GORE® EXCLUDER® AAA Endoprosthesis
ANNUAL CLINICAL UPDATE†
OCTOBER 2018

Abstract

This annual clinical update provides a review of the ongoing experience with the GORE® EXCLUDER® AAA Endoprosthesis used in the treatment of infrarenal abdominal aortic aneurysms (AAAs). Twenty years of worldwide commercial experience and detailed experience over the past year is presented. Additionally, this update summarizes five years of IDE clinical study data. Five-year data representing outcomes of 565 patients enrolled through two Phase II pivotal studies are collectively presented as the combined IDE cohort. Outcomes from the clinical studies have been favorable for patients treated with the GORE® EXCLUDER® Device.

These patients experienced fewer major adverse events compared to patients treated with open surgery. Aneurysm-related mortality was similar between the two groups. Through five years, only one (0.2%) patient in the combined IDE cohort experienced an aneurysm rupture, 19 (3.4%) were converted to open surgery, and two explanted devices had stent fractures. At five-year follow-up, 40 (16%) patients had endoleaks and 79 (34%) had aneurysm enlargement. The 20 years of commercial experience represent more than 297,000 devices distributed worldwide. Worldwide commercial adverse event data represent all events reported to Gore from May 15, 2016 to May 15, 2017. During this time, we received reports of 23 ruptures, 118 aneurysm enlargements, 39 conversions, 36 post-treatment migrations, 26 aneurysm-related deaths, 12 infections, 16 occlusions, 4 device infolding, and 1 device integrity observation. Data from the clinical trial studies along with results from worldwide commercial experience continue to confirm that the GORE® EXCLUDER® Device is a safe and effective therapy option in the treatment of AAAs.

The data included within this annual clinical update reaffirm that we are committed to providing access to clinical results and data from our worldwide experience to assist you in making informed treatment decisions for your patients diagnosed with AAAs.

Introduction

Since the introduction of the GORE® EXCLUDER® Device, the Medical Products Division of W. L. Gore & Associates, Inc., (Gore) has demonstrated its commitment to keeping physicians up-to-date regarding product performance data. We are pleased to provide you with our latest GORE® EXCLUDER® Device annual clinical update. This update summarizes five years of clinical study data and 20 years of reported adverse event data from worldwide commercial experience with the GORE® EXCLUDER® Device. The data will assist you in making informed treatment decisions for your patients diagnosed with infrarenal abdominal aortic aneurysms (AAAs). Five-year prospective, controlled clinical data and 20 years of worldwide commercial experience continue to support the safety and efficacy of treatment of abdominal aortic aneurysms with the GORE® EXCLUDER® Device. This report is divided into five primary sections:

- Section I summarizes the five-year clinical study data from the combined IDE cohort. This is a comprehensive group of all patients enrolled under two Phase II clinical study protocols: 98-03 evaluating the Original GORE® EXCLUDER® Device and 99-04 evaluating the Modified GORE® EXCLUDER® Device. Section I also contains data on the Low Permeability GORE® EXCLUDER® Device in the 04-04 post-approval clinical study. The Low Permeability GORE® EXCLUDER® Device is the only available design.
- Section II provides an update of worldwide commercial adverse events that have been reported to Gore throughout the past year from May 15, 2016 to May 15, 2017. This section includes information on aneurysm-related death, post-procedure aneurysm rupture, aneurysm enlargement, conversion, migration, device occlusion, infection, and infolding.
- Section III provides an analysis of all explanted devices returned to Gore from May 15, 2016 to May 15, 2017. Primary cause of explant and device durability data are reported.
- Section IV contains summary comments from the clinical study data as well as the worldwide experience with the GORE® EXCLUDER® Device
- Section V details patient selection and follow-up guidelines for commercial use of the GORE® EXCLUDER® Device

† Data contained in this document is current through May 15, 2017, unless otherwise noted. All Adverse Event definitions follow those used in Gore's clinical study protocols.

Device description

The GORE® EXCLUDER® Device is comprised of an implantable endoprosthesis which consists of four modular components and a delivery system. The two primary components are the Trunk-Ipsilateral Leg Endoprosthesis and the Contralateral Leg Endoprosthesis. There are two ancillary components, the Aortic Extender Endoprosthesis and the Iliac Extender Endoprosthesis. The Aortic Extender provides an extension component for additional fixation and / or sealing to the proximal edge of the Trunk-Ipsilateral Leg component. The Iliac Extender provides an extension component for additional fixation and / or sealing to the distal edge of the Ipsilateral Leg, Contralateral Leg, or previously placed distal component.

The graft material is expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene (FEP), and is attached to and supported by nitinol wire along its external surface. Nitinol anchors and an ePTFE / FEP sealing cuff are located at the proximal (aortic) end of the Trunk-Ipsilateral Leg component. An ePTFE / FEP sleeve is attached to the endoprosthesis and is used to constrain the endoprosthesis on the leading end of the delivery catheter. Radiopaque markers are attached to the stent graft and catheter (delivery system) to facilitate fluoroscopic visualization and orientation. Deployment of each component is achieved by pulling a deployment line that releases the sleeve and allows the stent graft to self-expand in vivo.

The GORE® C3® Delivery System received CE Mark approval in August 2010 and FDA approval in December 2010. While no changes were made to the GORE® EXCLUDER® Device, the GORE® C3® Delivery System provides the clinician with the ability to reposition the GORE® EXCLUDER® Device prior to final release from the delivery catheter. The modified delivery catheter for the Trunk-Ipsilateral Leg is designed to enable partial deployment of the trunk and contralateral leg-hole with the capability to constrain the anchors and position the device prior to full deployment. This brief description of the device and its construction will facilitate interpretation of the clinical results in this report.

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Section I – Clinical experience

Description of the U.S. clinical studies

The Original GORE® EXCLUDER® Device was released in Europe in September 1997. Based upon the one-year follow-up data from a Phase II Pivotal Study conducted in the U.S. (98-03), this device was approved for commercial distribution in the U.S. in November 2002. During the 98-03 clinical study, three modifications to the Original GORE® EXCLUDER® Device were made. Changes included modifications for continuous wire diameters, standardizing anchor cut angles, and a change to the width and location of the proximal sealing cuff. In addition to these changes, new Trunk-Ipsilateral Leg components were offered in shorter lengths. These changes did not affect the delivery system or operation of the Modified GORE® EXCLUDER® Device compared to the Original GORE® EXCLUDER® Device.

The Modified GORE® EXCLUDER® Device was released to the rest of the world in July 2002 and was approved for commercial distribution in the U.S. in February 2004 based upon one-year follow-up data from a second Phase II Pivotal Study (99-04). Results demonstrated that there are no differences in clinical performance between the Original and Modified GORE® EXCLUDER® Devices.

Clinical results for pivotal studies on the Original GORE® EXCLUDER® Device (98-03) and the Modified GORE® EXCLUDER® Device (99-04) on the treatment of patients for AAAs are pooled and reported as the combined IDE cohort for this annual update. For full details of clinical studies 98-03 and 99-04, reference the GORE® EXCLUDER® Device *Instructions for Use* (IFU). This represents the largest collection of prospective, controlled, clinical data for the GORE® EXCLUDER® Device.

In June 2004, a design enhancement was made to the GORE® EXCLUDER® Device in response to aneurysm enlargement concerns. This new device, the Low Permeability GORE® EXCLUDER® Device, differs from the Original and Modified GORE® EXCLUDER® Device designs by the addition of an interior layer that decreases the overall graft permeability. The luminal and abluminal ePTFE surface materials, microstructure, and characteristics of the Low Permeability GORE® EXCLUDER® Device are equivalent to the Original and Modified GORE® EXCLUDER® Devices. The Low Permeability GORE® EXCLUDER® Device was designed to provide equivalent performance while minimizing the potential for serous fluid migration through the graft material. In June 2004, the Low Permeability GORE® EXCLUDER® Device was approved by the FDA and released worldwide. **The Low Permeability GORE® EXCLUDER® Device is the only available design.**

A post-approval clinical study (04-04) was conducted to evaluate the clinical performance of the Low Permeability GORE® EXCLUDER® Device. The study is complete and summarized data from this study are presented in this annual clinical update. For full details of clinical study 04-04, reference the GORE® EXCLUDER® Device IFU. The GORE® EXCLUDER® Device product line includes 31 mm Trunk-Ipsilateral Leg and 32 mm Aortic Extender sizes to treat patients with larger proximal aortic neck diameters. The larger size GORE® EXCLUDER® Devices were approved by the FDA in March 2009.

This section of the GORE® EXCLUDER® AAA Endoprosthesis annual clinical update will provide an overview of the results from the clinical studies discussed above.

Pivotal study Original GORE® EXCLUDER® Device (98-03)

This U.S. Phase II Pivotal Study was designed to evaluate the safety and efficacy of the Original GORE® EXCLUDER® AAA Endoprosthesis. This multicenter (19 sites), non-randomized, prospective, controlled trial compared standard open surgical repair (Control, n = 99) to endovascular treatment with the GORE® EXCLUDER® Device (Test, n = 235) in the treatment of AAAs. An additional 49 Test patients were enrolled under the continued access protocol. Primary study endpoints were a comparison of major adverse event (MAE) rates between the Test and Control groups, and the assessment of aneurysm exclusion and major device events through one-year post-treatment. Patients were enrolled into the 98-03 study from December 1998 to January 2000 and into the continued access study between November 1999 and April 2000. All Test and Control patients were followed through five-years post-treatment. All 98-03 patients have completed five-year follow-up; this study has been closed. The 98-03 data included in the combined IDE cohort for this report represent the final study data. For full details of clinical study 98-03, reference the GORE® EXCLUDER® Device IFU.

