

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: Endovascular Graft

Device Trade Name: GORE® EXCLUDER® Iliac Branch Endoprosthesis

Device Prococode: MIH

Applicant's Name and Address: W. L. Gore & Associates, Inc. (Gore)
1505 N. Fourth St.
Flagstaff, Arizona 86004

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P020004/S123

Date of FDA Notice of Approval: February 29, 2016

The original GORE® EXCLUDER® AAA Endoprosthesis PMA (P020004) was approved on November 6, 2002, and is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below:

- Adequate iliac/femoral access
- Infrarenal aortic neck treatment diameter range of 19-29 mm and a minimum aortic neck length of 15 mm
- Proximal aortic neck angulation $\leq 60^\circ$
- Iliac artery treatment diameter range of 8-18.5 mm and iliac distal vessel seal zone length of at least 10 mm.

The iliac artery treatment diameter range extends up to 25 mm with the use of the Contralateral Leg Endoprosthesis (described below) as a distal extension.

The SSED to support this indication is available on the CDRH website and is incorporated by reference here. The current supplement was submitted to obtain premarket approval for the GORE® EXCLUDER® Iliac Branch Endoprosthesis for use in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis in the treatment of aortoiliac and common iliac artery aneurysms.

II. INDICATIONS FOR USE

Iliac Branch and Internal Iliac Components

The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE Device) is indicated for use 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:

- Adequate iliac / femoral access
- Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE
- External iliac artery treatment diameter range of 6.5-25 mm and seal zone length of at least 10 mm
- Internal iliac artery treatment diameter range of 6.5-13.5 mm and seal zone length of at least 10 mm
- 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

The IBE Device is intended for use with the following GORE® EXCLUDER® AAA Endoprosthesis Components:

Trunk-Ipsilateral Leg Endoprosthesis Components

The Trunk-Ipsilateral Leg Endoprosthesis 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 Components

The Contralateral Leg Endoprosthesis is intended to bridge the GORE® EXCLUDER® Trunk-Ipsilateral Leg Component to the GORE® EXCLUDER® Iliac Branch Endoprosthesis. Additionally, the Contralateral Leg Endoprosthesis 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 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.

III. 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.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the GORE® EXCLUDER® Iliac Branch Endoprosthesis labeling.

V. DEVICE DESCRIPTION

The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE Device) is an extension of the GORE® EXCLUDER® product family. The previously approved GORE® EXCLUDER® AAA Endoprosthesis (EXCLUDER AAA Device) components that are used with the IBE Device include the following: Trunk-Ipsilateral Leg Endoprosthesis, Contralateral Leg Endoprosthesis, Aortic Extender Endoprosthesis, and Iliac Extender Endoprosthesis, and their respective delivery systems. The Trunk-Ipsilateral Leg is intended to provide proximal seal and fixation for the endovascular repair of the aneurysm. The Contralateral Leg Endoprosthesis is intended to bridge the Trunk-Ipsilateral Leg Endoprosthesis to the IBE Device. The Aortic and Iliac Extender Endoprostheses and the Contralateral Leg Endoprosthesis can be used after deployment of the IBE Device and Trunk-Ipsilateral Leg Endoprosthesis. These extensions are used when additional diameter, length and / or sealing for aneurysmal exclusion is desired.

The Iliac Branch Component can treat external iliac artery diameters from 6.5 to 13.5 mm. The ability to extend the Iliac Branch Component distally with any Contralateral Leg Endoprosthesis expands the external iliac artery treatment range up to 25 mm. Throughout the remainder of this document, the Trunk-Ipsilateral Leg, Contralateral Leg, and Aortic and Iliac Extender Endoprostheses are referred to as “previously approved EXCLUDER components”.

The IBE Device is intended to isolate the common iliac artery from systemic pressure and to preserve blood flow to the internal iliac artery (also known as the hypogastric artery) in patients with common iliac artery aneurysms (CIAA) and aorto-iliac aneurysms (AIA). In addition to the information that follows, reference the IBE Device Instructions for Use for additional details.

The IBE Device consists of two modular components. The two components are the GORE® EXCLUDER® Iliac Branch Component (IBC) and the GORE® EXCLUDER® Internal Iliac Component (IIC). The IBE Device is designed to be used in conjunction with the previously approved EXCLUDER components (**Figure 1**) to treat patients with CIAA or AIA. The IBC is positioned within the CIA such that the internal iliac gate is at or above the internal iliac artery (also known as the hypogastric artery) ostium. The IBC is deployed to the internal iliac gate within the CIA, and the internal iliac artery is then cannulated through the internal iliac gate. The IIC is deployed into the internal iliac gate of the IBC and extends into and seals within the internal iliac artery. The remaining portion of the IBC is then deployed to extend into and provide seal within the external iliac artery. A Trunk-Ipsilateral Leg Endoprosthesis is then deployed in the aorta, and a Contralateral Leg Endoprosthesis is deployed within both the Trunk-Ipsilateral Leg Endoprosthesis contralateral gate and the proximal portion of the IBC, to seal and bridge the Trunk-Ipsilateral Leg Endoprosthesis and the IBE Device. This results in aneurysm exclusion with preservation of blood flow into the internal iliac artery.

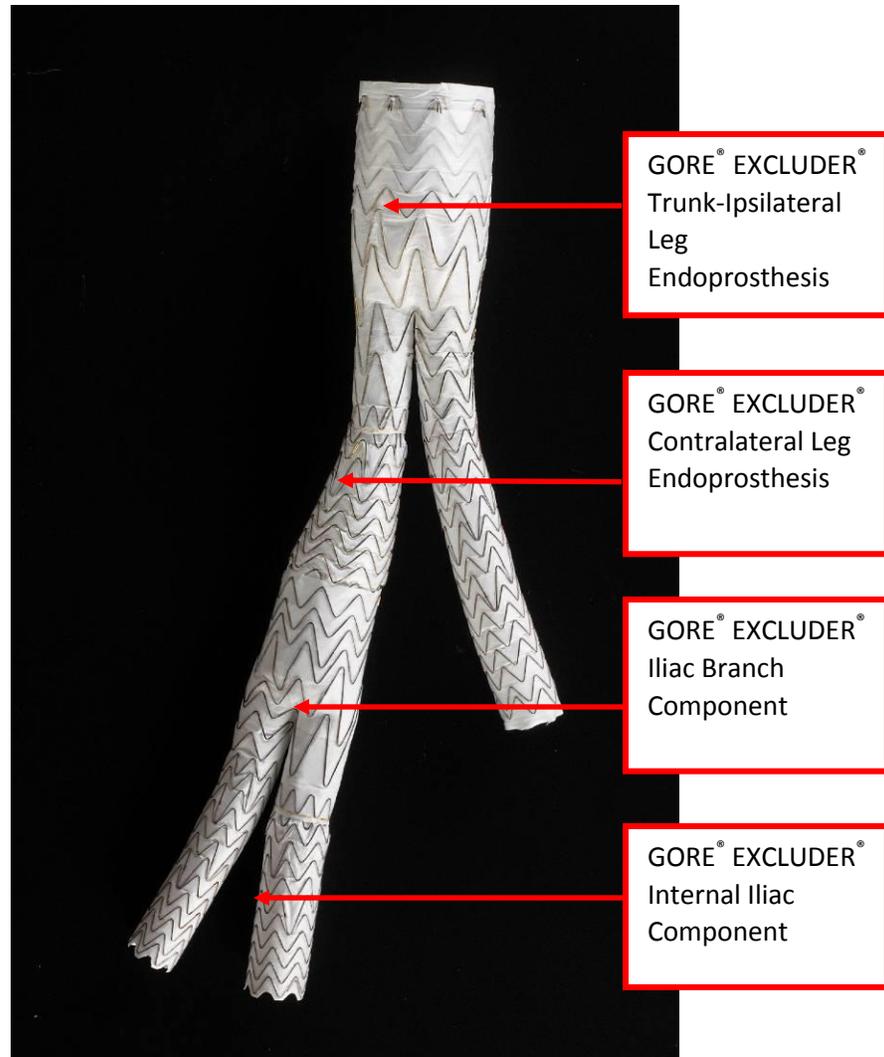


Figure 1: GORE® EXCLUDER® IBE System with a GORE® EXCLUDER®AAA Trunk-Ipsilateral Leg and Contralateral Leg Device

The IBE Device can be used either unilaterally or bilaterally. Bilateral deployment is utilized in the treatment of bilateral iliac aneurysms. **Figure 2** below demonstrates bilateral use of the IBE Device.

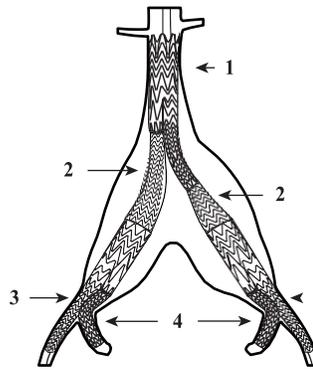


Figure 2: Bilateral Placement of the IBE Device. 1) GORE® EXCLUDER® Trunk-Ipsilateral Leg Endoprosthesis. 2) GORE® EXCLUDER® Contralateral Leg Endoprosthesis. 3) GORE® EXCLUDER® Iliac Branch Component. 4) GORE® EXCLUDER® Internal Iliac Component

GORE® EXCLUDER® Iliac Branch Component

The IBC (Figure 3) is similar in design, materials, and method of construction to the currently marketed 23 mm diameter GORE® EXCLUDER® Trunk-Ipsilateral Leg Endoprosthesis. As with the EXCLUDER AAA Device, the endoprosthesis is crushed into an expanded polytetrafluoroethylene (ePTFE) / fluorinated ethylene propylene (FEP) sewn sleeve and loaded onto the delivery catheter. The IBC distal diameter will be available in nominal diameters of 10, 12, and 14.5 mm and will treat external iliac artery diameters of 6.5 mm-13.5 mm (3). Please note, when a Contralateral Leg component is used to extend treatment in the external iliac artery, the maximum treatable diameter increases to 25 mm. The main differences between the 23 mm EXCLUDER Trunk-Ipsilateral Leg Endoprosthesis and the IBC are 1) a shorter device and the addition of a smaller (10 mm) ipsilateral leg to better accommodate intended iliac anatomy, and 2) the removal of the anchor row and sealing cuff as proximal seal and fixation to native artery is not intended for this device.

