INSTRUCTIONS FOR USE FOR:

ILIAC BRANCH ENDOPROSTHESIS

US

US English

Figures 1 - 3: Device Description

Figure 1

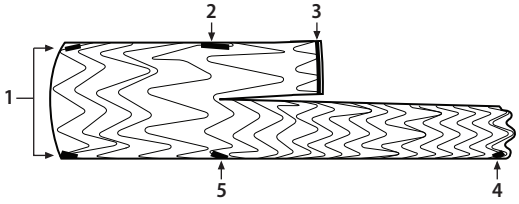


Figure 1: Iliac Branch Component (IBC); (Distal Iliac Diameters of 10, 12, or 14.5 mm)

Iliac Branch Component Radiopaque Markers:

- Two (2) short markers at proximal end
- One (1) long and one (1) short marker at the endoprosthesis bifurcation level. The long mark denotes the internal iliac leg side location and orientation.
- One (1) marker ring at the opening of the internal iliac leg hole.
- One (1) short marker at the distal end of the external iliac leg.

1. Radiopaque Markers (2)
2. Internal Iliac (Long) Radiopaque Marker
3. Radiopaque Marker Ring
4. Radiopaque Marker
5. External Iliac (Short) Radiopaque Marker

Figure 2

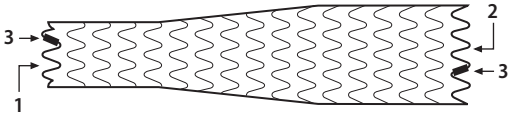


Figure 2: Internal Iliac Component (IIC); (Distal Iliac Diameters of 10, 12, or 14.5 mm)

Internal Iliac Component Radiopaque Markers:

- One (1) radiopaque marker at each end

1. Distal (leading) End
2. Proximal (trailing) End
3. Radiopaque Marker

Figure 3A

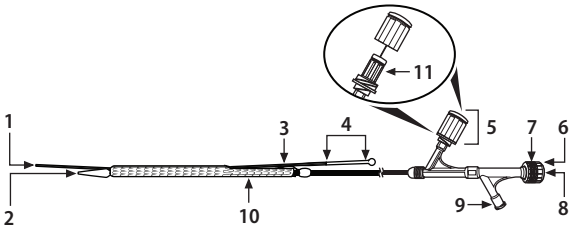


Figure 3A: IBC Delivery System - GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) Catheter

1. Leading End of Removeable Guidewire Tube (RGT)
2. Leading End of Delivery Catheter
3. Removeable Guidewire Tube (RGT)
4. Clear Window for Removeable Guidewire Tube (RGT)
5. White Outer Deployment Knob
6. Trailing end of Delivery Catheter
7. Tuohy-Borst Valve
8. Guidewire Lumen
9. Flushing Port
10. Constrained Endoprosthesis
11. Gray Inner Deployment Knob

Figure 3B

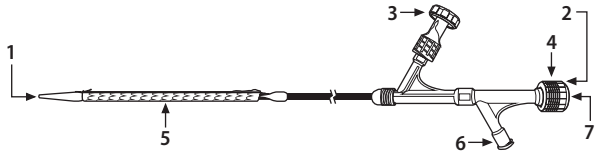


Figure 3B: IIC Delivery System - GORE® EXCLUDER® IBE Catheter

1. Leading End
2. Trailing End
3. Deployment Knob
4. Tuohy-Borst
5. Constrained Endoprosthesis
6. Flushing Port
7. Guidewire Lumen

Figure 3C

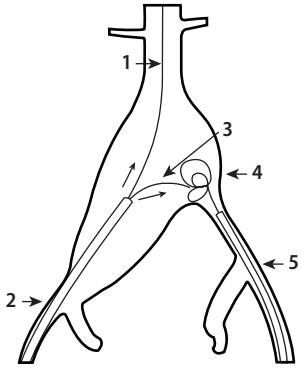
Figure 3C: Constrained IBC on Delivery Catheter with Radiopaque Markers and Removeable Guidewire Tube (RGT)

Figure 3D

Figure 3D: Constrained IIC on Delivery Catheter with Radiopaque Markers

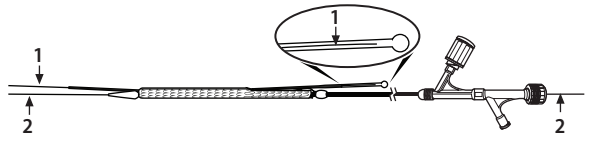
Figures 4 - 15: Unilateral IBE Placement

Figure 4



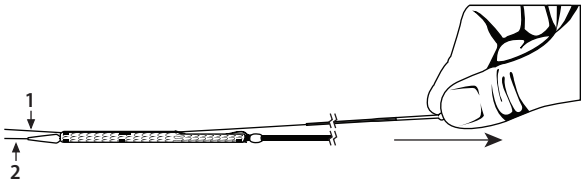
1. Aortic Wire
2. 16 Fr Sheath
3. Through-wire
4. Snare
5. 12 Fr x 45 cm Flexible Sheath

Figure 5



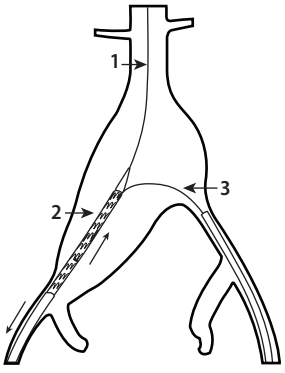
1. Through-wire
2. Aortic Wire

Figure 6



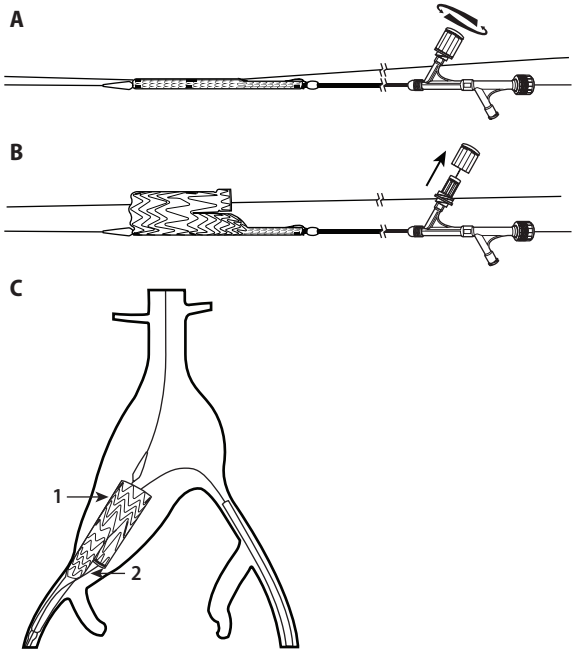
1. Through-wire
2. Aortic Wire

Figure 7



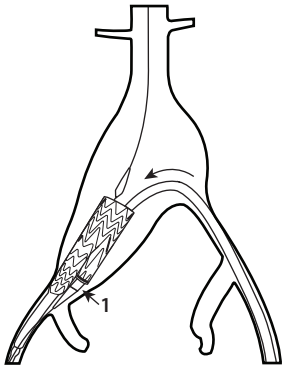
1. Aortic Wire
2. Constrained IBC
3. Through-wire

Figure 8



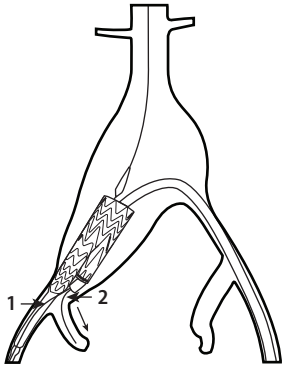
1. Partially Deployed IBC
2. Through-wire

Figure 9



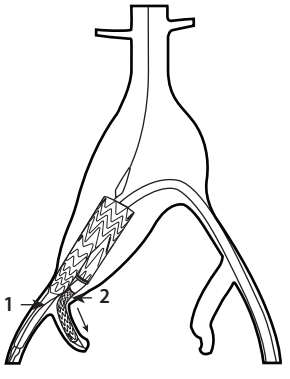
1. 12 Fr x 45 cm Flexible Sheath and Dilator

Figure 10



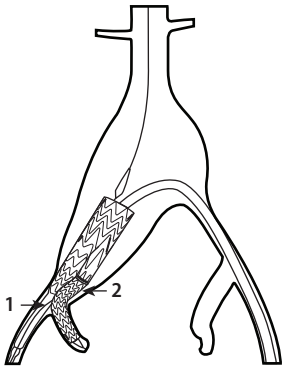
1. Through-wire
2. IIC Guidewire

Figure 11



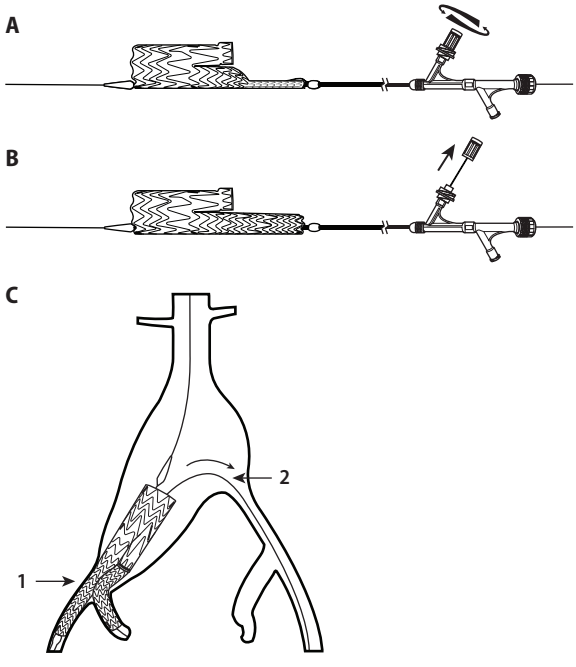
1. Through-wire
2. Constrained IIC

Figure 12



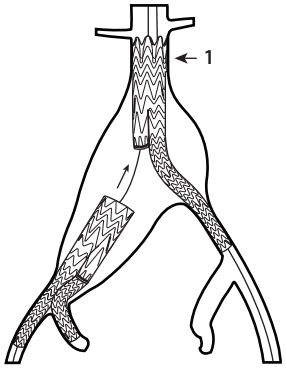
1. Through-wire
2. Deployed IIC

Figure 13



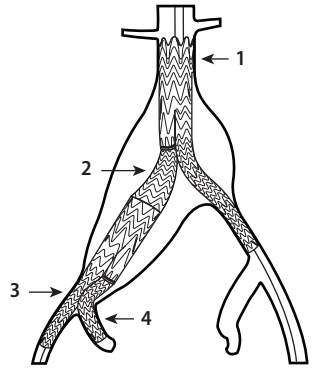
1. Deployed IBC
2. IIC Guidewire

Figure 14



1. GORE® EXCLUDER® Device - Trunk-Ipsilateral Component

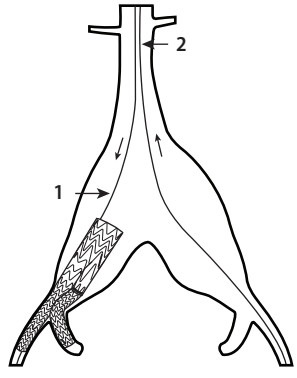
Figure 15



1. GORE® EXCLUDER® Device - Trunk-Ipsilateral Component
2. GORE® EXCLUDER® Device - Contralateral Leg Component
3. GORE® EXCLUDER® Iliac Branch Device - Iliac Branch Component
4. GORE® EXCLUDER® Iliac Branch Device - Internal Iliac Component

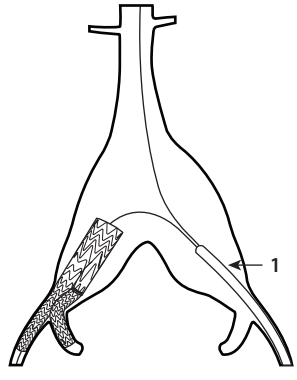
Figures 16 - 26: Bilateral IBE Placement

Figure 16



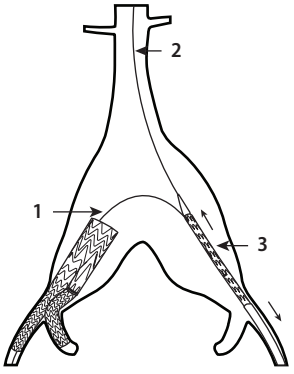
1. Through-wire
2. Aortic Wire

Figure 17



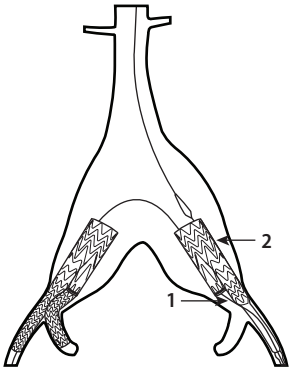
1. 16 Fr Sheath

Figure 18



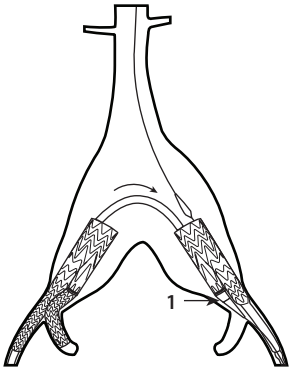
1. Through-wire
2. Aortic Wire
3. Constrained IBC

Figure 19



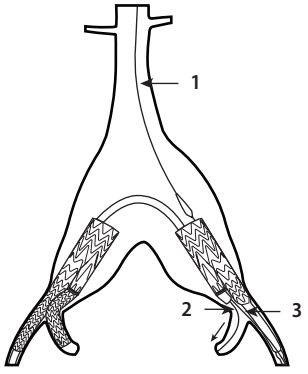
1. Through-wire
2. Partially Deployed IBC

Figure 20



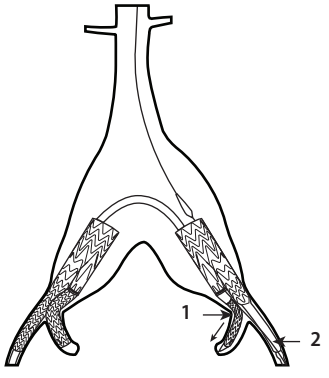
1. 12 Fr x 45 cm Flexible Sheath and Dilator

Figure 21



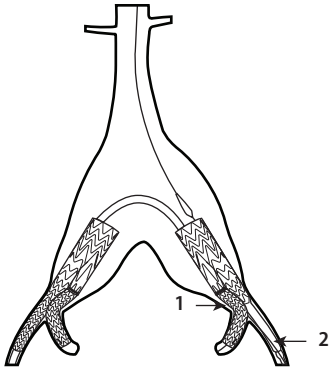
1. Aortic Wire
2. IIC Guidewire
3. Through-wire

Figure 22



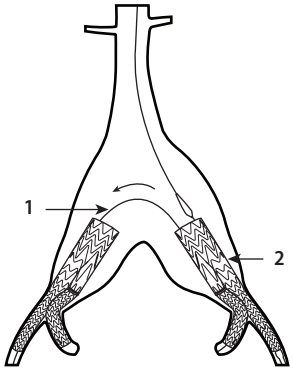
1. Constrained IIC
2. Through-wire

Figure 23



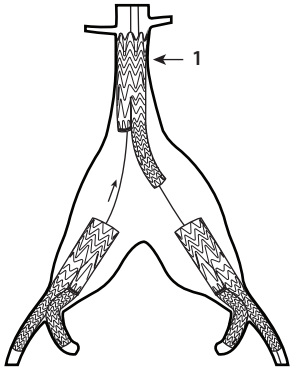
1. Deployed IBC
2. Through-wire

Figure 24



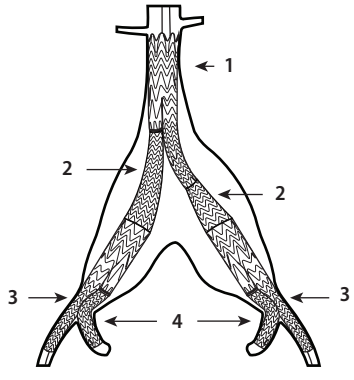
1. IIC Guidewire
2. Deployed IBC

Figure 25



1. GORE® EXCLUDER® Device - Trunk-Ipsilateral Component

Figure 26



1. GORE® EXCLUDER® Device - Trunk-Ipsilateral Component
2. GORE® EXCLUDER® Device - Contralateral Leg Component
3. GORE® EXCLUDER® Iliac Branch Device - Iliac Branch Component
4. GORE® EXCLUDER® Iliac Branch Device - Internal Iliac Component

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INSTRUCTIONS FOR USE

GORE® EXCLUDER® ILIAC BRANCH ENDOPROSTHESIS

NOTICE FOR USE WITHIN THE UNITED STATES

CAUTION: Carefully read all instructions prior to use. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.