Pivotal study Modified GORE® EXCLUDER® Device (99-04)

The 99-04 clinical study was initiated to evaluate the Modified GORE® EXCLUDER® Device. The primary objectives of the study were to compare the safety of the Modified GORE® EXCLUDER® Device to open surgical repair and to evaluate the effectiveness compared to the Original GORE® EXCLUDER® Device in the treatment of AAAs. A total of 193 Test patients were enrolled in the study from April 2000 to April 2001.

A total of 88 additional Test patients were enrolled from January 2001 to November 2002 under the continued access protocol. All patients were followed through five-year follow-up; this study has been closed. The 99-04 data included in the combined IDE cohort for this report represent the final study data. For full details of clinical study 99-04, reference the GORE® EXCLUDER® Device IFU.

Combined IDE cohort

Test patient data from the 98-03 (n = 235), 98-03 continued access (n = 49), 99-04 (n = 193), and 99-04 continued access (n = 88) were combined and reported as a single group. These 565 patients are collectively referred to as the combined IDE cohort. Pooling of data from 98-03 and 99-04 is justified based on the following conclusions from a propensity score analysis[2]:

- No overall difference in survival was detected between the studies when controlling for propensity score quintiles
- No overall difference in major adverse events (MAE) was detected between the studies when controlling for propensity score quintiles
- No overall difference in major device events (MDE) (either total MDE, major endoleaks, or aneurysm increase with intervention) was detected between the studies when controlling for propensity score quintiles

Detailed information and data regarding the Original GORE® EXCLUDER® Device (98-03), Modified GORE® EXCLUDER® Device (99-04), and Combined IDE Cohort clinical studies can be found in the GORE® EXCLUDER® AAA Endoprosthesis IFU. The GORE® EXCLUDER® AAA Endoprosthesis IFU is available on goremedical.com.

Throughout the entire five-year follow-up period, the combined IDE cohort patients showed greater freedom from major adverse events compared with the 98-03 Control patients. Through five years, freedom from major adverse events was 39% for the patients treated with the GORE® EXCLUDER® Device as part of the combined IDE cohort as compared to 15% for the 98-03 Control patients. These data reaffirm the safety of the GORE® EXCLUDER® Device over open surgical repair for the treatment of AAAs. A summary of the major device events through five years for the combined IDE cohort included 0.2% post-procedure ruptures, 3.4% surgical conversions, 1.8% aneurysm-related deaths, 0.7% post-procedure migration, and 5.1% aneurysm enlargement with reintervention. Most endoleaks reported were Type II. Endoleaks requiring reintervention were reported in only 1–4% of patients during each follow-up interval through five years.

Post-approval study Low Permeability GORE® EXCLUDER® Device (04-04)

The 04-04 post approval clinical study was initiated to assess aneurysm morphology changes through a two-year follow-up in patients treated with the Low Permeability GORE® EXCLUDER® Device in the treatment of AAAs. This study completed enrollment of 139 prospective and retrospective Test patients at eight sites in August 2006. Controls in the study are 120 randomly selected patients treated with the Original GORE® EXCLUDER® Device in the 98-03 clinical study. Two-year follow-up for the study was completed in February 2009 and study was closed in May 2009. Final two-year follow-up results comparing

[1] All GORE® EXCLUDER® Device clinical studies reported in this update have completed the protocol required follow-up and this information is unchanged from the previous clinical update.
[2] Rosenbaum PR, Rubin DB. Reducing bias in observational studies using subclassification on the propensity score. *Journal of the American Statistical Association* 1984;79(387):516-524.

the aneurysm morphology of the Test patients treated with the Low Permeability GORE® EXCLUDER® Device to the Control patients treated with the Original GORE® EXCLUDER® Device are shown in this report.

Patient visit compliance for the Test group was 96% at one month, 85% at six months, 95% at one year, and 98% at two years. Imaging compliance for these patients was 94% at one month, 82% at six months, 94% at one year, and 93% at two years. Seven patients in the 04-04 study died. Causes of death included two cases of myocardial infarction, one case of lung cancer, one case of esophageal cancer, two cases of pneumonia, and one case of abdominal sepsis / bowel perforation.

One explant was performed four-months post-treatment on a 04-04 Test patient as a result of an infected device in the presence of a mycotic aneurysm; this patient was successfully converted to open surgical repair. Explant analysis of the device showed no device integrity issues.

Patients in the 04-04 study were compared to 120 randomly selected patients treated with the Original GORE® EXCLUDER® Device in the 98-03 clinical study. Analyses of the pre-treatment characteristics for both groups show a balanced population. The incidence of major device events, including reintervention, migration, and patency through two-year post-treatment were similar for both groups. However, the incidence of minor Type II endoleaks (endoleaks requiring no reintervention) is higher for the Test group. We believe that this difference is a result of an improvement in imaging quality over time and not a clinically significant finding.

31 mm GORE® EXCLUDER® Device Study (03-02)

The GORE® EXCLUDER® Device product line includes a 31 mm Trunk-Ipsilateral Leg and 32 mm Aortic Extender to treat patients with larger proximal aortic neck diameters. The 03-02 study was initiated to evaluate the 31 mm GORE® EXCLUDER® Device compared to open surgical repair and to compare device performance to the Original GORE® EXCLUDER® Device in the treatment of AAAs with large proximal neck diameters. Enrollment of Test patients into this study was completed in January 2008 with a total of 35 patients enrolled. The larger size GORE® EXCLUDER® Devices were approved by the FDA in March 2009. Complete five-year follow-up data suggest that the treatment of infrarenal AAA with the 31 mm GORE® EXCLUDER® Device is a safe alternative to open surgical repair. The data support the conclusion that the efficacy of the 31 mm GORE® EXCLUDER® AAA Device is comparable to that of the smaller diameter sizes of the GORE® EXCLUDER® AAA Device.

[1] All GORE® EXCLUDER® Device clinical studies reported in this update have completed the protocol required follow-up and this information is unchanged from the previous clinical update.

Final data on aneurysm diameter and volume demonstrate that aneurysm enlargement is seen less in patients treated with the Low Permeability GORE® EXCLUDER® Device when compared to those treated with the Original GORE® EXCLUDER® Device (Control group). Table 1 shows an overview of preliminary aneurysm diameter data, while aneurysm volume change data is presented in **Table 2**. Both of these measures show similar trends. Of the patients that showed aneurysm volume increase ≥ 5% at the two-year follow-up visit, 53% (25 / 47) of the Control group and 0% (0 / 17) of the Test group had enlargement without a reported Type II endoleak during the 04-04 study. Type II endoleaks are a result of patient anatomy and are not indicative of device failure.

Table 1: Summary of the proportion of patients with aneurysm diameter increase ≥ 5 mm by study visit

	6 Months		1 Year		2 Years	
	Test	Control	Test	Control	Test	Control
Number of patients enrolled	139	120	139	120	139	120
Patients with available data[a]	103	88	114	94	104	100
≥ 5 mm decrease	25 (24.3%)	11 (12.5%)	45 (39.5%)	15 (16.0%)	51 (49.0%)	21 (21.0%)
No change	76 (73.8%)	75 (85.2%)	69 (60.5%)	76 (80.9%)	50 (48.1%)	60 (60.0%)
≥ 5 mm increase	2 (1.9%)	2 (2.3%)	0	3 (3.2%)	3 (2.9%)	19 (19.0%)

[a] Patients are considered to be available for evaluation if they had both a baseline (one month) and post-baseline measurement.

Table 2: Summary of the proportion of patients with aneurysm volume change ≥ 5% by study visit

	6 Months		1 Year		2 Years	
	Test	Control	Test	Control	Test	Control
Number of patients enrolled	139	120	139	120	139	120
Patients with available data[a]	102	86	112	92	104	101
≥ 5% decrease[b]	67 (65.7%)	34 (39.5%)	77 (68.8%)	35 (38.0%)	72 (69.2%)	31 (30.7%)
No change[b]	29 (28.4%)	32 (37.2%)	26 (23.2%)	26 (28.3%)	15 (14.4%)	23 (22.8%)
≥ 5% increase[b]	6 (5.9%)	20 (23.3%)	9 (8.0%)	31 (33.7%)	17 (16.3%)	47 (46.5%)

[a] Patients are considered to be available for evaluation if they had both a baseline (one month) and post-baseline measurement.
[b] Overall volume increase is computed as follows: if either distal renal to aortic bifurcation or right hypogastric to aortic bifurcation volume measurement increases ≥ 5% then the patient is considered an increaser. If either measure decreases ≥ 5% then the patient is considered a decreaser. Other non-missing combinations are considered no change.

Section II – Worldwide commercial experience

Summary of adverse events

From September 1997 through May 15, 2017 more than 297,000 GORE® EXCLUDER® Devices have been distributed. This includes more than 16,000 Original and Modified GORE® EXCLUDER® Devices and more than 281,000 Low Permeability GORE® EXCLUDER® Devices. Of these, more than 140,500 were deployed using the GORE® C3® Delivery System. The data presented in **Table 3** summarize adverse events from worldwide commercial experience that occurred in the past year from May 15, 2016 to May 15, 2017. From May 15, 2016 to May 15, 2017, more than 28,500 GORE® EXCLUDER® Devices have been distributed. The worldwide commercial experience has remained consistent with the acceptable performance exhibited in previous years. The new data reported in this clinical update is comparable to the previous year. Adverse event rates presented in **Table 3** are similar or lower than that reported in prior annual clinical updates. Each reported adverse event is not mutually exclusive and may contain multiple adverse events. The data outlined in this clinical update reflect adverse events on an interconnected basis, and each section may include and refer to events from another section.

