
Number of Devices per Subject²	N=134
1	51 (38.1%)
2	69 (51.5%)
3	12 (9.0%)
4	1 (0.7%)
5	1 (0.7%)
By Limb	
Resting ABI¹	N=199
Mean (Std Dev)	0.77 (0.22)
Treated Vessel(s)¹	N=201
CIA	154 (76.6%)
EIA	31 (15.4%)
CIA and EIA	16 (8.0%)
Device(s) Successfully Delivered¹	N=201 100%
Max Post-Procedure Residual Stenosis $\leq$ 30%¹	N=201 100%

By Lesion	
Disease Characterization²	N=210
Stenosis	182 (86.7%)
Occlusion	28 (13.3%)
Maximum Stenosis (%)²	N=182
Mean (Std Dev)	62.1 (15.9)
Lesion Length (mm)²	N=209
Mean (Std Dev)	26.6 (16.3)
Stented Length (mm)²	N=212
Mean (Std Dev)	45.2 (14.4)

¹ Site reported.

² Core lab determination.

D. Methods

Following enrollment at the index procedure, all evaluable subjects were assessed at 1 month (± 7 days) and 9 months (± 30 days) post-index procedure. The severity of adverse events was determined by the site investigator based on the ISO 14155 definition of serious and non-serious adverse events. All adverse events were reviewed and adjudicated by the Clinical Events Committee. The Clinical Events Committee determined the final relationship of each adverse event and categorized each adverse event as device-related, index procedure-related, disease-related, unrelated to device, procedure, or disease, or unknown relationship. The Data Safety and Monitoring Board provided oversight of safety trends and reviewed site reported protocol deviations and source data related to subject eligibility. Independent core laboratories evaluated angiographic and ultrasound imaging obtained during the study procedure and at follow-up visits.

E. Safety and Effectiveness Results

1. Primary Endpoint

The primary endpoint result consisted of a composite of Major Adverse Events (**Table 5**). No device- or procedure- related deaths and no myocardial infarctions for any subjects were reported within 30 days of the study procedure. No major amputations for any subjects were reported within 9 months of the study procedure. TLR was reported for 3 subjects within the 9 month follow-up interval. The GORE[®] VIABAHN[™] VBX Balloon Expandable Endoprosthesis demonstrated safety and effectiveness since the composite MAE of 2.3%, with the upper limit of the 95% confidence interval at 6.5%, was less than the performance goal of 17.0% ($p < 0.001$).

Table 5. Primary Endpoint

Primary Endpoint	Number (Fraction) [95% CI]
Subjects Available for Assessment	N=132
Composite MAE	3 (2.3%) [0.5%, 6.5%]
P-Value	<0.001
Device or Procedure Related Death Within 30 Days	0 (0.0%) [0%, 2.3%]
MI Within 30 Days	0 (0.0%) [0%, 2.3%]
TLR Within 9 Months	3 (2.3%) [0.5%, 6.5%]
Major Amputation Within 9 Months	0 (0.0%) [0%, 2.3%]

2. Secondary Endpoints and additional analyses

Acute Procedural Success was defined as $\leq 30\%$ residual stenosis prior to procedure completion and no device- or procedure-related serious adverse events (SAEs) before discharge. Thirty-day Clinical Success was defined as an improvement of at least one Rutherford Category at the 30-day visit as compared to pre-procedure and no device- or procedure-related SAEs within 30 days of the index procedure. Primary patency was defined as blood flow in the treated segment(s), without reintervention. Acute procedural success was 97.0% (N=134 subjects). Results of all other secondary endpoints at the pre-determined follow-up are summarized in **Table 6**. Kaplan-Meier estimates of survival probability at 1 month and 9 months are shown for primary patency, primary assisted patency, secondary patency, freedom from TLR, freedom from clinically-driven TLR, freedom from TVR, and freedom from clinically-driven TVR.

Upon discharge, there were no instances of residual stenosis greater than 30% (**Table 4**). Four subjects experienced 5 SAEs before discharge, resulting in a 97.0% acute procedural success rate. One subject did not show evidence of blood flow through the treated segment at 1 month follow-up yet no treatment was attempted, therefore resulting in 99.2% primary patency, primary assisted patency, and secondary patency at 30 days but 100% freedom from TLR at 30 days.

Table 6. Secondary Endpoints, by Subject¹

Endpoint	1 Month	9 Months
30-Day Clinical Success	90.8% (N=119)	N/A
Primary Patency	99.2% (N=128)	96.7% (N=98)
Primary Assisted Patency	99.2% (N=128)	99.2% (N=101)
Secondary Patency	99.2% (N=128)	99.2% (N=101)
fTLR	100% (N=133)	97.7% (N=109)
fCD-TLR	100% (N=133)	98.4% (N=110)

fTVR	100% (N=133)	97.7% (N=109)
fCD-TVR	100% (N=133)	97.7% (N=109)
Change in Rutherford From Pre-Procedure	Worsened / Maintained / Improved 0.8% / 5.1% / 94.1% (N=118)	Worsened / Maintained / Improved 0.0% / 5.4% / 94.6% (N=112)
Change in ABI From Pre-Procedure¹ Mean (Std Dev)	0.19 (0.22) (N=172)	0.19 (0.22) (N=168)
Change in Functional Status From Pre-Procedure		
EQ-5D	Worsened / Maintained / Improved	Worsened / Maintained / Improved
Mobility	6.1% / 49.6% / 44.3% (N=115)	3.5% / 54.4% / 42.1% (N=114)
Self-Care	1.7% / 93.9% / 4.3% (N=115)	2.6% / 92.1% / 5.3% (N=114)
Usual Activities	7.0% / 47.8% / 45.2% (N=115)	3.5% / 50.0% / 46.5% (N=114)
Pain / Discomfort	8.7% / 42.6% / 48.7% (N=115)	8.8% / 48.2% / 43.0% (N=114)
Anxiety / Depression	5.2% / 71.3% / 23.5% (N=115)	6.1% / 69.3% / 24.6% (N=114)
Own Health State (1 - 100)	7.0% / 73.7% / 19.3% (N=114)	15.0% / 64.6% / 20.4% (N=113)
WIQ	Median (IQR)²	Median (IQR)²
Differential Diagnosis	2 (0, 4) (N=115)	1 (0, 4) (N=114)
Walking Distance	10 (3, 19) (N=115)	10 (3, 18) (N=114)
Walking Speed	5 (1, 8) (N=114)	5 (0, 9) (N=114)
Stair Climbing	4 (1, 8) (N=107)	4 (0, 7) (N=110)

¹ ABI reported on per-limb basis.

² Higher scores indicate a healthier state.

Since a significant fraction of the overall population received kissing stents (42.5%, **Table 4**), additional analysis of the composite primary endpoint was conducted for this subgroup (**Table 7**).

Table 7. Primary Endpoint for the Kissing Stent Subgroup

Primary Endpoint - Kissing Stent Subgroup	Number (Fraction) [95% CI]
Subjects Available for Assessment	N=57
Composite MAE	2 (3.5%) [0.4%, 12.1%]
Device or Procedure Related Death Within 30 Days	0 (0.0%) [0%, 5.3%]
MI Within 30 Days	0 (0.0%) [0%, 5.3%]
TLR Within 9 Months	2 (3.5%) [0.4%, 12.1%]
Major Amputation Within 9 Months	0 (0.0%) [0%, 5.3%]

A description of all adjudicated/unrefuted SAEs through 9 months is provided in **Table 8**. Two (2) patients were censored from the primary endpoint analysis. The reasons for discontinuation (missing data) were lost to follow-up and death. This death occurred on Day 187 and was not associated with the study device or procedure. This death was related to subject co-morbidities that resulted in cardiac arrest. No subjects experienced a SAE related to the study device within 9 months. There were no unanticipated device-related events reported in the study within 9 months.

Table 8. Description of Serious Adverse Events Through 9 Months

Subjects Enrolled	134
Subjects Experiencing Serious Adverse Events	30 (22.4%) [43]
Blood and Lymphatic System Disorders	1 (0.7%) [1]
Haemorrhagic Anaemia	1 (0.7%) [1]
Cardiac Disorders	4 (3.0%) [4]
Acute Myocardial Infarction	1 (0.7%) [1]
Angina Pectoris	1 (0.7%) [1]
Cardiac Failure Congestive	1 (0.7%) [1]
Coronary Artery Disease	1 (0.7%) [1]
Gastrointestinal Disorders	3 (2.2%) [3]
Gastrointestinal Haemorrhage	1 (0.7%) [1]
Rectal Haemorrhage	1 (0.7%) [1]
Umbilical Hernia	1 (0.7%) [1]
General Disorders and Administration Site Conditions	2 (1.5%) [2]
Non-Cardiac Chest Pain	1 (0.7%) [1]
Vascular Stent Occlusion	1 (0.7%) [1]
Infections and Infestations	4 (3.0%) [4]
Clostridium Difficile Infection	1 (0.7%) [1]
Pneumonia	1 (0.7%) [1]

Postoperative Wound Infection	1 (0.7%) [1]
Urinary Tract Infection	1 (0.7%) [1]
Injury, Poisoning, and Procedural Complications	8 (6.0%) [10]
Arterial Restenosis	1 (0.7%) [1]
Humerus Fracture	1 (0.7%) [1]
Incisional Hernia	1 (0.7%) [1]
Joint Dislocation	1 (0.7%) [1]
Post Procedural Haematoma	1 (0.7%) [1]
Postoperative Ileus	1 (0.7%) [1]
Vascular Pseudoaneurysm	2 (1.5%) [2]
Wound Dehiscence	2 (1.5%) [2]
Metabolism and Nutrition Disorders	1 (0.7%) [1]
Hyperkalaemia	1 (0.7%) [1]
Neoplasms Benign, Malignant and Unspecified (including cysts and polyps)	2 (1.5%) [2]
Lung Adenocarcinoma	1 (0.7%) [1]
Prostate Cancer	1 (0.7%) [1]
Nervous System Disorders	2 (1.5%) [2]
Carotid Artery Stenosis	1 (0.7%) [1]
Vascular Dementia	1 (0.7%) [1]
Renal and Urinary Disorders	1 (0.7%) [1]
Acute Kidney Injury	1 (0.7%) [1]
Respiratory, Thoracic, and Mediastinal Disorders	1 (0.7%) [1]
Chronic Obstructive Pulmonary Disease	1 (0.7%) [1]
Vascular Disorders	8 (6.0%) [11]
Femoral Artery Dissection	1 (0.7%) [1]
Haematoma	1 (0.7%) [1]
Hypovolaemic Shock	1 (0.7%) [1]
Intermittent Claudication	2 (1.5%) [3]
Lymphocele	1 (0.7%) [1]
Peripheral Arterial Occlusive Disease	1 (0.7%) [1]
Peripheral Artery Stenosis	1 (0.7%) [1]
Peripheral Ischaemia	1 (0.7%) [1]
Poor Peripheral Circulation	1 (0.7%) [1]

3. Results by Gender

No statistically significant difference in the primary endpoint was observed based on gender.

4. Applicability to Pediatric Population

Peripheral artery disease is not typically found in pediatric populations. The VBX FLEX clinical study did not evaluate the safety and effectiveness of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in the pediatric population.

5. Summary of Results

The primary endpoint for the VBX FLEX clinical study consisted of a composite of major adverse events to evaluate the safety and effectiveness of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis through 9 months. The composite MAE of 2.3%, with the upper limit of the 95% confidence interval at 6.5%, was less than the performance goal of 17.0% (p<0.001). Within 9 months, no subjects experienced a SAE related to the study device and there were no unanticipated device-related events reported. Additionally, secondary endpoints including Rutherford status and functional status improved through 9 months follow-up, providing evidence of relief from clinical symptoms and a corresponding increase in quality of life. In conclusion, the VBX FLEX clinical study demonstrated that the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is safe and effective in treating subjects with de novo or restenotic lesions found in iliac arteries.

POST-APPROVAL STUDY

As a condition of US FDA pre-market approval of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, W. L. Gore & Associates continued to collect long-term follow-up data in the form of a Post-Approval study.

SUMMARY OF GORE® VIABAHN® VBX BALLOON EXPANDABLE ENDOPROSTHESIS POST-APPROVAL STUDY METHODS

The objective of the post-approval study was to evaluate the long terms safety and effectiveness of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Prospective, multicenter subject follow-up data from 27 clinical sites was collected from active pivotal study subjects up to 36 months post-treatment. The post-approval study endpoints were the following:

Table 9. Post-Approval Study Primary Endpoint

Post-Approval Primary Endpoint
Freedom from target lesion revascularization (TLR) at 36 months

Table 10. Post-Approval Study Secondary Endpoints

Post-Approval Study Secondary Endpoints		
Freedom from target vessel revascularization (TVR), annually, up to 36 months	Freedom from target lesion revascularization (TLR) at 12, 24 months	Patency at 12 months -Primary -Primary assisted -Secondary
Change in Rutherford category from pre- procedure, annually, up to 36 months	Change in Ankle-Brachial Index (ABI) and Toe Brachial Index (TBI) from pre-procedure, annually, up to 36 months	Change in functional status based on EQ-5D from pre-procedure, annually, up to 36 months
Change in functional status based on Walking Impairment Questionnaire (WIQ) from pre- procedure, annually, up to 36 months	Serious adverse events, annually, up to 36 months	

Between 17-DEC-2013 and 12-AUG-2015, 140 study subjects were enrolled at 27 sites for the prospective, multi-center, non-randomized, single-arm IDE clinical study. One-hundred and thirty-four (134) subjects met all eligibility criteria and reflect the per protocol population. Tables used in this report reflect the results of the PP population unless otherwise stated.