DESCRIPTION

Iliac Branch Component and Internal Iliac Component

The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) provides endovascular treatment of common iliac artery aneurysms or aortoiliac aneurysms.

The GORE® EXCLUDER® Iliac Branch Endoprosthesis is comprised of two components, the Iliac Branch Component (IBC) (**Figure 1**) and the Internal Iliac Component (IIC) (**Figure 2**). The Iliac Branch Component (IBC) is a bifurcated iliac branch device with an external iliac leg and an internal iliac artery gate. It is available in distal diameters of 10, 12, and 14.5 mm, and a proximal diameter of 23 mm. An Internal Iliac Component (IIC) is used to extend into the internal iliac artery. It is available in distal diameters of 10, 12, and 14.5 mm, and a proximal diameter of 16 mm. The graft material is expanded polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE and FEP), that is supported by nitinol (nickel titanium alloy) wire along its external surface. An ePTFE / FEP sleeve is used to constrain the endoprostheses on the leading end of their respective delivery catheters (**Figures 3A and 3B**).

The IBC is placed in the common iliac at a level wherein the internal iliac gate is at or proximal to the internal iliac artery. Deployment of the IBC initiates from the leading (aortic) end and proceeds toward the trailing end of the delivery catheter (**Figure 3C**). The IIC is introduced through the non-treatment femoral access side, (contralateral to the IBC delivery). The IIC delivery catheter (**Figure 3D**) is placed up-and-over the aortic bifurcation, through the internal iliac gate and into the internal iliac artery. Deployment of the IIC initiates from the trailing (common iliac) end and proceeds toward the leading (internal iliac) end of the delivery catheter. The ePTFE / FEP sleeve remains in situ between the endoprosthesis and the vessel wall.

The GORE® EXCLUDER® Iliac Branch Endoprosthesis is based on the design of the GORE® EXCLUDER® AAA Endoprosthesis; the graft materials are identical, maintaining the same luminal and abluminal ePTFE surfaces and materials specifications.

The GORE® EXCLUDER® Iliac Branch Endoprosthesis is to be used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis and is not intended to be used on its own.

The GORE® EXCLUDER® AAA Endoprosthesis is comprised of two components, the Trunk-Ipsilateral Leg Endoprosthesis (Trunk) and the Contralateral Leg Endoprosthesis. The graft material is expanded polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE and FEP), that is supported by nitinol (nickel titanium alloy) wire along its external surface. Nitinol anchors and an ePTFE / FEP sealing cuff are located at the aortic end of the Trunk. An ePTFE / FEP sleeve is used to constrain the endoprostheses on the leading end of the delivery catheter.

Deployment of both endoprostheses initiates from the leading (aortic) end and proceeds toward the trailing (iliac) end of the delivery catheter. The ePTFE / FEP sleeve remains in situ between the endoprosthesis and the vessel wall.

The GORE® EXCLUDER® Device Trunk-Ipsilateral and Contralateral Leg Components (distal diameters of 23 and 27 mm) Endoprostheses provide proximal seal and fixation for the GORE® EXCLUDER® Iliac Branch Endoprosthesis, and also provide endovascular treatment of infrarenal abdominal aortic aneurysms (AAAs). When treating bilateral iliac aneurysms, two Contralateral Leg Endoprostheses must be used to bridge to the two IBE devices, one on the ipsilateral side and one on the contralateral side. **For more information on use of these devices, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use.**

Materials

All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis and the GORE® EXCLUDER® AAA Endoprosthesis are composed of ePTFE, FEP, nitinol (nickel-titanium alloy), and gold.

INDICATIONS FOR USE

Iliac Branch and Internal Iliac Components

The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is intended to be used with the GORE® EXCLUDER® AAA Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including:

1. Adequate iliac / femoral access
2. Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE
3. External Iliac artery treatment diameter range of 6.5 – 25 mm and seal zone length of at least 10 mm
4. Internal iliac artery treatment diameter range of 6.5 – 13.5 mm and seal zone length of at least 10 mm
5. Adequate length from the lowest major renal artery to the internal iliac artery to accommodate the total endoprosthesis length, calculated by adding the minimum lengths of required components, taking into account appropriate overlaps between components

GORE® EXCLUDER® AAA Endoprosthesis Components used in conjunction with GORE® EXCLUDER® Iliac Branch Endoprosthesis

Trunk-Ipsilateral Leg Component

The Trunk-Ipsilateral Leg is intended to provide proximal seal and fixation for the endovascular repair of the aneurysm. For more information on the Trunk-Ipsilateral Leg Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use.

Contralateral Leg Endoprosthesis Component

The Contralateral Leg Endoprosthesis is intended to bridge the GORE® EXCLUDER® Device Trunk-Ipsilateral Component to the GORE® EXCLUDER® Iliac Branch Endoprosthesis following deployment of the GORE® EXCLUDER® Iliac Branch Endoprosthesis. Additionally, the Contralateral Leg Endprosthesis is intended to be used for distal extension of the Iliac Branch Component in the external iliac artery. The Iliac Branch Component can treat external iliac artery diameters up to 13.5 mm. This ability to extend the Iliac Branch Component distally with any Contralateral Leg Endoprosthesis expands the external iliac artery treatment range up to 25 mm. For more information on the Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use.

Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components

The Aortic and Iliac Extender Endoprostheses can be used after deployment of the GORE® EXCLUDER® Iliac Branch and GORE® EXCLUDER® AAA Endoprostheses. These extensions are used when additional length and / or sealing for aneurysmal exclusion is desired. For more information on Aortic Extender and Iliac Extender indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use.

CONTRAINDICATIONS

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

- Patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis and the GORE® EXCLUDER® AAA Endoprosthesis contain ePTFE, FEP, nitinol (nickel-titanium alloy), and gold.
- Patients with a systemic infection who may be at increased risk of endovascular graft infection.

US

WARNINGS AND PRECAUTIONS

General

- Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.
- The GORE® Medical Device 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. Reuse may result in infection, serious injury, or patient death.
- The long-term performance of stent-grafts has not been established. All patients should be advised this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive enhanced follow-up (see IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
- The GORE® EXCLUDER® Iliac Branch Endoprosthesis is not recommended in patients unable to undergo, or who will not be compliant with the necessary pre- and post-operative imaging and follow-up described in IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms and / or persistent endoleak. An increase in aneurysm size and / or persistent endoleak may lead to aneurysm rupture.
- Stent graft patency should be evaluated and monitored during follow-up. If reduced blood flow through any device or occlusion of a device is observed, a secondary intervention or surgical procedure may be required to re-establish flow if clinically necessary.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
- The GORE® EXCLUDER® Iliac Branch Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.

Patient Selection, Treatment, and Follow-Up

- The safety and effectiveness of the GORE® EXCLUDER® Iliac Branch Endoprosthesis have not been evaluated in the following patient populations:
  - traumatic aortic or iliac injury
  - leaking: pending rupture or ruptured aneurysms
  - mycotic aneurysms
  - pseudoaneurysms resulting from previous graft placement
  - revision of previously placed stent grafts
  - genetic connective tissue disease (e.g., Marfans or Ehlers-Danlos Syndromes)
  - concomitant thoracic aortic or thoracoabdominal aneurysms
  - inflammatory aneurysms
  - patients with active systemic infections
  - pregnant or nursing females
  - patients less than 21 years old
  - Ilio-femoral access vessel size and morphology (minimal thrombus, calcium and / or tortuosity) should be compatible with vascular access techniques and the vascular introducer sheaths and accessories necessary to deliver the endoprostheses.
- Successful exclusion of the aneurysm(s) may be affected by significant thrombus and / or calcium at the distal iliac artery interfaces. Irregular calcium and / or plaque may compromise the fixation and sealing of the implantation sites.
- The GORE® EXCLUDER® Iliac Branch Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and post-operative follow-up imaging.
- The GORE® EXCLUDER® Iliac Branch Endoprosthesis is not recommended in patients where weight and / or size compromises or prevents the necessary imaging requirements.
- The GORE® EXCLUDER® Iliac Branch Endoprosthesis is not recommended in patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis and the GORE® EXCLUDER® AAA Endoprosthesis contain ePTFE, FEP, nitinol (nickel-titanium alloy), and gold.
- In addition to standard EVAR anatomical considerations, additional anatomical considerations for placement of the GORE® EXCLUDER® Iliac Branch Endoprosthesis include, but are not limited to:
  - Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE
  - Internal iliac artery treatment diameter range of 6.5 – 13.5 mm
  - External iliac artery treatment diameter range of 6.5 – 25 mm
  - Anatomic suitability for the GORE® EXCLUDER® AAA Endoprosthesis
  - Adequate length from the lowest major renal artery to the internal iliac artery to accommodate a total endoprosthesis length of 165 mm, (**Tables 23 and 24**)
  - The length from the lowest major renal artery to the internal iliac artery should be evaluated to ensure the anatomy has adequate length to accommodate all GORE® EXCLUDER® Iliac Branch Endoprosthesis and GORE® EXCLUDER® AAA Endoprosthesis components. The length from the lowest major renal artery to the internal iliac artery should be adequate to accommodate a total endoprosthesis length of 165 mm (see **Table 23**).The total length of all devices on the Iliac Branch Endoprosthesis treatment side is calculated by measuring the length from the proximal section of the Trunk-Ipsilateral Leg Component (4, 5, or 6 cm based on size of Trunk-Ipsilateral Leg Component used), length of the Bridge Component (shortest length of 10 cm), and the length of the internal iliac gate of the Iliac Branch Component (2.5 cm). However, additional factors to consider when determining if the anatomy has adequate length to accommodate all devices include vessel tortuosity and the ability to cross the legs of the GORE® EXCLUDER® AAA Endoprosthesis.
- For bilateral IBE placement, anatomic suitability to receive the GORE® EXCLUDER® Iliac Branch Endoprosthesis should be evaluated on both sides. One bridge component will bridge from the contralateral gate of the Trunk-Ipsilateral Leg Component to the IBE device. The other bridge component will bridge from the ipsilateral leg of the Trunk-Ipsilateral Leg Component. The length from the lowest major renal artery to the internal iliac artery should be calculated for both treatment sides.
  - For the treatment side that will bridge with the contralateral gate, the length from the lowest major renal artery to the internal iliac artery should be adequate to accommodate a total endoprosthesis length of 165 mm (see **Table 23**).
  - For the treatment side that will bridge with the ipsilateral leg, the length from the lowest major renal artery to the internal iliac artery should be adequate to accommodate a total endoprosthesis length of 195 mm when using a 23 mm bridge component, and of 205 mm when using a 27 mm bridge component (see **Table 24**). The total length of all devices on the Iliac Branch Endoprosthesis treatment side is calculated by measuring the length of the ipsilateral leg of the Trunk-Ipsilateral Leg Component (12, 13, or 14 cm based on size of Trunk-Ipsilateral Leg Component used), taper length of Bridge Component used (5 cm for 23 mm Contralateral Leg Component, 6 cm for 27 mm Contralateral Leg Component), and the length of the internal iliac gate of the Iliac Branch Component (2.5 cm). However, additional factors to consider when determining if the anatomy has suitable length to receive all devices include vessel tortuosity and the ability to cross the legs of the GORE® EXCLUDER® AAA Endoprosthesis.

Implant Procedure

- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- Implantation of both GORE® EXCLUDER® Iliac Branch Endoprosthesis components (Iliac Branch Component and Internal Iliac Component) should be performed prior to implantation of any GORE® EXCLUDER® AAA Endoprosthesis components (Trunk-Ipsilateral Leg Component and Contralateral Leg Component as bridging component). For bilateral placement of IBE, one IBE Device (IBC and IIC) is implanted on each side prior to placement of the GORE® EXCLUDER® Device.
- Device selection should be performed based on sizing guidelines provided in **Tables 19 and 20**. Excessive oversizing may lead to adverse events, including device occlusion.
- Do not advance the device outside of the sheath. The sheath will protect the device from catheter breakage or premature deployment while tracking it into position.
- Do not rotate any delivery catheters while the endoprosthesis is inside the introducer sheath. Catheter breakage or premature deployment may occur.
- Do not rotate the Iliac Branch Component (IBC) delivery catheter beyond 360° to avoid delivery system damage and / or premature deployment.
- **Do not rotate the Internal Iliac Component (IIC) delivery catheter during delivery, positioning or deployment. Catheter breakage or premature deployment may occur.**

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- Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheaths. The sheath and undeployed device must be removed together.
- **Do not attempt to reposition the endoprosthesis after complete deployment of the device. Vessel damage or device misplacement may result.**
- Remove throughwire before deployment of the External Iliac leg of the Iliac Branch Component. Catheter breakage has occurred when this procedural step has not been appropriately followed.
- Do not continue advancing and withdrawing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage may occur.
- Incorrect deployment and/or movement of the endoprosthesis may require surgical intervention.
- Do not attempt to advance any GORE® EXCLUDER® Endoprostheses through smaller introducer sheaths than as recommended.
- Throughout this document, components and locations are referenced as contralateral and ipsilateral in reference to unilateral IBE Device placement (with respect to the IBE Device treatment access side). If bilateral IBE Device placement is planned, take note of ipsilateral and contralateral references in relation to location of the IBE Device treatment access side at that step in the implantation procedure.

MRI Safety Information

- MRI Safety Information can be found on page 28.