Aneurysm-related death

A total of 26 aneurysm-related deaths have been reported worldwide in patients treated with the GORE® EXCLUDER® Device within the past year from May 15, 2016 to May 15, 2017. Causes of aneurysm-related deaths are shown in **Table 4**.

Procedure-related complications was the leading cause of aneurysm-related death. Procedure-related complications include one non-aneurysm aortic ruptures due to ballooning in the proximal aortic neck and one non-aneurysm iliac rupture at the access site. Other less frequent procedure-related complications include embolic events, cardiac events, respiratory events, aortic dissection, aortic perforation, and ischemic events.

Evaluation of reported aneurysm-related deaths did not identify device malfunctions that subsequently led to death.

Table 3: Summary of GORE® EXCLUDER® Device worldwide performance

Aneurysm-related death[a]	26
Post-procedure aneurysm rupture	23
Aneurysm enlargement[b]	118
Conversion	39
Migration[c]	36
Device occlusion	16
Infection	12
Infolding	4

[a] Aneurysm-related deaths are defined as any deaths within 30 days or due to aneurysm rupture, a primary or secondary procedure, or surgical conversion[1].
[b] Aneurysm enlargement in this table is defined as any reported enlarging aneurysm with and without endoleak.
[c] During commercial use, migration is defined as any report of post-procedure device movement.

Table 4: Aneurysm-related death[a]

Procedure-related	**10**
Non-aneurysm aortic ruptures	1
Non-aneurysm iliac ruptures	1
Other complications	8
Comorbidity[b]	**4**
Aneurysm rupture	**6**
Endoleak	3
Indeterminate	3
Occlusion	**0**
Infection	**1**
Indeterminate	**5**
Total	**26**

[a] Aneurysm-related deaths are defined as any deaths within 30 days or due to aneurysm rupture, a primary or secondary procedure, or surgical conversion[1].
[b] Aneurysm-related death attributed to comorbidity is defined here as death that occurs within 30 days of a primary or secondary procedure; such death cannot be linked directly to the use of the device, but may be related to complications arising from the procedure.

[1] Chaikof EL, Blankensteijn JD, Harris PL, *et al*; Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of The Society for Vascular Surgery/American Association for Vascular Surgery. Reporting standards for endovascular aortic aneurysm repair. *Journal of Vascular Surgery* 2002;35(5):1048-1060.

Post-procedure aneurysm rupture

There have been 23 commercial post-procedure aneurysm ruptures reported among patients treated with the GORE® EXCLUDER® Device within the past year from May 15, 2016 to May 15, 2017. Post-procedure aneurysm rupture causes are shown in **Table 5**.

The primary cause of aneurysm rupture in patients treated with the GORE® EXCLUDER® Device is aneurysm enlargement with endoleak. It is necessary to monitor patients presenting with endoleak, regardless of endoleak type.

Two of the reported aneurysm ruptures were due to aneurysm enlargement in the absence of endoleak, seven were related to balloon inflation events, and three occurred during off label use of components.

Aneurysm enlargement

Aneurysm enlargement, defined as enlargement ≥ 5 mm with and without endoleak, has been reported in a total of 118 patients treated worldwide within the past year with the GORE® EXCLUDER® Device from May 15, 2016 to May 15, 2017, as shown in **Table 6**.

The Original GORE® EXCLUDER® Device was implanted in two of these patients. Of these patients, one report was attributed to aneurysm enlargement without endoleak, and one report was indeterminate.

Table 5: Post-procedure aneurysm rupture

Aneurysm rupture due to aneurysm enlargement with endoleak	**6**
Type I	5
Type II	0
Type III	0
Unspecified	1
Aneurysm rupture due to aneurysm enlargement without endoleak	**2**
Migration	**0**
Other[a]	**13**
Indeterminate	**2**
Total	**23**

[a] Other less-frequent events that have contributed to post-procedure aneurysm rupture include post-procedure conversion and the disease state of the patient's aorta.

There have been 105 reports of aneurysm enlargement with the Low Permeability GORE® EXCLUDER® Device associated with an endoleak. There was not sufficient information to identify the exact cause for aneurysm enlargement in the indeterminate category. Additionally, there was not sufficient information to identify to the exact type of endoleak with the information provided.

Table 6: Aneurysm enlargement

	Original GORE® EXCLUDER® Device	Low Permeability GORE® EXCLUDER® Device	Total
With endoleak	0	105	**105**
Without endoleak	1	1	**2**
Indeterminate	1	10	**11**
Total	**2**	**116**	**118**

Section II – Worldwide commercial experience

Conversion

Conversion to open surgical repair has been reported in 39 patients treated with the GORE® EXCLUDER® Device worldwide within the past year from May 15, 2016 to May 15, 2017.

The most common contributing factors to these reported conversions are shown in **Table 7**.

The primary causes for conversion were aneurysm enlargement with endoleak and infection. Of the conversions that were attributed to aneurysm enlargement with endoleak, six had a Type II endoleak identified, and seven had a Type I endoleak identified.

Migration

During commercial use of the GORE® EXCLUDER® Device, migration is defined as any report of post-procedure device movement. There were 36 commercial post-procedure migrations reported to Gore within the past year from May 15, 2016 to May 15, 2017 (**Table 3**). These migrations include reports of 26 migrations of the Trunk-Ipsilateral Leg Endoprosthesis, 7 migrations of the Contralateral Leg Endoprosthesis, and 3 migrations of extender components. A total of 14 of the migrations were reported to be associated with aneurysmal disease progression. It is known that pre-case planning which includes appropriate patient anatomical measurements and device selection within the IFU will minimize migration events. The low number of migrations reported during worldwide use of the GORE® EXCLUDER® Device reflects the low rate of migration experience in the GORE® EXCLUDER® Device clinical studies.

Device Occlusion

There were 16 occlusions reported in patients treated with the GORE® EXCLUDER® Device worldwide within the past year from May 15, 2016 to May 15, 2017 (**Table 3**). In the majority of these reports, the occlusions occurred shortly after the initial treatment. In many of these cases, the patient had narrow, tortuous iliac arteries associated with calcification and thrombus. There were no reported incidents of a kink associated with the GORE® EXCLUDER® Device.

The low number of occlusions reported during worldwide use of the GORE® EXCLUDER® Device reflects the low occlusion and high patency rates observed during the GORE® EXCLUDER® Device clinical studies.

Table 7: Conversion

Aneurysm rupture post-procedure	**0**
Aneurysm enlargement with endoleak	**12**
Aneurysm enlargement without endoleak	**0**
Endoleak	**1**
Implantation difficulties[a]	**3**
Non-aneurysm aortic rupture	0
Non-aneurysm iliac rupture	1
Access complications	0
Positioning complications[b]	2
Deployment complications	0
Cannulation difficulties	0
Aortoenteric fistula	**2**
Infection	**11**
Unsuitable anatomy	**6**
Other	**4**
Total	**39**

[a] Any problems associated with implantation of any component during the procedure.
[b] Of the positioning difficulties listed, one event was associated with the GORE® EXCLUDER® Device featuring C3® Delivery System.

Infection

There were 12 reported infections in patients treated with the GORE® EXCLUDER® Device worldwide within the past year from May 15, 2016 to May 15, 2017 (**Table 3**). None of the device infections was due to aortoenteric fistula. In seven cases, the exact cause of infection was unclear. The remaining five cases had a documented history of infection prior to the date of implantation. The low number of infections reported during worldwide use of the GORE® EXCLUDER® Device reflects the low infection rates observed in the GORE® EXCLUDER® Device clinical studies.

Device Infolding

There were 4 reported infolding events of the GORE® EXCLUDER® Device worldwide within the past year from May 15, 2016 to May 15, 2017 (**Table 3**). All 4 were cases of proximal Trunk infolding. Typically, infolding is resolved by ballooning or placing an additional stent or stent graft. Device infolding can be avoided through proper pre-procedure case planning and device selection, and ballooning the device post-implantation. According to the GORE® EXCLUDER® Device IFU, the device should be oversized 10–21% based on aortic inner diameter and 7–25% based on iliac inner diameter.

Section III – Explant analysis and device durability

Explant analysis

There were a total of 5 cases of GORE® EXCLUDER® Devices explanted and returned to Gore from worldwide commercial experience within the past year from May 15, 2016 to May 15, 2017 (Table 8). Gore has collected these devices for evaluation of evidence of biologic response, material integrity, and overall device durability. Cumulative worldwide commercial data analyzing primary cause of explant from September 1997 to May 15, 2017 can also be found in Table 8. The numbers presented below represent worldwide commercial data from May 15, 2016 to May 15, 2017. Cumulative worldwide commercial data from September 1997 to May 15, 2017 is also provided in parentheses.

Primary cause of explant

There have been no Low Permeability GORE® EXCLUDER® Devices explanted due to aneurysm enlargement without endoleak. The primary causes of explant for the Low Permeability devices were infection and aneurysm enlargement with endoleak.