Subjects available for each annual follow-up evaluation are described in **Table 11**.

Table 11. Subject Availability for Annual Follow-Up Evaluations

Number of Subjects Enrolled (134)	Reached the visit ¹	Available for visit ²	Data available ³
12 Months	134	130 (97.0%)	120 (92.3%)
24 Months	134	125 (93.3%)	117 (93.6%)
36 Months	134	115 (85.8%)	102 (88.7%)

¹ Subjects reached the beginning of the corresponding visit window.

² Subjects not discontinued prior to the corresponding visit, % of Reached.

³ Subjects completed the corresponding visit and the data is available in the system, % of Available.

SUMMARY OF THE POST-APPROVAL STUDY RESULTS

Post-Approval Study Primary Endpoint

Target Lesion Revascularization was defined as revascularization occurring within the treated segment(s) by means of a percutaneous vascular intervention, surgical bypass, thrombolysis, or other invasive means. Estimate of freedom from TLR (survival probability) is 91.4% at 36 months.

Table 12. Kaplan-Meier Estimates of Freedom from TLR by Subject

Time Post Treatment (days)	# at Risk Interval Start	Events Number (Cumulative)*	Censored Number (Cumulative)*	Survival Probability	95% C.I.
GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (N=134)					
[731-1095]	113	2 (11)	60 (72)	91.4%	(84.9%, 95.1%)

* Number in parenthesis represents cumulative events or censored observations through the end of interval.

Table 13. Post-Approval Study Secondary Endpoints

Endpoint	12 Months	24 Months	36 Months
Primary Patency	94.4% (N=124)	N/A	N/A
Primary Assisted Patency	98.4% (N=127)	N/A	N/A
Secondary Patency	99.2% (N=127)	N/A	N/A
fTLR	95.4% (N=129)	93.1% (N=124)	91.4% (N=113)
fCD-TLR	97.7% (N=130)	97.7% (N=127)	97.7% (N=119)
fTVR	95.4% (N=129)	92.3% (N=124)	90.6% (N=112)
fCD-TVR	97.7% (N=129)	96.9% (N=127)	96.1% (N=118)
Change in Rutherford from Pre-Procedure	Worsened / Maintained / Improved 0.0% / 5.3% / 94.7% (N=114)	Worsened / Maintained / Improved 1.0% / 4.9% / 94.1% (N=102)	Worsened / Maintained / Improved 0.0% / 7.9% / 92.1% (N=89)
Change in ABI from Pre-Procedure ^a Mean (Std Dev)	0.19 (0.24) (N=165)	0.17 (0.24) (N=148)	0.17 (0.26) (N=123)
Change in TBI from Pre-Procedure ^a Mean (Std Dev)	0.08 (0.15) (N=5)	0.06 (0.16) (N=9)	0.08 (0.19) (N=9)

Endpoint	12 Months	24 Months	36 Months
Change in Functional Status from Pre-Procedure			
ED-5D	Worsened / Maintained / Improved	Worsened / Maintained / Improved	Worsened / Maintained / Improved
Mobility	4.3% / 57.4% / 38.3% (N=115)	4.9% / 51.5% / 43.7% (N=103)	4.4% / 47.8% / 47.8% (N=90)
Self-Care	2.6% / 92.2% / 5.2% (N=115)	4.9% / 90.3% / 4.9% (N=103)	2.2% / 93.3% / 4.4% (N=90)
Usual Activities	7.8% / 47.8% / 44.3% (N=115)	7.8% / 49.5% / 42.7% (N=103)	4.4% / 46.7% / 48.9% (N=90)
Pain / Discomfort	10.4% / 38.3% / 51.3% (N=115)	12.6% / 39.8% / 47.6% (N=103)	7.8% / 48.9% / 43.3% (N=90)
Anxiety / Depression	7.0% / 71.3% / 21.7% (N=115)	6.8% / 68.9% / 24.3% (N=103)	5.6% / 64.4% / 30.0% (N=90)
Own Health State (1-100)	12.3% / 67.5% / 20.2% (N=114)	12.9% / 68.3% / 18.8% (N=101)	13.5% / 62.9% / 23.6% (N=89)
WIQ	Median (IQR)2	Median (IQR)2	Median (IQR)2
Differential Diagnosis	1 (0, 4) (N=115)	2 (-1, 4) (N=104)	1 (-1, 4) (N=90)
Walking Distance	9 (3, 18) (N=115)	11 (1, 17) (N=104)	9 (4, 18) (N=90)
Walking Speed	5 (1, 9) (N=115)	5 (1, 9) (N=104)	5 (1, 9) (N=90)
Stair Climbing	3 (1, 7) (N=109)	3 (0, 7) (N=99)	4 (0, 7) (N=87)

Table 14. Description of Serious Adverse Events Through 12 Months

Subjects Enrolled	134
Subjects Experiencing Serious Adverse Events	40 (29.9%) [67]
Blood and lymphatic system disorders	2 (1.5%) [2]
Anaemia	1 (0.7%) [1]
Haemorrhagic anaemia	1 (0.7%) [1]
Cardiac disorders	7 (5.2%) [8]
Acute myocardial infarction	2 (1.5%) [2]
Angina pectoris	1 (0.7%) [1]
Cardiac failure congestive	2 (1.5%) [2]
Coronary artery disease	1 (0.7%) [1]
Myocardial infarction	1 (0.7%) [1]
Myocardial ischaemia	1 (0.7%) [1]
Gastrointestinal disorders	5 (3.7%) [6]
Abdominal pain	1 (0.7%) [1]
Gastrointestinal haemorrhage	1 (0.7%) [2]
Haematemesis	1 (0.7%) [1]
Rectal haemorrhage	1 (0.7%) [1]
Umbilical hernia	1 (0.7%) [1]
General disorders and administration site conditions	3 (2.2%) [3]
Non-cardiac chest pain	1 (0.7%) [1]
Vascular stent occlusion	2 (1.5%) [2]
Infections and infestations	4 (3.0%) [5]
Clostridium difficile infection	1 (0.7%) [1]
Diverticulitis	1 (0.7%) [1]
Pneumonia	1 (0.7%) [1]
Postoperative wound infection	1 (0.7%) [1]
Urinary tract infection	1 (0.7%) [1]
Injury, poisoning and procedural complications	8 (6.0%) [10]
Arterial restenosis	1 (0.7%) [1]

Subjects Enrolled	134
Humerus fracture	1 (0.7%) [1]
Incisional hernia	1 (0.7%) [1]
Joint dislocation	1 (0.7%) [1]
Post procedural haematoma	1 (0.7%) [1]
Postoperative ileus	1 (0.7%) [1]
Vascular pseudoaneurysm	2 (1.5%) [2]
Wound dehiscence	2 (1.5%) [2]
Metabolism and nutrition disorders	1 (0.7%) [1]
Hyperkalaemia	1 (0.7%) [1]
Musculoskeletal and connective tissue disorders	1 (0.7%) [1]
Pain in extremity	1 (0.7%) [1]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (3.0%) [4]
Lung adenocarcinoma	1 (0.7%) [1]
Prostate cancer	1 (0.7%) [1]
Renal cell carcinoma	1 (0.7%) [1]
Squamous cell carcinoma	1 (0.7%) [1]
Nervous system disorders	3 (2.2%) [5]
Carotid artery stenosis	2 (1.5%) [3]
Transient ischaemic attack	1 (0.7%) [1]
Vascular dementia	1 (0.7%) [1]
Renal and urinary disorders	2 (1.5%) [2]
Acute kidney injury	2 (1.5%) [2]
Respiratory, thoracic and mediastinal disorders	2 (1.5%) [2]
Chronic obstructive pulmonary disease	1 (0.7%) [1]
Pulmonary embolism	1 (0.7%) [1]
Vascular disorders	11 (8.2%) [18]
Arterial occlusive disease	1 (0.7%) [1]
Femoral artery dissection	1 (0.7%) [1]
Haematoma	1 (0.7%) [1]
Hypovolaemic shock	1 (0.7%) [1]
Intermittent claudication	4 (3.0%) [6]
Lymphocele	1 (0.7%) [1]
Peripheral arterial occlusive disease	1 (0.7%) [1]
Peripheral artery occlusion	1 (0.7%) [1]
Peripheral artery stenosis	2 (1.5%) [2]
Peripheral ischaemia	1 (0.7%) [1]
Poor peripheral circulation	1 (0.7%) [1]
Vena cava thrombosis	1 (0.7%) [1]

Table 15. Description of Serious Adverse Events Through 24 Months

Subjects Enrolled	134
Subjects Experiencing Serious Adverse Events	54 (40.3%) [110]
Blood and lymphatic system disorders	3 (2.2%) [3]
Anaemia	2 (1.5%) [2]
Haemorrhagic anaemia	1 (0.7%) [1]

Cardiac disorders	9 (6.7%) [11]
Acute myocardial infarction	2 (1.5%) [2]
Angina pectoris	1 (0.7%) [1]
Atrial fibrillation	1 (0.7%) [1]
Cardiac failure congestive	2 (1.5%) [2]
Coronary artery disease	2 (1.5%) [2]
Myocardial infarction	1 (0.7%) [1]
Myocardial ischaemia	1 (0.7%) [2]
Gastrointestinal disorders	7 (5.2%) [8]
Abdominal pain	1 (0.7%) [1]
Colitis	1 (0.7%) [1]
Gastrointestinal haemorrhage	2 (1.5%) [3]
Haematemesis	1 (0.7%) [1]
Rectal haemorrhage	1 (0.7%) [1]
Umbilical hernia	1 (0.7%) [1]
General disorders and administration site conditions	8 (6.0%) [8]
Non-cardiac chest pain	2 (1.5%) [2]
Systemic inflammatory response syndrome	1 (0.7%) [1]
Vascular stent occlusion	3 (2.2%) [3]
Vascular stent stenosis	1 (0.7%) [1]
Vascular stent thrombosis	1 (0.7%) [1]
Infections and infestations	8 (6.0%) [10]
Clostridium difficile infection	1 (0.7%) [1]
Diverticulitis	1 (0.7%) [1]
Lower respiratory tract infection	1 (0.7%) [1]
Pneumonia	3 (2.2%) [3]
Postoperative wound infection	1 (0.7%) [1]
Scrotal abscess	1 (0.7%) [1]
Urinary tract infection	2 (1.5%) [2]
Injury, poisoning and procedural complications	9 (6.7%) [11]
Arterial restenosis	1 (0.7%) [1]
Femoral neck fracture	1 (0.7%) [1]
Humerus fracture	1 (0.7%) [1]
Incisional hernia	1 (0.7%) [1]
Joint dislocation	1 (0.7%) [1]
Post procedural haematoma	1 (0.7%) [1]
Postoperative ileus	1 (0.7%) [1]
Vascular pseudoaneurysm	2 (1.5%) [2]
Wound dehiscence	2 (1.5%) [2]
Metabolism and nutrition disorders	1 (0.7%) [1]
Hyperkalaemia	1 (0.7%) [1]
Musculoskeletal and connective tissue disorders	1 (0.7%) [1]
Pain in extremity	1 (0.7%) [1]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (4.5%) [7]
Lung adenocarcinoma	1 (0.7%) [1]
Lung cancer metastatic	1 (0.7%) [1]
Malignant respiratory tract neoplasm	1 (0.7%) [1]
Metastases to bone	1 (0.7%) [1]
Prostate cancer	1 (0.7%) [1]
Renal cell carcinoma	1 (0.7%) [1]
Squamous cell carcinoma	1 (0.7%) [1]
Nervous system disorders	7 (5.2%) [11]
Carotid artery disease	1 (0.7%) [1]
Carotid artery stenosis	4 (3.0%) [5]
Cerebellar infarction	1 (0.7%) [1]
Cerebral hypoperfusion	1 (0.7%) [1]
Syncope	1 (0.7%) [1]

Transient ischaemic attack	1 (0.7%) [1]
Vascular dementia	1 (0.7%) [1]
Renal and urinary disorders	4 (3.0%) [4]
Acute kidney injury	3 (2.2%) [3]
Ureterolithiasis	1 (0.7%) [1]
Respiratory, thoracic and mediastinal disorders	6 (4.5%) [7]
Chronic obstructive pulmonary disease	3 (2.2%) [3]
Hypoxia	1 (0.7%) [1]
Pneumothorax	1 (0.7%) [1]
Pulmonary embolism	1 (0.7%) [1]
Pulmonary mass	1 (0.7%) [1]
Vascular disorders	18 (13.4%) [28]
Accelerated hypertension	1 (0.7%) [1]
Aortic stenosis	1 (0.7%) [1]
Arterial occlusive disease	1 (0.7%) [1]
Femoral artery dissection	1 (0.7%) [1]
Haematoma	1 (0.7%) [1]
Hypovolaemic shock	1 (0.7%) [1]
Iliac artery occlusion	1 (0.7%) [1]
Intermittent claudication	4 (3.0%) [6]
Lymphocele	1 (0.7%) [1]
Orthostatic hypotension	1 (0.7%) [1]
Peripheral arterial occlusive disease	2 (1.5%) [2]
Peripheral artery occlusion	1 (0.7%) [1]
Peripheral artery stenosis	4 (3.0%) [4]
Peripheral ischaemia	1 (0.7%) [1]
Peripheral vascular disorder	2 (1.5%) [3]
Poor peripheral circulation	1 (0.7%) [1]
Vena cava thrombosis	1 (0.7%) [1]