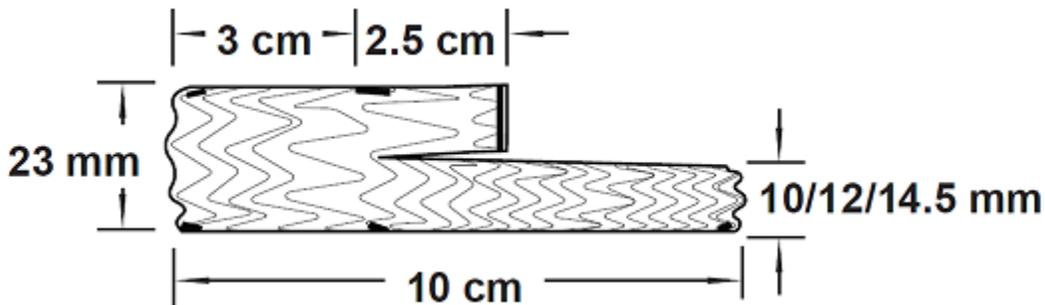


Figure 3: GORE® EXCLUDER® Iliac Branch Component

GORE® EXCLUDER® Iliac Branch Component Delivery System

The IBC delivery system is similar in design, materials, and method of construction to the currently marketed EXCLUDER AAA Device Delivery Systems. **Figure 4** shows the IBC delivery catheter, which features a removable guidewire tube (RGT) that provides pre-cannulation of the internal iliac gate of the device when cannulated with a second guidewire prior to insertion into the patient.

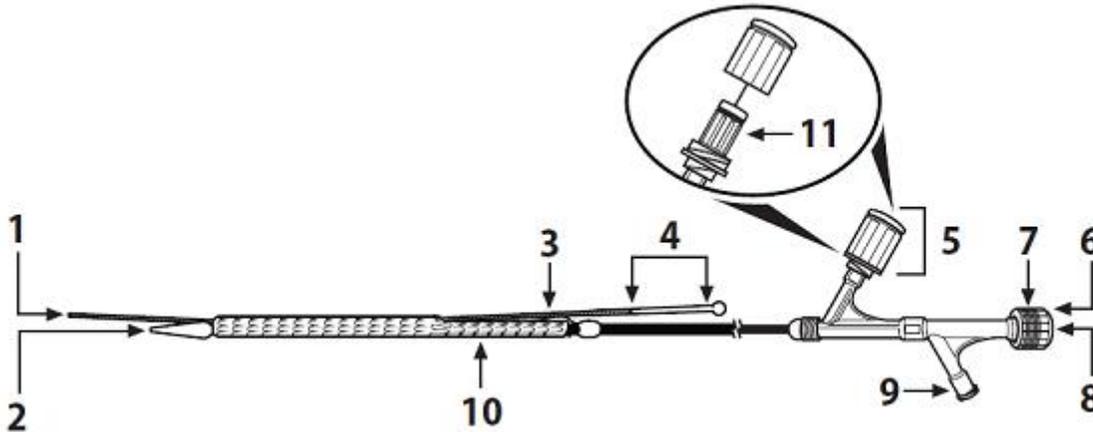


Figure 4: Iliac Branch Component Delivery System

1) Leading end of RGT, 2) Leading end of delivery catheter, 3) Removable guidewire tube (RGT), 4) Clear window for 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

The IBC is deployed in two stages by actuating two dedicated deployment lines (**Figure 5A**). The outer knob initiates the first deployment with an ePTFE deployment line. The inner knob will not be accessible until the outer knob is removed and will be subsequently used for the second deployment. Deployment of the first knob releases the constrained endoprosthesis to the level of the hypogastric gate (**Figure 5B**), and the external iliac leg remains constrained on the catheter. This delivery system provides physicians with the option to rotate and distally reposition the IBC after partial deployment in order to facilitate cannulation of the internal iliac artery. The endoprosthesis opens rapidly, with deployment initiating from the leading (aortic) end toward the trailing (iliac) end of the endoprosthesis. The sleeve remains in place between the exterior surface of the endoprosthesis and the vessel wall.

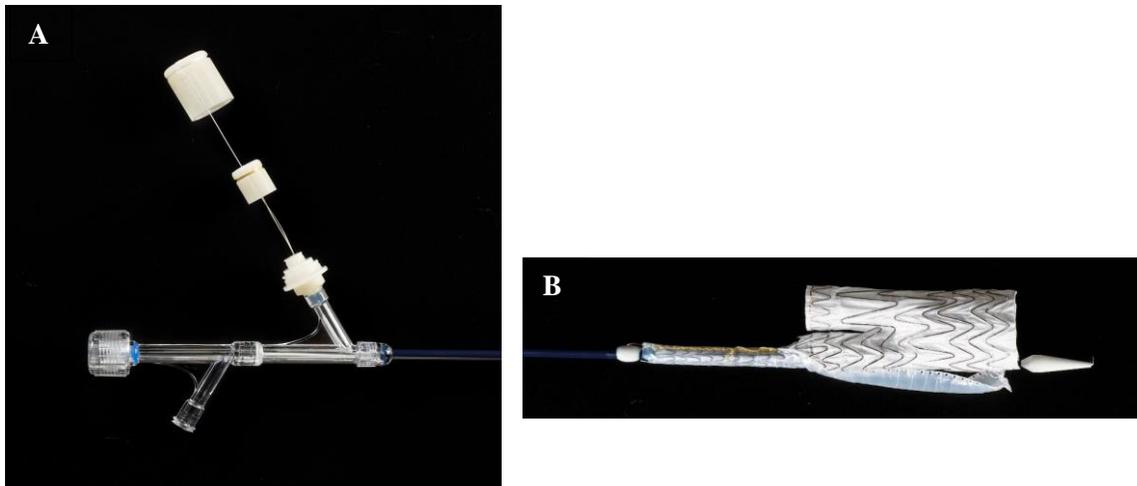


Figure 5: Two-Stage Deployment Overview

(A) Two-stage deployment using nested knobs on the GORE® EXCLUDER® Iliac Branch Endoprosthesis delivery catheter (B) The first knob releases the Endoprosthesis to the level of the pre-cannulated gate while the distal portion remains constrained on the catheter

GORE® EXCLUDER® Internal Iliac Component

The IIC is designed to preserve blood flow to the internal iliac artery while allowing exclusion of the CIAA or AIA (**Figure 6**). The IIC is identical in materials and method of construction to the currently marketed Iliac Extender Endoprosthesis, except the middle gold marker band has been removed. On the Iliac Extender Endoprosthesis, this middle marker band is present to note a 3 cm overlap with other EXCLUDER AAA Devices. As the overlap for the IIC with the IBC is 2.5 cm, the middle gold marker is not necessary. The IIC distal diameter will be available in nominal sizes of 10, 12, and 14.5 mm and will treat internal iliac diameters of 6.5 mm to 13.5 mm.

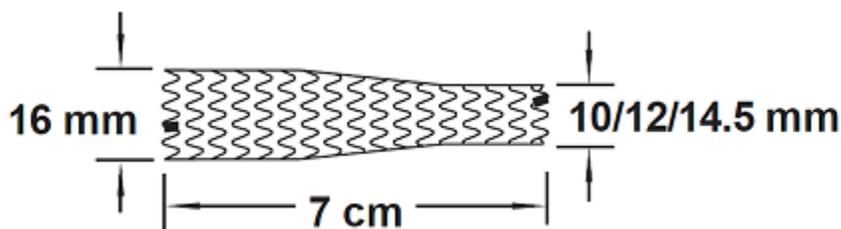


Figure 6: GORE® EXCLUDER® Internal Iliac Component

GORE® EXCLUDER® Internal Iliac Component Delivery System

The IIC is loaded on the catheter to accommodate insertion into the internal iliac artery through the internal iliac gate of the IBC, and will be deployed from the trailing end (common iliac) to leading end (internal iliac) (**Figure 7**).

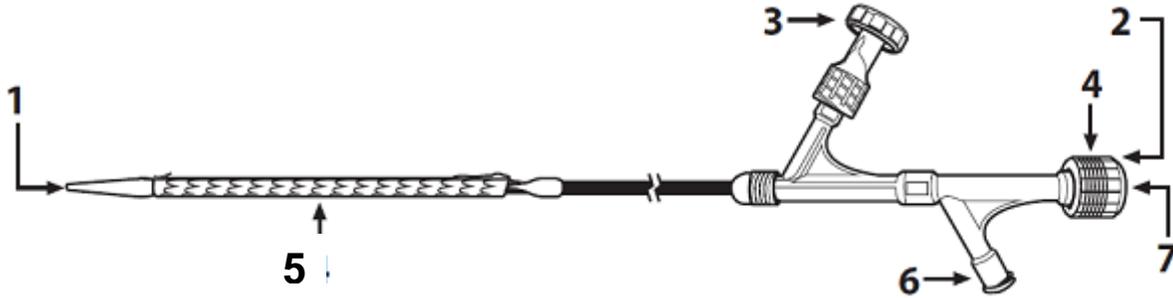


Figure 7: Internal Iliac Component Delivery System

- 1) Leading end, 2) Trailing end, 3) Deployment knob, 4) Tuohy-Borst valve, 5) Constrained endoprosthesis, 6) Flushing port, 7) Guidewire lumen

Device Configurations

Currently, the IBE Device includes the configurations outlined in **Tables 1 and 2** below.

Table 1: Iliac Branch Component Configurations

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)
CEB231010A	23	10	10	5.5	6.5 – 9	16	10 x 40
CEB231210A	23	12	10	5.5	10 – 11	16	12 x 40
CEB231410A	23	14.5	10	5.5	12 – 13.5	16	14 x 40

¹Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 7-35% in the external iliac vessel.

²GORE® DrySeal Introducer Sheaths are recommended to accommodate multiple guidewires.

Note: All dimensions are nominal.

Table 2: Internal Iliac Component Configurations

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)
HGB161007A	10	7	6.5 – 9	12 x 45	14 x 40	10 x 40
HGB161207A	12	7	10 – 11	12 x 45	14 x 40	12 x 40
HGB161407A	14.5	7	12 – 13.5	12 x 45	14 x 40	14 x 40

¹7 cm long Internal Iliac Component provides a maximum extension of 4.5 cm when placed into the Iliac Branch Component.

²Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 7-35% in the internal iliac vessel.

³Flexible Reinforced sheath.

Note: All dimensions are nominal.

Table 3 lists sizing information for EXCLUDER Device Contralateral Leg components when used in conjunction with the IBE Device.

Table 3: Contralateral Leg Bridging Component Sizing Information

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

¹Treatment 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.

²Recommended endoprosthesis oversizing relative to the IBC vessel diameter is 7-26%.

³Labeled Contralateral Leg length includes 3 cm overlap in contralateral gate of Trunk-Ipsilateral Leg 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.

Tables 4 and 5 display the total endovascular system lengths when treating contralateral and ipsilateral sides.