Table 8: Primary cause of explant

	Number of occurrences		
Reason for explant	**Original GORE® EXCLUDER® Device**	**Low Permeability GORE® EXCLUDER® Device**	**Total**
Implantation difficulties	0 (1)	6 (28)	**6 (29)**
Rupture	0 (5)	0 (11)	**0 (16)**
Aneurysm enlargement without endoleak	0 (21)	0 (0)	**0 (21)**
Aneurysm enlargement with endoleak	0 (11)	9 (57)	**9 (68)**
Endoleak	0 (2)	2 (14)	**2 (16)**
Migration	0 (1)	2 (11)	**2 (12)**
Infection	0 (0)	10 (26)	**10 (26)**
Aortoenteric fistula	0 (1)	3 (6)	**3 (7)**
Occlusion	0 (1)	2 (4)	**2 (5)**
Incidental autopsy	0 (1)	1 (1)	**1 (2)**
Other	0 (0)	2 (9)	**2 (9)**
Total cases	**0 (44)**	**37 (167)**	**37 (211)**

Section III – Explant analysis and device durability

Explant analysis and device durability — Device integrity observations

No Original GORE® EXCLUDER® Devices were explanted within the past year from May 15, 2016 to May 15, 2017. One Low Permeability GORE® EXCLUDER® Device was explanted within the past year from May 15, 2016 to May 15, 2017 and has been identified with a device integrity observation as shown in **Table 9**. Cumulative worldwide commercial data analyzing device integrity observations during explant analysis from September 1997 to May 15, 2017 can also be found in Table 9. These numbers represent worldwide commercial data from May 15, 2016 to May 15, 2017. Cumulative worldwide commercial data from September 1997 to May 15, 2017 is also provided in parentheses.

In the one event mentioned above, the device integrity event identified during explant analysis did not cause adverse events and was not the cause of explant.

Table 9: Device integrity observations during explant analysis

	Number of occurrences		
Observation	**Original GORE® EXCLUDER® Device**	**Low Permeability GORE® EXCLUDER® Device**	**Total**
Fracture only	0 (9)	0 (8)	**0 (17)**
ePTFE abrasion holes only	0 (3)	1 (7)	**1 (10)**
Fracture and ePTFE abrasion holes	0 (0)	0 (4)	**0 (4)**
No device integrity observations	0 (32)	36 (148)	**36 (180)**
Total cases	**0 (44)**	**37 (167)**	**37 (211)**

Section IV – Summary and conclusions

Overview

There have been more than 297,000 devices distributed worldwide, beginning in September 1997 through May 15, 2017. This includes more than 16,000 Original and Modified GORE® EXCLUDER® Devices and more than 281,000 Low Permeability GORE® EXCLUDER® Devices, of which, more than 140,500 were deployed using the GORE® C3® Delivery System. Five-year prospective, controlled clinical data and 20 years of worldwide commercial experience continue to support the safety and efficacy of treatment of abdominal aortic aneurysms with the GORE® EXCLUDER® Device.

Summary of clinical experience

Long-term durability and clinical data presented in this report indicate that the GORE® EXCLUDER® Device remains a safe and effective therapy option in the treatment of patients diagnosed with infrarenal AAAs. At five years, freedom from major adverse events was 39% for the patients treated with the GORE® EXCLUDER® Device as part of the combined IDE cohort as compared to 15% for the 98-03 Control patients.

The following is an overall summary of the Adverse Events data for the combined IDE cohort:

- 0.2% Post-procedure ruptures
- 3.4% Surgical conversions
- 1.8% Aneurysm-related deaths
- 0.7% Post-procedure migration
- 5.1% Aneurysm enlargement with reintervention

Most endoleaks reported were Type II. Endoleaks requiring reintervention were reported in only 1–4% of patients during each follow-up interval through five years.

The observations associated with aneurysm enlargement in the 98-03 Phase II Clinical Study prompted a design enhancement to the Original GORE® EXCLUDER® Device in June 2004. The modifications incorporated a low permeability interior layer while maintaining the same luminal and abluminal stent graft surfaces. A post-approval clinical study was conducted to evaluate aneurysm morphology with the Low Permeability GORE® EXCLUDER® Device. Final data demonstrate a lower incidence of aneurysm enlargement in patients treated with the Low Permeability GORE® EXCLUDER® Device when compared to patients treated with the Original GORE® EXCLUDER® Device.

The modifications made in the Low Permeability GORE® EXCLUDER® Device demonstrate our commitment to improving patient outcomes in the treatment of AAA disease.

Summary of worldwide commercial experience

From the reported worldwide commercial experience through May 15, 2017, the following adverse events have been reported to Gore:

- 428 Aneurysm-related deaths
- 174 Post-procedure ruptures
- 1,284 Aneurysm enlargements
- 873 Surgical conversions
- 280 Post-procedure migrations
- 195 Device occlusions
- 198 Infections
- 123 Infolding events
- 31 Device integrity observations

The reported adverse events above are not mutually exclusive. Each report may appear under multiple event types (e.g., a single report may be counted toward both the Aneurysm Enlargement category and the Surgical Conversions category as long as that report illustrates both adverse events).

Conclusions

The combined IDE cohort represents the largest prospective, controlled clinical trial data set available for the GORE® EXCLUDER® Device. Worldwide commercial adverse events support the low adverse events identified in the GORE® EXCLUDER® Device clinical trial data. In addition, the 04-04 post-approval clinical study and peer-reviewed publications provide supporting evidence for improved performance with the Low Permeability GORE® EXCLUDER® Device over the Original GORE® EXCLUDER® Device in the treatment of AAA disease. The GORE® EXCLUDER® Device continues to show acceptable durability. The GORE® EXCLUDER® Device remains a safe and effective device for the treatment of AAA disease.

Section V – Patient selection and follow-up

Regular follow-up of all patients treated with this device is required. Worldwide commercial experience and clinical data demonstrate that some adverse events may become apparent over time. As stated in the IFU, regular and consistent follow-up is a critical part of ensuring continuing safety and efficacy of aortic endovascular repair. Patients with specific clinical findings such as endoleak and / or aneurysm enlargement should receive enhanced follow-up. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient.

As outlined in the IFU, critical factors for successful clinical outcomes include:

- Appropriate patient selection, including:
  - adequate iliac / femoral access
  - infrarenal aortic neck treatment diameter range of 19–32 mm and a minimum neck length of 15 mm
  - proximal aortic neck angulation ≤ 60°
  - iliac artery treatment diameter range of 8–25 mm and iliac distal vessel seal zone length of at least 10 mm
- Device selection in accordance with the IFU
- Device deployment in accordance with the IFU
- Appropriate and timely patient follow-up

Adverse event reporting

Any adverse event involving the GORE® EXCLUDER® Device should be reported to Gore immediately. To report an event in the U.S., call 800.437.8181. Outside the U.S., contact your local Gore technical associate.

INDICATIONS FOR USE IN THE US

The GORE® EXCLUDER® Device 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 19–32 mm and a minimum aortic neck length of 15 mm; proximal aortic neck angulation ≤ 60°; iliac artery treatment diameter range of 8–25 mm and iliac distal vessel seal zone length of at least 10 mm. The Aortic and Iliac Extender Endoprostheses are intended to be used after deployment of the GORE® EXCLUDER® AAA Endoprosthesis. These extensions are intended to be used when additional length and / or sealing for aneurysmal exclusion is desired.

CONTRAINDICATIONS

The GORE® EXCLUDER® AAA Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials; Patients with a systemic infection who may be at increased risk of endovascular graft infection.

WARNINGS AND PRECAUTIONS

Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient. The GORE® Medical Device is designed for single use only; do not reuse device. Gore does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death. The long-term performance of stent grafts has not been established. All patients should be advised this treatment modality requires long-term, regular follow-up to assess patients' health status and stent graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive enhanced follow-up (See IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP). The GORE® EXCLUDER® AAA Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program. The GORE® EXCLUDER® AAA Endoprosthesis is not recommended in patients unable to undergo, or who will not be compliant with the necessary pre and post-operative imaging and follow-up described in IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP. Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms and / or persistent endoleak. An increase in aneurysm size and / or persistent endoleak may lead to aneurysm rupture. Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

PATIENT SELECTION, TREATMENT AND FOLLOW-UP

The safety and effectiveness of the GORE® EXCLUDER® AAA Endoprosthesis have not been evaluated in the following patient populations: traumatic aortic injury; leaking: pending rupture or ruptured aneurysms; mycotic aneurysms; pseudoaneurysms resulting from previous graft placement; revision of previously placed stent grafts; genetic connective tissue disease (e.g., Marfans or Ehlers-Danlos Syndromes); concomitant thoracic aortic or thoracoabdominal aneurysms; inflammatory aneurysms; patients with active systemic infections; pregnant or nursing females; morbidly obese patients; patients less than 21 years old; patients with less than 15 mm in length or › 60° angulation of the proximal aortic neck. Ilio-femoral access vessel size and morphology (minimal thrombus, calcium and / or tortuosity) should be compatible with vascular access techniques and accessories of the delivery profile of a 12–18 Fr vascular introducer sheath. Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation, short proximal aortic neck and significant thrombus and / or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. The US clinical studies quantify significant thrombus as thrombus ≥ 2 mm in thickness and / or ≥ 25% of the vessel circumference in the intended seal zone of the aortic neck. Irregular calcium and / or plaque may compromise the fixation and sealing of the implantation sites. The GORE® EXCLUDER® AAA Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and post operative follow-up imaging. The GORE® EXCLUDER® AAA Endoprosthesis is not recommended in patients exceeding weight and / or size limits which compromise or prevent the necessary imaging requirements. The GORE® EXCLUDER® AAA Endoprosthesis is not recommended in patients with known sensitivities or allergies to ePTFE, FEP, nickel, or titanium.

POTENTIAL DEVICE OR PROCEDURE RELATED ADVERSE EVENTS

Adverse events that may occur and / or require intervention include, but are not limited to: amputation; 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; 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; neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis); occlusion of device or native vessel; pulmonary complications (e.g., pneumonia, respiratory failure); renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure); surgical conversion; wound (e.g., infection, dehiscence); vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture, death).