Table 16. Description of Serious Adverse Events Through 36 Months

Subjects Enrolled	134
Subjects Experiencing Serious Adverse Events	72 (53.7%) [172]
Blood and lymphatic system disorders	3 (2.2%) [3]
Anaemia	2 (1.5%) [2]
Haemorrhagic anaemia	1 (0.7%) [1]
Cardiac disorders	18 (13.4%) [29]
Acute myocardial infarction	4 (3.0%) [6]
Angina pectoris	1 (0.7%) [1]
Angina unstable	1 (0.7%) [1]
Atrial fibrillation	2 (1.5%) [2]
Bradycardia	1 (0.7%) [2]
Cardiac failure chronic	1 (0.7%) [1]
Cardiac failure congestive	6 (4.5%) [7]
Cardiogenic shock	1 (0.7%) [1]
Chronic left ventricular failure	1 (0.7%) [1]
Coronary artery disease	3 (2.2%) [3]
Myocardial infarction	2 (1.5%) [2]
Myocardial ischaemia	1 (0.7%) [2]
Gastrointestinal disorders	12 (9.0%) [13]
Abdominal pain	1 (0.7%) [1]
Abdominal pain upper	1 (0.7%) [1]
Colitis	1 (0.7%) [1]
Gastrointestinal haemorrhage	2 (1.5%) [3]
Haematemesis	1 (0.7%) [1]
Inguinal hernia	1 (0.7%) [1]
Rectal haemorrhage	1 (0.7%) [1]

Salivary gland calculus	1 (0.7%) [1]
Small intestinal obstruction	1 (0.7%) [1]
Stomach mass	1 (0.7%) [1]
Umbilical hernia	1 (0.7%) [1]
General disorders and administration site conditions	10 (7.5%) [10]
Non-cardiac chest pain	3 (2.2%) [3]
Systemic inflammatory response syndrome	1 (0.7%) [1]
Vascular stent occlusion	3 (2.2%) [3]
Vascular stent stenosis	2 (1.5%) [2]
Vascular stent thrombosis	1 (0.7%) [1]
Hepatobiliary disorders	1 (0.7%) [1]
Cholecystitis	1 (0.7%) [1]
Infections and infestations	12 (9.0%) [17]
Arthritis infective	1 (0.7%) [1]
Clostridium difficile infection	1 (0.7%) [1]
Diverticulitis	1 (0.7%) [1]
Influenza	1 (0.7%) [1]
Lower respiratory tract infection	1 (0.7%) [1]
Pneumonia	5 (3.7%) [5]
Postoperative wound infection	1 (0.7%) [1]
Pyelonephritis	1 (0.7%) [1]
Scrotal abscess	1 (0.7%) [1]
Sepsis	1 (0.7%) [1]
Skin infection	1 (0.7%) [1]
Urinary tract infection	2 (1.5%) [2]
Injury, poisoning and procedural complications	11 (8.2%) [17]
Arterial restenosis	1 (0.7%) [1]
Cervical vertebral fracture	1 (0.7%) [2]
Craniocerebral injury	1 (0.7%) [1]
Femoral neck fracture	1 (0.7%) [1]
Humerus fracture	1 (0.7%) [1]
Incisional hernia	1 (0.7%) [1]
Joint dislocation	1 (0.7%) [1]
Post procedural haematoma	1 (0.7%) [1]
Postoperative ileus	1 (0.7%) [1]
Splenic rupture	1 (0.7%) [1]
Subdural haematoma	1 (0.7%) [1]
Traumatic renal injury	1 (0.7%) [1]
Vascular pseudoaneurysm	2 (1.5%) [2]
Wound dehiscence	2 (1.5%) [2]
Metabolism and nutrition disorders	4 (3.0%) [4]
Dehydration	1 (0.7%) [1]
Hyperkalaemia	1 (0.7%) [1]
Hyponatraemia	2 (1.5%) [2]
Musculoskeletal and connective tissue disorders	2 (1.5%) [2]
Lumbar spinal stenosis	1 (0.7%) [1]
Pain in extremity	1 (0.7%) [1]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (5.2%) [8]
Lung adenocarcinoma	1 (0.7%) [1]
Lung cancer metastatic	1 (0.7%) [1]
Malignant respiratory tract neoplasm	1 (0.7%) [1]
Metastases to bone	1 (0.7%) [1]
Metastatic neoplasm	1 (0.7%) [1]
Prostate cancer	1 (0.7%) [1]
Renal cell carcinoma	1 (0.7%) [1]
Squamous cell carcinoma	1 (0.7%) [1]
Nervous system disorders	10 (7.5%) [14]

Carotid artery disease	1 (0.7%) [1]
Carotid artery stenosis	4 (3.0%) [5]
Cerebellar infarction	1 (0.7%) [1]
Cerebral hypoperfusion	1 (0.7%) [1]
Cerebral infarction	1 (0.7%) [1]
Cerebrovascular accident	1 (0.7%) [1]
Sciatica	1 (0.7%) [1]
Syncope	1 (0.7%) [1]
Transient ischaemic attack	1 (0.7%) [1]
Vascular dementia	1 (0.7%) [1]
Renal and urinary disorders	7 (5.2%) [8]
Acute kidney injury	5 (3.7%) [6]
Nephropathy	1 (0.7%) [1]
Ureterolithiasis	1 (0.7%) [1]
Respiratory, thoracic and mediastinal disorders	10 (7.5%) [12]
Acute respiratory failure	1 (0.7%) [1]
Chronic obstructive pulmonary disease	4 (3.0%) [4]
Dyspnoea	2 (1.5%) [2]
Hypoxia	1 (0.7%) [1]
Pneumothorax	1 (0.7%) [1]
Pulmonary embolism	1 (0.7%) [1]
Pulmonary mass	1 (0.7%) [1]
Respiratory failure	1 (0.7%) [1]
Vascular disorders	20 (14.9%) [34]
Accelerated hypertension	1 (0.7%) [1]
Aortic stenosis	1 (0.7%) [1]
Arterial occlusive disease	1 (0.7%) [1]
Femoral artery dissection	1 (0.7%) [1]
Haematoma	1 (0.7%) [1]
Hypertension	1 (0.7%) [1]
Hypertensive emergency	1 (0.7%) [1]
Hypotension	1 (0.7%) [1]
Hypovolaemic shock	1 (0.7%) [1]
Iliac artery occlusion	1 (0.7%) [1]
Intermittent claudication	4 (3.0%) [6]
Lymphocele	1 (0.7%) [1]
Orthostatic hypotension	1 (0.7%) [1]
Peripheral arterial occlusive disease	2 (1.5%) [3]
Peripheral artery occlusion	2 (1.5%) [2]
Peripheral artery stenosis	5 (3.7%) [5]
Peripheral ischaemia	1 (0.7%) [1]
Peripheral vascular disorder	2 (1.5%) [3]
Poor peripheral circulation	1 (0.7%) [1]
Vena cava thrombosis	1 (0.7%) [1]

POST APPROVAL STUDY STRENGTH AND WEAKNESSES

A major strength of the VBX FLEX STUDY was that it was a prospective, multicenter study focused exclusively on understanding the safety and performance of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in the treatment of arterial occlusive disease in patients with de novo or restenotic lesions in the common and/or external iliac arteries. Additionally, the 36 month follow-up allowed for long-term evaluation of safety and effectiveness. Limitations of the study were the participation of only sites in US and New Zealand and that it was not randomized to a control arm.

POST APPROVAL STUDY CONCLUSIONS

The results of the post-approval evaluation suggest that the long-term performance of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in the primary treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5 mm-13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation continues to be a safe and effective treatment option. Furthermore, the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis had low rates of MAEs and device-related adverse events through end of study at 36 months, with clinical improvements in Rutherford Classification, the Quality of Life Questionnaires (WIQ and EQ-5D), and Ankle Brachial Index

(ABI)/Toe Brachial Index (TBI) measurements.

Clinical Evidence Supporting Use as a Bridging Stent:

SUMMARY OF EMBRACE REGISTRY METHODS

The EMBRACE Registry is a multicenter, retrospective and prospective registry initiated at 14 European clinical sites designed to evaluate use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in conjunction with a fenestrated or branched aortic stent graft. Site staff performed a search of the hospital database to identify patients treated using a GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in conjunction with a fenestrated or branched aortic stent graft; the search interval was January 1, 2017 to December 30, 2021. Sites reviewed potential patients in their database in sequential order and patients who met eligibility criteria and signed the informed consent form (ICF) were enrolled. Patients were categorized into FEVAR or BEVAR cohorts. Enrollment was monitored regularly to ensure broad participation across sites and countries, thereby promoting population heterogeneity and avoiding overrepresentation of any single site. No individual site contributed more than 30% of the study subjects. The registry data collection is ongoing with planned follow-up through 5 years. Follow-up data through 3 years has been reviewed and fully adjudicated by a core laboratory (Core Lab) and Clinical Events Committee (CEC). The site performed patient screening consecutively in reverse chronological order, beginning with the most recent procedure date, against the registry eligibility criteria. This order of patient screening allowed for enrollment of contemporary cases that reflected current clinical practice. A waiver of informed consent for any deceased patient was requested and approved based on local ethics committee regulations. Informed consent was obtained from all living study subjects at the time of enrollment; the only exception was for patients in Sweden, where local ethics committee regulations allowed for a full waiver given the observational and partially retrospective nature of the study.

A prospective analysis plan of the registry data was designed to statistically test the hypothesis of the Target Vessel Patency (at patient level) at 12 months (Primary Endpoint) in FEVAR and BEVAR cohorts separately. The results were evaluated against a Performance Goal of 77%. The performance goal was derived from an assumed 1-year target vessel patency of 87% derived from published literature on complex endovascular aortic aneurysm repair available at the time of protocol development [7] and a margin of 10%. An exact binomial exact test was used with a one-sided 97.5% confidence level ($\alpha = 0.025$) to test the null hypothesis.

Imaging components were analyzed based on core laboratory review (Core Lab). The core laboratory, Gore Imaging Services, performed independent assessment of computed tomographic angiography (CTA) studies submitted by registry sites. Primary and secondary endpoints were reviewed and adjudicated by an independent CEC.

The registry included use of VBX Devices (Reference **Table 27**) and the resulting clinical evidence is considered applicable to the Reduced Profile VBX Device. Both the VBX Device and Reduced Profile VBX Device have the same endoprosthesis design, intended use, principles of operation, deployment characteristics, and critical performance requirements, and risk profile. The modifications for the Reduced Profile VBX Device are limited to delivery system profile optimization and minor specification updates that are not expected to affect device deployment, stent expansion, long-term function, safety, or clinical performance.

Inclusion and Exclusion Criteria:

Enrollment in the EMBRACE Registry was limited to patients who met the following inclusion and exclusion criteria.

Inclusion Criteria:

- Patients treated with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a Bridging Stent in conjunction with a branched/fenestrated stent graft to allow endovascular aneurysm repair from 31 December 2021 until 01 January 2017
- Age ≥ 18 years at the time of implant
- Informed consent by the patient or next of kin/legal representative (or waiver for deceased patients), according to local regulations.

Exclusion Criteria

- Patient treated for ruptured aneurysm or who were otherwise hemodynamically unstable at the time of the procedure
- Patient treated for acute or sub-acute dissection, <90 days from onset of symptoms
- Patient treated using physician-modified endovascular grafts
- Patient intended to be treated with parallel graft (e.g., chimney, periscope, sandwich) or octopus (use of an off-the-shelf bifurcated aortic endografts and peripheral stent grafts to revascularize mesenteric and renal arteries) technique per the pre-treatment case plan.
- At the time of treatment, patient had known coagulation disorders including hypercoagulability that were not amenable to treatment
- Patient was pregnant at the time of treatment.
- Participation in another drug or device investigational registry within one year of device implant, that can confound the registry endpoints.
- Patient had known or suspected systemic infection (including treatment for mycotic aneurysm) at the time of implant.

Follow up Schedule

The registry was designed to include both retrospective and prospective follow-up. The retrospective phase incorporates all available data from the pre-procedure date through the date of enrollment (date of informed consent signature or waiver of informed consent). The prospective phase incorporates data collected from the date of enrollment through 5-year follow-up.

Follow-up is in accordance with standard of care with expectations of at least annual follow-up, based on guidelines and site physician feedback received during site qualification discussions. Imaging data is collected (if available) at baseline, treatment, post-op, and all follow-up visits (including any unplanned visits) throughout the 5-year duration of the study. Table 17 provides an outline of the registry follow-up phases along with the schedule of events.

Table 17. Schedule of Events

	Retrospective phase			Prospective phase ⁴	
	Baseline	Treatment	First post-operative visit (within 30 days)	Follow-up visits up to 5 years after treatment (annually)	Unplanned follow-up visit
Informed Consent or consent is waived	X				
Inclusion / Exclusion criteria	X				
Physical Examination	X				
Demographics & Medical History	X				
Case Planning ¹	X				
Procedure Details and Discharge		X			
Imaging ²	X	X	X	X	X
Medication ³	X	X	X	X	X
Adverse Events		X	X	X	X
Reinterventions ⁵		X	X	X	X
Lab results ⁶	X	X	X	X	X
¹ Available information used in case planning (e.g. diagrams, imaging) will be requested as part of registry documentation. ² Available imaging performed per the site standard of care for complex EVAR procedures and follow-up. This may include angiography, echocardiography, X-Ray, computed tomography and /or magnetic resonance. Any available imaging performed (fully anonymized) can be requested as part of registry documentation. ³ Medication collected: Antiplatelet and anticoagulant therapy. ⁴ The start of the prospective phase may change from subject to subject depending on the treatment date. ⁵ Data on any reintervention occurring during study follow-up was collected and included in study assessments. ⁶ Lab result will be collected, if available, and can include, RBC, WBC, platelet, Creatinine, eGFR.					