Table 4: Total 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

¹The 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 5: Total Length – Bridge Component via Ipsilateral Leg of Trunk-Ipsilateral Leg Component

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

¹The 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.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of common iliac or aortoiliac aneurysms, including medical management, open surgical repair, or internal iliac artery coverage or occlusion. Each alternative has its own advantages and disadvantages. A

patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The IBE Device is currently available in member states of the European Union and Australia. There have been no market withdrawals related to safety or effectiveness involving the IBE Device.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

- allergic reaction and/or anaphylactoid response to x-ray contrast dye, anti-platelet therapy, device materials
- amputation
- anesthetic complications
- aneurysm enlargement
- aneurysm rupture and death
- arterial or venous thrombosis and / or pseudoaneurysm
- arteriovenous fistula
- bleeding, hematoma, or coagulopathy
- bowel (e.g., ileus, transient ischemia, infarction, necrosis)
- cardiac (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension)
- claudication (e.g., buttock, lower limb)
- death
- dissection, perforation, or rupture of the aortic vessel & surrounding vasculature
- edema
- embolization (micro and macro) with transient or permanent ischemia
- endoleak
- 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
- fever and localized inflammation
- genitourinary (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- hepatic failure
- impotence
- infection (e.g., aneurysm, device or access sites)
- lymph fistula / complications

- multi-system organ failure
- neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis)
- occlusion of device or native vessel
- post-implant syndrome
- pulmonary complications (e.g., pneumonia, respiratory failure)
- radiation injury, late malignancy
- renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- surgical conversion
- tissue necrosis
- wound complications (e.g., infection, dehiscence)
- vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, seroma, bleeding, rupture, death)

For the specific adverse events that occurred in the clinical study, please see Section F. Safety and Effectiveness Results below.

IX. SUMMARY OF PRECLINICAL STUDIES

The design of the IBE Device is derived from the from the previously approved EXCLUDER components. Therefore, the potential effects of the design modifications and the new intended use (as compared to the EXCLUDER AAA Device) formed the basis for the preclinical test strategy. Additionally, ISO 25539-1 and commercial experience with the previously approved EXCLUDER components were considered in developing the preclinical testing. Where the design changes incorporated in the IBE Device as compared to the previously approved EXCLUDER components are not expected to significantly affect the results of previous testing, these results continue to be applicable to the IBE Device, and testing was not repeated. Such testing includes aspects of biocompatibility, durability, and performance testing. This approach is acceptable because of the extensive similarities of the IBE Device to the EXCLUDER Device in terms of design, materials, and construction.

The manufacturer completed or appropriately leveraged comprehensive preclinical studies, including *in vitro* benchtop and analytical testing (Section A), biocompatibility testing (Section A), animal studies (Section B), and sterility, packaging, and shelf-life testing (Section C) to support the safety and effectiveness of the IBE Device.

A. Laboratory Studies

In Vitro Benchtop and Analytical Testing

Appropriate *in vitro* and analytic testing was determined through reference to the testing of the previously approved EXCLUDER components and relevant standards. Where the design attributes incorporated in the IBE Device are not expected to significantly affect the results of previous testing, the previously approved EXCLUDER components results are applicable to the IBE Device, and testing was

not repeated. Such testing includes aspects of biocompatibility, durability, and performance testing. This approach is acceptable because of the extensive similarities of the IBE Device to the previously approved EXCLUDER components in terms of design, materials, and construction.

Table 6 provides a summary of the benchtop testing conducted to evaluate the performance of the IBE Device. All testing was conducted on devices representative of the final IBE Device intended for commercial use and subjected to 2x EO sterilization. The results of the laboratory studies provide preliminary evidence that the IBE Device is safe and effective and performs comparably to the previously approved EXCLUDER components.

Table 6: Summary of In Vitro Testing Performed on the IBE Device

Test	Test Summary	Results						
Endovascular System								
Simulated Use - Deployment accuracy*	<p>This test measures the ability of the IBC and IIC components to be deployed at the intended vessel location in an anatomical model.</p> <p>Acceptance Criteria: The combination IBC/IIC shall be within ± 5mm of the intended location before and after the deployment of an EXCLUDER® Device Trunk-Ipsilateral Leg and Contralateral Leg.</p>	PASS						
Stent Graft and Delivery Catheter Profile*	<p>This test measures profile of the stent graft constrained on the delivery catheter.</p> <p>Acceptance Criteria: Individual samples must pass through the ring gauge for each device type</p> <table border="1" data-bbox="542 1178 943 1276"> <thead> <tr> <th data-bbox="542 1178 721 1205">Device Type</th> <th data-bbox="721 1178 943 1205">Ring Gauge</th> </tr> </thead> <tbody> <tr> <td data-bbox="542 1205 721 1241">IBC</td> <td data-bbox="721 1205 943 1241">16+ Fr</td> </tr> <tr> <td data-bbox="542 1241 721 1276">IIC</td> <td data-bbox="721 1241 943 1276">12+ Fr</td> </tr> </tbody> </table>	Device Type	Ring Gauge	IBC	16+ Fr	IIC	12+ Fr	PASS
Device Type	Ring Gauge							
IBC	16+ Fr							
IIC	12+ Fr							

Endoprosthesis		
Simulated Use - Acute Migration*	<p>In an anatomical model with physiological pressure and flow at 37°C, this test evaluates the migration resistance of the IBE device.</p> <p>Acceptance Criteria: Acutely measured migration in-vitro should be within +/- 1mm to ensure adequate clinical migration resistance.</p>	PASS
FEA	<p>This test predicts the maximum principal mean and alternating strains of the Nitinol wire frame of the proximal IBC in combination with a 23mm BAC and the distal end of the 10mm IBC and IIC, when subjected to in vivo pulsatile loading conditions due to radial compression.</p> <p>Acceptance Criteria: This test characterizes the mean and alternating strains of the IBC and IIC components.</p>	The results demonstrate that the IBE component devices are consistent with currently marketed EXCLUDER components.
Integral Water Permeability*	<p>The Integral Water Permeability is characterized and compared to existing EXCLUDER® Device data. The IBE Device is pressurized to 120mmHg with 37°C water to evaluate the leak rate of the device normalized by surface area.</p> <p>Acceptance Criteria: Characterize the integral water permeability of the device with modular components (IBC and IIC) in place and compare test results to existing data.</p>	The integral water permeability of the IBE Device has been characterized and is comparable to existing data.
Radial Compression*	<p>This test measures the force to compress the proximal end of the IBC in an Instron tester at 37°C.</p> <p>Acceptance Criteria: The radial compression strength of the endoprosthesis as it is being crushed using a 1 cm wide loop must be ≥ 0.07 lbf/cm at 10% compression and be ≥ 0.31 lbf/cm at 20% compression or comparable to existing data.</p>	PASS
Simulated Use - Sealing/Leak*	<p>This test compares the leakage of an IBE and EXCLUDER® Device compared to the current EXCLUDER® Device. In an anatomical model with physiological pressure and flow at 37°C, the leak rate into the aneurysm sac of the model is measured.</p> <p>Acceptance Criteria: Compare IBE Device test results to EXCLUDER® Device data.</p>	The sealing and leakage of the IBE and EXCLUDER® Device has been characterized and is comparable to existing data.
Deployed Stent Graft Length*	<p>This test measures length of a deployed IBC and IIC stent graft in a 37°C water bath.</p> <p>Acceptance Criteria: -The deployed lengths of the IBC and IIC must be within the required ranges.</p>	PASS

Compressed Stent Graft Length*	<p>This test measures the compressed IBC and IIC stent graft on the IBC and IIC catheters.</p> <p>Acceptance Criteria: The IBC and IIC compressed stent graft lengths must be within the required ranges.</p>	PASS
Deployed Stent Graft Diameter*	<p>This test measures proximal and distal diameter (OD) of a deployed IBC and IIC stent graft in a 37°C water bath.</p> <p>Acceptance Criteria: The proximal and distal diameters of the IBC and IIC must be within the required ranges.</p>	PASS
Modular Component Separation Force*	<p>The force to separate IBC and IIC modular components is evaluated. Devices are deployed in a 37°C water bath and tested in an environmental chamber.</p> <p>Acceptance Criteria: The force required to separate components (IBC-27mm contra, IBC-23mm contra, IBC-IIC) will be compared to existing data.</p>	Modular component separation force was characterized and is comparable to existing data.
Magnetic Resonance Imaging Safety Test	<p>Magnetic resonance imaging (MRI) compatibility is evaluated.</p> <p>Acceptance Criteria: The IBE Device will be labeled as MR Conditional at 1.5 and 3.0 Tesla.</p>	<p>PASS - The IBE Device does not present an additional hazard or risk when implanted in a patient undergoing an MRI procedure, or who may be present in an MRI environment of 1.5 or 3 Tesla.</p> <p>The IFU labels the IBE Device as MR Conditional.</p>
Visibility / Radiopacity	<p>This test evaluates the visibility of the IBC and IIC components under fluoroscopy</p> <p>Acceptance Criteria: The loaded Endoprosthesis and delivery catheter must demonstrate sufficient radiopacity for safe and efficacious clinical use.</p>	The device demonstrated sufficient radiopacity.

Delivery System		
Catheter Bond Tensile*	<p>This test evaluates the tensile and torque strengths of selected catheter components.</p> <p>Acceptance Criteria: Force to separate body shaft to guidewire lumen must be ≥ 3.9 lbf. Force to separate the junction on the RGT must be ≥ 3.9 lbf.</p> <p>Acceptance Criteria: Force to pull the RGT through compressed stent graft will be characterized.</p> <p>Acceptance Criteria: Torque to remove male luer lock from distal 2-arm will be characterized.</p> <p>Acceptance Criteria: Torque to remove knob 1 and knob 2 from luer lock will be characterized.</p>	PASS Required catheter tensile and torque strengths were characterized.
Loaded Delivery Catheter Length*	<p>The device catheter working length is measured.</p> <p>Acceptance Criteria: The IBC and IIC catheter working lengths must be within the required ranges.</p>	PASS
Simulated Use - Guidewire Component Compatibility*	<p>The purpose of this test is to verify that the IBC and IIC delivery catheters are compatible with a 0.035" guidewire.</p> <p>Acceptance Criteria: The catheter must be compatible with a 0.035" guidewire. Insertion shall be without obstruction or excessive force.</p>	PASS
Simulated Use - Introducer Sheath Component Compatibility*	<p>The purpose of this test is to verify that IBC device is compatible with a 16Fr Gore DrySeal sheath and that the IIC device is compatible with a 12Fr Cook Flexor Sheath and a 12Fr Gore DrySeal Flex Sheath.</p> <p>Acceptance Criteria: The device must be able to successfully pass through the recommended sheath; the entire catheter must successfully exit the sheath.</p>	PASS
Delivery System Deployment Force*	<p>This test measures the force required to deploy the IBC and IIC in an aneurysm model in a water bath at 37°C.</p> <p>Acceptance Criteria: The deployment force for the IBC and IIC deployment lines must be ≤ 5 lbf.</p>	PASS