POTENTIAL DEVICE OR PROCEDURE RELATED ADVERSE EVENTS

Adverse events that may occur and / or require intervention include, but are not limited to:

1. allergic reaction and/or anaphylactoid response to x-ray contrast dye, anti-platelet therapy, device materials
2. amputation
3. anesthetic complications
4. aneurysm enlargement
5. aneurysm rupture and death
6. arterial or venous thrombosis and / or pseudoaneurysm
7. arteriovenous fistula
8. bleeding, hematoma, or coagulopathy
9. bowel (e.g., ileus, transient ischemia, infarction, necrosis)
10. cardiac (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension)
11. claudication (e.g., buttock, lower limb)
12. death
13. dissection, perforation, or rupture of the aortic vessel & surrounding vasculature
14. edema
15. embolization (micro and macro) with transient or permanent ischemia
16. endoleak
17. endoprosthesis: improper component placement; incomplete component deployment; component migration; separation of graft material from stent; occlusion; infection; stent fracture; graft material failure, dilatation, erosion, puncture, perigraft flow
18. fever and localized inflammation
19. genitourinary (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
20. hepatic failure
21. impotence
22. infection (e.g., aneurysm, device or access sites)
23. lymph fistula / complications
24. multi-system organ failure
25. neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis)
26. occlusion of device or native vessel
27. post-implant syndrome
28. pulmonary complications (e.g., pneumonia, respiratory failure)
29. radiation injury, late malignancy
30. renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
31. surgical conversion
32. tissue necrosis
33. wound (e.g., infection, dehiscence)
34. vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, seroma, bleeding, rupture, death)

DEVICE-RELATED ADVERSE EVENT REPORTING

Any adverse event involving the GORE® EXCLUDER® Iliac Branch Endoprosthesis should be reported to W. L. Gore & Associates immediately. To report an event in the US, call 800.437.8181 (as required by US Federal Regulation). Outside the US, contact your local Gore Representative.

SUMMARY OF CLINICAL STUDY (IBE 12-04 STUDY)

IBE 12-04 was a prospective, non-randomized, multi-center, single-arm evaluation designed to assess the safety and effectiveness of the IBE Device in subjects with isolated common iliac artery aneurysms (CIAA) or aorto-iliac aneurysms (AIA) involving both the abdominal aorta and common iliac artery. Subjects were classified as presenting with unilateral or bilateral common iliac aneurysm. Subjects with aneurysmal disease involving both iliac arteries could be treated with the IBE Device. In this circumstance, only one of the iliac arteries could be treated with the IBE Device. The internal iliac artery on the opposite side could be managed with coil embolization or surgical revascularization of the artery. Placement of the IBE Device could occur no less than 24 hours after the incision was made for the procedure performed to occlude the internal iliac artery on the opposite side or no less than 30 days after the incision was made for surgical revascularization of the internal iliac artery on the opposite side. Twenty-eight (28) US investigative sites enrolled 65 subjects from October 2013 to January 2015 (**Figure 27**). One subject withdrew from the study prior to the IBE Device procedure, and one subject withdrew as a bilateral subject and re-enrolled as a unilateral subject before the IBE Device procedure. A total of 63 subjects underwent the IBE Device procedure. Two subjects undergoing the IBE Device procedure were not eligible for longer-term effectiveness analysis. One of these subjects underwent femoral aneurysm repair concomitant with the IBE Device procedure, which was a violation of exclusion criteria. The other subject received an Iliac Extender in place of the Internal Iliac Component (IIC) due to initial difficulty in sheath advancement. Subject enrollment and eligibility for analysis are outlined in **Figure 27**.

Safety of the IBE Device was evaluated by confirming that the new aspects of the EVAR procedure associated with implantation of the IBE Device do not introduce new safety concerns. The primary safety endpoint of this study was a composite of the following events through 30 days after the initial procedure: death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure, and conversion to open surgical repair as determined by the Clinical Events Committee (CEC) according to the protocol definitions. With a performance goal of 80% freedom from safety events, planned sample size of 60 subjects to maintain statistical power >80%, and a one-sided proportion test with alpha=0.05, the study required at least 90% freedom from safety events in order to meet the performance goal.

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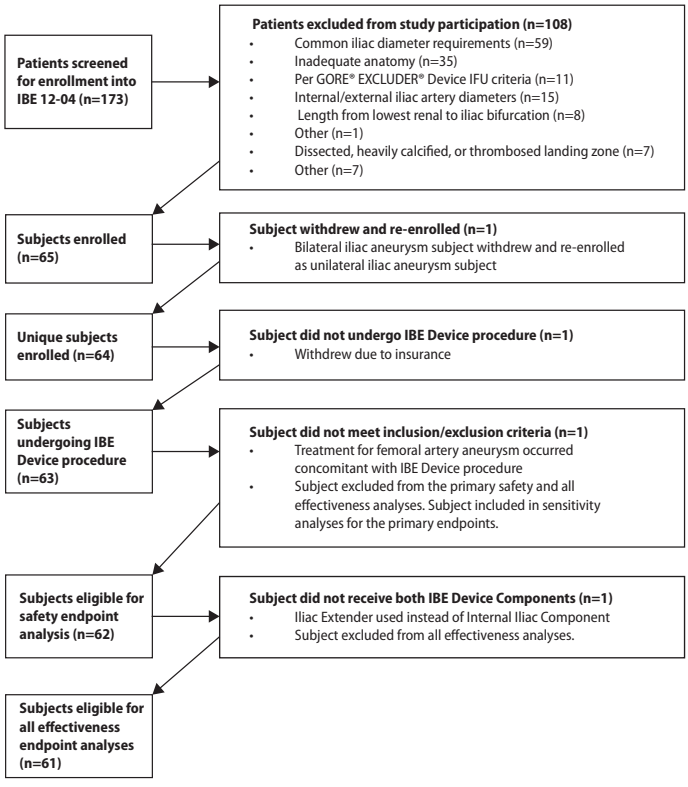
Effectiveness of the IBE Device was evaluated by focusing on aspects of the Iliac Branch Device that are unique from previously marketed GORE® EXCLUDER® Device components. The primary effectiveness endpoint was a composite of key events through the 6 month follow-up visit: reintervention on the Iliac Branch Component (IBC) or the Internal Iliac Component (IIC) due to Type IB or Type III endoleak as determined by the CEC, complete loss of blood flow in the leg of the IBC or the IIC due to thrombus or device failure as assessed by the Core Lab, and reintervention on the IBC or IIC to re-establish patency due to 60% occlusion or greater as determined by the CEC. The rate of reintervention or loss of patency across a number of publications was identified and summarized. A random effects meta-analysis resulted in a lower confidence limit of 85% freedom from such events. In order to show that outcomes with the IBE Device were consistent with historical performance of endovascular techniques, freedom from specified effectiveness endpoint events was required in >85% of subjects in order to statistically exceed the performance goal of 75% through the 6 month follow-up visit and a planned sample size of 60 subjects.
Patient related quality of life was assessed through a secondary endpoint of new onset buttock claudication arising from the side of the body treated with the IBC and IIC, as determined by the CEC through the six month follow-up visit. Buttock claudication can cause significant discomfort for a patient and is one of the more commonly reported complications associated with internal iliac artery coverage. The relative frequency of buttock claudication across a number of publications was identified and summarized. Using these results, a random effects meta-analysis was performed to estimate the overall frequency of buttock claudication when the internal iliac artery was sacrificed, and resulted in an upper confidence limit of 73% freedom from buttock claudication. In order to demonstrate clinical improvement, freedom from specified new claudication events was required in >83% of subjects in order to statistically exceed the performance goal of 73% through the 6 month follow-up visit and a planned sample size of 60 subjects.

Figure 27. Subject Enrollment and Analysis Inclusion



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Baseline Characteristics

Baseline assessments of IBE 12-04 subjects include demographics and risk factor evaluations, including medical history and comorbidities. **Table 1** provides demographic data. The majority of subjects enrolled were white males with a mean age of 69.6 years. Over 60% of the subjects enrolled into the study had a unilateral CIAA. **Table 2** provides subject medical history, with hypertension, hypercholesterolemia, and cigarette smoking presenting as the most common comorbidities.

Table 1. Subject Demographics

	IBE Cohort
Number of Enrolled Subjects[1]	64
Sex at Birth	
Male	63(98.4%)
Female	1(1.6%)
Race	
White	59(92.2%)
Black	5(7.8%)
Asian	0(0.0%)
American Indian or Alaska Native	0(0.0%)
Hawaiian or Pacific Islander	0(0.0%)
Other	0(0.0%)
Age (yrs)	
n	64
Mean (Std Dev)	69.6(8.4)
Median	69.5
Range	(51.0,88.0)
NYHA Classification	
I	27 (42.2%)
II	13 (20.3%)
III	1 (1.6%)
IV	0 (0.0%)
No Cardiac Disease	23 (35.9%)
ASA Classification	
I	4 (6.3%)
II	16 (25.0%)
III	37 (57.8%)
IV	7 (10.9%)
V	0 (0.0%)
Summary SVS Risk Score	
n	64
Mean(Std Dev)	6.0(2.8)
Median	6.0
Range	(0.0,13.0)
Iliac Aneurysm Presentation	
Bilateral	25(39.1%)
Unilateral	39(60.9%)

[1] One subject was not included to avoid double-counting in numerators and denominator, as they withdrew as a bilateral subject and re-enrolled as a unilateral subject before the IBE procedure.

Tables 1 and 2 include unique subjects enrolled (**Figure 27**).

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Table 2. Subject Medical History

	IBE Cohort
Number of Enrolled Subjects[1]	64
Hypertension	56 (87.5%)
Hypercholesterolemia	49 (76.6%)
Cigarette Smoking	39 (60.9%)
Peripheral Vascular Disease	27 (42.2%)
Cardiac Arrhythmia	23 (35.9%)
Other Concomitant Aneurysm	19 (29.7%)
Cancer	16 (25.0%)
Diabetes Mellitus	15 (23.4%)
Myocardial Infarction	15 (23.4%)
PCI	15 (23.4%)
Chronic Obstructive Pulmonary Disease	14 (21.9%)
Congestive Heart Failure	14 (21.9%)
Cerebrovascular disease	10 (15.6%)
Erectile Dysfunction[2]	10 (15.9%)
Coronary Artery Bypass Graft	9 (14.1%)
Aneurysm Symptomatic	7 (10.9%)
Thromboembolic Event	7 (10.9%)
Lower Limb Intervention	4 (6.3%)
Renal Insufficiency	4 (6.3%)
Paraplegia	0 (0.0%)
Renal Dialysis	0 (0.0%)

[1] One subject was not included to avoid double-counting in numerators and denominator, as they withdrew as a bilateral subject and re-enrolled as a unilateral subject before the IBE procedure.
[2] Males Only

Subject Compliance and Disposition

Subjects enrolled in IBE 12-04 and implanted with the IBE Device were required to return for follow-up visits at 1, 6, 12, 24, 36, 48, and 60 months. **Table 3** provides the follow-up compliance and disposition for effectiveness eligible subjects. Note: three subjects were not effectiveness eligible due to not undergoing the IBE Device procedure, receiving an Iliac Extender in place of the IIC, or undergoing concomitant femoral aneurysm repair which was a violation of exclusion criteria, respectively. For a given study period, data presented include the number of subjects eligible for follow-up (e.g., number eligible from previous period minus subject deaths, subjects discontinued or not yet due for their next follow-up visit). Thirty-six (36) subjects were within the 12 month window and 23 subjects were within the 24 month window at time of datalock. A total of two subjects undergoing the IBE device procedure were no longer eligible for study follow-up due to death. No deaths were determined to be aneurysm-related, device-related, or procedure-related.
Table 3 includes subjects eligible for all effectiveness endpoint analyses (**Figure 27**).

Table 3. Subject Compliance and Disposition by Study Interval

		Follow-up Compliance[1]					Events Prior to Next Interval[1]		
Study Period	**Eligible for follow-up**	**Subjects with Visit in Window[2]**	**Physical Exam Performed**	**Any CT Scan Performed**	**Contrast CT Performed[3]**	**Within Window No CT Yet[4]**	**Death**	**Discontinued**	**Not Due for Next Window**
Procedure	61	-	-	-	-	-	0	0	0
Post-Procedure	61	-	-	-	-	-	0	0	0
1 Month	61	60(98.4%)	59(96.7%)	60(98.4%)	59(96.7%)	0	0	0	0
6 Months	61	58(95.1%)	56(91.8%)	57(93.4%)	55(90.2%)	0	1(1.6%)	0	0
12 Months	60	48(80.0%)	46(76.7%)	47(78.3%)	43(71.7%)	11(18.3%)	1(1.7%)	0	36(60.0%)
24 Months	23	1(4.3%)	1(4.3%)	1(4.3%)	1(4.3%)	22(95.7%)	0	0	23(100.0%)

Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days)
[1] Percentages are based on number of subjects eligible for follow-up in study period.
[2] Any visit consisting of physical exam, CT scan, or MR scan.
[3] Contrast CT is necessary for Core Lab determination of endoleak, lumen obstruction, patency, or rupture.
[4] Subjects still within the study window out of those who have not yet had a CT scan.

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Analysis of pre-treatment and follow-up radiologic images was conducted by an independent Core Lab. **Table 4** presents the Core Lab assessments performed for follow-up imaging, and the percentage of subjects with assessments in each study period. Core Lab evaluation of endoleak, lumen obstruction, patency, and rupture was dependent on the availability of contrast-enhanced CT scan. Other assessments could be made using non-contrast CT. Critical parameters could be evaluated in over 85% of study subjects at 6 months.

Wire fracture observations are described in terms of the Stent Integrity Grading Scale where class 0 represents no fracture, class I is single tine fracture, class II is multiple tine fractures, class III is stent fracture with preserved alignment of components, class IV is stent fracture with mal-alignment of components, and class V is stent fracture in a trans-axial spiral configuration. Wire fracture was assessed for GORE® EXCLUDER® AAA Device and IBE components for all classes of fracture, but due to varying slice thickness of imaging was considered evaluable if the IBC and IIC components could be assessed for class IV and V fractures; the most significant types of fractures in nitinol stents that could have clinical sequelae are usually class IV and V. Further categorization of wire fracture assessment for the IBC and IIC components is presented in **Table 5**. A wire fracture assessment of the IBC and IIC components was evaluable in 96.7% of subjects in the 1 month study window and 90.2% of subjects in the 6 month study window.

Tables 4 and 5 include subjects eligible for all effectiveness endpoint analyses (**Figure 27**).

Table 4. Critical Parameters Evaluated by Independent Core Lab

Study Period	Eligible for follow-up	IBC Patency Evaluable	IIC Patency Evaluable	Endoleak Evaluable (All Types)	Rupture Evaluable	Migration Evaluable	Wire Fracture Evaluable [1]	Extrusion / Erosion Evaluable	Lumen Obstruction Evaluable	Device Compression Evaluable	Max Diameters Evaluable
1 Month	61	59 (96.7%)	59 (96.7%)	57 (93.4%)	59 (96.7%)	60 (98.4%)	59 (96.7%)	60 (98.4%)	59 (96.7%)	60 (98.4%)	60 (98.4%)
6 Months	61	55 (90.2%)	55 (90.2%)	53 (86.9%)	55 (90.2%)	57 (93.4%)	55 (90.2%)	57 (93.4%)	55 (90.2%)	57 (93.4%)	57 (93.4%)
12 Months	60	43 (71.7%)	43 (71.7%)	43 (71.7%)	43 (71.7%)	46 (76.7%)	46 (76.7%)	46 (76.7%)	43 (71.7%)	46 (76.7%)	46 (76.7%)

Study period definitions: 1 Month (15-59 days) 6 Months (60-242 days) 12 Months (243-546 days)

[1] Wire fracture imaging compliance for IBE Device components (IBC and IIC). Refer to **Table 5** below for further categorization. Image considered evaluable if class IV and V fractures could be ruled out, as nitinol stent fractures which could have clinical sequelae usually progress to class IV and V.

Fracture class definitions: 0 (no fracture), I (single tine fracture), II (multiple tine fractures), III (stent fracture with preserved alignment of components), IV (stent fracture with mal-alignment of components), V (stent fracture in a trans-axial spiral configuration).