EMBRACE Registry Endpoints:

The EMBRACE Registry endpoints were designed to evaluate the performance and safety of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis when used as a Bridging Stent with Branched and Fenestrated Endografts in the Treatment of Aortic Aneurysms Involving the visceral arteries (i.e., superior mesenteric, celiac trunk, and renal arteries). Reference **Table 18** and **Table 19** for the primary and secondary endpoints of the EMBRACE Registry.

Table 18. Primary Endpoints

EMBRACE Primary Endpoint
Target vessel patency (patient level) at 12 months
- Uninterrupted patency with no occlusion or procedure performed to maintain patency on the VBX Stent Graft or native target vessel.

Table 19. Secondary Endpoints

EMBRACE Secondary Endpoints	
Secondary Performance Outcomes	Primary Technical Success (Total Endovascular Procedure) - Placement of bridging stents, patency of all components (including modular aortic components and bridging stents), and freedom from Type I or Type III Endoleaks at completion angiography.
	Target Vessel Technical Success - Catheterization and VBX Device placement in all intended target vessels.
	Target vessel instability at 12 months and annually through 5 years post-implant - A composite endpoint of any branch related complication leading to aneurysm rupture, death, occlusion, component separation or reintervention to maintain branch patency or to treat a branch related component separation or endoleaks.
	Target vessel patency, patient level, annually from 2-5 years post-implant
	Target vessel patency, vessel level analysis, annually from procedure to 5 years post-implant
	Reintervention (total and reintervention that can be attributed to branches originally treated with the VBX Stent Graft) at 12 months and annually through 5 years post-implant - Any repeat vascular or nonvascular procedure (e.g. wound debridement, hernia or laparotomy-related interventions) related to the index procedure.
Secondary Safety Outcomes	Aneurysm-related mortality at 12 months and annually through 5 years post-implant - All-cause death within 30 days or any death related to rupture, aortic complication, or complication from a secondary intervention.
	Major Adverse Events at 30 days - All-cause mortality, respiratory failure, renal deterioration, bowel ischemia, permanent paraplegia or major stroke.

EMBRACE Registry Follow Up:

A total of 300 patients were screened for the registry with 41 patients failing to meet eligibility criteria. The primary reasons for non-enrollment were refusal to sign the informed consent form (20/41, 48.8%), failure to meet eligibility criteria (14/41, 34.1%), and other reasons (7/41, 17.1%). The most frequently reported eligibility criteria were ruptured aneurysm/hemodynamic instability (n=6), not treated with VBX bridging stent (n=5), and acute or subacute dissection within 90 days (n=3). Data lock for the primary analysis was completed on October 14, 2025, with 12 centers contributing data on 259 patients. The primary analysis was performed following the data export based on complete one-year follow-up. The study evaluated 92 subjects with 194 VBX-treated vessels in the FEVAR cohort and 136 subjects with 401 VBX-treated vessels in the BEVAR cohort. The registry data collection is ongoing with planned follow-up through 5 years. Follow-up data through 3 years has been reviewed and fully adjudicated by Core Lab and CEC for all available patients. Reference **Table 20** and **Table 21** for the number of subjects in each follow-up window.

Table 20 Subject Availability for Annual Follow-Up Evaluations FEVAR

	Eligible for Follow-up	Subject with Any Visit in Window	Subject with CT Imaging in Window*	Follow-up Pending	Subjects with Interpretable Imaging ³	Subject Status		
						Death	Lost to Follow-up ¹	Not Due for Next Window ²
Procedure	92	-	-	-	-	0	-	0
1 Year	92	87(94.6%)	89(96.7%)	0 (0.0%)	89(96.7%)	7	2	9
2 Year	83	69(83.1%)	64(77.1%)	0 (0.0%)	62(74.7%)	2	1	3
3 Year	80	59(73.8%)	52(65.0%)	0 (0.0%)	51(63.8%)	6	2	8
4 Year	72	41(56.9%)	35(48.6%)	0 (0.0%)	34(47.2%)	10	1	20
5 Year	52	28(53.8%)	23(44.2%)	9(17.3%)	23(44.2%)	0	0	37

Procedure Day (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)

¹Lost to follow, subject withdrawal, investigator decision to withdraw subject or other reason.

²Numbers reflect the sum of deaths, lost-to-follow up, and pending visits.

³Core Laboratory determined imaging was of sufficient quality to allow assessment of vessel-level characteristics or device integrity outcomes (e.g., wire fracture, separation, migration, and endoleak).

Table 21 Subject Availability for Annual Follow-Up Evaluations BEVAR

	Eligible for Follow-up	Subject with Any Visit in Window	Subject with CT Imaging in Window*	Follow-up Pending	Subjects with Interpretable Imaging ³	Subject Status		
						Death	Lost to Follow-up ¹	Not Due for Next Window ²
Procedure	136	-	-	-	-	3	-	3
1 Year	133	120(90.2%)	122(91.7%)	0 (0.0%)	121(91.0%)	32	5	37
2 Year	96	69(71.9%)	64(66.7%)	0 (0.0%)	63(65.6%)	10	0	10
3 Year	86	57(66.3%)	50(58.1%)	0 (0.0%)	50(58.1%)	7	0	7
4 Year	79	47(59.5%)	41(51.9%)	0 (0.0%)	40(50.6%)	12	1	22
5 Year	57	20(35.1%)	15(26.3%)	9(15.8%)	15(26.3%)	2	4	46

Procedure Day (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)

¹Lost to follow, subject withdrawal, investigator decision to withdraw subject or other reason.

²Numbers reflect the sum of deaths, lost-to-follow up, and pending visits.

³Core Laboratory determined imaging was of sufficient quality to allow assessment of vessel-level characteristics or device integrity outcomes (e.g., wire fracture, separation, migration, and endoleak).

Subject Demographics:

The baseline demographics and baseline medical history of the patients studied in the EMBRACE registry are provided in **Table 22**. Although the study population was enrolled from European centers, relevant co-variants (e.g., smoking history, diabetes, chronic kidney disease, hypertension, SVS Risk) are consistent with similar studies comprised of U.S. patients [3, 4, 5]. The majority of subjects treated within the EMBRACE Registry were male with a mean age of approximately 73 years reference **Table 22**.

Table 22. Subject Demographics

	FEVAR	BEVAR
Number of Subjects Enrolled	92	136
Gender	92	136
Male	80 (87.0%)	99 (72.8%)
Female	12 (13.0%)	37 (27.2%)
Age (years)		
n	92	136
Mean (Std Dev)	72.7 (8.1)	73.0 (8.9)
Median	74	74
(Min, Max)	(45, 87)	(28, 89)
Smoking History	92	131
Never	15 (16.3%)	30 (22.9%)
Current	19 (20.7%)	26 (19.8%)
Former	58 (63.0%)	75 (57.3%)
Classification For Chronic Kidney Disease	89	131
No chronic kidney disease	61 (68.5%)	94 (71.8%)
Stage 1	3 (3.4%)	4 (3.1%)
Stage 2	3 (3.4%)	5 (3.8%)
Stage 3	19 (21.3%)	22 (16.8%)
Stage 4	2 (2.2%)	5 (3.8%)
Stage 5	1 (1.1%)	1 (0.8%)
Diabetes	92	134
Yes	14 (15.2%)	22 (16.4%)
Chronic Obstructive Pulmonary Disease (COPD)	91	135
Yes	31 (34.1%)	45 (33.3%)
Myocardial Infarction	92	134
Yes	29 (31.5%)	31 (23.1%)
SVS: Hypertension Score	92	136
None	20 (21.7%)	22 (16.2%)
Easily controlled with Single Drug	30 (32.6%)	51 (37.5%)
Controlled with 2 Drugs	30 (32.6%)	46 (33.8%)
Requires more than 2 drugs or Uncontrolled	12 (13.0%)	17 (12.5%)

	FEVAR	BEVAR
SVS: Total Score		
n	83	111
Mean (Std Dev)	6.8 (4.2)	7.6 (4.7)
Median	7.0	7.0
(Min, Max)	(0.0, 17.0)	(0.0, 19.0)
SVS: Total Score Category	83	111
None	67 (80.7%)	75 (67.6%)
Mild	16 (19.3%)	36 (32.4%)
Moderate	0 (0%)	0 (0%)
Severe	0 (0%)	0 (0%)

*SVS, Society for Vascular Surgery. Total SVS score = (4 × cardiac) + (2 × pulmonary) + (2 × renal) + hypertension + age; component scores range from 0 to 3, and the weighted total ranges from 0 to 30. The normalized category score equals the total score divided by 10. Chaikof EL, Fillinger MF, Matsumura JS, et al. Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair. *Journal of Vascular Surgery*. 2002;35:1061-1066. doi:10.1067/mva.2002.123991.

Summary of Disease and Procedure Characteristics:

Table 23–Table 27 summarize the characteristics of the disease states treated (obtained from case planning documentation, procedural data, and the summary of implanted devices).

Table 23. Case Planning Data

	FEVAR	BEVAR
Number of Subjects Enrolled	92	136
Pre-Procedure Contrast CT		
Yes	90 (97.8%)	125 (91.9%)
Aneurysm Type		
Thoracoabdominal aneurysm	27 (29.3%)	103 (75.7%)
I	6 (6.5%)	11 (8.1%)
II	6 (6.5%)	21 (15.4%)
III	4 (4.3%)	33 (24.3%)
IV	11 (12.0%)	33 (24.3%)
Pararenal aneurysm	20 (21.7%)	18 (13.2%)
Infrarenal aneurysm	24 (26.1%)	0 (0.0%)
Juxtarenal aneurysm	18 (19.6%)	6 (4.4%)
Unknown	3 (3.3%)	9 (6.6%)
Dissection Present		
Yes	10 (10.9%)	13 (9.6%)
No	71 (77.2%)	87 (64.0%)
Indeterminate	7 (7.6%)	20 (14.7%)
Unknown	4 (4.3%)	16 (11.8%)
Etiology		
Degenerative	81 (88.0%)	123 (90.4%)
Dissection	6 (6.5%)	9 (6.6%)
Congenital	1 (1.1%)	0 (0%)
Other	4 (4.3%) ¹	4 (2.9%) ²

¹ FEVAR: Pseudoaneurysm (1), Type 1A Endoleak following EVAR (2), Chronic Type B Aortic Dissection (1)

² BEVAR: Penetrating Aortic Ulcer (1), TAAA Type 5 (1), Type 1A Endoleak following EVAR (1), Proximal Saccular/Seam Aneurysm (1)

Table 24. Procedural Data (Patient Level)

	FEVAR	BEVAR
Number of Subjects Enrolled	92	136
Type of Fenestrated Branched Graft	92	134 ¹
COOK Custom	82 (89.1%)	42 (31.3%)
Zenith® Fenestrated AAA Endovascular Graft	7 (7.6%)	0 (0%)
Zenith® t-Branch® Thoracoabdominal Endovascular Graft	0 (0%)	73 (54.5%)
Terumo Anaconda™ Fenestrated	1 (1.1%)	0 (0%)
Jotec E-nside	0 (0%)	9 (6.7%)
Jotec Custom	0 (0%)	7 (5.2%)
Other	2 (2.2%)	3 (2.2%)
Total Procedure Duration (Hours)		
n	82	121
Mean (Std Dev)	4.2 (1.6)	4.7 (1.6)
Median	4	4
(Min, Max)	(2, 10)	(1, 10)
Devices Successfully Navigated to Intended Location ²		
Yes	90 (97.8%)	135 (99.3%)
Devices Deployed as Intended ²		
Yes	91 (98.9%)	136 (100.0%)
Devices Delivery Catheters Successfully Removed ²		
Yes	92 (100.0%)	136 (100.0%)
Devices Patent at End of Procedure ²		
Yes	92 (100.0%)	136 (100.0%)

¹ The type of aortic device was not available from the medical record for two subjects.

² All components including the VBX Device

Table 25. Treated Artery Data (Vessel Level) FEVAR

Number of Subjects Enrolled	92			
	Celiac Trunk	Superior Mesenteric Artery (SMA)	Left Renal	Right Renal
Number of Subjects with Artery Treated	45 (48.9%)	61 (66.3%)	47 (51.1%)	41 (44.6%)
Status of Artery Prior To Procedure				
Patent	37 (82.2%)	58 (95.1%)	39 (83.0%)	39 (95.1%)
Stenosis > 50%	3 (6.7%)	1 (1.6%)	2 (4.3%)	0 (0%)
25% < Stenosis <= 50%	4 (8.9%)	2 (3.3%)	6 (12.8%)	1 (2.4%)
<= 25% Stenosis	1 (2.2%)	0 (0%)	0 (0%)	1 (2.4%)
Fenestration Diameter (mm) ¹				
6x6	0 (0%)	0 (0%)	16 (34.0%)	14 (34.1%)
6x8	5 (11.1%)	6 (9.8%)	24 (55.1%)	21 (51.2%)
8x8	36 (80.0%)	50 (81.9%)	3 (6.4%)	0 (0%)
Access Site				
Femoral artery	42 (93.3%)	58 (95.1%)	45 (95.7%)	40 (97.6%)
Iliac artery	0 (0%)	1 (1.6%)	0 (0%)	0 (0%)
Axillary	3 (6.7%)	1 (1.6%)	1 (2.1%)	0 (0%)
Brachial	0 (0%)	0 (0%)	0 (0%)	1 (2.4%)
Other	0 (0%)	1 (1.6%)	1 (2.1%)	0 (0%)

¹Total number does not add up to 100% as fenestration diameter was not documented in the medical record for all patients.