Simulated Use - Deployment Reliability Test*	<p>This test evaluates various aspects of deployment including guidewire compatibility, pushability, trackability, torquability, and deployment, and retraction.</p> <p>Acceptance Criteria: The delivery catheter must be compatible with specified guidewires and sheaths in simulated anatomy and provide sufficient ability to torque. The endoprosthesis must fully deploy. All deployment lines, delivery catheters and sheaths must be fully removable without impacting the deployed device. The IBC must be able to reposition 5mm distally when partially deployed. Specified components must meet all relevant post-deployment dimensional and physical inspection requirements.</p>	PASS
Simulated Use - Catheter Angular Rotation to Failure	<p>This test measures the number of IBC catheter rotations to failure with the leading end fixed in an aneurysm model at 37°C water bath.</p> <p>Acceptance Criteria: The proximal hub must rotate 360° without mechanical damage or failure when the distal end is fixed.</p>	PASS
Simulated Use - IBC Septum Sealing*	<p>This test measures leak rate through the IBC catheter handle in an aneurysm model pressurized in a 37°C water bath.</p> <p>Acceptance Criteria: At 120 mmHg, the sealing septum must exhibit a leakage rate less than the specified limit before initial deployment and after the proximal end of the device has been deployed.</p>	PASS
Deployment Mechanism Knob to Line Tensile*	<p>This test measures the tensile strength of the knob-to-line joints of the deployed IBC catheter.</p> <p>Acceptance Criteria: The deployment line attachment strength must be > 5.5 lbf.</p>	PASS
Sheath Retraction Force	<p>This test measures the force required to pull the IBC catheter through the introducer sheath.</p> <p>Acceptance Criteria: Sheath retraction force (distal olive over lip of introducer) must be < 8.1 lbf.</p>	PASS

*Indicates testing repeated at aging time points for shelf life evaluation.

Biocompatibility Evaluation

The IBE Device was evaluated for biological safety as per FDA Memo #G95-1 “Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing” to demonstrate the suitability of the materials for their intended use in an abdominal stent graft system. Biocompatibility testing from other marketed Gore medical products with the same or similar materials and processing was leveraged for the IBC endoprosthesis, the IIC endoprosthesis, and the IIC delivery system. Due to differences in the materials and processing of the IBC delivery system (as compared to other marketed Gore medical products), biocompatibility testing was performed on the IBC delivery system. **Table 7** summarizes the IBC delivery system testing.

Table 7: Summary of IBC Catheter Biocompatibility Evaluation

Test Performed	Extract(s) Conditions	Test Article and Control(s) Used	Acceptance Criteria	Results
Cytotoxicity <i>MEM Elution Test</i>	The test article was extracted in MEM media with 10% FBS at 37°C for 24 hours at a ratio of 6 cm ² / ml extract.	Test: IBC catheter. Neg. Control = media; high density polyethylene. Pos. Control = natural rubber.	No signs of cellular morphologic change or death that exceed a Grade of 2 should be seen for the test article extracts at 48 hours.	PASS Test article had no biological reactivity at 48 hours (Grade 0). Non-cytotoxic.
Sensitization <i>Kligman Maximization Test</i>	Extraction: 0.9% USP NaCl; cottonseed oil Conditions: 50 ± 2°C, 72 ± 2 hours. Extraction ratio 6 cm ² / ml extract.	Test: IBC catheter. Neg. Control = 0.9% USP NaCl, cottonseed oil. Pos. Control = Dinitrochlorobenzene (DNCB).	A sensitizing response is not observed in more than 8% of the animals. This is a Grade 1 sensitization classification.	PASS No reaction (0%, sensitization) occurred in any of the test animals. Grade I weak allergenic potential. Non-sensitizing
Irritation <i>Intracutaneous Injection Test</i>	The test article was extracted in 0.9% USP NaCl and cottonseed oil at 50° C for 72 hours at a ratio of 6 cm ² / ml extract.	Test: IBC catheter. Neg. Control = 0.9% USP NaCl, cottonseed oil. Pos. Control: N/A.	None of the test extract injection sites show a greater biological reaction than the control injection sites. The difference in the mean score for test and control is ≤ 1.	PASS None of the test sites showed a greater biological reaction than the controls sites. The difference in the mean score for test and control was 0. Non-irritant.
Acute Systemic Toxicity <i>Systemic Injection</i>	The test article was extracted in 0.9% USP NaCl and cottonseed oil at 50 C for 72 hours at a ratio of 6 cm ² / ml extract.	Test: IBC catheter. Neg. Control = 0.9% USP NaCl, cottonseed oil. Pos. Control: N/A	Animal Weight: A body weight loss of no more than 10% in three of animals. Clinical Observations: none of the test animals show significantly greater biological reactions than controls. If two or more animals show either marked symptoms of toxicity or die, then the sample does not meet the requirements of the test.	PASS Four test and three control animals lost insignificant weight (< 8%), no systemic toxicity signs in any animals, no significantly greater biological reaction than controls. Non-toxic.

Table 7: Summary of IBC Catheter Biocompatibility Evaluation

Test Performed	Extract(s) Conditions	Test Article and Control(s) Used	Acceptance Criteria	Results
Pyrogenicity <i>Rabbit Pyrogen Test (Material Mediated)</i>	The test article was extracted in 0.9% USP NaCl at 50°C for 72 hours at a ratio of 6 cm ² / ml extract.	Test: IBC catheter. Neg. Control = 0.9% USP NaCl. Pos. Control: N/A .	None of the animals have a temperature increase ≥ 0.5°C.	PASS None of the test animals showed a temperature increase above baseline (0°) Non – pyrogenic.
Hemocompatibility <i>Hemolysis Direct Contact ASTM</i>	The test article was in direct contact with plasma at a ratio of 6 cm ² / ml.	Test: IBC catheter. Neg. Control = PBS; HDPE. Pos. control = Buta-N Rubber.	Percentage hemolysis must be < 5 % to be non-hemolytic.	ACCEPTABLE ¹ 7.39% hemolysis Hemolytic.
Hemocompatibility <i>Hemolysis Direct Contact ASTM</i>	The test articles were in direct contact with plasma at a ratio of 6 cm ² / ml.	Test: IBC catheter. Neg. Control = PBS; HDPE. Pos. control = Buta-N Rubber.	Percentage hemolysis must be < 5 % to be non-hemolytic.	PASS 0.0% hemolysis for both catheter and RGT. Non-Hemolytic.
Hemocompatibility <i>Hemolysis Direct Contact ASTM</i>	The test articles were in direct contact with plasma at a ratio of 6 cm ² / ml.	Test: IBC catheter. Neg. Control = PBS; HDPE. Pos. control = Buta-N Rubber.	Percentage hemolysis must be < 5 % to be non-hemolytic.	PASS 0.08% hemolysis Non-Hemolytic.
Hemocompatibility <i>Complement Activation Direct Contact</i>	The test article was in direct contact with plasma at a ratio of 6 cm ² / ml.	Test: IBC catheter. Neg. Control = HDPE plastic. Pos. Control = C3-A = latex rubber. SC5b-9 = cellulose acetate.	The test article concentration of C3a and SC5b-9 is not significantly greater than the concentration in either the untreated or negative control plasma.	PASS The plasma exposed to the test article for 90 min. did not exhibit a significant increase in C3a or SC5b-9 when compared to untreated or negative control plasma. The test sample does not activate complement.
Hemocompatibility <i>Prothrombin Time Assay Direct Contact</i>	The test article was in direct contact with plasma at a ratio of 6 cm ² / ml.	Test: IBC catheter. Neg. Control = Plasma a: without test article and b: in presence of HDPE. Pos. Control = Oxalic acid.	No statistically significant difference is found between the PT of the plasma exposed to the test article and that of the plasma exposed to either the negative control or the untreated control	PASS The average PT value for the test article (13.5 sec.) did not significantly differ from the mean of the negative (14.4 sec.) and untreated controls (13.5 sec.) No effect on coagulation.

Table 7: Summary of IBC Catheter Biocompatibility Evaluation

Test Performed	Extract(s) Conditions	Test Article and Control(s) Used	Acceptance Criteria	Results
Hemocompatibility <i>In Vivo</i> <i>Thrombogenicity</i>	The test article was in direct contact with blood in an <i>in vivo</i> canine model.	Test: IBC catheter. Control = HDPE.	A thrombosis score with a grade of < 3.	PASS Minimal Thrombosis with a grade 0 on one test article and Grade 1 on the other test article. Non-thrombogenic.

¹The initial test of the IBC catheter for hemolysis resulted in a hemolysis index of 7.39% which is just above the hemolytic index acceptance criteria of < 5%. That test included the catheter and removable guidewire tube (RGT) in the same test sample. The hemolysis test was repeated using the same lot of catheters and RGT. The catheter and RGT were tested separately since the RGT is removed prior to use in the patient. This second test resulted in a hemolytic index of 0% for both the catheter and RGT. A third test of a new lot of catheters, without the RGT since it does not contact the patient, resulted in a hemolytic index of 0.08% well below the acceptance level of <5%. The initial hemolytic index of 7.39% was not confirmed in the two additional hemolysis tests. These results indicate that the IBC catheter is non-hemolytic and thus safe for use as a medical device.

The materials evaluated and used in the components of the IBE Device are considered biologically safe for use in a device classified as an Implant Device with permanent contact (>30 days) to circulating blood and tissues. The materials used in the components of the IBE Device delivery system are considered biologically safe for use in a device classified as an External Communicating Device with limited exposure (≤24 hours) to circulating blood (ISO 10993-1:2009).

B. Animal Studies

No animal testing was conducted on the IBE Device. Information from clinical use and animal study data from the previously approved EXCLUDER components was appropriately leveraged based on the similarities in the IBE Device design and materials. Additionally, a validated bifurcated iliac animal model is not available to address delivery and deployment. These attributes were assessed in simulated use testing, as described above.

C. Additional Studies

Sterilization, Packaging and Shelf Life

The IBE Device has a labeled shelf-life of three years. Device packaging materials and the EO sterilization cycle are the same as those used with the previously approved EXCLUDER components. The sterilization and packaging testing was leveraged from the previously approved EXCLUDER components; no new testing was performed for the IBE Device.