Table 5. Adequate Imaging to Assess IBC and IIC Wire Fracture

	Study Period		
	1 Month	6 Months	12 Months
Eligible for follow-up	61	61	60
IBC/IIC Wire Fracture Evaluated			
Yes	59 (96.7%)	55 (90.2%)	46 (76.7%)
All Classes	38 (62.3%)	38 (62.3%)	25 (41.7%)
Class IV and V (Large Slice Thickness)[1]	21 (34.4%)	17 (27.9%)	21 (35.0%)
No	2 (3.3%)	6 (9.8%)	14 (23.3%)
Poor Image Quality	1 (1.6%)	2 (3.3%)	0
Image Not Available	1 (1.6%)	4 (6.6%)	14 (23.3%)

Study period definitions: 1 Month (15-59 days) 6 Months (60-242 days) 12 Months (243-546 days)

[1] Class IV and V fractures were ruled out. Class I, II, and some class III fractures could not be ruled out due to large slice thickness of imaging.

Fracture class definitions: 0 (no fracture), I (single tine fracture), II (multiple tine fractures), III (stent fracture with preserved alignment of components), IV (stent fracture with mal-alignment of components), V (stent fracture in a trans-axial spiral configuration).

Subject Characteristics

Subjects underwent pre-treatment imaging to assess aortic morphology (**Tables 6 and 7**). Patient pre-treatment aortic imaging measurements were evaluated in two groups (**Table 6**): those presenting with abdominal aortic aneurysms (Aortoiliac Aneurysms, aortic diameter ≥50 mm) and those presenting without abdominal aortic aneurysms (Isolated Iliac Aneurysms, aortic diameter <50 mm). Measurements in **Table 7** are reported separately for the IBE treated side and the non-IBE side. In both tables, information is reported for subjects presenting with unilateral iliac aneurysms and bilateral iliac aneurysms, separately as well as combined across the two groups.

T**ables 6 and 7** include unique subjects enrolled (**Figure 27**).

Table 6. Pre-Treatment Imaging Measurements – Abdominal Aorta (Site-Reported)

	Aortoiliac Aneurysms (aortic diameter > 50 mm)			Isolated Iliac Aneurysms (aortic diameter < 50 mm)		
All diameters and lengths reported in mm	**Unilateral Iliac Aneurysms**	**Bilateral Iliac Aneurysms**	**All**	**Unilateral Iliac Aneurysms**	**Bilateral Iliac Aneurysms**	**All**
Aortic diameter at proximal implantation site						
n	15	10	25	24	15	39
Mean (Std Dev)	23.5 (2.5)	22.9 (2.2)	23.3 (2.4)	22.6 (2.3)	23.2 (2.3)	22.9 (2.3)
Median	23.1	22.1	22.6	22.4	23.7	23.0
Range	(20.2, 28.3)	(20.9, 28.0)	(20.2, 28.3)	(20.0, 29.0)	(19.8, 27.5)	(19.8, 29.0)
Aortic diameter - 15mm distal to proximal implantation site						
n	15	10	25	24	15	39
Mean (Std Dev)	24.1 (2.9)	23.8 (2.4)	24.0 (2.7)	22.4 (2.4)	24.0 (2.5)	23.0 (2.5)
Median	23.0	23.2	23.0	21.9	24.9	23.0
Range	(20.7, 28.4)	(21.0, 28.0)	(20.7, 28.4)	(19.0, 28.4)	(19.4, 27.5)	(19.0, 28.4)
Aortic neck length						
n	15	10	25	24	15	39
Mean (Std Dev)	36.5 (11.9)	33.9 (8.4)	35.5 (10.5)	43.6 (22.9)	33.6 (18.0)	39.7 (21.5)
Median	33.1	36.3	34.6	35.0	30.0	30.5
Range	(23.0, 60.0)	(15.0, 42.0)	(15.0, 60.0)	(15.0, 105.0)	(20.0, 93.4)	(15.0, 105.0)

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Maximum aortic diameter						
n	15	10	25	24	15	39
Mean (Std Dev)	56.1 (5.2)	58.8 (6.0)	57.2 (5.5)	34.9 (7.2)	41.7 (6.6)	37.5 (7.6)
Median	56.5	60.1	57.0	34.0	43.0	38.0
Range	(49.6, 67.1)	(49.7, 67.0)	(49.6, 67.1)	(20.7, 46.8)	(25.0, 49.1)	(20.7, 49.1)

	Aortoiliac Aneurysms (aortic diameter > 50 mm)			Isolated Iliac Aneurysms (aortic diameter < 50 mm)		
All diameters and lengths reported in mm	**Unilateral Iliac Aneurysms**	**Bilateral Iliac Aneurysms**	**All**	**Unilateral Iliac Aneurysms**	**Bilateral Iliac Aneurysms**	**All**
Length from lowest renal artery to native aortic bifurcation						
n	15	10	25	24	15	39
Mean (Std Dev)	123.2 (10.0)	129.1 (25.1)	125.6 (17.4)	106.7 (13.4)	111.8 (18.0)	108.7 (15.3)
Median	120.0	121.5	120.0	107.5	106.0	107.0
Range	(109.0, 140.3)	(106.0, 196.0)	(106.0, 196.0)	(72.0, 136.0)	(75.0, 138.0)	(72.0, 138.0)
Distal aortic neck diameter						
n	15	10	25	24	15	39
Mean (Std Dev)	38.8 (10.0)	31.9 (7.4)	36.0 (9.5)	25.6 (5.2)	33.8 (7.2)	28.8 (7.2)
Median	35.6	29.8	33.5	25.3	34.0	27.0
Range	(28.6, 57.0)	(21.7, 44.0)	(21.7, 57.0)	(18.5, 37.5)	(22.0, 49.0)	(18.5, 49.0)

Table 7. Pre-treatment Imaging Measurements - Iliac (Site-Reported)

	IBE Side			Non-IBE Side		
All diameters and lengths reported in mm	**Unilateral Iliac Aneurysms**	**Bilateral Iliac Aneurysms**	**All**	**Unilateral Iliac Aneurysms**	**Bilateral Iliac Aneurysms**	**All**
Length from lowest renal artery to internal iliac artery						
n	39	25	64	39	25	64
Mean (Std Dev)	185.9 (18.9)	192.9 (29.8)	188.7 (23.8)	173.3 (22.4)	193.8 (33.7)	181.3 (28.9)
Median	185.0	190.0	186.5	170.0	191.0	178.4
Range	(156.0, 231.0)	(153.0, 275.0)	(153.0, 275.0)	(117.0, 217.0)	(145.0, 288.0)	(117.0, 288.0)
Length from the aortic bifurcation to internal iliac artery						
n	39	25	64	-	-	-
Mean (Std Dev)	68.8 (20.3)	74.9 (27.0)	71.2 (23.1)	-	-	-
Median	69.7	70.0	70.0	-	-	-
Range	(25.0, 111.0)	(42.6, 135.0)	(25.0, 135.0)	-	-	-
Minimum common iliac artery diameter within proximal IBE implantation zone						
n	39	25	64	-	-	-
Mean (Std Dev)	22.2 (6.1)	23.1 (5.0)	22.6 (5.6)	-	-	-
Median	20.5	22.2	21.3	-	-	-
Range	(17.0, 50.0)	(17.0, 37.7)	(17.0, 50.0)	-	-	-
Common iliac artery diameter at iliac bifurcation						
n	39	25	64	-	-	-
Mean (Std Dev)	24.3 (8.0)	25.2 (7.8)	24.7 (7.9)	-	-	-
Median	23.3	23.0	23.2	-	-	-
Range	(14.0, 54.0)	(14.6, 46.0)	(14.0, 54.0)	-	-	-
Maximum common iliac artery diameter						
N	39	25	64	-	-	-
Mean (Std Dev)	38.4 (10.0)	40.2 (11.6)	39.1 (10.6)	-	-	-
Median	36.3	39.0	37.0	-	-	-
Range	(25.4, 72.0)	(25.0, 62.0)	(25.0, 72.0)	-	-	-
Common iliac artery diameter at intended landing zone[1]						
n	-	-	-	39	18	57
Mean (Std Dev)	-	-	-	18.8 (4.0)	32.5 (16.7)	23.1 (11.7)
Median	-	-	-	19.0	27.0	21.0
Range	-	-	-	(10.0, 25.0)	(8.0, 76.0)	(8.0, 76.0)

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External iliac artery diameter at intended landing zone[2]						
n	39	25	64	18	25	43
Mean (Std Dev)	11.2 (1.9)	10.8 (1.3)	11.1 (1.7)	10.6 (1.8)	10.7 (1.6)	10.7 (1.7)
Median	11.0	11.0	11.0	10.0	10.8	10.4
Range	(6.6, 15.8)	(8.4, 13.0)	(6.6, 15.8)	(6.6, 15.0)	(7.9, 14.0)	(6.6, 15.0)
Internal iliac artery diameter at intended landing zone						
n	39	25	64	-	-	-
Mean (Std Dev)	10.2 (1.7)	10.6 (1.5)	10.4 (1.6)	-	-	-
Median	10.2	10.9	10.4	-	-	-
Range	(7.1, 13.1)	(6.5, 13.0)	(6.5, 13.1)	-	-	-
Access vessel diameter						
n	39	25	64	39	25	64
Mean (Std Dev)	11.0 (2.2)	10.1 (1.4)	10.7 (2.0)	11.0 (2.1)	10.0 (1.6)	10.6 (2.0)
Median	11.0	10.1	10.5	11.0	10.0	10.3
Range	(6.6, 15.8)	(6.5, 13.0)	(6.5, 15.8)	(6.5, 15.0)	(7.0, 13.0)	(6.5, 15.0)

[1] Measurement not required on IBE side, or on non-IBE side for subjects with bilateral iliac aneurysms. Any measurements provided are included in this table.
[2] Measurement on non-IBE side not required for subjects with unilateral iliac aneurysm. Any measurements provided are included in this table.

Procedure

Table 8 provides device usage for patients implanted with the IBE Device. Diameter distribution of all IBE Devices implanted (IBC and IIC) are presented in **Table 9**. Sixty-three (63) IBCs were implanted in 63 subjects and 68 IICs were implanted in 62 subjects. One subject was not implanted with an IIC due to difficulty in sheath advancement. Multiple IICs were used in five subjects for various reasons including distal extension to gain length and / or address tortuosity, as well as to improve overlap with the IBC. **Table 10** presents the diameter and length distributions of implanted Bridging Components. Seventy-three (73) Bridging Components were implanted in 63 subjects.
Tables 8, 9, and 10 include subjects undergoing IBE Device procedure (**Figure 27**).

Table 8. Device Use at Initial Procedure

	IBE Cohort
Number of Subjects with Devices Implanted	63
IBE Device Components	
Subjects with Iliac Branch Components (IBC) Implanted	63 (100.0%)
Subjects with Internal Iliac Components (IIC) Implanted[1]	62 (98.4%)
GORE® EXCLUDER® Device Components	
Subjects with Trunks Implanted	63 (100.0%)
Subjects with Contralateral Legs Implanted	63 (100.0%)
Subjects with Aortic Extenders Implanted	6 (9.5%)
Subjects with Iliac Extenders Implanted	11 (17.5%)

[1] One subject underwent the IBE Device procedure with successful placement and deployment of the investigational IBC, but difficulty in sheath advancement resulted in failure to place the IIC. Eventually, a commercially available GORE® EXCLUDER® AAA Endoprosthesis Iliac Extender was used in place of the investigational IIC.

Table 9. Number of Implanted Subjects by IBE Device Component Sizes

	IBC			IIC	
Distal Leg Diameter (mm)	**Subjects (N=63)**	**Devices (N=63)**		**Subjects (N=62)**	**Devices (N=68)**
10	10 (15.9%)	10 (15.9%)		17 (27.4%)	17 (25.0%)
12	24 (38.1%)	24 (38.1%)		17 (27.4%)	18 (26.5%)
14.5	29 (46.0%)	29 (46.0%)		29 (46.8%)	33 (48.5%) [1]

[1] Multiple IICs were used for distal extension to gain length and / or address tortuosity and also to improve overlap with the IBC.

Table 10. Number of Implanted Subjects by Contralateral Leg Bridging Component Size

Distal Leg Diameter (mm)	Length (cm)	Subjects (N=63)	Devices (N=73)
23	10	3 (4.8%)	3 (4.1%)
23	12	5 (7.9%)	5 (6.9%)
27	10	27 (42.9%)	30 (41.1%)
27	12	22 (34.9%)	23 (31.5%)
27	14	12 (19.0%)	12 (16.4%)

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Table 11 provides procedure and recovery data for all subjects in which the IBE procedure was attempted. All subjects survived the endovascular procedure. Median hospital stay was 1 day (range of 1 – 11 days). Fourteen (14) subjects required an ICU stay. For subjects with an ICU stay, the median length of ICU stay was 1.1 days. Median time to return to normal daily activities, as reported by subjects, was 27 days. Additional procedures performed during endovascular treatment included stenting procedure (n=5, 7.9%) and embolization (n=2, 3.2%). Two subjects had additional stents deployed within the external iliac leg of the IBC for distal extension and to address vessel tortuosity, and two subjects had an additional stent deployed on the non-IBE side for distal extension to address vessel tortuosity. Additional stents were self-expanding bare metal and nitinol stents. One patient had a bare metal balloon expanding stent placed in a pre-existing stenotic renal. Renal stenting was unrelated to stent-graft placement. No interaction has been identified or reported between the IBE components and additional stents. Coil embolization procedures were performed on the right accessory renal artery and the right ileolumbar artery. Embolization procedures were performed prior to stent-graft placement and were unrelated to the effectiveness of the stent-grafts. "Other Procedures" (n=4, 6.3%) were primarily to treat access related complications including arteriotomy, endarterectomy, and percutaneous access to surgical femoral artery cut-down.
Table 11 includes subjects undergoing IBE Device procedure (**Figure 27**).

Table 11. Procedure and Recovery

	IBE Cohort
Subjects Initiating IBE Procedure	63
Anesthesia Method	
General	55(87.3%)
Regional	0(0.0%)
Local	8(12.7%)
Endovascular Access Method on IBE Side	
Percutaneous	31(49.2%)
Cut-down	31(49.2%)
Cut-down and Conduit	1(1.6%)
Endovascular Access Method on Non-IBE Side	
Percutaneous	30(47.6%)
Cut-down	32(50.8%)
Cut-down and Conduit	1(1.6%)
Procedure Time (minutes)	
n	63
Mean (Std Dev)	151.8(47.6)
Median	145
Range	(68,334)
Blood Loss (mL)	
n	63
Mean (Std Dev)	247.6(181.9)
Median	200
Range	(0,1000)
Transfusion	1(1.6%)
Additional Procedures at Treatment	9(14.3%)
Stent	5(7.9%)
Embolization	2(3.2%)
Other	4(6.3%)
ICU Stay	14 (22.2%)
ICU Days	
N	14
Mean (Std Dev)	1.4 (0.8)
Median	1.1
Range	(1, 3)
Hospitalization Duration (days)	
N	63
Mean (Std Dev)	2.0 (1.8)
Median	1.0
Range	(1, 11)
Return to Normal Activities (days)	
N	63
Mean (Std Dev)	32.5 (41.0)
Median	27.0
Range	(1, 205[1])

[1] Three patients had values for return to normal activities greater than 200 days (200, 203, 205). All reported a 6 month follow-up visit. One patient reported incision site infection. One patient reported bilateral groin hematomas. One patient had pre-existing medical conditions (COPD), swelling of leg on non-IBE treatment side, and experienced buttock claudication due to embolization of non-IBE treatment side.