Table 26. Treated Artery Data (Vessel Level) BEVAR

Number of Subjects Enrolled	136			
	Celiac Trunk	Superior Mesenteric Artery (SMA)	Left Renal	Right Renal
Number of Subjects with treated artery	96 (70.6%)	108 (79.4%)	96 (70.6%)	101 (74.3%)
Status of Artery Prior To Procedure				
Patent	82 (85.4%)	105 (97.2%)	89 (92.7%)	96 (95.0%)
Stenosis > 50%	5 (5.2%)	0 (0%)	3 (3.1%)	3 (3.0%)
25% < Stenosis <= 50%	7 (7.3%)	1 (0.9%)	3 (3.1%)	2 (2.0%)
<= 25% Stenosis	2 (2.1%)	2 (1.9%)	1 (1.0%)	0 (0%)
Portal/Branch Configuration				
External branch	79 (82.3%)	90 (83.3%)	77 (80.2%)	81 (80.2%)
Internal branch	17 (17.7%)	18 (16.7%)	19 (19.8%)	20 (19.8%)
Portal/Branch Orientation ¹				
Cranial	27 (28.4%)	30 (27.8%)	26 (27.1%)	29 (28.7%)
Caudal	68 (71.6%)	78 (72.2%)	70 (72.9%)	72 (71.3%)
Access Site				
Femoral artery	42 (43.8%)	47 (43.5%)	43 (44.8%)	45 (44.6%)
Iliac artery	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Axillary	45 (46.9%)	51 (47.2%)	46 (47.9%)	49 (48.5%)
Brachial	8 (8.3%)	9 (8.3%)	6 (6.3%)	6 (5.9%)
Other ²	1 (1.0%)	1 (0.9%)	1 (1.0%)	1 (1.0%)

¹ The portal/branch orientation was not documented in the medical record for one subject.

² The site reported “Access Site” as “common femoral artery [AFC] and brachial artery” for 1 subject.

Table 27. VBX Device Details by Treated Artery by Cohort

	FEVAR (N=92)	BEVAR (N=136)
Number of Subjects Enrolled	92	136
Total number of arteries treated with VBX devices	196	467
Average number of VBX devices used per subject (Std. Dev)	2.1 (1.1)	3.4 (1.5)
Subjects with Branch Components		
Celiac Treated	45 (48.9%)	96 (70.6%)
1 Device	44 (47.8%)	86 (63.2%)
2 Devices	1 (1.1%)	10 (7.4%)
3 Devices	0	0
SMA Treated	61 (66.3%)	108 (79.4%)
1 Device	61 (66.3%)	88 (64.7%)
2 Devices	0	20 (14.7%)
3 Devices	0	0
Left Renal Treated	47 (51.1%)	96 (70.6%)
1 Device	47 (51.1%)	75 (55.1%)
2 Devices	0	19 (14.0%)
3 Devices	0	2 (1.5%)
Right Renal Treated	41 (44.6%)	101 (74.3%)
1 Device	40 (43.5%)	88 (64.7%)
2 Devices	1 (1.1%)	13 (9.6%)
3 Devices	0	0
VBX Device Size (Subjects [Devices])		
VBX Device Diameter (mm)	89 [193]	136 [458]
5	1 (1.1%) [1]	8 (5.9%) [10]
6	34 (37.0%) [51]	84 (61.8%) [145]
7	34 (37.0%) [50]	61 (44.9%) [99]
8	45 (48.9%) [60]	68 (50.0%) [96]
9	5 (5.4%) [6]	34 (25.0%) [47]
10	4 (4.3%) [5]	19 (14.0%) [24]
11	4 (4.3%) [4]	7 (5.1%) [7]
8L	14 (15.2%) [16]	24 (17.6%) [30]
VBX Device Length (mm)	89 [193]	136 [458]
15	0 (0%) [0]	0 (0%) [0]
19	3 (3.3%) [3]	1 (0.7%) [1]
29	68 (73.9%) [124]	7 (5.1%) [7]
39	38 (41.3%) [55]	34 (25.0%) [51]
59	5 (5.4%) [7]	94 (69.1%) [164]
79	3 (3.3%) [4]	105 (77.2%) [235]

Header row represents number of non-missing CRF fields, where applicable

SUMMARY OF EMBRACE REGISTRY Results

EMBRACE Registry Primary Endpoint:

The primary endpoint for the EMBRACE Registry was target vessel primary patency (patient level) at 12 months. In the FEVAR and BEVAR arms, target vessel primary patency at 12 months was 98.8% and 92.2% respectively, and hence the Performance Goal of 77% was met for both cohorts. Reference **Table 28**. Subjects without a reported event who were discontinued prior to the 1-year follow-up window, or those missing 1-year imaging were excluded from the analysis. The remaining 80 and 90 subjects were evaluated for target vessel primary patency in the FEVAR and BEVAR cohorts, respectively.

- One (1) subject in the FEVAR cohort experienced a right renal artery stent occlusion at Day 110 resulting in a loss of target vessel patency. The right renal artery stent occlusion was left untreated.
- In the BEVAR cohort, 5 subjects experienced a VBX branch occlusion (Day 43 to 383; most occurring late in the 1-year follow-up window), and 2 subjects exhibited stenosis in the VBX branch that required reintervention (i.e., ballooning which was noted as effective).

Table 28. Primary Endpoint for FEVAR and BEVAR Arms

	FEVAR		BEVAR	
	Total	P-value ²	Total	P-value ²
Number of Subjects Enrolled	92	-	136	-
Discontinued at beginning of 1 Year Window ¹	7	-	33	-
Deceased	5	-	28	-
LTF	2	-	5	-
Withdrew Consent	0	-	0	-
Other	0	-	0	-
Missing 1 Year Imaging	5	-	13	-
Number of Subjects Eligible for Analysis ²	80	-	90	-
Subjects Free From Patency Loss at 12 Months	79 (98.8%)	<.0001	83 (92.2%)	0.0001
95% Lower Confidence Limit ³	92.3%	-	83.5%	-

¹ Subjects that did not lose patency and discontinued study prior to beginning of 1 Year Window

² Subjects with event of interest by end of 1 year window (post procedure day 455), or event-free and still in study at beginning of 1 year window (post procedure day 275)

³ Based on one-sided Clopper-Pearson (Exact) binomial confidence interval

A tipping point analysis using a best-case-to-worst case approach was performed to evaluate the robustness of the primary endpoint results for each cohort. For the FEVAR cohort, if all 12 subjects (those discontinued or missing 1 year imaging) were assumed to be endpoint failures, the Performance Goal (PG) would still be met. For the BEVAR cohort, if 15 of the 46 subjects were endpoint failures, then the PG would still be met; if 16 or more of the subjects with missing data were failures, the PG would not be met.

EMBRACE REGISTRY SECONDARY ENDPOINTS FOR FEVAR AND BEVAR COHORTS

Technical Success:

Primary Technical success was defined as catheterization and placement of all components during the index procedure to exclude the target lesion. Target Vessel Technical success was defined as catheterization and VBX stent graft placement in all intended target vessels. Target Vessel Technical success in the FEVAR and BEVAR arms was 100% and 98.5%, respectively. Reference **Table 29** for a summary of additional outcomes. In the BEVAR cohort, two (2) subjects did not achieve target vessel technical success for the following reasons: failure to navigate and deploy VBX stent graft (1), and failure to gain target vessel access (1). Since data collection was initiated in EMBRACE registry, updated SVS Reporting Standards [6] have been published. As defined in the standard, the following must be met for primary technical success: 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 that extends beyond 30 days by confirmatory imaging (CTA, magnetic resonance angiography [MRA], or duplex ultrasound), and patency of all aortic modular stent graft components and intended side branch components. While the specific definition from the SVS reporting standard was not used in the technical success analysis, all elements of the SVS definition are captured in the study based on variables available from the EMBRACE registry database.

Table 29. Technical Success

	FEVAR	BEVAR
Number of Subjects Enrolled	92	136
Primary Technical Success ¹	88/92 (95.7%)	130/135 (96.3%)
Target Vessel Technical Success (VBX) ²	92/92 (100.0%)	134/136 (98.5%)
¹ Complete endovascular system implantation in the index procedure to treat lesion		
² VBX implantation in target visceral arteries (site reported retained)		

Major Adverse Events:

Major Adverse Events were defined as all-cause mortality, myocardial infarction, respiratory failure, renal function deterioration, bowel ischemia, permanent paraplegia, or major stroke. The Major Adverse Event endpoint was based on CEC adjudicated data and reported at 30 days. **Table 30** and **Table 31** list all Major Adverse Events at 30 days as well as through available five-year follow-up.

None of the all-cause mortality events through 30 days were adjudicated as VBX-related. In the FEVAR cohort, the all-cause mortality events (2) were adjudicated as procedure-related. The all-cause mortality events (13 subjects) in the BEVAR cohort were adjudicated as procedure-related (9), disease-related (1) and unknown relationship (3). In the FEVAR cohort, 2 (2.2%) subjects experienced renal deterioration within 30 days of the procedure. None of these events were CEC adjudicated as VBX-related. Thirteen (9.6%) subjects in the BEVAR cohort experienced renal deterioration within 30 days of the procedure. None of these events were CEC adjudicated as VBX-related.

In the FEVAR cohort, bowel ischemia was reported in 1 subject (1.1%) within 30 days of the procedure. In the BEVAR cohort, bowel ischemia was reported for 1 subject (0.7%) within 30 days of the procedure. None of these events were CEC adjudicated as VBX-related.

In the FEVAR cohort, permanent paraplegia was reported for 1 subject (1.1%) within 30 days of the procedure. No major stroke events were reported within 30 days of the procedure in the FEVAR cohort. In the BEVAR cohort, permanent paraplegia and major stroke rates were 4.4% (6 subjects) and 2.2% (3 subjects), respectively. None of these events were CEC adjudicated as VBX-related.

Table 30. Major Adverse Events FEVAR

	30Day	1 Year	2 Year	3 Year	4 Year	5 Year	Total ²
Number of Subjects at Risk ¹	92	89	84	80	74	59	92
Any Major Adverse Event (MAE)	3 (3.3%)	4 (4.5%)	4 (4.8%)	5 (6.3%)	10 (13.5%)	1 (1.7%)	26 (28.3%)
All-cause mortality	2 (2.2%)	4 (4.5%)	3 (3.6%)	5 (6.3%)	10 (13.5%)	1 (1.7%)	25 (27.2%)
Myocardial infarction (MI): MI resulting in severe hemodynamic dysfunction necessitating resuscitation, cardiac arrest, or fatal outcome	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Respiratory failure requiring prolonged (>24 hours from anticipated) mechanical ventilation or reintubation	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	1 (1.1%)
Any renal function deterioration according to the RIFLE classification system	2 (2.2%)	0 (0%)	2 (2.4%)	0 (0%)	0 (0%)	0 (0%)	4 (4.3%)
Bowel ischemia requiring surgical resection or not resolving with medical therapy	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Permanent paraplegia (any grade 3 A-C spinal cord injury) in a patient who is not ambulatory	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Any major stroke defined according to National Institutes of Health Stroke Scale (NIHSS) or equivalent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
¹ Numbers represent subjects remaining in the study during or beyond the specified window. Follow-up begins at the end of the previous window and continues until the start of the subsequent window. Only the first occurrence of each adverse event type is counted for a subject. Windows: 30 Day (0-30 days), 1 Year (31-365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)							
² Events may be underestimated as study follow-up is ongoing.							

Table 31. Major Adverse Events BEVAR

	30Day	1 Year	2 Year	3 Year	4 Year	5 Year	Total ²
Number of Subjects at Risk ¹	136	123	98	88	83	64	136
Any Major Adverse Event (MAE)	23 (16.9%)	22 (17.9%)	10 (10.2%)	8 (9.1%)	14 (16.9%)	4 (6.3%)	71 (52.2%)
All-cause mortality	13 (9.6%)	20 (16.3%)	10 (10.2%)	5 (5.7%)	14 (16.9%)	4 (6.3%)	66 (48.5%)
Myocardial infarction (MI): MI resulting in severe hemodynamic dysfunction necessitating resuscitation, cardiac arrest, or fatal outcome	0 (0%)	2 (1.6%)	1 (1.0%)	0 (0%)	0 (0%)	1 (1.6%)	4 (2.9%)

	30Day	1 Year	2 Year	3 Year	4 Year	5 Year	Total ²
Respiratory failure requiring prolonged (>24 hours from anticipated) mechanical ventilation or reintubation	3 (2.2%)	0 (0%)	0 (0%)	1 (1.1%)	0 (0%)	0 (0%)	4 (2.9%)
Any renal function deterioration according to the RIFLE classification system	13 (9.6%)	3 (2.4%)	0 (0%)	2 (2.3%)	1 (1.2%)	0 (0%)	19 (14.0%)
Bowel ischemia requiring surgical resection or not resolving with medical therapy	1 (0.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)
Permanent paraplegia (any grade 3 A-C spinal cord injury) in a patient who is not ambulatory	6 (4.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (4.4%)
Any major stroke defined according to National Institutes of Health Stroke Scale (NIHSS) or equivalent	3 (2.2%)	0 (0%)	1 (1.0%)	0 (0%)	2 (2.4%)	0 (0%)	6 (4.4%)
¹ Numbers represent subjects remaining in the study during or beyond the specified window. Follow-up begins at the end of the previous window and continues until the start of the subsequent window. Only the first occurrence of each adverse event type is counted for a subject. Windows: 30 Day (0-30 days), 1 Year (31-365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)							
² Events may be underestimated as study follow-up is ongoing.							