Shelf life testing was performed on the IBE Device, with the relevant tests identified with asterisks in Table 6 above. Product testing was performed on samples that were 2X EO sterilized prior to aging. Accelerated aging studies on the IBE Device demonstrated that the device meets three-year shelf life specifications. Additionally,

real-time aging studies out to three years have been completed with all acceptance criteria being met.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of endovascular treatment with the IBE Device for CIAA and AIA in the US under IDE #G130038. Data from this clinical study were the basis for the PMA Supplement approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between October 2013 and January 2015. The database for this Panel Track Supplement reflected data collected through November 5, 2015, and included 64 unique patients. There were 28 investigational sites.

The study (IBE 12-04) was a prospective, non-randomized, multi-center, single-arm clinical study 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. 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 8.

This study evaluated safety and effectiveness through comparison to performance goals. Performance goals were established through a review of data from historical AAA endovascular clinical studies and scientific publications examining internal iliac artery treatment. This resulted in a safety performance goal of 80% freedom from safety endpoint events at 30 days. With this performance goal and a 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.

With regards to effectiveness, the primary effectiveness endpoint was a composite of the following 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.

This study utilized an independent Data Safety Monitoring Board (DSMB) that reviewed safety data during the accrual phase of the study and on an ongoing basis as needed. A Clinical Events Committee (CEC) reviewed adverse events for inclusion as endpoint events, all reinterventions through 12-month follow-up performed due to Type IB or Type III endoleak or 60% occlusion involving the investigational components, and inclusion/exclusion criteria deviations. Because IBE Device patients can present with bilateral iliac aneurysms but the study was limited to unilateral treatment, a Bilateral Recommendation Committee reviewed screening images and provided treatment recommendations. Finally, a Core Lab reviewed subject images for study critical events (e.g. endoleak, occlusion, stent fracture).

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the IBE 12-04 study was limited to patients who met the following inclusion criteria:

1. Common iliac to be treated must have a maximum diameter ≥ 25 mm with or without concomitant AAA along with:
 - minimum diameter ≥ 17 mm within the proximal implantation zone of IBE as assessed by flow lumen; calcium excluded
 - diameter ≥ 14 mm at the iliac bifurcation as assessed by flow lumen; calcium excluded
2. Adequate native anatomy to receive the GORE[®] EXCLUDER[®] and IBE Devices, including:
 - Adequate iliac / femoral access
 - Infrarenal aortic neck diameter 19-32 mm
 - Infrarenal aortic neck length ≥ 15 mm
 - Aortic neck angle $\leq 60^\circ$
 - Iliac artery seal zone of at least 10 mm with treatment diameter ranges of the following as assessed by flow lumen and thrombus, if present; calcium excluded:
 - 6.5–13.5 mm for the IBE side internal iliac artery
 - 6.5–25 mm for the IBE side external iliac artery
 - 8–25 mm for the non-IBE side iliac artery
3. An ICF signed by subject or legally authorized representative
4. Male or infertile female*
5. Able to comply with protocol requirements including following-up
6. Life expectancy > 2 years
7. Age > 21 years
8. Surgical candidate

* *Infertile female – condition which prevents pregnancy, e.g., hysterectomy, tubal ligation or post-menopausal for greater than 1 year.*

Patients were not permitted to enroll in the IBE 12-04 study if they met any of the following exclusion criteria:

1. Mycotic or ruptured aneurysm
2. Known concomitant thoracic aortic aneurysm which requires intervention
3. American Society of Anesthesiologists (ASA) class V (moribund patient not expected to live 24 hours with or without operation)
4. Renal insufficiency defined as creatinine > 2.5 mg/dL or patient undergoing dialysis
5. NYHA class IV
6. Dissected, heavily calcified, or heavily thrombosed landing zone(s)
7. Tortuous or stenotic iliac and / or femoral arteries
8. Participating in another investigational device or drug study within 1 year of treatment
9. Systemic infection which may increase the risk of endovascular graft infection

10. Known degenerative connective tissue disease, e.g., Marfan or Ehler-Danlos Syndrome
11. Planned concomitant surgical procedure or major surgery within 30 days of treatment date (with the exception of surgical procedures required for bilateral iliac artery treatment)
12. Known history of drug abuse
13. Known sensitivities or allergies to the device materials

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 1, 6, 12, 24, 36, 48, and 60 months postoperatively.

Preoperatively, patient demographics, medical history, and relevant baseline anatomical measurements were collected for each study subject. Postoperatively, the objective parameters measured during the study included site-reported measurements (maximum common iliac artery diameter on the IBE Device side) and Core Lab evaluations (maximum abdominal aortic diameter, maximum right common iliac artery diameter, maximum left common iliac artery diameter, device migration, intercomponent migration, endoleak, wire fracture, extrusion/erosion, lumen obstruction, device compression, patency, and rupture), using the assessments and testing listed in **Table 8**. Adverse events and complications were recorded at all visits.

Follow-up visits are scheduled at appointed times after the date of treatment. In order to provide flexibility for scheduling follow-up visits, a period during which each visit is recommended (i.e., ideal window) is provided below in **Table 9**. Also included in the table are the analysis windows used for this study. Analysis windows include all study days in order to include all data reported. All data in this report are presented by analysis window unless stated otherwise.

Table 8: Subject Schedule of Events

Diagnostic Test	Pre-treatment	Treatment	1 month	6 months	12, 24, 36, 48, and 60 months
Physical examination	X		X	X	X
Creatinine concentration	X				
Spiral computed tomography (contrast)	X		X	X	X
Spiral computed			X		

tomography (non contrast)					
Angiography	X¹	X			
¹ Pre-enrollment angiogram not required if contrast enhanced spiral CT with 3-D reconstruction has been performed ≤ 180 Days prior to treatment					

Table 9: Protocol Windows

Follow-up Visit	Ideal Window (days)	Analysis Window (days)
Procedure	0	0
Post-Procedure*	1-14	1-14
1 Month	23-44	15-59
6 Months	150-210	60-242
12 Months	275-455	243-546
24 Months	640-820	547-911
36 Months	1005-1185	912-1275
48 Months	1370-1550	1276-1640
60 Months	1735-1915	1641-2006
*Post-Procedure visit is not required		

3. Clinical Endpoints

With regards to safety, the primary 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, compared to the performance goal.

With regards to effectiveness, the primary effectiveness endpoint was a composite of the following 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, compared to the performance goal.

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.

With regard to success/failure, study success was defined as meeting the primary safety and effectiveness endpoints. The IBE 12-04 study was considered successful if the null hypotheses for the test of primary safety (≤ 0.80) and effectiveness (≤ 0.75) were rejected.

B. Accountability of PMA Cohort

At the time of database lock, of 64 unique patients enrolled in the PMA study, 98.4% (63) patients are available for primary safety endpoint analysis at 30 days and 96.9% (62) patients are available for primary effectiveness endpoint analysis at the 6 month post-operative visit.

Subjects were screened and enrolled per the criteria outlined above. One hundred seventy-three (173) subjects were screened for eligibility for the IBE 12-04 Study; 108 subjects were excluded from study participation and identified as screen failures (**Figure 8**). The most common primary reason for exclusion from the study was common iliac artery diameters (Inclusion 1) and adequate anatomy to receive the GORE[®] EXCLUDER[®] AAA Endoprosthesis and the IBE Device (Inclusion 2).

A total of 65 subjects were considered to be enrolled into the study; however, one subject withdrew then re-enrolled, resulting in a total of 64 unique study subjects. An additional subject withdrew from the study prior to the IBE Device procedure. One subject was not considered eligible for the primary endpoint and all effectiveness and device-specific safety analyses because they did not meet the selection criteria for the study. An additional subject did not receive both IBE device components so was included in the primary safety endpoint, but excluded from device-specific safety (i.e., serious and non-serious device events) and all effectiveness endpoints.

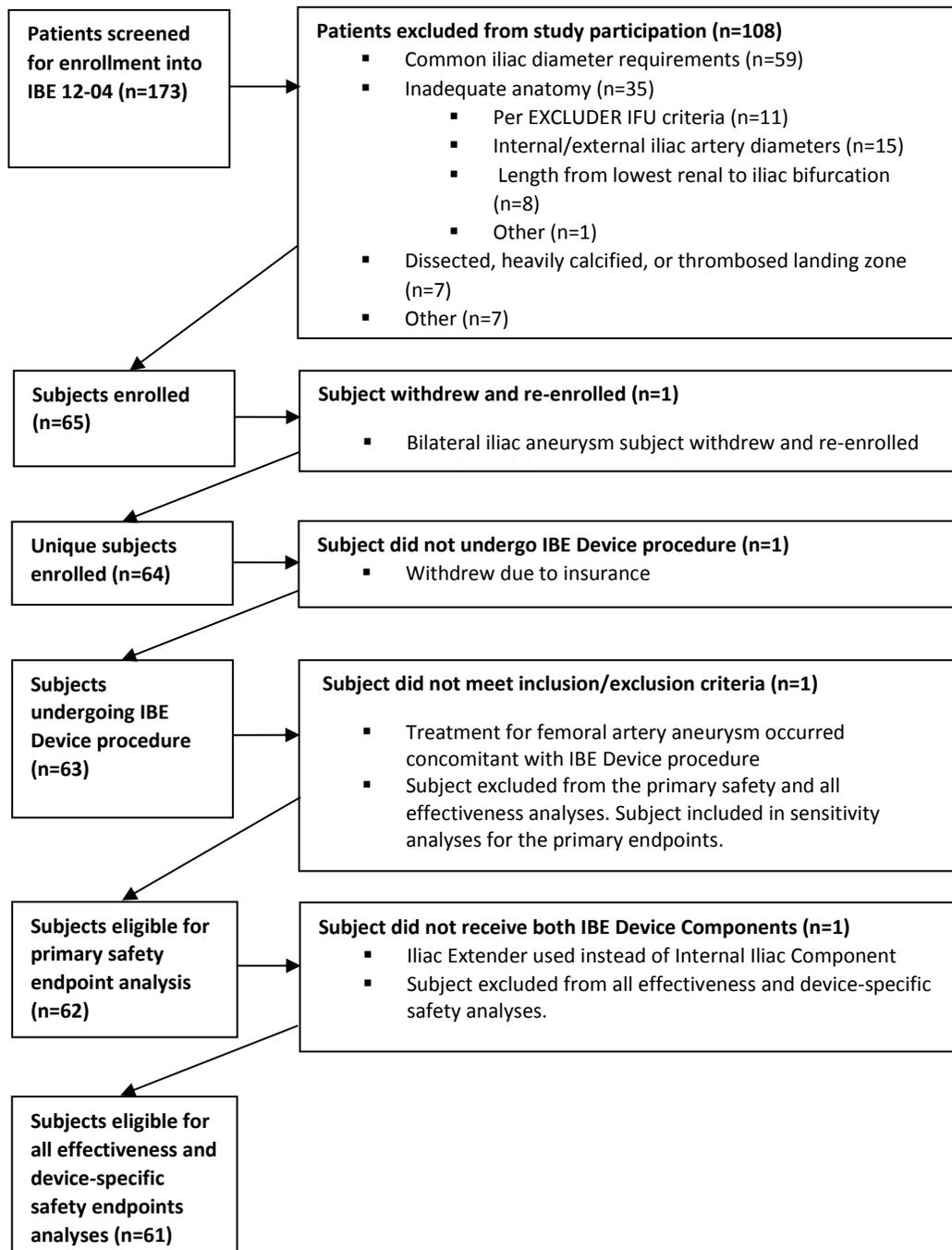


Figure 8: Subject Enrollment and Analysis Inclusion

Table 10 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, and 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 (i.e., number eligible from previous period minus subject deaths, subjects discontinued or not yet due for their next follow-up visit). All 61 subjects were eligible for the primary endpoint analysis at 6 months, 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 10 includes subjects eligible for all effectiveness endpoint analyses (Figure 8).