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Overall technical success was 95.2% (60 / 63) as shown in **Table 12**. One subject was not implanted with the IIC as described in the footnote for **Table 8** above. Two other subjects had procedural endoleaks (Type IB and Type III), both of which were absent at 1 month follow-up without requiring secondary intervention. The procedural Type III endoleak was ballooned, but a final angiography was not performed after ballooning. The Type III endoleak was not present at 1 month follow-up. Additionally, the procedural Type 1B endoleak was not present at 1 month follow-up.

Table 12 includes subjects undergoing IBE Device procedure (**Figure 27**).

Table 12. Procedural Technical Success

	IBE Cohort
Subjects Initiating IBE Procedure	63
Technical Success	60(95.2%)
Successful access	63(100.0%)
Successful deployment of IBE and GORE® EXCLUDER® Device components	62(98.4%)
Patent IBE and GORE® EXCLUDER® Device components	63(100.0%)
Absence of Type I and III endoleaks	61(96.8%)
Successful removal of IBE delivery catheters	63(100.0%)
Successful access site closure	63(100.0%)

Safety and Effectiveness Outcomes

The primary safety endpoint for this study was a composite of key Adverse Events (AEs) within 30 days of the initial procedure. These events were death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure and conversion to open surgical repair. No subjects experienced a primary safety endpoint event (**Table 13**), thus the 95% Lower Confidence Limit exceeded the performance goal of 80%.

Table 13 includes subjects eligible for safety endpoint analysis (**Figure 27**).

Table 13. Primary Safety Endpoint Analysis

Primary Safety Endpoint Analysis	Eligible for Analysis	Endpoint Event	Percent Free from Endpoint Event (95% LCL)
Safety Eligible[1]	62	0	100.0% (95.8%)

[1] All enrolled subjects initiating IBE procedure and meeting inclusion/exclusion criteria 95% LCL represents one-sided 95% Lower Confidence Limit by Wilson method.

The primary effectiveness endpoint for this study was a composite of key events through the 6 month follow-up visit. These events included reintervention on the IBC or the IIC due to Type IB or Type III endoleak as determined by the Clinical Events Committee (CEC), complete loss of blood flow in the leg of the IBC or the IIC due to thrombus or device failure assessed by an independent Core Lab and reintervention on the IBC or the IIC to re-establish patency due to 60% occlusion or greater. Two subjects undergoing the IBE Device procedure were not eligible for effectiveness analysis. One of these subjects underwent femoral aneurysm repair concomitant with the IBE Device procedure, which was a violation of exclusion criteria. The other subject received an Iliac Extender in place of the Internal Iliac Component (IIC) due to initial difficulty in sheath advancement. The primary effectiveness endpoint was met, 95.1% of subjects (58/61) were free from endpoint events (**Table 14**), and the 95% Lower Confidence Limit exceeded the performance goal of 75%. Three patients were identified with a loss of patency in the IIC at 1 month follow-up, all of which were asymptomatic and did not require reintervention. The secondary effectiveness endpoint for this study was defined as new onset buttock claudication arising from the side of the body treated with the IBC and IIC through the 6 month follow-up visit. No subjects experienced a secondary effectiveness endpoint event (**Table 12**), thus the 95% Lower Confidence Limit exceeded the performance goal of 73%. Three sensitivity analyses were performed supplementally for each of the endpoints: i) inclusion of the subject with femoral aneurysm repair which CEC adjudicated as a 'Minor' exclusion criteria violation, ii) excluding subjects without follow-up or CT imaging in the required timeframe, and iii) counting subjects without follow-up or CT imaging in the required timeframe as endpoint events in a worst-case analysis. For all sensitivity analyses, the performance goals were exceeded, consistent with the main analyses. No primary effectiveness endpoint or buttock claudication events occurred in the two subjects excluded from all effectiveness analyses. One of these subjects was excluded due to use of an iliac extender in place of an IIC. This subject was reported to have an occluded internal iliac artery on the IBE treatment side (i.e. iliac extender was occluded, not IBE device component). This occlusion was due to excessive oversizing, and has been reported as asymptomatic and has not required intervention to date.

Table 14 includes subjects eligible for all effectiveness endpoint analyses (**Figure 27**).

Table 14. Effectiveness Endpoint Analysis

Primary Effectiveness Endpoint Analysis	Eligible for Analysis	Endpoint Event	Percent Free from Endpoint Event (95% LCL)
Effectiveness Eligible[1]	61	3	95.1% (88.3%)
Secondary Effectiveness Endpoint Analysis			
Effectiveness Eligible[1]	61	0	100.0% (95.8%)

[1] All enrolled subjects having IBC and IIC components implanted and meeting inclusion/exclusion criteria 95% LCL represents one-sided 95% Lower Confidence Limit by Wilson method.

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Serious adverse events are defined as adverse events that led to death or serious deterioration in the health of the subject that resulted in a life threatening illness or injury, permanent impairment of a body structure or body function, inpatient or prolonged hospitalization, or medical or surgical intervention to prevent life threatening illness or injury or permanent impairment.

Serious device events, a subset of the serious adverse events, were designated based on applicable MedDRA terms relating to the IBE or GORE® EXCLUDER® Devices, or relating to vessel access. Five subjects (8.2%) had serious device events reported during the study (**Table 15**). Two reinterventions were performed, one to treat a Type II endoleak (inferior mesenteric artery) and one to treat a dissection in the external iliac artery. Other serious device events included a groin hematoma, an infected incision and right groin pseudoaneurysm. No serious device events were reported in the two subjects who were excluded from all effectiveness endpoint analyses.

Table 15 includes subjects eligible for all effectiveness endpoint analyses (**Figure 27**).

Table 15. Serious Device Events by Study Period (Site Reported)

	Post-Treatment Follow-up Period						
	Procedure	**Post-Procedure**	**1 Month**	**6 Months**	**12 Months**	**24 Months**	**Total**
Number of Subjects	61	61	61	61	50	2	61
Number of Subjects with Imaging Evaluation or Serious Device Event[1]	61	3	60	57	47	1	61
Subjects With Serious Device Event	1(1.6%)	1(33.3%)	3(5.0%)	0	0	0	5(8.2%)
Serious Device Events	1	1	3	0	0	0	5
Stent-graft Endoleak	0	0	1(1.7%)	-	-	-	1(1.6%)
Stent-graft endoleak type II[2]	-	-	1(1.7%)	-	-	-	1(1.6%)
Iliac artery dissection	0	0	1(1.7%)	-	-	-	1(1.6%)
Access-Related Event	1(1.6%)	1(33.3%)	1(1.7%)	-	-	-	3(4.9%)
Groin hematoma	0	0	1(1.7%)	-	-	-	1(1.6%)
Incision site infection	0	1(33.3%)	0	-	-	-	1(1.6%)
Vascular pseudoaneurysm	1(1.6%)	0	0	-	-	-	1(1.6%)

[1] Number of subjects with CT or MR imaging follow-up, or serious device event identified by other means in the given window. Used as denominator for percentages.

[2] Intervention performed to embolize inferior mesenteric artery.

Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) Total(0-2006 days). Dashes are used below headings with zero values.

Non-serious device events, a subset of the non-serious adverse events, were designated based on applicable MedDRA terms relating to the IBE or GORE® EXCLUDER® Devices, or relating to vessel access (**Table 16**). Thirty-six subjects (59.0%) experienced one or more non-serious device events. The majority of subjects with reported non-serious device events have a Type II endoleak (44.3%). A small Type IB endoleak was reported at the time of the IBE Device procedure and resolved at the 1 month CT with no treatment required. A Type III endoleak was noted at final angiography for another subject. The junction between the IBC and bridging component was ballooned again and additional angiography was not performed. The endoleak was not present at the 1 month CT.

The 1 month CTs for three subjects show that the IICs had occluded. No reinterventions have been reported to date. Another subject had aortic stent-graft thrombosis noted at time of the 6 month CT. The site described the event as common iliac artery mural thrombus with some projection into the lumen. The event is ongoing and no treatment has been required thus far.

Other non-serious device events include complication of device removal for one subject. During removal of the IBC delivery system, the delivery catheter fractured. It was reported that the catheter became stuck during removal and fractured when traction was applied. The IBC delivery system was completely removed and no other treatment was required. Based on the information provided, the throughwire was not removed before deployment of the external iliac leg of the Iliac Branch Component and wrapped around the IBC delivery catheter (wire wrap), which hindered the ability to remove the delivery catheter and led to delivery catheter fracture upon delivery catheter removal. One subject had a femoral artery dissection which was treated with an arteriotomy at time of procedure and two subjects had iliac artery dissections reported at the 1 month CT and have required no treatment thus far. Incision site bleeding was reported as resolved the day of the IBE Device procedure after pressure dressing and SURGICEL® application. One subject experienced incision site cellulitis on postoperative day (POD) 45 that was treated with drug therapy and later resolved. Another subject had incision site ecchymosis on POD 2 that resolved with no treatment on POD 25. One subject had a groin hematoma which resolved the day after the IBE Device procedure and another subject experienced post procedural bleeding. A renal infarct was identified at 1 month follow-up due to an accessory renal artery intentionally covered by the GORE® EXCLUDER® Device during the procedure. No treatment has been required. A vascular pseudoaneurysm was noted at the 1 month CT that is ongoing and has not required any treatment thus far.

Table 16 includes subjects eligible for all effectiveness endpoint analyses (**Figure 27**).

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Table 16. Non-Serious Device Events by Study Period (Site Reported)

	Post-Treatment Follow-up Period						
	Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	Total
Number of Subjects	61	61	61	61	50	2	61
Number of Subjects with Imaging Evaluation or Non-Serious Device Event[1]	61	3	60	57	47	1	61
Subjects With Non-Serious Device Event	14(23.0%)	2(66.7%)	22(36.7%)	3(5.3%)	1(2.1%)	0	36(59.0%)
Non-Serious Device Events	14	2	25	3	1	0	45
Stent-Graft Endoleak	9(14.8%)	1(33.3%)	16(26.7%)	2(3.5%)	1(2.1%)	-	27(44.3%)
Stent-graft endoleak type IB	1(1.6%)	0	0	0	0	-	1(1.6%)
Stent-graft endoleak type II	7(11.5%)	1(33.3%)	16(26.7%)	2(3.5%)	1(2.1%)	-	27(44.3%)
Stent-graft endoleak type III	1(1.6%)	0	0	0	0	-	1(1.6%)
Aortic stent-graft thrombosis	0	0	0	1(1.8%)	0	-	1(1.6%)
Complication of device removal	1(1.6%)	0	0	0	-	-	1(1.6%)
Device occlusion	0	0	3(5.0%)	0	0	-	3(4.9%)
Iliac artery dissection	0	0	2(3.3%)	0	0	-	2(3.3%)
Renal infarction	0	0	1(1.7%)	0	0	-	1(1.6%)
Access-Related Event	4(6.6%)	1(33.3%)	2(3.3%)	0	0	-	6(9.8%)
Femoral artery dissection	1(1.6%)	0	0	-	-	-	1(1.6%)
Incision site bleeding	1(1.6%)	0	0	-	-	-	1(1.6%)
Incision site cellulitis	0	0	1(1.7%)	-	-	-	1(1.6%)
Incision site ecchymosis	0	1(33.3%)	0	-	-	-	1(1.6%)
Incision site hematoma	1(1.6%)	0	0	-	-	-	1(1.6%)
Post procedural bleeding	1(1.6%)	0	0	-	-	-	1(1.6%)
Vascular pseudoaneurysm	0	0	1(1.7%)	-	-	-	1(1.6%)

[1] Number of subjects with CT or MR imaging follow-up, or non-serious device event identified by other means in the given window. Used as denominator for percentages.
If a single subject had more than one event, they are only counted once in the category heading row and totals.
Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) Total(0-2006 days). Dashes are used below headings with zero values.

Serious and non-serious thrombosis related events, a subset of the serious and non-serious adverse events, were designated based on applicable MedDRA terms relating to vessel thrombosis within or distal to the area treated by the IBE or GORE® EXCLUDER® Devices. There were no serious thrombosis related events. Non-serious thrombosis events are provided in **Table 17**. There were three device occlusions and one thrombosis (common iliac artery mural thrombus with some projection into the lumen) in the IBE device. Six subjects (9.8%) experienced intermittent claudication on or after the IBE Device procedure. Five subjects experienced claudication on the non-IBE treatment side out of 23 subjects who underwent coil embolization on the non-IBE treatment side per the study protocol. One additional subject experienced claudication with an unspecified location. The CEC determined that this event did not meet the secondary effectiveness endpoint event of new onset buttock claudication arising from the IBE treatment side. Claudication is a known risk when the internal iliac artery is embolized. Zero claudication events were reported on the IBE Device treatment side. Worsening of pre-existing erectile dysfunction was reported for one subject. This subject did not undergo a staged embolization procedure nor experience a device or vessel occlusion, and the worsening erectile dysfunction is described as a function of age and not related to the device or procedure by the Investigator.
Table 17 includes subjects eligible for all effectiveness endpoint analyses (**Figure 27**).

Table 17. Non-Serious Thrombosis Related Events (Site Reported)

	Post-Treatment Follow-up Period						
	Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	Total
Number of Subjects	61	61	61	61	50	2	61
Any Non-Serious Thrombosis-Related Event	0	1 (1.6%)	8 (13.1%)	2 (3.3%)	0	0	11 (18.0%)
Vascular disorders	-	1 (1.6%)	4 (6.6%)	1 (1.6%)	-	-	6 (9.8%)
Intermittent claudication	-	1 (1.6%)	4 (6.6%)	1 (1.6%)	-	-	6 (9.8%)
Reproductive system and breast disorders	-	0	1 (1.6%)	0	-	-	1 (1.6%)
Erectile dysfunction	-	-	1 (1.6%)	-	-	-	1 (1.6%)
General disorders and administration site conditions	-	0	3 (4.9%)	1 (1.6%)	-	-	4 (6.6%)
Device occlusion[1]	-	-	3 (4.9%)	-	-	-	3 (4.9%)
Vascular stent thrombosis[2]	-	-	-	1 (1.6%)	-	-	1 (1.6%)

[1] Device occlusion of IIC.
[2] One subject had aortic-stent graft thrombosis noted. Site described the event as common iliac artery mural thrombus with some projection into the lumen. The event is ongoing and no treatment has been required thus far. Thrombus present in overlap between bridging component and IBC, no intervention or clinical sequale reported to date.
* Note: Column header counts and denominators are the number of subjects at risk at the start of each interval. Entries Represent MedDRA SOC and PT and are identified by increasing level of indentation. Dashes are used below headings with zero values.
Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) Total(0-2006 days)

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An independent Core Lab was utilized to assess CT images collected for the study. All GORE® EXCLUDER® and IBE Device components were assessed for Core Lab findings as reported in **Table 18**, except for 'Non-patent IBE Device Component', which was specific to the IBE Device. The denominator for each assessment indicates the number of images in each study window where the Core Lab fully evaluated all components or a finding occurred through partial evaluation. Analysis of study imaging was conducted both pre- and post-treatment. The Core Lab identified no ruptures, migrations, wire fractures, extrusion / erosion events, or device compressions. The Core Lab identified three subjects with non-patent IICs (also captured under Lumen Obstruction) at the time of 1 month follow-up. These same subjects are captured at the 6, 12, and 24 month follow-up periods. There were no new on-set non-patent IICs (Lumen Obstruction) after 1 month. There were zero Type I, III, or IV endoleaks reported. The most common event identified by the Core Lab was Type II endoleak with 57.9% of subjects having Type II endoleak in the 1 month window and 54.7% of subjects in the 6 month window. The source (lumbar artery / arteries and inferior mesenteric artery) for all reported Type II endoleaks were associated with the treatment area of the previously marketed GORE® EXCLUDER® Device (abdominal aorta). No vessels in the region of the IBE device were specifically identified as sources for the Type II endoleaks. The observation of Type II endoleaks did not lead to increases in aneurysm enlargement or reintervention rates. These results are similar to those site reported. Variations between site reported and Core Lab are due to differences in evaluation method. Site reported data captures new-onset findings, while Core Lab captures outcomes regardless of prior existence.