Target Vessel Instability:

Target vessel instability is a composite end point of any branch-related complication leading to aneurysm rupture, death, occlusion, component separation, or reintervention to maintain branch patency or to treat a branch-related component separation or endoleaks. Target Vessel Instability endpoint was based on the CEC and Core Lab adjudicated data and reflects complete data through 3-year follow-up.

In the FEVAR cohort, five (5) subjects have experienced a Target Vessel Instability event through 5-year follow-up. The events include 3 occlusion events (2 with reinterventions) and 3 endoleak reinterventions (2 Type IIlc, 1 Type 1c).

In the BEVAR cohort, 27 subjects experienced Target Vessel Instability through available 5-year follow-up, including 13 subjects with vessel occlusion and 16 subjects with endoleak requiring a reintervention (12 Type Ic, 2 Type IIlc, 1 Type Ib, and 1 Type Ia).

Table 32 and **Table 33** summarize the target vessel instability events for the FEVAR and BEVAR cohort, respectively through available 5-year follow-up.

Table 32. Target Vessel Instability Events FEVAR

	Procedure ¹	1 Year ¹	2 Year ¹	3 Year ¹	4 Year ¹	5 Year ¹	Total ³
Number of Subjects ²	92	92	84	80	74	59	92
Evaluable Subjects	92	87	80	76	70	56	92
Target Vessel Instability	0 (0%)	4 (4.6%)	2 (2.5%)	0 (0%)	0 (0%)	0 (0%)	5 (5.4%)
Vessel Occlusion	0 (0%)	1 (1.1%)	2 (2.5%)	0 (0%)	0 (0%)	0 (0%)	2 (2.2%)
Aneurysm Related Death	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Rupture of Treated Segment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reintervention Reason							
Endoleak	0 (0%)	3 (3.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (3.3%)
Occlusion	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)

¹Beginning at end of previous window and continuing to beginning of subsequent window: Procedure Day (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732- 1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)

²Numbers represent subjects in or past window

³ Total represents number of subjects experiencing a TVI event. Subjects may experience an event in multiple time windows Events may be underestimated as study follow-up is ongoing.

Table 33. Target Vessel Instability Events BEVAR

	Procedure ¹	1 Year ¹	2 Year ¹	3 Year ¹	4 Year ¹	5 Year ¹	Total ³
Number of Subjects ²	136	133	98	88	83	64	136
Evaluable Subjects	133	117	88	75	65	49	133
Target Vessel Instability	0 (0%)	14 (12.0%)	7 (8.0%)	7 (9.3%)	1 (1.5%)	1 (2.0%)	27 (20.3%)
Vessel Occlusion	0 (0%)	2 (1.7%)	5 (5.7%)	6 (8.0%)	1 (1.5%)	0 (0%)	13 (9.8%)
Aneurysm Related Death	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Rupture of Treated Segment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reintervention Reason							
Endoleak	0 (0%)	12 (10.3%)	2 (2.3%)	1 (1.3%)	0 (0%)	1 (2.0%)	16 (12.0%)
Disconnection	0 (0%)	1 (0.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.8%)
Kink	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	1 (0.8%)
Stenosis	0 (0%)	2 (1.7%)	2 (2.3%)	0 (0%)	0 (0%)	0 (0%)	4 (3.0%)
Occlusion	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	1 (0.8%)

¹Beginning at end of previous window and continuing to beginning of subsequent window: Procedure Day (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732- 1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)
²Numbers represent subjects in or past window
³ Total represents number of subjects experiencing a TVI event. Subjects may experience an event in multiple time windows Events may be underestimated as study follow-up is ongoing.

Reference **Table 34** and **Table 35** for Kaplan-Maier estimates of Freedom from Target Vessel Instability in the FEVAR and BEVAR arms, respectively, at the individual vessel level for timepoints with adjudicated data. Freedom from Target Vessel Instability for all vessels at 1, 2, and 3 years in the FEVAR cohort was 97.5%, 97.5%, and 94.7%, respectively. In the BEVAR cohort, the Freedom from Target Vessel Instability at 1, 2, and 3 years was 94.3%, 91.8%, and 87.2%, respectively.

Table 34. Kaplan- Meier Estimates of Freedom from Target Vessel Instability FEVAR

FEVAR						
Vessel	Time Post Treatment (Years**)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	Vessels Free from Instability (%)	95% C.I.
All Vessels	Procedure Day	194	0 (0)	5 (5)	100%	(100.0%, 100.0%)
	1 Year	189	4 (4)	33 (38)	97.5%	(93.6%, 99.1%)
	2 Year	152	3 (7)	13 (51)	95.5%	(90.7%, 97.8%)
	3 Year	136	1 (8)	33 (84)	94.7%	(89.6%, 97.3%)
Celiac Trunk	Procedure Day	45	0 (0)	2 (2)	100%	(100.0%, 100.0%)
	1 Year	43	1 (1)	5 (7)	97.4%	(83.2%, 99.6%)
	2 Year	37	0 (1)	3 (10)	97.4%	(83.2%, 99.6%)
	3 Year	34	0 (1)	7 (17)	97.4%	(83.2%, 99.6%)
Left Renal Artery	Procedure Day	47	0 (0)	0 (0)	100%	(100.0%, 100.0%)
	1 Year	47	1 (1)	10 (10)	97.4%	(83.2%, 99.6%)
	2 Year	36	1 (2)	2 (12)	94.6%	(79.9%, 98.6%)
	3 Year	33	1 (3)	9 (21)	91.4%	(75.6%, 97.2%)
Right Renal Artery	Procedure Day	41	0 (0)	0 (0)	100%	(100.0%, 100.0%)
	1 Year	41	1 (1)	8 (8)	97.1%	(81.4%, 99.6%)
	2 Year	32	1 (2)	4 (12)	93.8%	(77.3%, 98.4%)
	3 Year	27	0 (2)	6 (18)	93.8%	(77.3%, 98.4%)
Superior Mesenteric Artery	Procedure Day	61	0 (0)	3 (3)	100%	(100.0%, 100.0%)
	1 Year	58	1 (1)	10 (13)	98.0%	(86.6%, 99.7%)
	2 Year	47	1 (2)	4 (17)	95.7%	(83.9%, 98.9%)
	3 Year	42	0 (2)	11 (28)	95.7%	(83.9%, 98.9%)
Number in Parenthesis represents cumulative events or censored observations through end of interval.						

Table 35. Kaplan- Meier Estimates of Freedom from Target Vessel Instability FEVAR

BEVAR						
Vessel	Time Post Treatment (Years**)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	Vessels Free Instability (%)	95% C.I.
All Vessels	Procedure Day	401	0 (0)	31 (31)	100%	(100.0%, 100.0%)
	1 Year	370	18 (18)	103 (134)	94.3%	(91.1%, 96.4%)
	2 Year	249	6 (24)	33 (167)	91.8%	(88.0%, 94.5%)
	3 Year	210	10 (34)	23 (190)	87.2%	(82.4%, 90.7%)
Celiac Trunk	Procedure Day	96	0 (0)	4 (4)	100%	(100.0%, 100.0%)
	1 Year	92	4 (4)	27 (31)	94.8%	(86.8%, 98.0%)

BEVAR						
Vessel	Time Post Treatment (Years**)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	Vessels Free Instability (%)	95% C.I.
	2 Year	61	1 (5)	10 (41)	93.1%	(84.0%, 97.1%)
	3 Year	50	2 (7)	8 (49)	89.3%	(78.5%, 94.8%)
Left Renal Artery	Procedure Day	96	0 (0)	8 (8)	100%	(100.0%, 100.0%)
	1 Year	88	3 (3)	24 (32)	95.9%	(87.9%, 98.7%)
	2 Year	61	4 (7)	8 (40)	89.1%	(78.4%, 94.7%)
	3 Year	49	2 (9)	4 (44)	85.2%	(73.3%, 92.1%)
Right Renal Artery	Procedure Day	101	0 (0)	9 (9)	100%	(100.0%, 100.0%)
	1 Year	92	6 (6)	26 (35)	92.4%	(83.9%, 96.5%)
	2 Year	60	1 (7)	8 (43)	90.7%	(81.2%, 95.5%)
	3 Year	51	3 (10)	3 (46)	85.2%	(73.8%, 91.9%)
Superior Mesenteric Artery	Procedure Day	108	0 (0)	10 (10)	100%	100.0%, 100.0%)
	1 Year	98	5 (5)	26 (36)	94.1%	(86.3%, 97.5%)
	2 Year	67	0 (5)	7 (43)	94.1%	(86.3%, 97.5%)
	3 Year	60	3 (8)	8 (51)	88.8%	(78.5%, 94.3%)
Number in Parenthesis represents cumulative events or censored observations through end of interval.						

Target Vessel Primary Patency Through 3 Years:

The Target vessel primary patency endpoint was based on Core Lab adjudicated data. Patient-level target vessel primary patency at 3 years for the FEVAR and BEVAR arms are estimated at 97.4% and 81.3% respectively. Reference **Table 36** and **Table 37** for additional timepoints.

Table 36. Kaplan-Meier Estimates of Target Vessel Primary Patency (Patient Level) for FEVAR

FEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects with Primary Patency	95% C.I.
Procedure Day	92	0 (0)	3 (3)	100%	(100.0%, 100.0%)
1 Year	89	1 (1)	12 (15)	98.8%	(91.6%, 99.8%)
2 Year	76	1 (2)	7 (22)	97.4%	(89.8%, 99.3%)
3 Year	68	0 (2)	14 (36)	97.4%	(89.8%, 99.3%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Table 37. Kaplan-Meier Estimates of Target Vessel Primary Patency (Patient Level) for BEVAR

BEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects with Primary Patency	95% C.I.
Procedure Day	136	0 (0)	12 (12)	100%	(100.0%, 100.0%)
1 Year	124	3 (3)	37 (49)	97.1%	(91.2%, 99.0%)
2 Year	84	6 (9)	10 (59)	89.8%	(81.2%, 94.6%)
3 Year	68	6 (15)	8 (67)	81.3%	(70.6%, 88.4%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Primary Patency by Vessel:

A summary of the estimates for target vessel primary patency (vessel level analysis) at all available timepoints for the FEVAR and BEVAR arms are shown in Table 38 and Table 39.

Table 38. Kaplan-Meier Estimates Primary Patency by Vessel FEVAR

FEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects with Primary Patency	95% C.I.
Group: Celiac Trunk					
Procedure Day	45	0 (0)	2 (2)	100%	(100.0%, 100.0%)
1 Year	43	0 (0)	5 (7)	100%	(100.0%, 100.0%)
2 Year	38	0 (0)	3 (10)	100%	(100.0%, 100.0%)
3 Year	35	0 (0)	7 (17)	100%	(100.0%, 100.0%)
Group: Left Renal Artery					
Procedure Day	47	0 (0)	0 (0)	100%	(100.0%, 100.0%)
1 Year	47	0 (0)	10 (10)	100%	(100.0%, 100.0%)
2 Year	37	1 (1)	2 (12)	97.1%	(81.4%, 99.6%)
3 Year	34	0 (1)	9 (21)	97.1%	(81.4%, 99.6%)
Group: Right Renal Artery					
Procedure Day	41	0 (0)	0 (0)	100%	(100.0%, 100.0%)
1 Year	41	1 (1)	8 (8)	97.1%	(81.4%, 99.6%)
2 Year	32	1 (2)	4 (12)	93.8%	(77.3%, 98.4%)
3 Year	27	0 (2)	6 (18)	93.8%	(77.3%, 98.4%)
Group: Superior Mesenteric Artery					
Procedure Day	61	0 (0)	3 (3)	100%	(100.0%, 100.0%)
1 Year	58	0 (0)	10 (13)	100%	(100.0%, 100.0%)
2 Year	48	1 (1)	4 (17)	97.7%	(84.9%, 99.7%)
3 Year	43	0 (1)	11 (28)	97.7%	(84.9%, 99.7%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Table 39. Kaplan-Meier Estimates Primary Patency by Vessel BEVAR

BEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects with Primary Patency	95% C.I.
Group: Celiac Trunk					
Procedure Day	96	0 (0)	4 (4)	100%	(100.0%, 100.0%)
1 Year	92	1 (1)	28 (32)	98.7%	(91.2%, 99.8%)
2 Year	63	1 (2)	10 (42)	97.0%	(88.2%, 99.2%)
3 Year	52	2 (4)	9 (51)	93.1%	(82.6%, 97.4%)
Group: Left Renal Artery					
Procedure Day	96	0 (0)	8 (8)	100%	(100.0%, 100.0%)
1 Year	88	1 (1)	25 (33)	98.6%	(90.5%, 99.8%)
2 Year	62	4 (5)	8 (41)	91.9%	(81.6%, 96.6%)
3 Year	50	1 (6)	4 (45)	89.9%	(78.8%, 95.4%)
Group: Right Renal Artery					
Procedure Day	101	0 (0)	9 (9)	100%	(100.0%, 100.0%)
1 Year	92	1 (1)	28 (37)	98.7%	(91.4%, 99.8%)
2 Year	63	2 (3)	8 (45)	95.4%	(86.2%, 98.5%)
3 Year	53	4 (7)	4 (49)	87.9%	(76.1%, 94.1%)
Group: Superior Mesenteric Artery					
Procedure Day	108	0 (0)	10 (10)	100%	(100.0%, 100.0%)
1 Year	98	1 (1)	28 (38)	98.8%	(91.6%, 99.8%)
2 Year	69	0 (1)	7 (45)	98.8%	(91.6%, 99.8%)
3 Year	62	1 (2)	8 (53)	96.9%	(88.0%, 99.2%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Freedom from Reinterventions:

Reinterventions were defined as any repeat vascular or nonvascular procedure related to the index procedure.