GORE® EXCLUDER® Iliac Branch Endoprosthesis
ANNUAL CLINICAL UPDATE†
OCTOBER 2018

GORE
Creative Technologies Worldwide

Abstract

This annual clinical update provides a review of the ongoing experience with the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) used in the treatment of common iliac or aortoiliac artery aneurysms. The IDE was approved on March 27, 2013, and FDA approval received on February 29, 2016. Detailed commercial experience over the past year is presented. Additionally, this document provides an update to IBE clinical study data. The IBE 12-04 clinical study data contain both unilateral and bilateral placement patients. Additionally, bilateral IBE placement data are reported alongside bilateral IBE subsets from the Global Registry for Endovascular Aortic Treatment (GREAT) and Iliac Branch Excluder Registry (IceBERG). This supplemental information is provided due to the limited placement of bilateral IBEs in 12-04. Follow-up data is presented up to 36 months.

Four years of commercial experience represent more than 5,000 IBEs distributed worldwide. Worldwide commercial adverse event data represent all events reported to Gore throughout the past year from May 15, 2016 to May 15, 2017. During this time, there have been no reported aneurysm-related deaths , post-procedure ruptures, , infections or device integrity observations, two aneurysm enlargements, four conversions to open repair, and ten device occlusions were reported.

The data included within this annual clinical update reaffirm that we are committed to providing access to clinical results and data from our worldwide experience to assist you in making informed treatment decisions for your patients diagnosed with common iliac or aortoiliac artery aneurysms.

Introduction

Since the introduction of the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), the Medical Products Division of W. L. Gore & Associates, Inc., (Gore) has demonstrated its commitment to keeping physicians up-to-date regarding product performance data. We are pleased to provide you with our latest IBE annual clinical update. This update summarizes additional clinical study data and reported adverse event data from worldwide commercial experience with the IBE. These data will assist you in making informed treatment decisions for your patients diagnosed with common iliac or aortoiliac artery aneurysms. Early clinical results and four years of worldwide commercial experience support the safety and effectiveness of treatment of common iliac or aortoiliac artery aneurysms with the IBE. This report is divided into five primary sections:

- Section I summarizes an update to the clinical study data for IBE. Clinical data is presented for patients receiving either unilateral or bilateral IBE placement. Unilateral IBE placement clinical data is presented from 12-04 clinical study, and bilateral IBE placement clinical data is presented from 12-04 clinical study, GREAT Registry data, and IceBERG registry data. Follow-up data is presented up to 36 months after the initial procedure.
- Section II provides an update of worldwide commercial adverse events reported to Gore from May 15, 2016 to May 15, 2017. This section includes information on aneurysm-related death, post-procedure aneurysm rupture, aneurysm enlargement, conversion, and device occlusion.
- Section III provides an analysis of all explanted devices returned to Gore from May 15, 2016 to May 15, 2017
- Section IV contains summary comments from the clinical study data, as well as the worldwide experience with the GORE® EXCLUDER® Iliac Branch Endoprosthesis
- Section V details patient selection and follow-up guidelines for commercial use of the GORE® EXCLUDER® Iliac Branch Endoprosthesis

† Data contained in this document is current through May 15, 2017, unless otherwise noted. All Adverse Event definitions follow those used in Gore's clinical study protocols.

Device description

The IBE 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 aortoiliac artery aneurysms (AIA).

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

The IBE is composed of the same materials as the GORE® EXCLUDER® AAA Endoprosthesis. The graft material is expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene (FEP), and is attached to, and supported by, nitinol wire along its external surface. An ePTFE / FEP sleeve is attached to the endoprosthesis and is used to constrain the endoprosthesis on the leading end of the delivery catheters. Radiopaque markers are attached to the stent graft and catheter (delivery system) to facilitate fluoroscopic visualization and orientation. Deployment of each endoprosthesis component is achieved by pulling a deployment line that releases the sleeve and allows the stent graft to self-expand in vivo. This brief description of the device and its construction will facilitate interpretation of the clinical results in this report.

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Section I – Clinical experience

Description of clinical studies

This section summarizes an update to currently available IBE clinical data. This clinical data is separated into two subsections: Patients in the IBE 12-04 study and patients from the three data sources (Continued Access of the 12-04 clinical study, GREAT data, and IceBERG data).

Sixty-five patients were enrolled at 28 investigational sites in Primary Enrollment, and 63 of these patients received IBE. All patients receiving IBE in Primary Enrollment underwent unilateral IBE placement. Thirty-five patients were enrolled at 20 sites for the Continued Access cohort. Thirty-one of these patients underwent unilateral IBE placement and four patients received bilateral placement.

In order to supplement the information about bilateral IBE placement, the subset of registry patients who received bilateral IBE are provided from GREAT (n = 14 bilateral) and IceBERG (n = 19 bilateral) are shown alongside bilateral placement patients from 12-04 (n = 4 bilateral).

Description of GORE® EXCLUDER® Iliac Branch Endoprosthesis for the treatment of common iliac artery aneurysms or aortoiliac aneurysms (IBE 12-04)

The evaluation of the GORE® EXCLUDER® Iliac Branch Endoprosthesis for the Treatment of Common Iliac Artery Aneurysms or Aortoiliac Aneurysms clinical study (IDE G130038; NCT 01883999) is a prospective, nonrandomized, multicenter, single-arm evaluation study to assess the safety and effectiveness of the GORE® EXCLUDER® Iliac Branch Endoprosthesis for treatment of patients with common iliac artery aneurysms (CIAA) or aortoiliac aneurysms (AIA). The IBE received FDA approval in February 2016 and has been marketed commercially in the U.S. since.

The IBE 12-04 study is a multicenter study with a maximum of up to 50 sites and up to 200 patients treated with the IBE (minimum of 60 patients in the IBE 12-04 Primary Enrollment and up to 140 Continued Access patients). Enrollment began in October 2013 and closed in April 2016. As of this report, there are 33 active sites.

Sixty-five patients were enrolled at 28 investigational sites in Primary Enrollment. With the protocol amendment 2, the study began enrollment in a Continued Access portion of the study. Thirty-five patients were enrolled at 20 sites for the Continued Access cohort. A total of 94 patients underwent unilateral IBE placement, and four patients underwent bilateral IBE placement. Two patients withdrew prior to the IBE procedure.

The IBE 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

Patients were classified as presenting with unilateral or bilateral common iliac aneurysm disease. Patients with aneurysmal disease involving both iliac arteries could be treated with IBE. For Primary Enrollment of the study, only one of the iliac arteries could be treated with IBE. The internal iliac artery on the opposite side could be managed with coil embolization or surgical revascularization of the artery. Placement of the IBE 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. For Continued Access of this study, patients were eligible to receive bilateral placement of the IBE if they presented with appropriate anatomy and met all other inclusion and exclusion criteria.

IBE 12-04 Clinical Study

Results for the IBE 12-04 Primary Enrollment and Continued Access patients through five years of implantation will be presented as they become available. Primary Enrollment and Continued Access data are pooled because the cohorts were enrolled from a common array of study sites and utilize the same protocol, follow-up, and data collection processes. Data as of September 13, 2017 are provided below. Additional information regarding procedural outcomes can be found in the *Instructions for Use* (IFU).

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 migration and patency are shown in the following tables. Reports of losses of device integrity, reasons for conversion, and causes of aneurysm-related death and rupture are also described.

When available, core lab imaging results are used to provide consistency in image review, documentation, and reporting purposes.

Summary of patients with available data

Patients enrolled in the IBE 12-04 Primary Enrollment and Continued Access cohorts are required to return for follow-up visits at 1-, 6-, 12-, 24-, 36-, 48-, and 60-months post-treatment. Evaluation methods include a physical examination and spiral CTA of the abdomen and pelvis.

Table 1 summarizes compliance follow-up visits directed by the investigational plan and imaging requirements for patients undergoing the IBE procedure who were eligible for the effectiveness endpoint analysis in the Primary Enrollment (n = 61), plus Continued Access patients (n = 35). Two patients underwent an IBE procedure but were not eligible for effectiveness endpoint analysis in the Primary Enrollment. The first ineligible patient received an Iliac Extender Component in place of the Internal Iliac Component. The second ineligible patient underwent concomitant femoral aneurysm repair which was a violation of exclusion criteria. The column "Within window no CT yet" shows the number of patients with pending follow-up visits.

Table 1 also summarizes patients that were discontinued or deceased. At the time of this report, ten patients have discontinued. Reasons for discontinuations are: five withdrawn and five lost to follow-up. While nine patients have died through the 36-month follow-up visit, and one additional patient had an unknown date of death at time of data snapshot, none have been aneurysm related. The number of patients who were assessed for each core lab parameter is reported as the denominator in the appropriate table (e.g., the number of patients assessed for patency, lumen obstruction, or compression appear as individual denominators in **Table 3**).

Table 1: Patient disposition and compliance by study interval for effectiveness eligible patients

		Follow-up compliance[1]					Events prior to next interval[1]		
Study period	Eligible for follow-up	Patients 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	96	—	—	—	—	—	0	0	0
Post-procedure	96	—	—	—	—	—	0	0	0
1 month	96	94 (97.9%)	93 (96.9%)	94 (97.9%)	93 (96.9%)	0	0	0	0
6 months	96	89 (92.7%)	86 (89.6%)	88 (91.7%)	85 (88.5%)	0	3 (3.1%)	1 (1.0%)	0
12 months	92	85 (92.4%)	83 (90.2%)	83 (90.2%)	78 (84.8%)	0	1 (1.1%)	3 (3.3%)	2 (2.2%)
24 months	86	58 (67.4%)	55 (64.0%)	56 (65.1%)	53 (61.6%)	13 (15.1%)	3 (3.5%)	5 (5.8%)	24 (27.9%)
36 months	54	25 (46.3%)	24 (44.4%)	23 (42.6%)	18 (33.3%)	27 (50.0%)	2 (3.7%)	1 (1.9%)	38 (70.4%)
48 months	13	1 (7.7%)	1 (7.7%)	1 (7.7%)	0	12 (92.3%)	0	0	13 (100.0%)
60 months	0	—	—	—	—	—	—	—	—

Effectiveness eligible IBE 12-04 patients included in this table. Study period definitions: Study period definitions: 1 month (15-59 days), 6 months (60-242 days), 12 months (243-546 days), 24 months (547-911 days), 36 months (912-1275 days), 48 months (1276-1640 days), 60 months (1641-2006 days)
[1] Percentages are based on number of patients eligible for follow-up in study period.
[2] Any visit consisting of physical exam, CT scan, or MR scan.
[3] Contrast CT is necessary for core lab determination of endoleak, lumen obstruction, patency, or rupture.
[4] Patients still within the study window out of those who have not yet had a CT scan.