Table 10. Subject Compliance and Disposition by Study Interval

Study Period	Follow-up Compliance ¹						Events Prior to Next Interval ¹		
	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)

¹Percentages are based on number of subjects eligible for follow-up in study period.

²Any visit consisting of physical exam, CT scan, or MR scan.

³Contrast CT is necessary for Core Lab determination of endoleak, lumen obstruction, patency, or rupture.

⁴Subjects still within the study window out of those who have not yet had a CT scan.

Analysis of pre-treatment and follow-up radiologic images was conducted by an independent Core Lab. **Table 11** 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 previously approved EXCLUDER components and IBE Device 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 12**. 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, with 62.3% of subjects evaluated for all fracture classes in the 1 month and 6 month study windows.

When considering the impact of slice thickness in assessing subclinical device fractures, while slice thickness does impact the ability to identify individual wireform fractures (Class I, Class II, and some Class III), most nitinol stent fractures that could have clinical sequelae progress to Class IV and V, and these can be detected in thicker slice CT imaging. Sequelae of Type III endoleak, migration, and limb occlusion will also be detected in thicker slice CT imaging.

Tables 11 and 12 include subjects eligible for all effectiveness endpoint analyses (Figure 8).

Table 11. 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	IBE 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 12. 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%)
Only 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).

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an endovascular stent graft study performed in the US.

Baseline assessments of all enrolled IBE 12-04 subjects include demographics and risk factor evaluations, including medical history and comorbidities. **Table 13** 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 14** provides subject medical history, with hypertension, hypercholesterolemia, and cigarette smoking presenting as the most common comorbidities.

Tables 13 and 14 include the 64 unique subjects enrolled (**Figure 8**).

Table 13. 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

Table 13. Subject Demographics

	IBE Cohort
Range	(0.0,13.0)
Iliac Aneurysm Presentation	
Bilateral	25(39.1%)
Unilateral	39(60.9%)

¹One 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.

Table 14. 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%)

¹One 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.

²Males Only

Subjects underwent pre-treatment imaging to assess aortic morphology (**Tables 15 and 16**). Patient pre-treatment aortic imaging measurements were evaluated in two groups (**Table 15**): those presenting with abdominal aortic aneurysms (Aortoiliac Aneurysms, aortic diameter \geq 50 mm) and those presenting without abdominal aortic aneurysms (Isolated Iliac Aneurysms, aortic diameter $<$ 50 mm). Measurements in **Table 16** 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.

Tables 15 and 16 include unique subjects enrolled (Figure 8).

Table 15. 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)
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)
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)

Table 15. Pre-Treatment Imaging Measurements – Abdominal Aorta (Site-Reported)

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 16. Pre-treatment Imaging Measurements – Iliac (Site-Reported)

All diameters and lengths reported in mm	IBE Side			Non-IBE Side		
	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 zone¹						
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

Table 16. Pre-treatment Imaging Measurements – Iliac (Site-Reported)

Range	-	-	-	(10.0, 25.0)	(8.0, 76.0)	(8.0, 76.0)
External iliac artery diameter at intended landing zone²						
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)

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

²Measurement on non-IBE side not required for subjects with unilateral iliac aneurysm. Any measurements provided are included in this table.

D. Device Usage

Table 17 provides device usage for patients implanted with the IBE Device. Diameter distribution of all IBE Devices implanted (IBC and IIC) are presented in **Table 18**. 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 19** presents the diameter and length distributions of implanted Contralateral Leg components. Seventy-three (73) Contralateral Leg components were implanted in 63 subjects. Multiple Contralateral Leg components were used in 9 subjects to provide an adequate bridge between the Trunk-Ipsilateral Leg Endoprosthesis and the IBE Device.

Tables 17, 18, and 19 include subjects undergoing IBE Device procedure (**Figure 8**).

Table 17. 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%)
EXCLUDER AAA Device Components	
Subjects with Trunk-Ipsilateral Legs 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%)

¹One 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 EXCLUDER AAA Endoprosthesis Iliac Extender was used in place of the investigational IIC.

Table 18. Number of Implanted Subjects by IBE Device Component Sizes

Distal Leg Diameter (mm)	IBC		IIC	
	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

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

Table 19. 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%)

E. Procedural Data

Table 20 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-expandable 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 20 includes subjects undergoing IBE Device procedure (**Figure 8**).

Table 20. 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)

Table 20. Procedure and Recovery

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.

F. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the study cohort of 62 patients undergoing the IBE procedure and meeting the selection criteria for the study. The key safety outcomes for this study are presented below in **Tables 21 and 22**. Adverse device effects are reported in **Tables 23 to 25**.

Key Adverse Events (Primary Safety Endpoint):

The primary safety endpoint was defined as 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 21**), thus the 95% Lower Confidence Limit exceeded the performance goal of 80%.

Table 21 includes subjects eligible for safety endpoint analysis (**Figure 8**).

Table 21. 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%)

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

Adverse effects that occurred in the PMA clinical study:

Serious Adverse Events

Serious adverse events (**Table 22**) 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.

Table 22 includes subjects undergoing IBE Device procedure (**Figure 8**).

Table 22. Serious Adverse Events (Site Reported)

	IBE Cohort		
Serious Events Within 30 Days			
Subjects Initiating IBE Procedure	63		
Urinary tract infection	3 (4.8%)		
Abdominal pain	1 (1.6%)		
Haematoma	1 (1.6%)		
Hypotension	1 (1.6%)		
Hypoxia	1 (1.6%)		
Incision site infection	1 (1.6%)		
Otitis media	1 (1.6%)		
Peripheral artery aneurysm	1 (1.6%)		
Peripheral artery dissection	1 (1.6%)		
Pulmonary embolism	1 (1.6%)		
Stent-graft endoleak	1 (1.6%)		
Tachycardia	1 (1.6%)		
Urinary retention postoperative	1 (1.6%)		
Vascular pseudoaneurysm	1 (1.6%)		
Serious Events After 30 Days			
	6 Months	12 Months	24 Months
Subjects with SAE Data	63	51	2
Cardiac failure congestive	3		
Aortic dissection	2		
Chronic obstructive pulmonary disease	2		
Hypoxia	2		
Acute myocardial infarction	1		
Angina unstable	1		
Arteriosclerosis coronary artery	1		
Arthralgia	1		
Ascites	1		
Bradycardia	1		
Cellulitis	1		
Cerebrovascular accident	1		
Contrast media allergy	1		
Diarrhea	1		
Diverticular perforation	1		
Dysphagia	1		
Haemoptysis	1		

Hip fracture	1
Myocardial infarction	1
Osteoarthritis	1
Pneumonia	1
Syncope	1
Urinary retention	1
Vascular stent thrombosis	1
Ventricular fibrillation	1
Withdrawal syndrome	1

Mortality

Two deaths were reported, one of a myocardial infarction at 132 days and one of a cerebrovascular accident at 391 days, resulting in a freedom from all-cause mortality of 97%. Neither death was considered to be aneurysm related, so freedom from aneurysm-related mortality was 100%.

Serious Device Events

Serious device events, a subset of the serious adverse events, were designated based on applicable MedDRA terms relating to the IBE or EXCLUDER AAA Devices, or relating to vessel access. Five subjects (8.2%) had serious device events reported during the study (**Table 23**). 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 and device-specific safety endpoint analyses (i.e., the subject who did not meet the selection criteria for the study and the subject who did not receive the IIC component).

Table 23 includes subjects eligible for all effectiveness and device-specific safety endpoint analyses (**Figure 8**).

Table 23. Serious Device Events by Study Period (Site Reported)

	Post-Treatment Follow-up Period						Total
	Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	
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%)

¹Number 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.

²Intervention 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

Non-serious device events, a subset of the non-serious adverse events, were designated based on applicable MedDRA terms relating to the IBE or EXCLUDER AAA Devices, or relating to vessel access (**Table 24**). 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. 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. The IBC delivery system was completely removed and no other treatment was required. 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 EXCLUDER AAA 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 24 includes subjects eligible for all effectiveness and device-specific safety endpoint analyses (**Figure 8**).

Table 24. Non-Serious Device Events by Study Period (Site Reported)

	Post-Treatment Follow-up Period						Total
	Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	
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.

Thrombosis-Related Events

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 25**. There were three device occlusions and one thrombosis (common iliac artery mural thrombus with some projection into the lumen) in the IBE device. In addition, six subjects (9.8%) experienced intermittent claudication on or after the IBE Device procedure. Zero claudication events were reported on the IBE Device treatment side. 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. Also, worsening of pre-existing erectile dysfunction was reported for one subject. This subject did not undergo a staged embolization procedure or 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.

The subject who was excluded from this analysis due to use of an iliac extender in place of an IIC 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 25 includes subjects eligible for all effectiveness and device-specific endpoint analyses (**Figure 8**).

Table 25. Non-Serious Thrombosis-Related Events (Site Reported)

	Post-Treatment Follow-up Period						Total
	Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	
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%)

¹Device occlusion of IIC.

²One 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)

2. Effectiveness Results

Effectiveness Endpoint Analysis

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 26**), 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 26**), thus the 95% Lower Confidence Limit exceeded the performance goal of 73%.

Three sensitivity analyses were performed 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.

Table 26 includes subjects eligible for all effectiveness endpoint analyses (**Figure 8**).

Table 26. 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%)

¹All 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

Procedural Technical Success

Overall technical success was 95.2% (60 / 63) as shown in **Table 27**. 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). The procedural Type III endoleak was ballooned, but a final angiography was not performed after ballooning. Both endoleaks were absent at 1 month follow-up

Table 27 includes subjects undergoing IBE Device procedure (**Figure 8**).