Reinterventions were further categorized as Major and Minor as follows:

- Major reinterventions included the deployment of proximal or distal aortic or iliac extensions, removal of the device, use of thrombectomy or thrombolysis, and any major open surgical procedure.
- Minor reinterventions included endovascular procedures (percutaneous transluminal angioplasty, atherectomy, stenting) without thrombectomy or thrombolysis, interventions to treat branch stenosis, Type II or branch-related endoleaks, and minor surgical procedures (patch angioplasty) for access vessels.

Reintervention endpoints were based on CEC adjudicated data through 3-year follow-up. In the FEVAR cohort, 11 (12.0%) subjects experienced 13 major reinterventions. The most common reason for major reintervention was Type IB endoleak (7 events, 53.8%). One (1) subject underwent a major reintervention for a left renal stent occlusion which the CEC adjudicated as VBX-related. No other major reinterventions were adjudicated as VBX-related by the CEC.

For the BEVAR cohort, 23 (16.9%) subjects experienced 28 major reinterventions. The most common reasons for major reintervention were endoleak (11 events, 39.3%), thrombosis/occlusion (6 events, 21.4%), and rupture (4 events, 14.3%). No major reintervention were adjudicated by the CEC as VBX-related.

The estimates of freedom from VBX-related reintervention are presented in **Table 40** for FEVAR and **Table 41** for BEVAR.

Table 40. Kaplan-Meier Estimates of Freedom from Reintervention in FEVAR

FEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	%Subjects Free from Reintervention	95% C.I.
Group: Major					
Procedure Day	92	0 (0)	0 (0)	100%	(100.0%, 100.0%)
1 Year	92	0 (0)	11 (11)	100%	(100.0%, 100.0%)
2 Year	81	1 (1)	3 (14)	98.7%	(91.4%, 99.8%)

3 Year	77	0 (1)	7 (21)	98.7%	(91.4%, 99.8%)
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FEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects Free from Reintervention	95% C.I.
Group: Minor					
Procedure Day	92	0 (0)	0 (0)	100%	(100.0%, 100.0%)
1 Year	92	3 (3)	8 (8)	96.6%	(89.7%, 98.9%)
2 Year	81	0 (3)	4 (12)	96.6%	(89.7%, 98.9%)
3 Year	77	1 (4)	6 (18)	95.3%	(87.8%, 98.2%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Table 41. Kaplan-Meier Estimates of Freedom from Reintervention in BEVAR

BEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects Free from Reintervention	95% C.I.
Group: Major					
Procedure Day	136	0 (0)	3 (3)	100%	(100.0%, 100.0%)
1 Year	133	0 (0)	42 (45)	100%	(100.0%, 100.0%)
2 Year	91	0 (0)	12 (57)	100%	(100.0%, 100.0%)
3 Year	79	0 (0)	9 (66)	100%	(100.0%, 100.0%)
Group: Minor					
Procedure Day	136	0 (0)	3 (3)	100%	(100.0%, 100.0%)
1 Year	133	9 (9)	33 (36)	92.2%	(85.5%, 95.9%)
2 Year	91	3 (12)	9 (45)	89.0%	(81.3%, 93.6%)
3 Year	79	4 (16)	5 (50)	84.2%	(75.4%, 90.1%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Freedom from Aneurysm-Related Mortality:

Freedom from Aneurysm-related mortality endpoint was based on CEC adjudicated data. None of the events were adjudicated by the CEC as VBX-related. Freedom from Aneurysm-related mortality through 3 years for FEVAR and BEVAR is 96.6% and 88.9% respectively. Reference **Table 42** and **Table 43** for additional time points.

Table 42. Kaplan-Meier Estimates of Freedom from Aneurysm-related Mortality for FEVAR

FEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects Free from Aneurysm Related Mortality (%)	95% C.I.
Procedure Day	92	0 (0)	0 (0)	100%	(100.0%, 100.0%)
30 Day	92	2 (2)	1 (1)	97.8%	(91.6%, 99.5%)
1 Year	89	0 (2)	4 (5)	97.8%	(91.6%, 99.5%)
2 Year	85	0 (2)	5 (10)	97.8%	(91.6%, 99.5%)
3 Year	80	1 (3)	12 (22)	96.6%	(89.7%, 98.9%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

Table 43. Kaplan-Meier Estimates of Freedom from Aneurysm-related Mortality for BEVAR

BEVAR					
Time Post Treatment (Years)	Number at Risk at Start of Interval	Number of Events During Interval *	Number Censored During Interval *	% Subjects Free from Aneurysm Related Mortality (%)	95% C.I.
Procedure Day	136	3 (3)	0 (0)	97.8%	(93.3%, 99.3%)
30 Day	133	10 (13)	0 (0)	90.4%	(84.1%, 94.3%)
1 Year	123	2 (15)	21 (21)	88.9%	(82.2%, 93.1%)
2 Year	100	0 (15)	15 (36)	88.9%	(82.2%, 93.1%)
3 Year	85	0 (15)	12 (48)	88.9%	(82.2%, 93.1%)

Number in Parenthesis represents cumulative events or censored observations through end of interval.

All-Cause Mortality:

Reference **Table 44** and **Table 45** for a summary of all-cause mortality rates for FEVAR and BEVAR, respectively. Cause of death is listed below all-cause mortality numbers. For FEVAR, 1 all-cause mortality event was CEC adjudicated as VBX-related [i.e., left renal stent occlusion (POD 586), thrombolysis performed, related mortality]. For BEVAR, to date, no VBX-related death has been reported in the BEVAR cohort.

Table 44. All-Cause Mortality FEVAR

	Procedure ²	1 Year ²	2 Years ²	3 Years ²	4 Years ²	5 Years ²	Total
Number of Subjects ¹	92	92	84	80	74	59	92
Not Yet in Window	0	0	0	0	0	3	0
All-Cause Mortality ⁴	0 (0%)	6 (6.5%)	3 (3.6%)	5 (6.3%)	10 (13.5%)	1 (1.7%)	25 (27.2%)
Aneurysm Related Death ³	0 (0%)	2 (2.2%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	3 (3.3%)
Myocardial Infarction ³	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Respiratory Failure ³	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	1 (1.1%)
Renal Function Deterioration ³	0 (0%)	1 (1.1%)	1 (1.2%)	0 (0%)	1 (1.4%)	0 (0%)	3 (3.3%)
Bowel Ischemia ³	0 (0%)	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Permanent Paraplegia ³	0 (0%)	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Major Stroke ³	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Rupture of Treated Segment ³	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	1 (1.1%)
Reintervention as Part of Treatment ³	0 (0%)	1 (1.1%)	3 (3.6%)	1 (1.3%)	4 (5.4%)	1 (1.7%)	10 (10.9%)
Reason for Reintervention ³							
Endoleak	0 (0%)	0 (0%)	2 (2.4%)	1 (1.3%)	2 (2.7%)	1 (1.7%)	6 (6.5%)
Disconnection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Kink	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	1 (1.1%)
Stenosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	1 (1.1%)
Occlusion	0 (0%)	0 (0%)	1 (1.2%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Rupture	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Migration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reintervention Classification ³							
Major	0 (0%)	1 (1.1%)	2 (2.4%)	1 (1.3%)	2 (2.7%)	0 (0%)	6 (6.5%)
Minor	0 (0%)	1 (1.1%)	1 (1.2%)	0 (0%)	2 (2.7%)	1 (1.7%)	5 (5.4%)

¹Numbers represent subjects still in the study in or past window
²Beginning at end of previous window and continuing to beginning of subsequent window: Procedure (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)
³CEC adjudicated cause of death at time of data export
⁴Not all causes of death were known

Table 45. All-Cause Mortality BEVAR

	Procedure ²	1 Year ²	2 Years ²	3 Years ²	4 Years ²	5 Years ²	Total
Number of Subjects ¹	136	133	98	88	83	64	136
Not Yet in Window	0	0	0	0	0	4	0
All-Cause Mortality ⁴	3 (2.2%)	30 (22.6%)	10 (10.2%)	5 (5.7%)	14 (16.9%)	4 (6.3%)	66 (48.5%)

	Procedure ²	1 Year ²	2 Years ²	3 Years ²	4 Years ²	5 Years ²	Total
Aneurysm Related Death ³	2 (1.5%)	7 (5.3%)	0 (0%)	0 (0%)	1 (1.2%)	0 (0%)	10 (7.4%)
Myocardial Infarction ³	0 (0%)	2 (1.5%)	1 (1.0%)	0 (0%)	0 (0%)	1 (1.6%)	4 (2.9%)
Respiratory Failure ³	0 (0%)	3 (2.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (2.2%)
Renal Function Deterioration ³	0 (0%)	11 (8.3%)	0 (0%)	1 (1.1%)	3 (3.6%)	0 (0%)	15 (11.0%)
Bowel Ischemia ³	0 (0%)	1 (0.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)
Permanent Paraplegia ³	0 (0%)	6 (4.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (4.4%)
Major Stroke ³	0 (0%)	3 (2.3%)	1 (1.0%)	0 (0%)	2 (2.4%)	0 (0%)	6 (4.4%)
Rupture Of Treated Segment ³	0 (0%)	2 (1.5%)	0 (0%)	0 (0%)	1 (1.2%)	0 (0%)	3 (2.2%)
Reintervention as Part Of Treatment ³	0 (0%)	8 (6.0%)	2 (2.0%)	1 (1.1%)	5 (6.0%)	1 (1.6%)	17 (12.5%)
Reason for Reintervention ³							
Endoleak	0 (0%)	3 (2.3%)	1 (1.0%)	1 (1.1%)	2 (2.4%)	1 (1.6%)	8 (5.9%)
Disconnection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Kink	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Stenosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.2%)	0 (0%)	1 (0.7%)
Occlusion	0 (0%)	1 (0.8%)	0 (0%)	0 (0%)	3 (3.6%)	0 (0%)	4 (2.9%)
Rupture	0 (0%)	2 (1.5%)	1 (1.0%)	0 (0%)	1 (1.2%)	0 (0%)	4 (2.9%)
Migration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reintervention Classification ³							
Major	0 (0%)	3 (2.3%)	1 (1.0%)	1 (1.1%)	4 (4.8%)	0 (0%)	9 (6.6%)
Minor	0 (0%)	6 (4.5%)	1 (1.0%)	0 (0%)	2 (2.4%)	1 (1.6%)	10 (7.4%)

¹Numbers represent subjects still in the study in or past window
²Beginning at end of previous window and continuing to beginning of subsequent window: Procedure (Day 0), 1 Year (1- 365 days), 2 Year (366-731 days), 3 Year (732-1096 days), 4 Year (1097-1461 days), 5 Year (1462-1826 days)
³CEC adjudicated cause of death at time of data export
⁴Not all causes of death were known

Summary of Core Lab Findings

Table 46 and **Table 47** summarize the Core Lab device event findings at the vessel-level for FEVAR and BEVAR through available five-year follow up, respectively.

The most commonly reported Core Lab finding was compression/invagination in VBX-treated vessels. Core Lab prospectively defined compression as evidence of the device being crushed or compressed by surrounding anatomy (e.g., calcium, thrombus, or vessel wall), resulting in a focal reduction in device diameter. Invagination was prospectively defined as evidence of the study device collapsing on itself in the absence of external anatomical compression. The Core Lab did not distinguish between compression and invagination during image adjudication or data reporting. Rather, any vessel meeting either definition was recorded as a single Core Lab imaging endpoint of compression/invagination. The majority of findings were not associated with reported clinical sequelae or the need for reintervention. The following is a subject-level summary of compression/invagination findings for each cohort:

- For FEVAR, of the 21 subjects with one or more Core Lab-adjudicated compression/invagination findings, 19 subjects had no associated VBX-related adverse event. Two subjects underwent three endovascular reinterventions for two device occlusions and one Type IIIC endoleak. Of the three adverse events, two resolved without sequelae, and one resulted in a fatal outcome following thrombolysis for left renal artery device occlusion. Overall, this resulted in a rate of 2.2% (95% CI: 0.3–7.6) for subjects with both a compression/invagination finding and a VBX-related adverse event.
- For BEVAR, of the 35 subjects with one or more Core Lab-adjudicated compression/invagination findings, 27 subjects with a compression/invagination event had no VBX-related adverse events. The remaining eight subjects experienced nine VBX-related adverse events. Four subjects were left untreated. Four (4) subjects underwent 5 endovascular reinterventions for stenosis (1), occlusion (2), and endoleaks (3). The outcome of the reinterventions was reported as follows: 3 resolved without further sequelae, 1 resolved with sequelae, and 1 with unknown resolution, resulting in an overall rate of 6.0% (95% CI: 2.6 – 11.5) for subjects with both a compression/invagination event and VBX-related adverse event.

Branch dissections were observed; however, the origin of the dissection (e.g. iatrogenic, degenerative) could not be identified by the Core Lab. Thus, the number of branch dissections included in the Core Lab Findings table includes all dissections.