All-cause mortality

Causes of death are summarized in **Table 2**. Six patients in Primary Enrollment died and the causes were myocardial infarction, cerebrovascular accident, chronic obstructive pulmonary disease, aortic dissection, ventricular tachycardia, and cardio-respiratory arrest. These deaths were not considered safety endpoint events since they did not occur within 30 days of index procedure.

Four patient deaths have been reported in IBE 12-04 Continued Access patients and the causes were metastatic hepatic cancer, cardiac arrest, aortic dissection rupture, and gastroesophageal cancer.

Kaplan-Meier estimates for all-cause mortality are provided (**Figure 1**).

Ten patient deaths have been recorded thus far during the study; however no deaths were aneurysm-related (Kaplan-Meier estimates for aneurysm-related deaths are shown in **Figure 2**).

Figure 1: Kaplan-Meier estimates of freedom from all-cause mortality through last contact IBE 12-04

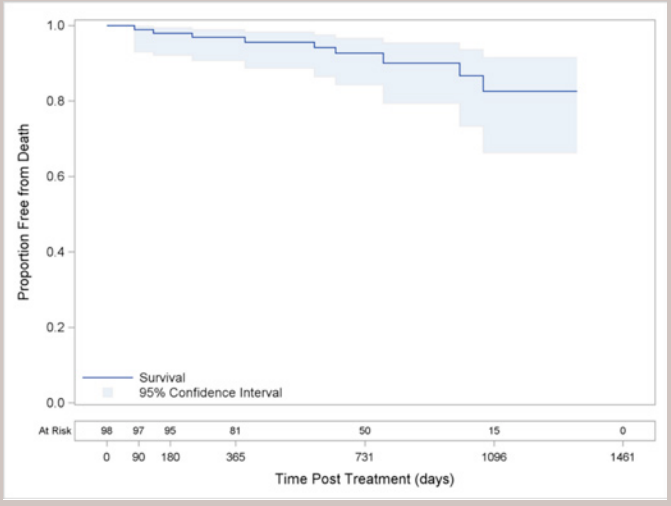


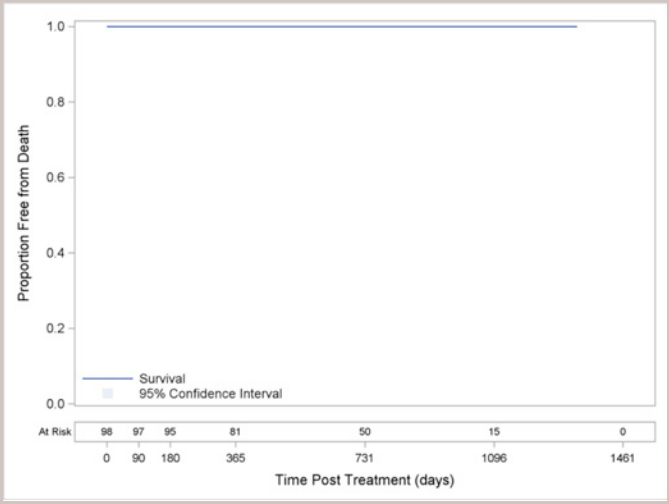
Table 2: Cause of death IBE 12-04

Study day	Cause of death	Aneurysm-related death
78	Hepatic cancer metastatic	No
132	Myocardial infarction	No
242	Cardiac arrest	No
391	Cerebrovascular accident	No
587	Aortic dissection rupture	No
647	Chronic obstructive pulmonary disease	No
783	Gastroesophageal cancer	No
999	Aortic dissection	No
1065	Ventricular tachycardia	No
Indeterminate at snapshot	Cardio-respiratory arrest	No

Aneurysm-related mortality

There were no aneurysm-related deaths in the IBE 12-04 clinical study (primary enrollment and continued access) through this reporting period. The Kaplan-Meier estimates are provided below in **Figure 2**.

Figure 2: Kaplan-Meier estimates of freedom from aneurysm-related death through last contact IBE 12-04



Summary of patency, lumen obstruction, and device compression

A summary of patency, lumen obstruction, and compression data collected on patients is described in **Table 3**. There were no new findings since the last update—all of the findings in the recent 24-month images were previously identified in earlier images. Per core lab evaluation, there were six non-patent device occurrences (five Internal Iliac Component, one Iliac Branch Component), one device compression, and six lumen obstructions. These occurred among six patients as lumen obstruction (unintentional obstruction of blood flow through the vascular lumen due to the device) was noted for all those experiencing non-patent device or compression. The one device compression was reported for a patient which had an occluded internal iliac component at one-month follow-up due to coverage of the Internal Iliac Component with the distal end of the bridge component. Evaluation identified that the Internal Iliac Component was deployed slightly above the Iliac Branch Component flow divider and was subsequently covered by the bridge component. The denominator for each assessment indicates the number of patients with images that could be fully evaluated for the parameter of interest in the study window.

Table 3: Summary of core lab device findings of non-patency, lumen obstruction, and compression by follow-up period

Post-treatment follow-up period	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total
Number of patients	96	96	87	64	27	2	0	96
Number of patients with CT or MR scan	94	88	83	56	23	1	—	96
Number of patients with CT scan	94	88	83	56	23	1	—	96
Non-patent IBE component	6 / 91 (6.6%)	4 / 85 (4.7%)	3 / 78 (3.8%)	2 / 53 (3.8%)	0 / 18	0/0	—	6 / 96 (6.3%)
Non-patent iliac branch component	1 / 91 (1.1%)	0 / 85	0 / 78	0 / 53	0 / 18	0/0	—	1 / 96 (1.0%)
Non-patent internal iliac component	5 / 91 (5.5%)	4 / 85 (4.7%)	3 / 78 (3.8%)	2 / 53 (3.8%)	0 / 18	0/0	—	5 / 96 (5.2%)
Lumen obstruction	6 / 91 (6.6%)	4 / 85 (4.7%)	3 / 78 (3.8%)	2 / 53 (3.8%)	0 / 18	0/0	—	6 / 96 (6.3%)
Device compression	1 / 92 (1.1%)	1 / 88 (1.1%)	1 / 82 (1.2%)	0 / 54	0 / 18	0/0	—	1 / 96 (1.0%)

Effectiveness eligible IBE 12-04 patients included in this table.
NOTE: Denominators used in calculation of percentages are number of patients with an evaluable result (a definitive yes or no response representing all device components was available).
Study period definitions: 1 month (15-59 days), 6 months (60-242 days), 12 months (243-546 days), 24 months (547-911 days), 36 months (912-1275 days), 48 months (1276-1640 days), 60 months (1641-2006 days).

Reinterventions and conversion to surgical repair

The primary effectiveness endpoint is determined as a composite of the following events through the six-month follow-up visit:

- Reintervention on the Iliac Branch Component or the Internal Iliac Component 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 Iliac Branch Component or the Internal Iliac Component due to thrombus or device failure as assessed by an independent core lab
- Reintervention on the Iliac Branch Component or the Internal Iliac Component to re-establish patency due to 60% occlusion or greater as determined by the CEC

Reintervention data is presented below in **Table 4** for patients who underwent an IBE procedure.

Five patients had eight reinterventions within the first six months after the index procedure. Through all follow-up to date, nine patients have had 14 reinterventions.

- One patient with thrombosis of the endovascular graft in the right external iliac artery on POD 1 was treated with thrombectomy the same day which resolved the event. It was reported that the Trunk-Ipsilateral Leg Endoprosthesis of the GORE® EXCLUDER® Device was landed in significant tortuosity.
- One patient noted buttock pain on POD 37, bilateral external iliac artery occlusions on POD 39, and right superficial femoral thrombosis on POD 40. It was reported the device components were patent and intervention was performed distal to the implanted devices. This patient received four thrombectomies among POD 39 and POD 47. The right external iliac occlusion resolved with sequelae, and the other events resolved without sequelae. The Investigator noted the cause of the thrombosis is unknown, although this patient was difficult to anticoagulate and may have an unnamed pro coagulant disorder. The Investigator also reported that the Gore devices were not thrombosed and that the thromboses were in the native external iliac vessels. Additionally, the patient had bilateral femoral aneurysms noted at the time of procedure.
- One patient with left external iliac artery dissection on POD 23 was treated with stent on POD 26 which resolved the event. The one-month follow-up CT showed the dissection identified by an intimal flap at the distal edge of a nitinol stent that was deployed during the IBE procedure in the external iliac artery.
- One patient with Type II endoleak on POD 0 was treated with embolization on POD 77 which resolved the event. The endoleak originated from the inferior mesenteric, lumbar, and right internal iliac arteries.
- One patient with Type II endoleak on POD 34 was treated with embolization on POD 252 which resolved the event. The endoleak originated from the inferior mesenteric and lumbar arteries.
- One patient with Type II endoleak of the aorta and left common iliac artery on POD 0 (with exacerbation noted on POD 369) was treated with embolization on POD 413 and POD 627 which resolved after the second treatment. The endoleak originated from the lumbar arteries.
- One patient with Type II endoleak on POD 16 was treated with embolization on POD 465. The endoleak was ongoing until additional embolization occurred on POD 808 which resolved the event. The endoleak originated from the lumbar arteries.
- One patient with Type II endoleak of the distal left limb on non-IBE side on POD 0 was treated with coil embolization of the inferior mesenteric artery (noted as an “other procedure”) on POD 193 which resolved the event. The endoleak originated from the inferior mesenteric, lumbar, and middle sacral arteries.
- One patient with Type II endoleak on POD 189 was treated with embolization on POD 686 and the event is ongoing. The endoleak originated from the lumbar arteries.