Table 27. 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® components	62(98.4%)
Patent IBE and GORE® EXCLUDER® 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%)

Post-Procedural Core Lab Findings

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 28**, 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, extrusion / erosion events, or device compressions. The Core Lab identified three subjects with non-patent IICs (also captured under Lumen Obstruction) beginning at the time of 1 month follow-up. There were no new on-set non-patent IICs (Lumen Obstruction) after 1 month. There were no 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 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.

The Core Lab identified no wire fractures. From the outset of the IBE 12-04 study, the scope of wire fracture assessment included all 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 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 previously approved EXCLUDER components and IBE Device components for any class of fracture.

Table 28 includes subjects eligible for all effectiveness endpoint analyses (**Figure 8**).

Table 28. 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 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)

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

Change in Maximum Aortic and Iliac Diameters

Core Lab radiological data was used to assess any changes in aneurysm diameter (**Table 29**). 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 29 includes subjects eligible for all effectiveness endpoint analyses (**Figure 8**).

Table 29. Change in Maximum Aortic and Iliac Diameters – Core Lab

	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			
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			
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.

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

²The 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.

Secondary Interventions

Secondary interventions are summarized in the Serious and Non-Serious Device Events sections above. In summary, three (3) secondary interventions were performed, two (2) to treat Type II endoleaks and one (1) to treat a dissection in the external iliac artery.

3. Subgroup Analyses

Only one female subject was enrolled in this study, likely due to the low incidence of iliac artery aneurysms in females and anatomy that is not amenable to treatment with the IBE Device (e.g., small common iliac artery and internal/external iliac artery diameters). As such, no information is available to assess the effects of gender on outcomes.

G. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 230 investigators of which none were full-time or part-time employees of the sponsor and 4 had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 0
- Significant payment of other sorts: 4
- Proprietary interest in the product tested held by the investigator: 0
- Significant equity interest held by investigator in sponsor of covered study: 0

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. The information provided does not raise any questions about the reliability of the data.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

A. Comparison to Previous EXCLUDER Device Data

Key clinical outcomes were assessed for the present study and all prior EXCLUDER AAA Device clinical studies (AAA 98-03, AAA 99-04, AAA 03-02, and AAA 04-04) in order to place IBE 12-04 data into context with historical results. Imaging results were evaluated based on Core Lab evaluations to improve consistency and alignment within evaluations.

The AAA 98-03 and AAA 99-04 studies were the pivotal trials supporting PMA approval of the EXCLUDER AAA Device and evaluated its use in the treatment of abdominal aortic aneurysms when compared to open surgical repair. The AAA 04-04 study was a post-approval study that evaluated change in aneurysm morphology in patients treated with the EXCLUDER AAA Device following a design change to address endotension. The 03-02 study evaluated the 31 mm EXCLUDER AAA Device line extension in comparison to previous EXCLUDER AAA Device test subjects and controls.

The selected key clinical outcomes included the following:

- primary safety endpoint (death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure, and conversion)
- endoleaks
- rupture
- aneurysm growth
- migration

Events comprising the 30 day primary safety endpoint (zero in this study) showed equivalent or decreased rates for the current study compared to previous EXCLUDER AAA Device studies (**Table 30**).

Table 30: Summary of 30-Day Safety Events, IBE, and Previous EXCLUDER AAA Device Studies

	Combined IDE (AAA 98-03 AAA 99-04)	AAA 04-04¹	AAA 03-02	IBE 12-04
Number of Subjects	565	139	42	63
30 Day Safety Events				
Death	7(1.2%)	0	0	0
Stroke	1(0.2%)	-	0	0
Myocardial Infarction	4(0.7%)	-	0	0
Bowel Ischemia	3(0.5%)	-	0	0
Paraplegia	0	-	0	0
Respiratory Failure	1(0.2%)	-	0	0

	Combined IDE (AAA 98-03 AAA 99-04)	AAA 04-04¹	AAA 03-02	IBE 12-04
Renal Failure	2(0.4%)	-	0	0
Conversion	4(0.7%)	0	0	0

¹The focus of AAA 04-04 was effectiveness data; events which were not collected appear as a dash.

As shown in **Tables 31 and 32**, the rate of Core Lab identified Type II endoleaks in the IBE 12-04 study was 57.9% at 1 month and 54.7% at 6 months. This was greater than the most recent EXCLUDER AAA Device study utilizing a Core Lab, AAA 04-04 (enrollment began June 2005, 6 month follow-up completed in February 2007), where the rate was 46.9% (n=61/130) at 1 month and 36.0% (n=40/111) at 6 months. The apparent increase in the Type II endoleak rate can likely be attributed to improvement in imaging sensitivity and the ability to identify Type II endoleaks. While the rate of Type II endoleaks was slightly increased compared to historical EXCLUDER AAA Device clinical data, this observation did not lead to any significant clinical impact. The observation of Type II endoleaks did not lead to increases in aneurysm enlargement or reintervention rates. Through the 6 month follow-up visits, the Core Lab identified one common iliac artery diameter enlargement and no abdominal aortic diameter enlargement. Additionally, there was only one report of a reintervention to address a Type II endoleak on POD 252 (after the six month study window).

Aneurysm rupture rates (zero in all studies) were equivalent between the current study and historical EXCLUDER AAA Device data. The Core Lab observed abdominal aortic aneurysm growth rate was 0% at 6 months for the IBE 12-04 study. This Core Lab observed aneurysm growth rate and all other outcomes were consistent with prior EXCLUDER AAA Device study results. Additionally, migration rates (zero in the current study) were equivalent or lower than those previously reported for EXCLUDER AAA Device studies.

Table 31: Summary of Effectiveness Events in One Month Window, IBE, and Previous EXCLUDER AAA Device Studies

	Combined IDE (AAA 98-03 AAA 99-04)¹	AAA 04-04²	AAA 03-02³	IBE 12-04⁴
Number of Subjects	565	139	42	63
Site Reported (New or Ongoing)				
Type I Endoleak	14/538 (2.6%)	1/139 (0.7%)	2/39 (5.1%)	1/62 (1.6%)
Type II Endoleak	123/538 (22.9%)	31/139 (22.3%)	17/39 (43.6%)	26/62 (41.9%)
Type III Endoleak	3/538 (0.6%)	0/139	0/39	1/62 (1.6%)
Indeterminate Endoleak	14/538 (2.6%)	0/139	0/39	0/62

	Combined IDE (AAA 98-03 AAA 99-04)¹	AAA 04-04²	AAA 03-02³	IBE 12-04⁴
Core Lab Assessed				
Type I Endoleak	7/351 (2.0%)	1/130 (0.8%)	-	0/57
Type II Endoleak	41/351 (11.7%)	61/130 (46.9%)	-	33/57 (57.9%)
Type III Endoleak	1/351 (0.3%)	1/130 (0.8%)	-	0/57
Indeterminate Endoleak	20/351 (5.7%)	0/130	-	1/57 (1.8%)
Aneurysm Rupture (Site or Core Lab)	0/565	0/139	0/42	0/63
Reintervention for Type II Endoleak (Site)	2/538 (0.4%)	1/139 (0.7%)	0/39	0/62

¹Combined IDE data from EXCLUDER Device IFU where applicable, study window included post-operative days 1-60.

²AAA 04-04 data from Final Study Report, study window included post-operative days 15-60.

³AAA 03-02 data from Final Study Report, study window included post-operative days 15-60, collected site-reported data only.

⁴IBE 12-04 data from PMA Clinical Report, study window included post-operative days 15-59.

Table 32: Summary of Effectiveness Events in Six Month Window, IBE, and Previous EXCLUDER AAA Device Studies

	Combined IDE (AAA 98-03 AAA 99-04)¹	AAA 04-04²	AAA 03-02³	IBE 12-04⁴
Number of Subjects	553	135	42	63
Site Reported (New or Ongoing)				
Type I Endoleak	6/509 (1.2%)	1/135 (0.7%)	0/39	0/60
Type II Endoleak	106/509 (20.8%)	7/135 (5.2%)	18/39 (46.2%)	26/60 (43.3%)
Type III Endoleak	6/509 (1.2%)	0/135	1/39 (2.6%)	0/60
Indeterminate Endoleak	15/509 (2.9%)	1/135 (0.7%)	0/39	0/60
Core Lab Assessed				
Type I Endoleak	9/324 (2.8%)	0/111	-	0/53
Type II Endoleak	45/324 (13.9%)	40/111 (36.0%)	-	29/53 (54.7%)
Type III Endoleak	2/324 (0.6%)	0/111	-	0/53
Indeterminate Endoleak	29/324 (9.0%)	1/111 (0.9%)	-	0/53
Migration (Core Lab)	Trunk: 0/370 Component: 1/254 (0.4%)	1/135 (0.7%)	-	0/57
AAA Growth 5mm or Greater (Core Lab)	13/372 (3.5%)	2/103 (1.9%)	-	0/57
Aneurysm Rupture (Site or Core Lab)	0/553	0/135	0/42	0/63
Reintervention for Type II Endoleak (Site)	16/509 (3.1%)	4/135 (3.0%)	2/39 (5.1%)	0/60

¹Combined IDE data from EXCLUDER Device IFU where applicable, study window included post-operative days 61-242.

²AAA 04-04 data from Final Study Report, study window included post-operative days 61-244.

³AAA 03-02 data from Final Study Report, study window included post-operative days 61-242, collected site-reported data only.

⁴IBE 12-04 data from PMA Clinical Report, study window included post-operative days 60-242.

B. Continued Access

The IBE 12-04 study protocol was amended following completion of enrollment to allow for continued access to the IBE Device during PMA review and approval. This amendment allowed for the enrollment of 140 additional subjects at the 50 investigational sites participating in the pivotal study. All enrollment, procedural requirements, and follow-up was per the 12-04 study protocol, with the exception that bilateral placement of the IBE Device was allowed for continued access subjects. Thus far, 24 subjects have been enrolled under continued access.

Reported Events for All Continued Access Subjects

Through November 5, 2015, one death has been reported in 24 CA subjects. One subject died on post-operative day (POD) 78 of metastatic cancer.

Four SAEs were reported in three continued access subjects (**Table 33**) through 30 days. One subject experienced abdominal pain on POD 19. The event resolved on POD 43 and was noted as unrelated to the device or procedure by the Investigator. Another subject had an occlusion of the Contralateral Leg Component which was used as a distal extension to the Ipsilateral Leg of the EXCLUDER Trunk Device on the non-IBE Device side and a thrombectomy was performed on POD 1. Additionally, the subject had an ileus that resolved the day of discharge (POD 5). Another subject experienced right upper thigh pain on the day of the IBE Device procedure and treated with physical therapy before resolving on POD 4.

Table 33: Serious Adverse Events through 30 Days – Continued Access

	IBE Cohort
Subjects Initiating IBE Procedure	24
Any Serious Event	3(12.5%)
Abdominal pain	1(4.2%)
Device occlusion ¹	1(4.2%)
Pain in extremity	1(4.2%)
Postoperative ileus ¹	1(4.2%)

¹One subject experienced device occlusion and postoperative ileus.