From the outset of the IBE 12-04 study, the scope of wire fracture assessment included all GORE® EXCLUDER® and IBE Device components for all classes of fracture, as represented by the denominators for wire fracture in **Table 18**. Restricting wire fracture assessment to IBE Device components, and to class IV and V fractures; the most significant types of fractures in nitinol stents that could have clinical sequelae are usually class IV and V, results in denominators of 59 subjects evaluated at 1 month, 55 subjects evaluated at 6 months, and 46 subjects evaluated at 12 months as discussed previously in **Tables 4 and 5**. The smaller, more conservative, denominators reported below reflect the ongoing study processes which examine all GORE® EXCLUDER® and IBE Device components for any class of fracture.

Table 18 includes subjects eligible for all effectiveness endpoint analyses (**Figure 27**).

Table 18. Summary of Post-Procedural Core Lab Findings

	Post Treatment Follow-up Period				
	1 Month	**6 Month**	**12 Month**	**24 Month**	**Total**
Number of Subjects	61	61	50	2	61
Number of Subjects With CT or MR Scan	60	57	47	1	61
Number of Subjects With CT Scan	60	57	47	1	61
Non-patent IBE Device Component	3/59(5.1%)	2/55(3.6%)	2/43(4.7%)	0/1	3/61(4.9%)
Non-patent Iliac Branch Component (IBC)	0/59	0/55	0/43	0/1	0/61
Non-patent Internal Iliac Component (IIC)	3/59(5.1%)	2/55(3.6%)	2/43(4.7%)	0/1	3/61(4.9%)
Endoleak	34/57(59.6%)	29/53(54.7%)	18/43(41.9%)	0/1	37/60(61.7%)
Type I	0/57	0/53	0/43	0/1	0/60
Type IA	0/57	0/53	0/43	0/1	0/60
Type IB	0/57	0/53	0/43	0/1	0/60
Type II	33/57(57.9%)	29/53(54.7%)	18/43(41.9%)	0/1	37/60(61.7%)
Type III	0/57	0/53	0/43	0/1	0/60
Type IV	0/57	0/53	0/43	0/1	0/60
Indeterminate	1/57(1.8%)	0/53	0/43	0/1	1/60(1.7%)
Rupture	0/59	0/55	0/43	0/1	0/61
AAA Rupture	0/59	0/55	0/43	0/1	0/61
Common Iliac Artery Rupture	0/59	0/55	0/43	0/1	0/61
Common Iliac Artery Rupture on IBE Side	0/59	0/55	0/43	0/1	0/61
Migration	0/60	0/57	0/46	0/1	0/61
Prosthesis Migration ≥10mm	0/60	0/57	0/46	0/1	0/61
Intercomponent Migration ≥10mm	0/60	0/57	0/46	0/1	0/61
Wire Fracture[1]	0/30	0/28	0/16	0/0	0/35
Extrusion/Erosion	0/60	0/57	0/46	0/1	0/61
Lumen Obstruction	3/59(5.1%)	2/55(3.6%)	2/43(4.7%)	0/1	3/61(4.9%)
Device Compression	0/60	0/57	0/46	0/1	0/61

Denominators used in calculation of percentages are number of subjects with an evaluable result.
Study period definitions: 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) Total(15-2006 days)

[1] Denominator for wire fracture includes subjects evaluable for all GORE® EXCLUDER® and IBE Device components with image slice thickness sufficient to rule out all classes of wire fracture.

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Core Lab radiological data was used to assess any changes in aneurysm diameter (**Table 19**). No subjects had an increase in the maximum abdominal aortic diameter, and one subject had an increase (axial view only, orthogonal view did not show an increase) in the maximum common iliac diameter on the IBE Device treatment side at 6 months. As shown in **Table 18**, this subject had a Type II endoleak. During the 12 month follow-up visits at time of datalock, the Core Lab identified one abdominal aortic diameter enlargement and no common iliac artery diameter enlargement.

Table 19 includes subjects eligible for all effectiveness endpoint analyses (**Figure 27**)

Table 19. Change in Maximum Aortic and Iliac Diameters – Core Lab Reported

	6 Months	12 Months	24 Months
Number of Subjects with Available Data for Abdominal Aorta Evaluation[1]	57	46	1
Change in Maximum Abdominal Aortic Diameter from Baseline - Axial			
> 5mm Decrease	6(10.5%)	14(30.4%)	0
No Change	51(89.5%)	31(67.4%)	1(100.0%)
> 5mm Increase	0(0.0%)	1(2.2%)	0
Change in Maximum Abdominal Aortic Diameter from Baseline - Orthogonal			
> 5mm Decrease	4(7.0%)	10(21.7%)	0
No Change	53(93.0%)	35(76.1%)	1(100.0%)
> 5mm Increase	0	1(2.2%)	0
Endoleaks in Subjects with > 5mm Increase in Maximum Abdominal Aortic Diameter[2]	-	1(100.0%)	-
Type IA	-	0	-
Type IB	-	0	-
Type II	-	1	-
Type III	-	0	-
Type IV	-	0	-
Indeterminate	-	0	-
Number of Subjects with Available Data for Common Iliac Evaluation[1]	57	46	1
Change in Maximum Common Iliac Artery Diameter from Baseline (IBE Side) - Axial			
> 5mm Decrease	12(21.1%)	17(37.0%)	1(100.0%)
No Change	44(77.2%)	29(63.0%)	0
> 5mm Increase	1(1.8%)	0	0
Change in Maximum Common Iliac Artery Diameter from Baseline (IBE Side) - Orthogonal			
> 5mm Decrease	6(10.5%)	15(32.6%)	1(100.0%)
No Change	51(89.5%)	31(67.4%)	0
> 5mm Increase	0	0	0
Endoleaks in Subjects with > 5mm Increase in Maximum Common Iliac Artery Diameter on IBE Side[2]	1(100.0%)	-	-
Type IA	0	-	-
Type IB	0	-	-
Type II	1	-	-
Type III	0	-	-
Type IV	0	-	-
Indeterminate	0	-	-

Study period definitions: 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days). If multiple observations are contained within a single study window, the observation closest to the target study window date is used.

[1] Subjects must have a baseline (1 month) and a post-baseline measurement to be available for evaluation.

[2] The percentage of endoleaks is among subjects with an increase in vessel diameter from either Axial or Orthogonal views. The sum of the type of endoleaks may add up to more than the number of subjects with endoleaks, for subjects can have multiple types.

Conclusions: IBE 12-04 Study

Technical success was 95.2%.The percentage of subjects free from primary effectiveness endpoint events was 95.1%; 3 subjects had asymptomatic occlusions of the IBE component. Additionally, all subjects were free from buttock claudication through 6 months. Available results up to 12 months have not identified any additional risks or new adverse events which were not identified at 6 month follow-up. Compared to results found at 6 months, there have been no new thrombosis related events (serious or non-serious), no new serious device events, and only type II endoleak related non-serious device events identified with 12 month follow-up. No subjects experienced a safety endpoint event. These results support the conclusion that the IBE Device is a safe and effective treatment option for AIA and CIAA.

Bilateral Placement of IBE

Subjects with bilateral CIAAs are eligible for bilateral placement of the IBE Device if anatomical requirements are met on both sides. Treatment diameters are identical for bilateral IBE placement compared to unilateral IBE, though it should be noted that the minimum total treatment length requirement on the ipsilateral side should be longer than the contralateral side (**Tables 1 and 2**). Use of the IBE Device in bilateral configuration is similar to that with unilateral placement. Both IBE Devices (IBC and IIC) are implanted prior to placement of the GORE® EXCLUDER® Device. See **Figures 16 – 26** for representative schematics of bilateral IBE Device placement and page 27 for directions.

Of the 24 subjects enrolled in Continued Access, three subjects (12.5%) have been treated bilaterally with the IBE Device. Average procedure time for these three patients was 330.0 minutes (236, 269, 485 minutes), with 100% technical success. All three subjects have one month follow-up available, and one subject has 6 month follow-up available. There have been no serious device events, no thrombosis related events, and no aneurysm enlargement (aortic or common iliac) reported for any of the bilateral patients. Two subjects have reported non-serious type II endoleaks. One subject had a non-serious, new, stable focal dissection of the left external iliac artery reported at one month follow-up that was reported to be not clinically significant. This subject also had pre-existing stable focal dissections of both the right external iliac artery and the superior mesenteric artery. No treatment has been reported for this stable focal dissection.

Of the 64 unique subjects enrolled in Primary Enrollment, 25 had bilateral iliac aneurysms. Of these 25, twenty subjects did not have adequate internal and / or external iliac artery diameters or adequate length to accommodate a total endoprosthesis length of 165 mm on both sides. Of the remaining five subjects, three subjects did not have adequate length on the ipsilateral side to accommodate a total endoprosthesis length of 195 mm. Ultimately, two subjects (3%) would have met anatomic criteria for bilateral IBE device placement. This is due to patients not meeting anatomic requirements for IBE placement on both sides (i.e. internal iliac artery diameters, external iliac artery diameters, common iliac artery diameters, and treatment lengths, which are necessary for bilateral treatment).

Results have not identified additional risks or adverse events related to bilateral IBE placement as compared to unilateral IBE placement.

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PATIENT SELECTION AND TREATMENT

(SEE WARNINGS AND PRECAUTIONS)

Individualization of Treatment

Gore recommends that the GORE® EXCLUDER® Iliac Branch Endoprosthesis sizing should follow the treatment range recommendations as described in **Tables 20 and 21**. The length to the internal iliac gate of the GORE® EXCLUDER® Iliac Branch Endoprosthesis, together with the GORE® EXCLUDER® AAA and Contralateral Leg Endoprosthesis, should not exceed the distance from the most distal (lowest) major renal artery to the ostium of the internal iliac artery on the IBE treatment side. Lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters / lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.

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

- Patient's age and life expectancy
- Co-morbidities (e.g., cardiac, pulmonary or renal insufficiency prior to surgery, morbid obesity)
- Patient's suitability for open surgical repair
- Patient's anatomical suitability for endovascular repair
- The risk of aneurysm rupture compared to the risk of treatment with the GORE® EXCLUDER® Iliac Branch Endoprosthesis and GORE® EXCLUDER® AAA Endoprosthesis.
- Ability to tolerate general, regional, or local anesthesia
- Ilio-femoral access vessel size and morphology (minimal thrombus, calcium and / or tortuosity) should be compatible with vascular access techniques and the vascular introducer sheaths and accessories necessary to deliver the endoprostheses.
- Successful exclusion of the aneurysm(s) may be affected by significant thrombus and / or calcium at the distal iliac artery interfaces. Irregular calcium and / or plaque may compromise the fixation and sealing of the implantation sites.
- For IBC, external iliac artery lengths of at least 30 mm of which at least 10 mm must be non-aneurysmal seal zone of 6.5 – 13.5 mm in diameter, or ≤ 25 mm in diameter if extending with Iliac Extender Endoprosthesis (see GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use).
- For IIC, internal iliac artery length of at least 30 mm of which at least 10 mm must be non-aneurysmal seal zone of 6.5 – 13.5 mm in diameter.
- Follow all required patient selection criteria set forth in the GORE® EXCLUDER® AAA Endoprosthesis Instruction For Use.
- Freedom from significant femoral / iliac artery occlusive disease that would impede inflow and / or outflow of stent-grafts. The final treatment decision is at the discretion of the physician and patient.

PATIENT COUNSELING INFORMATION

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

- Risks and differences between endovascular repair and open surgical repair
- Potential advantages of traditional open surgical repair
- Potential advantages of endovascular repair
- The possibility that subsequent interventional or open surgical repair of the aneurysm may be required after initial endovascular repair
- Potential benefits of preservation of blood flow in the internal iliac artery

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

1. The long-term safety and effectiveness of endovascular repair has not been established. Physicians should advise all patients that this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive additional follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms, e.g., pain, numbness, weakness (see IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
2. Regular follow-up including imaging of the device should be performed at least every 12 months for all patients and additional imaging for patients with known endoleaks or aneurysm enlargement for the duration of the implant (see IMAGING GUIDELINES AND POST- OPERATIVE FOLLOW UP).
3. Physicians must advise all patients that it is important to seek prompt medical attention if he / she experiences signs or symptoms of limb occlusion, aneurysm enlargement or rupture. Signs of graft limb occlusion include pain in the hip(s) or leg(s) during walking, or discoloration or coolness of the leg. Aneurysm rupture may be asymptomatic, but usually presents as pain, numbness, weakness in the legs; any back, chest, abdominal, or groin pain, dizziness, fainting, rapid heartbeat, or sudden weakness.
4. Procedure related risks include cardiac, pulmonary, neurologic, bowel, and bleeding complications. Device related risks include occlusion, endoleak, aneurysm enlargement, fracture, potential for reintervention and open surgical conversion, rupture and death (See POTENTIAL DEVICE OR PROCEDURE RELATED ADVERSE EVENTS).

HOW SUPPLIED

The GORE® EXCLUDER® Iliac Branch Endoprosthesis is preloaded on a delivery catheter and supplied sterile and non-pyrogenic.

Storage and Handling

1. Do not resterilize; for single use only.
2. Do not use if damaged or if sterile barrier has been compromised.
3. Do not use after the "use by" (expiration) date printed on the label.
4. Store in a cool, dry place.

CLINICAL USE INFORMATION

Physician Training Program

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

CAUTION: The GORE® EXCLUDER® Iliac Branch Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.