Abdominal aneurysm enlargement was reported by core lab in two of these patients. Two were at the treated segment of the aortic, iliac, or hypogastric vessel, but were not primary effectiveness endpoint events.

There were no conversions to surgical repair in the IBE 12-04 clinical study through this reporting period.

Table 4: Summary of patients with reinterventions by follow-up period

	Post-treatment follow-up period									
	Procedure	Post-procedure	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total
Number of patients	98	98	98	98	89	66	27	2	0	98
With any reintervention	0	1 (1.0%)	2 (2.0%) [5]	2 (2.0%)	3 (3.4%)	3 (4.5%)	0	0	—	9 (9.2%) [14]
Conversion to open repair	—	0	0 (0%)	0	0	0	—	—	—	0
Thrombectomy	—	1 (1.0%)	1 (1.0%) [4]	0	0	0	—	—	—	2 (2.0%) [5]
Embolectomy	—	0	0 (0%)	0	0	0	—	—	—	0
PTA	—	0	0 (0%)	0	0	0	—	—	—	0
Stent	—	0	1 (1.0%)	0	0	0	—	—	—	1 (1.0%)
Stent graft	—	0	0 (0%)	0	0	0	—	—	—	0
Embolization	—	0	0 (0%)	1 (1.0%)	3 (3.4%)	3 (4.5%)	—	—	—	5 (5.1%) [7]
Drug therapy	—	0	0 (0%)	0	0	0	—	—	—	0
Other surgery, treatment, or procedure	—	0	0 (0%)	1 (1.0%)	0	0	—	—	—	1 (1.0%)

All patients undergoing an IBE procedure are included in this table.
Note: Column header counts and denominators are the number of patients at risk at the start of each interval. Reinterventions determined from Adverse Events treatments meeting definitions per sponsor Adverse Events review.
Study period definitions: Procedure (0 day), Post-procedure (1-14 days), 1 month (15-59 days), 6 months (60-242 days), 12 months (243-546 days), 24 months (547-911 days), 36 months (912-1275 days), 48 months (1276-1640 days), 60 months (1641-2006 days).
Numbers in [brackets] denote number of reinterventions if different than number of patients with reintervention.

Explanted Devices

No devices have been explanted in the IBE 12-04 clinical study as of this report.

Summary of endoleak, aneurysm rupture, endoprosthesis migration, wire fracture, and extrusion / erosion

A summary of additional data collected on events is described below in **Table 5**. Per core lab evaluation, there were no post-procedure Type I, III, or IV endoleaks, aneurysm ruptures (abdominal aorta, common iliac arteries on IBE or non-IBE placement side), device migrations (prosthesis or intercomponent), wire fractures, or device extrusions / erosions.

A summary of the remaining results include 60 patients with Type II endoleaks, five of whom also had indeterminate endoleak.

Table 5: Summary of additional core lab device findings by follow-up period

Post-treatment follow-up period	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total
Number of patients	96	96	87	64	27	2	0	96
Number of patients with CT or MR scan	94	88	83	56	23	1	—	96
Number of patients with CT scan	94	88	83	56	23	1	—	96
Endoleak	56 / 89 (62.9%)	44 / 81 (54.3%)	38 / 78 (48.7%)	18 / 53 (34.0%)	5 / 18 (27.8%)	0 / 0	—	60 / 95 (63.2%)
Type I	0 / 89	0 / 81	0 / 78	0 / 53	0 / 18	0 / 0	—	0 / 95
Type IA	0 / 89	0 / 81	0 / 78	0 / 53	0 / 18	0 / 0	—	0 / 95
Type IB	0 / 89	0 / 81	0 / 78	0 / 53	0 / 18	0 / 0	—	0 / 95
Type II	55 / 89 (61.8%)	44 / 81 (54.3%)	37 / 78 (47.4%)	15 / 53 (28.3%)	5 / 18 (27.8%)	0 / 0	—	60 / 95 (63.2%)
Type III	0 / 89	0 / 81	0 / 78	0 / 53	0 / 18	0 / 0	—	0 / 95
Type IV	0 / 89	0 / 81	0 / 78	0 / 53	0 / 18	0 / 0	—	0 / 95
Indeterminate	1 / 89 (1.1%)	0 / 81	1 / 78(1.3%)	3 / 53 (5.7%)	0 / 18	0 / 0	—	5 / 95 (5.3%)
Rupture	0 / 91	0 / 85	0 / 78	0 / 53	0 / 18	0 / 0	—	0 / 96
AAA rupture	0 / 91	0 / 85	0 / 78	0 / 53	0 / 18	0 / 0	—	0 / 96
Common iliac artery rupture	0 / 91	0 / 85	0 / 78	0 / 53	0 / 18	0 / 0	—	0 / 96
Common iliac artery rupture	0 / 91	0 / 85	0 / 78	0 / 53	0 / 18	0 / 0	—	0 / 96
Migration	0 / 92	0 / 88	0 / 83	0 / 55	0 / 18	0 / 0	—	0 / 96
Endoprosthesis migration ≥ 10 mm	0 / 92	0 / 88	0 / 83	0 / 55	0 / 18	0 / 0	—	0 / 96
Intercomponent migration ≥ 10 mm	0 / 92	0 / 88	0 / 83	0 / 55	0 / 18	0 / 0	—	0 / 96
Wire fracture[1]	0 / 44	0 / 42	0 / 34	0 / 23	0 / 8	0 / 0	—	0 / 57
Extrusion / erosion	0 / 92	0 / 88	0 / 82	0 / 55	0 / 18	0 / 0	—	0 / 96

Effectiveness eligible IBE 12-04 patients included in this table.
NOTE: Denominators used in calculation of percentages are number of patients with an evaluable result (a definitive yes or no response representing all device components was available).
Study period definitions: 1 month (15-59 days), 6 months (60-242 days), 12 months (243-546 days), 24 months (547-911 days), 36 months (912-1275 days), 48 months (1276-1640 days), 60 months (1641-2006 days)
[1] Wire fracture was assessed as Yes / No / Unknown. Unknown (not included in denominators) was specified if no fracture had been found but even a portion of a device could not be assessed due to factors such as device overlap and image slice thickness.

Aneurysm enlargement

Abdominal aneurysm enlargement

As demonstrated in **Table 6**, no abdominal aneurysm enlargement was shown in the first six months after initial treatment in the IBE 12-04 study. Freedom from aneurysm enlargement was 97.5% at 12 months and 90.7% at 24 months.

Table 6 shows that only two out of 80 (2.5%) patients from the IBE study cohort had abdominal aortic enlargement at the 12-month visit, and both of those patients had a Type II endoleak. Five out of 54 (9.3%) patients had abdominal aortic enlargement at the 24-month visit, although only three (5.6%) showed enlargement in both axial and orthogonal views, and all of these had a Type II endoleak. Three of these patients had newly reported increases and the other two were previously reported at 12 months (including the patient with increase noted at 36 months).

Table 6: Change in maximum abdominal aortic diameter from baseline — Core lab

	6 months	12 months	24 months	36 months	48 months	60 months
Number of patients with available data[1]	84	80	54	18	0	0
Change in maximum abdominal aortic diameter from baseline – Axial						
5 mm decrease	7 (8.3%)	20 (25.0%)	14 (25.9%)	5 (27.8%)	—	—
No change	77 (91.7%)	58 (72.5%)	36 (66.7%)	12 (66.7%)	—	—
5 mm increase	0	2 (2.5%)	4 (7.4%)	1 (5.6%)	—	—
Change in maximum abdominal aortic diameter from baseline – Orthogonal						
5 mm decrease	5 (6.0%)	15 (18.8%)	11 (20.4%)	6 (33.3%)	—	—
No change	79 (94.0%)	63 (78.8%)	39 (72.2%)	11 (61.1%)	—	—
5 mm increase	0	2 (2.5%)	4 (7.4%)	1 (5.6%)	—	—
Endoleaks in patients with 5 mm increase in maximum abdominal aortic diameter[2]	—	2 (100.0%)	3 (60.0%)	1 (100.0%)	—	—
Type IA	—	0	0	0	—	—
Type IB	—	0	0	0	—	—
Type II	—	2	1	1	—	—
Type III	—	0	0	0	—	—
Type IV	—	0	0	0	—	—
Indeterminate	—	0	2	0	—	—

Effectiveness eligible IBE 12-04 patients included in this table.
NOTE: The sum of the type of endoleaks may add up to more than the number of patients with endoleaks, for patients can have multiple types.
Study period definitions: 1 month (15-59 days), 6 months (60-242 days), 12 months (243-546 days), 24 months (547-911 days), 36 months (912-1275 days), 48 months (1276-1640 days), 60 months (1641-2006 days). If multiple observations are contained within a single study window, the observation closest to the target study window date is used.
[1] Patients must have a baseline (1 month) and a post-baseline measurement to be available for evaluation.
[2] The percentage of endoleaks is among patients with an increase in vessel diameter from either axial or orthogonal views.