Table 46. Summary of Core Lab Findings FEVAR

	1 Year ²	2 Year ²	3 Year ²	4 Year ²	5 Year ²	Total
Number of Subjects at Risk ¹	92	83	80	72	52	92
Subjects with CT in Window ³	89	62	51	35	23	89
VBX-Treated Vessels at Risk	195	170	165	151	111	195
VBX-Treated Vessels with Available Imaging ³	188	122	96	62	50	188
Vessels with Adequate Imaging for Vessel-Level Assessment ⁴	188	122	96	61	50	188
Stenosis Evaluable	188	121	94	57	50	188
Stenotic >50 %	1 (0.5%)	4 (3.3%)	0 (0%)	0 (0%)	1 (2.0%)	5 (2.7%)
Vessels with Adequate Imaging for Device Compression/Invagination ⁶	188	120	94	60	50	188
Device Compression/Invagination	16 (8.5%)	13 (10.8%)	8 (8.5%)	3 (5.0%)	3 (6.0%)	23 (12.2%)
Vessels with Adequate Imaging for Dissection Present (Branch Vessel) ⁶	188	118	94	57	48	188
Dissection Present (Branch Vessel)	10 (5.3%)	3 (2.5%)	1 (1.1%)	1 (1.8%)	1 (2.1%)	12 (6.4%)
Vessels with Adequate Imaging for Wire Fracture ⁵	188	122	96	61	50	188
Wire Fracture	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

	1 Year ²	2 Year ²	3 Year ²	4 Year ²	5 Year ²	Total
Vessels with Adequate Imaging for Device Component Separation⁵	188	122	96	61	50	188
Device Component Separation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Vessels with Adequate Imaging for Migration⁵	188	122	96	61	50	188
Migration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Vessels with Adequate Imaging for Endoleak⁵	188	122	96	61	50	188
Endoleak	2 (1.1%)	2 (1.6%)	1 (1.0%)	0 (0%)	0 (0%)	3 (1.6%)
Endoleak Type	2	2	1	0	0	3
Type IA	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IB	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IC	1 (0.5%)	1 (0.8%)	0 (0%)	-	-	1 (0.5%)
Type II	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IIIA	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IIIB	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IIIC	1 (0.5%)	1 (0.8%)	1 (1.1%)	-	-	2 (1.1%)
Type III general	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Type IV	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Indeterminate	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)
Unknown	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)

¹Numbers represent subjects still in the study in or past window
²Beginning at end of previous window and continuing to start of subsequent window: 1 Year (1- 455 days), 2 Year (456-820 days), 3 Year (821-1185 days), 4 Year (1186-1550 days), 5 Year (after 1550 days); Note: Procedural/30 Day outcomes were not assessed by the Core Laboratory.
³CTs that have been reviewed by Core Lab imaging at time of table creation.
⁴Core Laboratory determined imaging was of sufficient quality to allow assessment of vessel-level characteristics.
⁵Core Laboratory determined imaging was of sufficient quality to allow assessment of device integrity outcomes (e.g., wire fracture, separation, migration, and endoleak).
⁶Of the imaging that was considered of sufficient quality to allow assessment of vessel-level characteristics or device integrity outcomes as presented in Table 20 and 21, a subset of imaging was determined by the Core Lab to be adequate quality for compression/invagination and dissection.

Table 47. Summary of Core Lab Findings BEVAR

	1 Year	2 Year	3 Year	4 Year	5 Year	Total
Number of Subjects at Risk^{1,2}	133	96	86	79	57	133
Subjects with CT in Window³	118	62	50	41	15	122
VBX-Treated Vessels at Risk	394	288	260	239	172	394
VBX-Treated Vessels with Available Imaging³	357	183	143	136	47	364
Vessels with Adequate Imaging for Vessel-Level Assessment⁴	357	183	143	134	47	364
Stenosis Evaluable (>50%)	353	180	143	131	43	360
Stenotic > 50%	8 (2.3%)	7 (3.9%)	2 (1.4%)	1 (0.8%)	2 (4.7%)	17 (4.7%)
Vessels with Adequate Imaging for Device Compression/Invagination⁶	353	183	142	134	45	360
Device Compression/Invagination	30 (8.5%)	12 (6.6%)	12 (8.5%)	8 (6.0%)	7 (15.6%)	43 (11.9%)
Vessels with Adequate Imaging for Dissection Present (Branch Vessel)⁶	357	173	142	127	40	364
Dissection Present (Branch Vessel)	17 (4.8%)	8 (4.6%)	5 (3.5%)	4 (3.1%)	1 (2.5%)	22 (6.0%)
Vessels with Adequate Imaging for Wire Fracture⁵	357	183	143	134	47	364
Wire Fracture	0 (0%)	0 (0%)	1 (0.7%)	3 (2.2%)	1 (2.1%)	3 (0.8%)
Vessels with Adequate Imaging for Device Component Separation⁵	357	183	143	134	47	364
Device Component Separation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.1%)	1 (0.3%)
Vessels with Adequate Imaging for Migration⁵	357	183	143	134	47	364
Migration	1 (0.3%)	1 (0.5%)	1 (0.7%)	0 (0%)	1 (2.1%)	2 (0.5%)
Vessels with Adequate Imaging for Endoleak⁵	357	183	143	134	47	364
Endoleak	10 (2.8%)	4 (2.2%)	5 (3.5%)	2 (1.5%)	1 (2.1%)	16 (4.4%)
Endoleak Type	10	4	5	2	1	16
Type IA	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type IB	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type IC	10 (2.8%)	4 (2.2%)	2 (1.4%)	0 (0%)	0 (0%)	12 (3.3%)
Type II	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type IIIA	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type IIIB	0 (0%)	0 (0%)	1 (0.7%)	2 (1.5%)	1 (2.1%)	2 (0.5%)
Type IIIC	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type III general	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%)
Indeterminate	0 (0%)	0 (0%)	2 (1.4%)	0 (0%)	0 (0%)	2 (0.5%)
Unknown	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

	1 Year	2 Year	3 Year	4 Year	5 Year	Total
¹ Numbers represent subjects still in the study in or past window						
² Beginning at end of previous window and continuing to start of subsequent window: 1 Year (1- 455 days), 2 Year (456-820 days), 3 Year (821-1185 days), 4 Year (1186-1550 days), 5 Year (after 1550 days); Note: Procedural/30 Day outcomes were not assessed by the Core Laboratory.						
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⁵ Core Laboratory determined imaging was of sufficient quality to allow assessment of device integrity outcomes (e.g., wire fracture, separation, migration, and endoleak).						
⁶ Of the imaging that was considered of sufficient quality to allow assessment of vessel-level characteristics or device integrity outcomes as presented in Table 20 and 21, a subset of imaging was determined by the Core Lab to be adequate quality for compression/invagination and dissection.						

EMBRACE Registry Conclusions:

The EMBRACE Registry provides multicenter, independently adjudicated, hypothesis tested clinical data that supports the safety and effectiveness of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in conjunction with fenestrated or branched aortic endovascular grafts. The primary outcome of the EMBRACE registry analysis was target vessel patency at 12 months. The 12 month target vessel patency rate reported was 98.8% and 92.2% in the FEVAR and BEVAR cohorts, respectively. For both cohorts, the pre-specified Performance Goal of 77% was met. Composite rate of MAEs through 30 days was 3.3% and 16.9 % for the FEVAR and BEVAR cohorts, respectively. None of the MAEs through 30 days were adjudicated as VBX device-related. Data are available on all evaluable patients through 3-year follow-up, with complete Core Laboratory review and CEC adjudication. At 3 years, imaging was of sufficient quality to allow assessment of vessel-level characteristics and device integrity outcomes for 51 of 80 FEVAR subjects (63.8%) and 50 of 86 BEVAR subjects (58.1%). Four- and five-year follow-up remain ongoing and are not yet fully reviewed or adjudicated.

It is noted that BEVAR cohort outcomes are less favorable than those reported for the FEVAR cohort, especially as it relates to outcomes such as target vessel instability, endoleaks and major adverse events such as mortality and renal deterioration. Additionally, the tipping point analysis suggested higher uncertainty for the BEVAR cohort related to target vessel patency at 1 year. Although FEVAR and BEVAR procedures may involve a similar number of visceral vessels, the difference in outcomes may be attributed to different underlying anatomical conditions. BEVAR typically requires longer bridging distances and treatment of more extensive lesions, resulting in greater procedural complexity.

It is important to acknowledge that the real-world evidence in EMBRACE registry was derived from retrospective data collected from outside the United States during routine clinical care. As a result, clinical practice, patient and device selection, procedural techniques, and the timing and availability of follow-up assessments were not prospectively standardized and may have varied across sites. Additionally, uncertainty exists regarding lack of a complete characterization of patient attrition across all eligibility criteria, methods used during the retrospective medical-record review, and given the extent of censored subjects in the endpoint analysis. Patient attrition and missing imaging beyond the 1-year timepoint has limited the availability of longer-term outcomes in the EMBRACE registry; however, supplemental clinical data sources provide additional longer term outcome data. Another major limitation of the dataset is representation of aortic endografts with which the VBX Device was evaluated as a bridging stent; these limitations informed the device labeling.

Overall, the results from the EMBRACE Registry, as well as supplemental data, support use of the VBX Device as a bridging stent in fenestrated and branched endovascular aortic repair in patients who have appropriate anatomy.

SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

EXPAND Registry:

The EXPAND Registry (NCT03720704) is a European, post-market clinical follow-up study initiated upon receipt of CE Mark for the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in 2017. The primary objective of this registry was to collect real-world post-market safety and performance data of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in peripheral vessels (inclusive of visceral vessels) in patients who required interventional treatment; the registry includes use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent with fenestrated and branched aortic main body components.

The registry evaluated 39 subjects with 102 treated vessels in the FEVAR cohort and 73 subjects with 222 treated vessels in the BEVAR cohort. The primary endpoint for the EXPAND Registry was a composite of Procedural Success and Freedom from VBX Device-related Serious Adverse Events through 30 days.

- For FEVAR, 39 (100%) subjects met the Procedural Success criteria, and 38 (97.4%) met the Freedom from VBX-related SAEs criteria. Therefore, 38 (97.4%) subjects met the composite primary endpoint (95% CI 86.5% - 99.9%).
- For BEVAR, 73 (100%) subjects met the Procedural Success criteria, and 71 subjects were available for VBX-related SAE assessment; of those, 70 (98.6%) were free from VBX-related SAEs. Therefore, 70 (98.6%) subjects met the composite primary endpoint (95% CI 92.4% - 100.0%).

The secondary endpoint of Target Vessel Technical Success (same endpoint definition as the EMBRACE registry) at the index procedure was achieved for all subjects in each cohort (100% FEVAR and 100% BEVAR). The Kaplan-Meier estimate for Primary Patency at 1-year and 3 years at the vessel level was 100% and 95.1%, respectively, for the FEVAR subgroup and 96.0% and 93.4%, respectively, for the BEVAR subgroup. The Kaplan-Meier estimate for Freedom from Target Vessel Instability at 1-year and 3 years was 100% and 98.7%, respectively, for the FEVAR subgroup and 96.5% and 94.1%, respectively, for the BEVAR subgroup. Limitations of this data include the observational design, lack of core lab adjudication, and a limited number of subjects with longer-term follow-up. Despite the limitations, the EXPAND Registry results supplement the EMBRACE data with additional longer-term safety and effectiveness outcomes for the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis when used as a bridging stent for FEVAR and BEVAR.

EMBRACE Registry Mixed Cohort:

In addition to the FEVAR and BEVAR cohorts, a separate cohort of patients with GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as bridging stents in aortic endovascular grafts containing a mix of branches and fenestrations (mixed cohort) was enrolled and analyzed descriptively, comprising of 31 subjects with 67 VBX-treated vessels. The Target Vessel Technical Success at the index procedure was achieved for all subjects (100%). Primary Technical Success was achieved in 83.9% of subjects. No subject experienced Type I or Type III endoleaks that extended beyond 30 days. The Kaplan-Meier estimate of primary patency at 1, 2, and 3 years is 100%. Three (3, 12%) VBX Stent Graft related adverse events occurred in three patients (Type 1C, Type IIIC and Type II endoleaks), and no VBX Stent Graft related deaths were reported. The outcomes observed in the combined FEVAR/BEVAR cohort were consistent with those observed in the FEVAR and BEVAR analyses, providing additional supportive evidence for the use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in FEVAR and BEVAR procedures.

GORE TAMBE PMA:

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis has been evaluated as a bridging stent with the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) Device. Reference the TAMBE Device SSED and IFU for information regarding clinical results.

U.S. Aortic Research Consortium:

The US-ARC is a multicenter collaborative research consortium established in 2018 with the primary objective of evaluating outcomes of custom-made fenestrated and branched endovascular devices for treating patients with complex abdominal, thoracoabdominal, and arch aneurysms. The consortium aggregates prospectively collected data from physician-sponsored investigational device exemption studies, and has published analyses including pooled patient- and vessel-level outcomes from FEVAR/BEVAR procedures. Published US-ARC analyses [3, 4] include clinical experience with GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis used in fenestrations and branches. The US-ARC data provide additional supportive evidence regarding use of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a bridging stent in FEVAR/BEVAR.

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DEFINITIONS

EC REP Authorised Representative in the European Community

REF Catalogue Number

 Caution

Rx 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

 Contains a Medicinal Substance

 Contains Biological Material of Animal Origin

 Date of Manufacture

 Do Not Resterilize

 Do Not Reuse

 Do Not Use if Package is Damaged

 Importer into the European Community

 Keep Dry

 Manufacturer

MD Medical Device

 MR Conditional

SN Serial Number

 Single Sterile Barrier System

STERILE EO Sterilized using Ethylene Oxide

 Store at 15°C - 30°C

UDI Unique Device Identifier

 Use By

 Catheter Working Length

 Final Stent ID

 Guidewire Compatibility

 Inflation Pressure

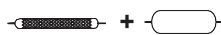
 Introducer Sheath

 Max Post-Dilated Stent Diameter

NP Nominal Pressure

 Nominal Stent Diameter

RBP Rated Burst Pressure

 Second Balloon Required, Not Included

 Stent Length



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