The recommended skills / knowledge requirements for physicians using the GORE® EXCLUDER® Iliac Branch Endoprosthesis include certification of the GORE® EXCLUDER® AAA Endoprosthesis, as well as those outlined below:

Patient selection:

1. Knowledge of the natural history of abdominal aortic (AAA), common iliac, and aortoiliac aneurysms, and co-morbidities associated with aneurysmal disease
2. Knowledge of radiographic image interpretation, device selection and sizing

A multi-disciplinary team that has combined procedural experience with:

1. Femoral cutdown, arteriotomy, and repair
2. Percutaneous access and closure techniques
3. Non-selective and selective guidewire and catheter techniques
4. Fluoroscopic and angiographic image interpretation
5. Embolization
6. Angioplasty
7. Endovascular stent placement
8. Snare techniques
9. Appropriate use of radiographic contrast material
10. Techniques to minimize radiation exposure
11. Expertise in necessary patient follow-up modalities

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Required Materials

1. Two 0.035" (0.89 mm) 'super stiff' guidewires, 145 cm or longer (180 cm is recommended)
2. 0.035" (0.89 mm) flexible guidewire, 160 cm or longer (260 cm is recommended)
3. Angiographic radiopaque marker catheter
4. Snare catheter
5. Contrast media
6. Syringe
7. Heparin and heparinized saline
8. 16 Fr introducer sheath (**Table 20**)
9. 12 Fr flexible reinforced introducer sheath (**Table 21**)
10. Large diameter, low pressure aortic balloon (monitor balloon volumes and pressures as recommended in balloon catheter Instructions For Use)
11. Percutaneous transluminal angioplasty (PTA) balloons (**Tables 20-22**)
12. Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis and the required materials for implantation (see the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use)
13. GORE® EXCLUDER® Aortic Extender and Iliac Extender Endoprostheses as needed (see the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use)

Table 20: Iliac Branch Component Sizing Guide*

Part Number	Proximal IBC Diameter (mm)	Distal IBC Diameter[1] (mm)	Overall Device Length (cm)	Length to Internal Iliac Gate (cm)	Intended External Iliac Vessel Diameter[1] (mm)	Recommended Introducer Sheath[2] (Fr)	Recommended Angioplasty Balloon Size (Distal) (mm x mm)
CEB231010	23	10	10	5.5	6.5 – 9	16	10 x 40
CEB231210	23	12	10	5.5	10 – 11	16	12 x 40
CEB231410	23	14.5	10	5.5	12 – 13.5	16	14 x 40

[1] Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 7-35% in the external iliac vessel.
[2] GORE® DrySeal Introducer Sheaths are recommended to accommodate multiple guidewires. The GORE® EXCLUDER® AAA Endoprosthesis is not compatible with introducer sheaths longer than 40 cm (total length including the hemostatic valve).
* Note: All dimensions are nominal.

Table 21: Internal Iliac Component Sizing Guide*

Part Number	IIC Distal Diameter[1] (mm)	Overall Device Length[1] (cm)	Intended Internal Iliac Vessel Diameter[2] (mm)	Recommended Introducer Sheath[3] (Fr x cm)	Recommended Balloon Size for IBC-IIC Overlap (mm)	Recommended Angioplasty Balloon Size (Distal) (mm x mm)
HGB161007	10	7	6.5 – 9	12 x 45	14 x 40	10 x 40
HGB161207	12	7	10 – 11	12 x 45	14 x 40	12 x 40
HGB161407	14.5	7	12 – 13.5	12 x 45	14 x 40	14 x 40

[1] 7 cm long Internal Iliac Component provides a maximum extension of 4.5 cm when placed into the Iliac Branch Component.
[2] Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 7-35% in the internal iliac vessel.
[3] Flexible Reinforced sheath.
* Note: All dimensions are nominal.

Table 22: Contralateral Leg Endoprosthesis* Sizing Guide for Bridging to the IBC

Common Iliac Artery Diameter at Proximal Landing Zone[1] (mm)	Contralateral Leg Endoprosthesis Distal Diameter[2] (mm)	Overall Device Lengths[3] (cm)	Recommended Angioplasty Balloon Size for IBC Overlap (mm x mm)
17 – 18	23	10, 12, 14	18 x 40
19 – 20	23	10, 12, 14	20 x 40
20 – 21.5	23	10, 12, 14	22 x 40
>21.5	27	10, 12, 14	24 x 40

[1] Treatment diameters reflect use of Contralateral Leg Endoprosthesis as bridging component to IBC only. For traditional use of Contralateral Leg Endoprosthesis to provide arterial apposition, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions for Use.
[2] Recommended endoprosthesis oversizing relative to the IBC vessel diameter is 7-26%.
[3] Labeled Contralateral Leg length includes 3 cm overlap in contralateral gate of Trunk-Ipsilateral Endoprosthesis, and 3 cm overlap in proximal end of Iliac Branch Endoprosthesis.
* Note: All dimensions are nominal. Please see GORE® EXCLUDER® AAA Endoprosthesis Instructions for Use.

Table 23: Total Iliac Branch Endoprosthesis Side Length – Bridge Component via Contralateral Gate of Trunk-Ipsilateral Leg Component

Trunk-Ipsilateral Leg Endoprosthesis Diameter (mm)	Total Iliac Branch Endoprosthesis Side Length (mm)[1]
23, 26, 28.5	165
31	175
35	185

[1] The recommended minimum lengths are calculated by adding the minimum lengths of the fully deployed required devices, taking into account taper lengths and appropriate overlaps between the devices in a straight anatomy configuration.

Table 24: Total Iliac Branch Endoprosthesis Side Length – Bridge Component via Ipsilateral Leg of Trunk-Ipsilateral Leg Component

	Total Iliac Branch Endoprosthesis Side Length (mm)[1]	
Trunk-Ipsilateral Leg Endoprosthesis Diameter (mm)	23 mm Bridge Component	27 mm Bridge Component
23, 26, 28.5	195	205
31	205	215
35	215	225

[1] The recommended minimum lengths are calculated by adding the minimum lengths of the fully deployed required devices, taking into account taper lengths and appropriate overlaps between the devices in a straight anatomy configuration.

DIRECTIONS FOR USE

Throughout this document, components and locations are referenced as contralateral and ipsilateral in reference to unilateral IBE Device placement (with respect to the IBE Device treatment access side). If bilateral IBE Device placement is planned, take note of ipsilateral and contralateral references in relation to location of the IBE Device treatment access side at that step in the implantation procedure.

Pre-Treatment Planning

1. Determine accurate size of anatomy and proper size of Iliac Branch Component (**Table 20**), Internal Iliac Component (**Table 21**), Contralateral Leg Endoprostheses (**Table 22**), Trunk-Ipsilateral Leg Endoprosthesis and, if necessary, Aortic and Iliac Extender Endoprostheses (see GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use).
2. Use high resolution, non-contrast and contrast enhanced computerized tomography (CT / CTA) at ≤ 3 mm acquisition and reconstruction collimation.
3. Use multiple-view Digital Subtraction Angiography (DSA) with a radiopaque marker catheter or spiral CT multi-planar reconstruction.

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4. For angiography, use correct imaging angulation (cranial-caudal, lateral-oblique) to accurately identify origin of branch vessel anatomy.
5. Consider breath-hold technique to optimize Digital Subtraction Angiography (DSA) image quality.

Anatomical Requirements

1. Ilio-femoral access vessel size and morphology (minimal thrombus, calcium and / or tortuosity) that is compatible with vascular access techniques and the labeled vascular introducer sheath size necessary to deliver the endoprostheses.
2. Successful exclusion of the aneurysm(s) may be affected by significant thrombus and / or calcium at the distal iliac artery interfaces. The US clinical studies for the GORE® EXCLUDER® AAA Endoprosthesis quantify significant thrombus as thrombus ≥ 2 mm in thickness and / or ≥ 25% of the vessel circumference in the intended seal zone of the distal iliac artery. Irregular calcium and / or plaque may compromise the fixation and sealing of the implantation sites.
3. For IBC, minimum common iliac diameter of ≥ 17 mm in diameter at the proximal IBC landing zone.
4. For IBC, distal external iliac artery lengths of at least 30 mm of which at least 10 mm must be non-aneurysmal seal zone of 6.5 - 13.5 mm in diameter, or 6.5 – 25 mm in diameter if extending with Iliac Extender Endoprosthesis.
5. For IIC, distal internal iliac artery length of at least 30 mm of which at least 10 mm must be non-aneurysmal seal zone of 6.5 - 13.5 mm in diameter.
6. Freedom from significant femoral / iliac artery occlusive disease that would impede inflow or outflow of stent-grafts.
7. Patient's anatomical suitability for endovascular repair.
8. The length from the lowest major renal artery to the internal iliac artery should be evaluated to ensure the anatomy has adequate length to accommodate all GORE® EXCLUDER® Iliac Branch Endoprosthesis and GORE® EXCLUDER® AAA Endoprosthesis components.
   - For unilateral IBE device placement, the length from the lowest major renal artery to the internal iliac artery should be adequate to accommodate a total endoprosthesis length of 165 mm (**see Table 23**). However, additional factors to consider when determining if the anatomy has adequate length to accommodate all devices include vessel tortuosity and the ability to cross the legs of the GORE® EXCLUDER® AAA Endoprosthesis.
   - For bilateral IBE placement, anatomic suitability to receive the GORE® EXCLUDER® Iliac Branch Endoprosthesis should be evaluated on both sides. One bridge component will bridge from the contralateral gate of the Trunk-Ipsilateral Leg Component to the IBE device. The other bridge component will bridge from the ipsilateral leg of the Trunk-Ipsilateral Leg Component. The length from the lowest major renal artery to the internal iliac artery should be calculated for both treatment sides.
   - For the treatment side that will bridge with the contralateral gate, the length from the lowest major renal artery to the internal iliac artery should be adequate to accommodate a total endoprosthesis length of 165 mm (**see Table 23**).
   - For the treatment side that will bridge with the ipsilateral leg, the length from the lowest major renal artery to the internal iliac artery should be adequate to accommodate a total endoprosthesis length of 195 mm when using a 23 mm bridge component, and of 205 mm when using a 27 mm bridge component (**see Table 24**). However, additional factors to consider when determining if the anatomy has suitable length to receive all devices include vessel tortuosity and the ability to cross the legs of the GORE® EXCLUDER® AAA Endoprosthesis.

Arterial Access and Angiography

1. Following standard practices, access the intended iliac treatment side via a percutaneous diagnostic sheath, and perform marker catheter Digital Subtraction Angiography (AP, oblique and lateral views as necessary) to confirm the correct device component sizing, and deployment locations. Consider breath-hold technique to optimize image quality. Leave marker catheter in place at the level of the renal arteries.
2. Use an accurate radiopaque patient marking method to assure accurate device positioning and deployment locations.
3. Following standard practices, perform percutaneous access and / or surgical exposure of the vessels selected to receive the Trunk-Ipsilateral Leg Endoprosthesis and IBE introducer sheaths.
4. Following the manufacturer's Instructions For Use, advance through the IBE treatment side a 0.035" (0.89 mm) 'super stiff' guidewire or acceptable equivalent to the level of the renal arteries exchanging through an angiographic catheter.
5. Following the manufacturer's Instructions For Use, prepare and advance the recommended 16 Fr introducer sheath over the guidewire, through the ilio-femoral anatomy and up to the level of the distal aortic neck according to standard practice.
   CAUTION: Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
6. Following the manufacturer's Instructions For Use, advance through the non-IBE treatment side a 0.035" (0.89 mm) 'super stiff' guidewire or acceptable equivalent to the level of the renal arteries exchanging through an angiographic catheter.
7. Following the manufacturer's Instructions For Use, prepare and advance the recommended 12 Fr flexible reinforced introducer sheath over the guidewire, through the ilio-femoral anatomy and up to the level of the aortic bifurcation and remove the 0.035" (0.89 mm) 'super stiff' guidewire.
8. Following the manufacturer's Instructions For Use, advance through the recommended 16 Fr introducer sheath a second wire, an 0.035" (0.89 mm) flexible guidewire of at least 180 cm in length (260 cm is recommended) to the level of the aortic bifurcation for snaring (**Figure 4**).
9. Following the manufacturer's Instructions For Use, prepare and advance a snare catheter through, and snare and pull through the flexible guidewire, thus generating a flexible throughwire (**Figure 4**).
10. Use standard heparinized saline to flush the sheath to prevent thrombus formation.

Device Preparation

1. **CAUTION:** Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
2. Remove the appropriately sized device delivery catheters from their packaging and examine for possible damage.
3. Remove protective packaging cover(s) from the leading end of the delivery catheters, and remove the stainless steel packaging mandrels from 1) the delivery catheter (for IBC and IIC) and 2) the removable guidewire tube (RGT) (IBC only).
   CAUTION: Do NOT remove the RGT at this point. The RGT provides pre-cannulation of the internal iliac gate, and removal of the RGT prior to cannulating with the throughwire (step 2 below) will remove this feature.
4. Flush the flushing port on the trailing end of the delivery catheter with heparinized saline (**Figures 3A and 3B**).

Iliac Branched Component Positioning and Deployment

1. Use fluoroscopic visualization for all guidewire, sheath and device catheter manipulations.
2. Advance the Iliac Branch Component (IBC) device catheter over the 0.035" (0.89 mm) 'super stiff' guidewire, and cannulate the removable guidewire tube (RGT) with the 0.035" (0.89 mm) flexible throughwire (**Figure 5**). Remove the RGT leaving the throughwire in the constrained endoprosthesis (**Figure 6**).
3. Advance the IBC delivery catheter over both guidewires, through the recommended 16 Fr introducer sheath into the common iliac artery to the approximate level of intended landing zone (**Figure 7**).
   WARNING: Do not advance the device outside of the sheath. The sheath will protect the device from catheter breakage or premature deployment while tracking it into position.
   WARNING: Do not rotate the device delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or premature deployment may occur.
   WARNING: Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage may occur.
4. While maintaining the delivery catheter in position, withdraw the introducer sheath (**Figure 7**) and visually verify that the leading end of the introducer sheath is not covering the Iliac Branch Component (IBC).
   CAUTION: Visually verify the throughwire is not wrapped around the IBC guidewire or delivery catheter. If wire wrap is observed, rotate the device and delivery catheter to resolve.
   WARNING: Wire wrap can lead to catheter breakage due to interactions between the throughwire and IBC delivery catheter.
5. Magnify and center the fluoroscope to the level of the common iliac artery. Reposition and rotate the Iliac Branch Component delivery catheter as necessary to properly position the device in the correct orientation in regard to the anatomy. The long radiopaque marker should be oriented toward the internal iliac artery and the internal iliac leg radiopaque ring should be proximal to the origin of the internal iliac artery in order to obtain internal iliac access.
   WARNING: Do not rotate the IBC delivery catheter beyond 360° to avoid delivery system damage and / or premature deployment.

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6. Stabilize the Iliac Branch Component (IBC) delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
   WARNING: Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheath. The sheath and undeployed device must be removed together.
7. Loosen the White Outer Deployment Knob (**Figure 8A**). Confirm final device position and orientation and deploy the IBC using a steady and continuous pull of the deployment knob to release the proximal endoprosthesis past the internal iliac leg hole of the IBC. Pull the deployment knob straight out and away from the catheter handle (**Figure 8B**). Deployment initiates from the leading (aortic) end toward the trailing (iliac) end. The external iliac leg will remain constrained on the delivery catheter (**Figure 8C**). If the Iliac Branch Component (IBC) is not properly positioned following removal of the White Outer Deployment Knob, continue to Section: Optional Repositioning of Iliac Branch Component Endoprosthesis.
   WARNING: Do not attempt to remove a partially deployed Iliac Branch Component (IBC).
   WARNING: Do not loosen and remove the Gray Inner Deployment Knob (**Figure 3**) until ready to proceed to External Iliac Leg Deployment of Iliac Branch Component (IBC) (**Figure 12**). Removal of the Gray Inner Deployment Knob will deploy the constrained external iliac leg of the Iliac Branch Component (IBC) and the device will no longer repositionable.

Optional Repositioning of Iliac Branched Component

1. Magnify and center the fluoroscopic image on the IBC. Manually reposition by rotating the Iliac Branch Component (IBC) up to 90˚ in either direction as necessary to properly position the device to access the internal iliac artery (**Figure 8C**). The long radiopaque marker and internal iliac leg radiopaque ring should be oriented toward the internal iliac artery. The IBC can also be repositioned distally to bring the internal iliac gate in proximity to the internal iliac ostium.
   CAUTION: Excessive repositioning of the IBC may result in tissue damage and / or thrombus dislodgment. Repositioning IBC in a proximal direction after partial deployment is not recommended. The internal iliac leg hole should be kept proximal to the internal iliac ostium.