In addition to the occlusion described above, the 1 month CT for another subject showed that the IIC had occluded. No treatment has been reported thus far; therefore, this event was considered to be non-serious by the site. The 1 month CT for another subject showed both an occlusion of the IIC and

compression on right (non-IBE side) iliac limb. No treatment has been required thus far.

One subject had bilateral external iliac artery occlusions and underwent thrombectomy procedures on POD 39 and POD 47. This event is not considered to be a device event due to site reported information that the device components were patent and not intervened on.

Two of the occlusion events in continued access subjects were potentially attributable to the IBE Device. Information regarding thrombotic events will be further evaluated over the course of five year follow-up.

None of the serious adverse events discussed in this section involved subjects that received bilateral treatment with the IBE Device.

Information Regarding Bilateral Placement of the IBE Device

The IBE 12-04 study did not allow for use of the IBE bilaterally, even in patients with bilateral internal iliac aneurysms. The continued access arm did allow for bilateral treatment with the IBE Device. As indicated by the outcomes reported for the IBE 12-04 study, embolization of the internal iliac artery is associated with a risk of buttock claudication. Embolization may also be associated with a risk of erectile dysfunction and colonic ischemia. The bilateral use of the IBE Device may provide an option to maintain blood flow into both internal iliac arteries in a patient.

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 (see **Tables 4 and 5**). Use of the IBE Device in bilateral configuration is similar to that with unilateral placement. Both IBE components (IBC and IIC) are implanted prior to placement of the EXCLUDER AAA Device. See **Figure 2** for a schematic of bilateral placement of the IBE Device.

Of the 24 subjects enrolled in continued access, three subjects (12.5%) have been treated bilaterally with the IBE Device. Notably, for the IBE 12-04 study, 2 of the 25 subject who had bilateral iliac aneurysms would have been considered candidates for bilateral use of the IBE Device (3% of the unique 64 subjects enrolled). 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 165mm 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 195mm.

For the three subjects who were treated bilaterally in Continued Access, the average procedure time 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 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 to date for this stable focal dissection.

Technical success was achieved in 3 additional patients treated bilaterally (i.e., an additional continued access subject and 2 captured under a world-wide GORE registry).

Results have not identified additional risks or adverse events related to bilateral IBE placement as compared to unilateral IBE placement, suggesting that use of the IBE bilaterally is technically feasible; however, additional data is needed post-approval to further characterize the bilateral use of the IBE Device.

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM THE PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The primary effectiveness endpoint of the IBE 12-04 study was specific to the IBE Device components and consisted of a composite of the following:

- reintervention on the IBC or the 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 an independent 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 primary effectiveness endpoint was met as 95.1% of subjects were free from endpoint events, which statistically exceeded the performance goal.

The secondary effectiveness endpoint was defined as new onset of buttock claudication arising from the side of the body treated with the IBC and IIC through the 6 month follow-up visit as determined by the CEC. The secondary effectiveness endpoint was met as all subjects were free from buttock claudication on the IBE side, which statistically exceeded the performance goal.

Overall technical success was 95.2% (60 / 63), with one subject not implanted with the IIC due to difficulties in sheath advancement. Two other subjects had procedural endoleaks.

No device migrations, intercomponent migrations, wire fractures, extrusions / erosions, compressions or ruptures have been reported. To date, the most common site reported and Core Lab observed device events have been non-serious Type II endoleaks. One common iliac artery diameter enlargement (axial view only) and no abdominal aortic diameter enlargements were identified by the Core Lab. No UADEs have been reported as of database lock.

These results confirm that the IBE Device is effective at isolating common iliac artery aneurysms (CIAAs) and aorto-iliac aneurysms (AIAs) while maintaining blood flow into the internal iliac artery.

B. Safety Conclusions

The risks of the IBE Device are based on nonclinical laboratory and animal studies conducted with both the IBE Device and the previously approved EXCLUDER AAA Device, as well as data collected in a clinical study conducted to support PMA approval, as described above.

No new safety risks were identified with the use of the IBE Device in the treatment of CIAA or AIA when compared to endovascular treatment of abdominal aortic aneurysms (AAA) with the EXCLUDER AAA Device. Evidence supporting the safety of the IBE Device from the present study includes:

- No primary safety endpoint events

- Low number of SAEs through 30 Days (84% freedom from 30-day SAE)
- No aneurysm related deaths

The primary safety endpoint was defined as a composite of key adverse events 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; therefore, the 95% Lower Confidence Limit exceeded the performance goal of 80%.

The results of the assessments with the IBE Device used with the EXCLUDER AAA Device demonstrate a reasonable assurance of the safety of endovascular repair of CIAA and AIA, providing a means of avoiding complications associated with internal iliac artery coverage.

C. Benefit-Risk Conclusions

The probable benefits of the IBE Device are based on data collected in a clinical study conducted to support PMA approval, as described above. Primary benefits of treatment with the IBE Device are comparable to those of endovascular treatment with the previously approved EXCLUDER AAA Device, with the addition of minimizing the sequelae known to be associated with loss of internal iliac flow. An additional potential benefit is the ability to treat internal iliac arteries with diameters as small as 6.5 mm as compared to the limit of 8 mm for the previously approved EXCLUDER components. This may expand the eligibility of patients for endovascular repair.

When assessing the unique benefits and risks associated with the IBE Device for the treatment of CIAAs or AIAs, it is appropriate to consider the results from the present study within the context of the clinical effectiveness of the IBE Device compared to alternative endovascular treatment methods for CIAAs and AIAs, specifically the high patency and low claudication rates.

Current methods to treat CIAAs or AIAs by endovascular techniques are limited and include hybrid surgical-endovascular repair and internal iliac artery occlusion. Hybrid surgical-endovascular repair introduces additional clinical risk due to a more invasive procedure. Patients treated with internal iliac artery occlusion are at increased risk of buttock claudication or new onset sexual dysfunction, in addition to other more severe outcomes including gluteal necrosis, spinal cord ischemia, and colonic infarction.

Of the subjects who had claudication reported after the IBE Device procedure (n = 6), none were adjudicated to be specific to the IBE treatment side. All of these subjects who had reported claudication on the non-IBE treatment side also had staged procedures involving coil embolization and stent graft

coverage of the internal iliac artery on the non-IBE treatment side. These same subjects did not report of claudication on the IBE treatment side, evidence further confirming the benefit of internal iliac preservation.

The IBE study results presented are notable for the high patency rates, and low reintervention rates at 6 months for patients treated with the IBE Device, in absence of buttock claudication on the IBE side. Those patients who presented with subsequent branch vessel occlusion after IBE Device implantation were asymptomatic, did not require reintervention, and did not experience adverse events. Preservation of the internal iliac artery blood flow with the IBE Device provides positive clinical outcomes without the introduction of additional risks.

The low rate of events was observed even though the IBE procedure for AIA and CIAA is more complex than the standard endovascular repair of AAA with the EXCLUDER AAA Device due to the increased number of components required (a minimum of 4 devices is needed for IBE placement, as compared to a minimum of 2 devices) and additional steps required to implant the components.

The rate of site reported Type II endoleaks was slightly increased compared to historical clinical data for the EXCLUDER AAA Device. This observation did not lead to any significant clinical impact out to six months of follow-up. The observation of Type II endoleaks did not lead to increases in core lab identified aneurysm enlargement or reintervention rates. During the 6 month follow-up visits, Core Lab identified no abdominal aortic diameter enlargement and one common iliac artery diameter enlargement. There was only one reintervention to address a Type II endoleak on POD 252. The presence of Type II endoleaks at six months did not appear indicative of additional risks affecting clinical outcome to this time point. The Type II endoleak rates noted may be increased when compared to prior studies because of interval improvements in imaging modalities and imaging techniques which have occurred since previous EXCLUDER AAA Device clinical trials.

Additional factors to be considered in determining risks and benefits for the IBE Device include:

- limited clinical study results for female subjects,
- limited data on patients treated bilaterally with IBE Device,
- absence of long-term patient follow-up, and
- limitations in the numbers of patients with anatomy consistent with the indications for use.

In conclusion, given the available information above, the data support that the probable benefits outweigh the probable risks for use of the IBE Device with the EXCLUDER AAA Device 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.

D. Overall Conclusions

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

The use of the device in the study was associated with high patency rates, low reintervention rates, and a safety profile that is similar to the previously approved EXCLUDER AAA Device. The added benefits of preservation of flow into the internal iliac artery were clear; none of the subjects experienced buttock claudication on the side of IBE treatment. Late occlusions of the device were noted to be asymptomatic.

Patients who have anatomy appropriate to receive the IBE Device are likely to obtain the benefits of aneurysm exclusion and maintenance of flow into the iliac branches.

The totality of the information to date supports a positive benefit-risk profile for the IBE Device in the treatment of CIAAs or AIAs.

XIV. CDRH DECISION

CDRH issued an approval order on February 29, 2016. The final conditions of approval cited in the approval order are described below.

The sponsor has agreed to include as part of the Annual Report a copy of the clinical update provided to physician users at least annually. At a minimum, this update will include:

- a. For the IDE and Continued Access subjects that received unilateral device placement through 5 years of implantation, a summary of the number of patients for whom the data are available, with the rates of aneurysm-related mortality, aneurysm rupture, secondary endovascular procedures, conversion to surgical repair, endoleak, aneurysm enlargement, and prosthesis migration and patency. Reports of losses of device integrity, reasons for conversion, and causes of aneurysm-related death and rupture are to be described.

- b. Information regarding any data they have on subjects that received bilateral device placement (e.g., Continued Access subjects and subjects whose data is captured through your ongoing GREAT and ICEBERG Registries). The clinical updates will include procedural data and the information listed in item 1a above through 5 years of implantation for a minimum of 10 subjects that received bilateral device placement. In addition, the clinical updates will provide a discussion of any lessons learned from bilateral use of the device.
- c. A summary of explant findings and any relevant information from commercial experience within and outside of the U.S.

In addition, the Office of Device Evaluation (ODE) will lead the review of Post-Approval Study data that consists of the extended follow-up data out to 5 years for subjects enrolled in the IBE 12-04 clinical study, which was initiated prior to device approval. This includes data from the pivotal study and continued access cohorts in accordance with the previously approved Investigational Device Exemption protocol. The data should include a summary of the number of patients for whom data are available and the rates of adverse events, such as aneurysm-related mortality, aneurysm rupture, secondary endovascular procedures, conversion to open surgical repair, endoleak, aneurysm enlargement, prosthesis migration and patency, and losses of device integrity.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.