Flexible Sheath Positioning and Internal Iliac Artery Cannulation through Internal Iliac Leg Hole

1. Use fluoroscopic visualization for all guidewire, sheath, and device catheter manipulations.
2. The internal iliac leg hole is pre-cannulated via the throughwire as per steps 1 though 3 above, Iliac Branch Component Positioning.
3. Following manufacturer's Instructions For Use, introduce a recommended 12 Fr flexible reinforced sheath of 45 cm in length over the 0.035" (0.89 mm) throughwire via femoral access contralateral to the IBE treatment side.
4. Advance the flexible reinforced sheath along the throughwire up and over the aortic bifurcation, into and through the proximal opening of the Iliac Branch Component (IBC) to the level of the internal iliac leg hole (**Figure 9**).
5. Following manufacturer's Instructions For Use, introduce and advance an appropriate additional 0.035" (0.89 mm) guidewire (IIC guidewire) (and catheter if necessary) through the 12 Fr flexible reinforced sheath and internal iliac leg hole, and cannulate the internal iliac artery (Figure 10), and exchange for a 0.035" (0.89 mm) 'super stiff' guidewire if necessary.
   NOTE: It is recommended to maintain the throughwire throughout IIC deployment to provide sheath stability.
   CAUTION: Removal of the throughwire may result in loss of internal iliac leg hole cannulation.
6. Visually verify that the IIC guidewire is within the internal iliac artery by standard practice, such as angiography.
   NOTE: It is recommended to maintain the throughwire throughout IIC deployment to provide sheath stability.
   CAUTION: Removal of the throughwire may result in loss of internal iliac leg hole cannulation.

Internal Iliac Component Positioning and Deployment

1. Prepare the device delivery catheter as detailed in the "Device Preparation" section, and cannulate the Internal Iliac Component (IIC) device catheter lumen over the 0.035" (0.89 mm) IIC guidewire, and advance the delivery catheter through the 12 Fr flexible reinforced introducer sheath and into the internal iliac artery (**Figure 11**).
   WARNING: Do not advance the device through the IBC without the sheath. The sheath will protect the device from catheter breakage or premature deployment while tracking it to the internal iliac artery.
   WARNING: Do not rotate the delivery device catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or premature deployment may occur.
   WARNING: Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of the resistance. Vessel or catheter damage may occur.
2. Align the radiopaque marker of the anatomically proximal (catheter trailing) end of the IIC device with the long radiopaque marker on the partially deployed IBC. With the alignment of these markers, an approximate 2.5 cm overlap will be achieved.
3. While maintaining the delivery catheter in position, withdraw the introducer sheath and visually verify that the leading end of the introducer sheath is not covering the Internal Iliac Component (IIC).
   WARNING: Do not rotate the Internal Iliac Component (IIC) delivery catheter during delivery, positioning, or deployment. Catheter breakage or premature deployment may occur.
4. Stabilize the Internal Iliac Component (IIC) delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
   WARNING: Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheath. The sheath and undeployed device must be removed together.
5. Loosen the deployment knob. Visually confirm final device position. Deploy the Internal Iliac Component (IIC) by using a steady, continuous pull of the deployment knob to release the endoprosthesis (**Figure 12**). Pull the deployment knob straight out and away from the catheter side-arm. Deployment initiates from the trailing (common iliac) end toward the leading (internal iliac) end.
   WARNING: Do not attempt to reposition the endoprosthesis after deployment has been initiated. Vessel damage or device misplacement may result.
   WARNING: Incorrect deployment or movement of the endoprosthesis may require surgical intervention.
6. Use fluoroscopic guidance during withdrawal of the delivery catheter to assure safe removal from the patient. If resistance is felt during removal of the delivery catheter through the introducer sheath, stop and assess cause of resistance. If necessary, withdraw delivery catheter and introducer sheath together.
7. If extension of the Internal Iliac Component (IIC) is required for adequate seal, repeat steps 1 through 6 with an additional Internal Iliac Component (IIC). A minimum overlap of 3 cm is required between Iliac Extender Endoprostheses.
8. Following manufacturer's Instructions For Use, advance and inflate a 14 mm PTA balloon catheter to seat the proximal end of the Internal Iliac Component (IIC) within the internal iliac artery leg hole overlap region. Follow manufacturer's recommended method for preparation and use of iliac dilation balloons, carefully monitoring both volume and pressure to avoid complications.
9. With the 14 mm PTA balloon in position, carefully remove the throughwire.
   WARNING: Remove throughwire before deployment of the External Iliac leg of the Iliac Branch Component. Catheter breakage may occur due to interactions between the throughwire and IBC delivery catheter.
10. Following manufacturer's Instructions For Use, advance and inflate the appropriate size PTA balloon (**Table 20**) to seat the distal end of the Internal Iliac Component (IIC) within the internal iliac artery. Follow manufacturer's recommended method for preparation and use of iliac dilation balloons, carefully monitoring both volume and pressure to avoid complications.

External Iliac Leg Deployment of Iliac Branched Component

1. Loosen the Gray Inner Deployment Knob by turning 90˚ counter-clockwise (**Figure 13A**). Deploy the external iliac leg of the IBC using a steady and continuous pull of the deployment knob straight out and away from the catheter handle to release the endoprosthesis (**Figures 13B and 13C**).
2. Use fluoroscopic guidance during withdrawal of the delivery catheter to assure safe removal from the patient. If resistance is felt during removal of the delivery catheter through the introducer sheath, stop and assess cause of resistance. If necessary, withdraw delivery catheter and introducer sheath together.
3. Following manufacturer's Instructions For Use, advance and inflate the appropriate size PTA balloon (**Table 20**) to seat the distal end of the external iliac leg of the Iliac Branch Component within the external iliac artery. Following manufacturer's recommended method for size selection, preparation, and use of PTA balloons. Carefully inflate the balloon to avoid complications.
   WARNING: Do not attempt to reposition the endoprosthesis after complete deployment of the device. Vessel damage or device misplacement may result.
   WARNING: Incorrect deployment or movement of the endoprosthesis may require surgical intervention.

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Trunk-Ipsilateral Leg Endoprosthesis Positioning and Deployment

NOTE: Please consult the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use (IFU) for information pertaining to the Trunk-Ipsilateral Leg Endoprosthesis.

1. Use fluoroscopic visualization for all guidewire, sheath and device catheter manipulations.
2. From the side contralateral to the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) treatment side, withdraw the IIC guidewire to the level of the native aortic bifurcation, then advance the IIC guidewire in the aorta past the renal arteries.
3. Following the manufacturer's Instructions For Use, prepare and advance the appropriate introducer sheath over the guidewire, through the ilio-femoral anatomy and into the aortic neck according to standard practice.
4. Position and deploy the Trunk-Ipsilateral Leg Endoprosthesis as described in GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use (**Figure 14**).
5. Cannulate the contralateral leg hole as described in the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use (**Figure 14**).
6. Visually verify the length from long radiopaque marker on the Trunk-Ipsilateral Leg Endoprosthesis to long radiopaque marker on the IBC before proceeding to Section:

Contralateral Leg Endoprosthesis as Bridge to IBC - Positioning and Deployment

NOTE: Please consult the GORE® EXCLUDER® AAA Endoprosthesis Instructions for Use (IFU) for information pertaining to the Contralateral Leg Endoprosthesis.

CAUTION: Only 23 mm or 27 mm distal diameter Contralateral Leg Endoprosthesis is compatible with the Iliac Branch Component (IBC). Use of a Contralateral Leg Endoprosthesis with a distal diameter <23 mm may result in potential adverse events.

WARNING: Incorrect deployment of the Endoprosthesis may require surgical intervention.

1. Following manufacturer's Instructions For Use, prepare the device delivery catheter, and advance the delivery catheter through the appropriate introducer sheath to the level of the long radiopaque marker.
   WARNING: Do not advance the device outside of the sheath. The sheath will protect the device from catheter breakage or premature deployment while tracking it into position.
   WARNING: Do not rotate the device delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or premature deployment may occur.
   WARNING: Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage may occur.
2. While maintaining the delivery catheter in position, withdraw the introducer sheath, and visually verify that the leading end of the introducer sheath is below the Contralateral Leg Endoprosthesis.
3. Align the radiopaque marker of the proximal end of the Contralateral Leg Endoprosthesis with the long radiopaque marker on the Trunk-Ipsilateral Leg Endoprosthesis. With the alignment of these markers, an approximate 3 cm overlap will be achieved.
4. Visually verify that the distal Contralateral Leg radiopaque marker is aligned with the proximal edge of the long and short radiopaque markers of the Iliac Branch Component. (IBC). Alignment of these markers will achieve an approximate 3 cm overlap.
   WARNING: Deployment below these radiopaque markers may result in the Contralateral Leg Endoprosthesis deploying within the external iliac leg of the IBC, leading to insufficient blood flow into the internal iliac artery.
5. Deploy the Contralateral Leg Endoprosthesis according to the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use (IFU) (**Figure 15**).
6. Following manufacturer's Instructions For Use, advance and inflate the appropriate size PTA balloon (**Table 22**) to seat the distal end of the Contralateral Leg Endoprosthesis within the proximal end of the Iliac Branch Component. Carefully inflate the balloon to avoid complications.

Completion of the Procedure

1. Perform extended imaging angiography to confirm exclusion of the aneurysm(s). Consider breath-hold technique to optimize Digital Subtraction Angiography (DSA) image quality. Please consult the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use (IFU) for information pertaining to the use of Aortic and Iliac Extenders. These extensions can be used when additional length and / or sealing for aneurysmal exclusion is desired.
2. Close arterial access according to standard practice.
3. Follow up patients as necessary to provide proper surveillance of the long-term performance of the endoprosthesis, procedure, and status of the aneurysm (See IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).

Bilateral Device Placement

1. Following the steps outlined in the Pre-Treatment Planning, Anatomical Requirements, and Arterial Access and Angiography sections above, determine which side will receive the IBE Device first.
   NOTE: Each side must receive a Contralateral Leg bridging component. Refer to **Tables 23 and 24** for treatment length considerations.
2. For placement of the initial IBE Device, refer to the above sections.
3. Placement of the second IBE Device follows the same procedure as above.
4. Following placement of both IBE Devices, placement of the GORE® EXCLUDER® Device should follow the steps outlined above.
   NOTE: Both IBE Devices must be in place before placing the GORE® EXCLUDER® Device.
5. Upon placement of the GORE® EXCLUDER® Device, the Contralateral Leg bridging components may be placed on each side, as outlined above. The order of placement should be determined by relevant procedural and patient considerations per physician discretion.
6. Complete the procedure as outlined in the Completion of the Procedure section above.

IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

General

The long-term safety and effectiveness of endovascular repair has not been established. All patients should be advised this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive additional follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms (e.g., pain, numbness, weakness).

Regular and consistent follow-up is a critical part of ensuring continuing safety and efficacy of aortic endovascular repair. Physicians should tailor patient follow up to the needs and circumstances of each individual patient. At least one annual physician visit and the imaging schedule is recommended (**Table 25**).

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

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

Alternative imaging recommendations for patients with CT or angiography contrast intolerance issues include CO2 angiography, MRI / MRA with or without contrast, and ultrasound. These imaging and surveillance modalities may be less sensitive and difficult to compare with diagnostic findings from previous or subsequent follow-up exams.

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Table 25. Recommended Schedule for Patient Imaging Follow Up

Schedule for Patient Imaging Follow-Up			
Visit	**Angiogram**	**Abdominal X-Ray[1]**	**CT Pre-Contrast and Contrast**
Pre-Treatment	X[2]		X[2]
Treatment (Pre and Post Deployment)	X		
Discharge		X	
1 Month			X
3 Month			X[3]
6 Month		X	X
12 Month (Annually Thereafter)		X	X

[1] Recommended if wire fracture is suspected
[2] Imaging should be performed ≤ six months prior to procedure
[3] Recommended if endoleak and/or aneurysm enlargement reported at one month

Angiographic Imaging

Angiographic images are recommended pre-treatment to evaluate the length and tortuosity of abdominal aorta, iliac and common femoral arteries.

1. Images should include an angiographic marker catheter with incremental one centimeter radiopaque marks over a 10 to 20 cm length.
2. The following views are recommended for optimal evaluation and case planning:
   - Abdominal aorta; Supine-AP, Lateral
   - Pelvis (to include bilateral common femorals); AP, both obliques

Angiographic images are recommended during the treatment procedure both pre- and post-deployment to evaluate device placement and orientation. Selective angiography during subsequent follow-up exams may provide useful device position and device integrity information.

CT / CTA Images

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

Non-contrast and contrast enhanced baseline and follow-up exams are important for optimal patient surveillance. The following CT / CTA imaging guidelines are recommended (**Table 26**).

Table 26. CT / CTA Imaging Guidelines

	Pre-Contrast	**CT / CTA**
IV Contrast	No	Yes
Injection Volume (ml)	NA	150
Injection Rate (cc / sec)	NA	≥ 2.5
Delay	NA	Smart-Prep*, CARE or equivalent
Start Position	Diaphragm	1 cm above Celiac Axis
End Position	Proximal Femur	Femoral Bifurcation
Scan FOV	Large	Large
DFOV	32 cm	32 cm
Scan Type	Helical	Helical
Rotation Speed	0.8	0.8
Slice Thickness (mm)	≤ 2.0 mm	≤ 2.0 mm
Scan Mode	HS	HS
Table Speed (mm / rot)	15	15
Interval (mm)	2.0	2.0
KV / mA	120 / 300	120 / 300
Reconstruction / Algorithm	≤ 3.0 mm Soft	≤ 3.0 mm Soft

*** Smart Prep**	**ROI Loc:** 1 cm Sup. to Celiac Axis **Scan Phase:** 3 Sec **MA:** 40	**Monitor Delay:** 6 Sec **Monitor ISD:** 3 Sec **Enhance Thres:** 100 HU

Abdominal X-Ray Film Series (multi-view)

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

- Supine – frontal (AP)
- Lateral
- 45^0 LPO
- 45^0 RPO

Ensure the entire device is captured on each single image format.

MRI Safety Information

MR Conditional

Non-clinical testing has demonstrated the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is MR Conditional. A patient with this device can be scanned safely, immediately after placement, in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the GORE® EXCLUDER® Iliac Branch Endoprosthesis is expected to produce a maximum temperature rise of less than 3.6^o C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the GORE® EXCLUDER® Iliac Branch Endoprosthesis when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. This artifact does not obscure the device lumen.

Image Artifact:

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the IBE. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5 mm relative to the size and shape of this implant.

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PATIENT TRACKING INFORMATION

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

Additional Surveillance and Treatment

Additional surveillance and possible treatment is recommended for:

1. Aneurysms with Type I endoleak
2. Aneurysms with Type III endoleak
3. Aneurysm enlargement ≥ 5 mm of maximum diameter (regardless of endoleak status)
4. Branch vessel stenosis or occlusion

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

DEFINITIONS

EC REP Authorised Representative in the European Community

REF Catalogue Number

Caution

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

Consult Instructions for Use

Date of Manufacture

Do Not Resterilize

Do Not Reuse

Do Not Use if Package is Damaged

Keep Dry

Manufacturer

MR Conditional

SN Serial Number

STERILE Sterile

STERILE EO Sterilized using Ethylene Oxide

Store in a Cool Place

Use By

Catheter Working Length

Delivery Profile

Guidewire Compatibility

20028068

Manufacturer

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