Common iliac aneurysm enlargement

As demonstrated in **Table 7** below, one patient in the unilateral IBE placement cohort developed common iliac aneurysm enlargement (growth) as demonstrated in only one CT view (one at six months and one at 12 months), and Type II endoleak was present at both of these follow-ups. However, there were no reports of aneurysm enlargement when evaluated with orthogonal view. The remaining patients had common iliac aneurysm(s) that either remained stable or decreased in size.

Compared to historical GORE® EXCLUDER® Device clinical studies, the reported rates for Type II endoleaks is higher in IBE 12-04. While the reported rates of Type II endoleak reinterventions in the 12-04 trial through 12-month follow-up were similar or smaller than those in prior GORE® EXCLUDER® Device studies, the rate in the 12-04 trial may be greater in the 24-month follow-up window. This may be due to treatment for previously identified Type II endoleaks occurring later than in historical studies. Some of the increase in reported Type II endoleak rates may also be due to improvements in imaging modalities and imaging techniques, which have improved substantially since previous GORE® EXCLUDER® Device clinical trials were conducted.

Table 7: Change in maximum common iliac artery diameter (unilateral IBE) from baseline (IBE side) — Core lab

	6 months	12 months	24 months	36 months	48 months	60 months
Number of patients with available data[1]	81	78	53	18	0	0
Change in maximum common iliac artery diameter from baseline (IBE side) – Axial						
5 mm decrease	18 (22.2%)	31 (39.7%)	24 (45.3%)	9 (50.0%)	—	—
No change	62 (76.5%)	46 (59.0%)	29 (54.7%)	9 (50.0%)	—	—
5 mm increase	1 (1.2%)	1 (1.3%)	0	0	—	—
Change in maximum common iliac artery diameter from baseline (IBE side) – Orthogonal						
5 mm decrease	13 (16.0%)	28 (35.9%)	24 (45.3%)	9 (50.0%)	—	—
No change	68 (84.0%)	50 (64.1%)	29 (54.7%)	9 (50.0%)	—	—
5 mm increase	0	0	0	0	—	—
Endoleaks in patients with 5 mm increase in maximum common iliac artery diameter on IBE side[2]	1 (100.0%)	1 (100.0%)	—	—	—	—
Type IA	0	0	—	—	—	—
Type IB	0	0	—	—	—	—
Type II	1	1	—	—	—	—
Type III	0	0	—	—	—	—
Type IV	0	0	—	—	—	—
Indeterminate	0	0	—	—	—	—

Effectiveness eligible IBE 12-04 patients with unilateral device placement are included in this table.
NOTE: The sum of the type of endoleaks may add up to more than the number of patients with endoleaks, for patients can have multiple types.
Study period definitions: 1 month (15-59 days), 6 months (60-242 days), 12 months (243-546 days), 24 months (547-911 days), 36 months (912-1275 days), 48 months (1276-1640 days), 60 months (1641-2006 days). If multiple observations are contained within a single study window, the observation closest to the target study window date is used.
[1] Patients must have a baseline (1 month) and a post-baseline measurement to be available for evaluation.
[2] The percentage of endoleaks is among patients with an increase in vessel diameter from either axial or orthogonal views.

Device adverse events

Nine patients experienced serious device adverse events (SAE) through the 36-month follow-up period. **Table 8** below is a summary of these SAEs. One patient experienced a rupture of a Type B thoracic aortic dissection which resulted in death on POD 587. Events which were previously discussed as reinterventions but do not appear as SAEs did not meet the definition of serious events or were not attributable to the device. Five of the patients were previously discussed as having reinterventions.

- One patient with Type II endoleak on POD 34 was treated with embolization on POD 252 which resolved the event
- One patient with Type II endoleak of the aorta and left common iliac artery on POD 0 (with additional onset noted on POD 524) was treated with embolization on POD 413 and the event is ongoing
- One patient with thrombosis of the stent graft in right external iliac artery on POD 1 was treated with thrombectomy the same day which resolved the event
- One patient with left external iliac artery dissection on POD 23 was treated with a stent on POD 26 which resolved the event
- One patient with Type II endoleak on POD 189 was treated with embolization on POD 686 and the event is ongoing

Three of the nine patients had SAEs related to the access site.

- One patient with bilateral groin hematomas on POD 15 received wound vac and antibiotics and the event resolved on POD 71
- One patient with an infected incision on POD 7 underwent drainage on POD 8 as well as drug therapy and the event resolved on POD 70
- One patient with groin pseudoaneurysm on POD 0 underwent surgical repair of the pseudoaneurysm and evacuation of hematoma the same day which resolved the event.

Table 9 is a summary of device thrombosis-related SAEs with MedDRA® codes. There were only two patients with thrombosis events (one each peripheral artery thrombosis and device occlusion). No unanticipated adverse device events occurred during this reporting period.

Table 8: Summary of serious device events by follow-up period

	Post-treatment follow-up period									
	Procedure	Post-procedure	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total
Number of patients	96	96	96	96	87	64	27	2	0	96
Number of patients with imaging evaluation or serious device event	96	4	94	88	83	57	23	1	—	96
Any serious device event	1 (1.0%)	2 (50.0%)	3 (3.2%)	1 (1.1%)	1 (1.2%)	1 (1.8%)	—	—	—	9 (9.4%)
Stent graft endoleak	0	0	1 (1.1%)	1 (1.1%)	1 (1.2%)	0	—	—	—	3 (3.1%)
Stent graft endoleak Type II	—	—	1 (1.1%)	1 (1.1%)	1 (1.2%)	—	—	—	—	3 (3.1%)
Aortic dissection rupture	0	0	0	0	0	1 (1.8%)	—	—	—	1 (1.0%)
Device occlusion	0	1 (25.0%)	0	0	0	0	—	—	—	1 (1.0%)
Iliac artery dissection	0	0	1 (1.1%)	0	0	0	—	—	—	1 (1.0%)
Access-related event	1 (1.0%)	1 (25.0%)	1 (1.1%)	0	0	0	—	—	—	3 (3.1%)
Groin hematoma	0	0	1 (1.1%)	—	—	—	—	—	—	1 (1.0%)
Incision site infection	0	1 (25.0%)	0	—	—	—	—	—	—	1 (1.0%)
Vascular pseudoaneurysm	1 (1.0%)	0	0	—	—	—	—	—	—	1 (1.0%)

Effectiveness eligible IBE 12-04 patients included in this table.
Note: Percentages are based on the number of patients with CT or MR imaging follow-up, or non-serious device event in the given window. Dashes are used below headings with zero values.
Study period definitions: 1 month (15-59 days), 6 months (60-242 days), 12 months (243-546 days), 24 months (547-911 days), 36 months (912-1275 days), 48 months (1276-1640 days), 60 months (1641-2006 days).

Table 9: Summary of serious thrombosis-related AEs by MedDRA® term[1] and follow-up period

	Post-treatment follow-up period									
	Procedure	Post-procedure	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total
Number of patients	96	96	96	96	87	64	27	2	0	96
Any serious thrombosis-related event	0	1 (1.0%)	1 (1.0%)	0	0	0	0	0	—	2 (2.1%)
SOC — Vascular disorders	—	0	1 (1.0%)	—	—	—	—	—	—	1 (1.0%)
PT — Peripheral artery thrombosis	—	—	1 (1.0%)	—	—	—	—	—	—	1 (1.0%)
SOC — Product issues	—	1 (1.0%)	0	—	—	—	—	—	—	1 (1.0%)
PT — Device occlusion	—	1 (1.0%)	—	—	—	—	—	—	—	1 (1.0%)

Effectiveness eligible IBE 12-04 patients included in this table.
Note: Column header counts and denominators are the number of patients at risk at the start of each interval. Entries represent MedDRA® SOC, HLT, and PT and are identified by increasing level of indentation. Dashes are used below headings with zero values.
Study period definitions: 1 month (15-59 days), 6 months (60-242 days), 12 months (243-546 days), 24 months (547-911 days), 36 months (912-1275 days), 48 months (1276-1640 days), 60 months (1641-2006 days).
[1] MedDRA® Version: V20.1

Bilateral IBE placement

IBE 12-04 bilateral device placement study results are presented alongside results from the subsets of bilateral placement patients enrolled in GREAT (GRT 10-11) and IceBERG for clarity and to compare similar data sets.

GORE® EXCLUDER® Iliac Branch Endoprosthesis for the treatment of common iliac artery aneurysms or aortoiliac aneurysms (IBE 12-04 Bilateral Limb)

See "Description of Clinical Studies" for a description of the IBE 12-04 study. Bilateral IBE placement was only allowed in Continued Access.

Thirty-five patients were enrolled at 20 sites for the Continued Access cohort. Of these, four patients were enrolled at three sites for treatment of bilateral iliac aneurysms with bilateral device placement.

GREAT (GRT 10-11)

GREAT (GRT 10-11) is a global observational registry designed to obtain data on device performance and clinical outcomes of patients with aortic disease pathologies treated with all commercially available Gore endovascular aortic products.

GREAT is a prospective, observational registry that is a non-randomized, multicenter, single-arm evaluation. The registry includes patients with various aortic disease pathologies and treated with any commercially available Gore endovascular aortic product. This study is being conducted under an IDE within the U.S. (IDE G120012/S004; NCT 01658787).

GREAT allows patient enrollment for initial procedures and reinterventions (regardless of original intervention). This registry is a tool for collecting and organizing observational data for descriptive reporting as well as evaluating "real world" experience of clinical practice and patient outcomes during treatment and throughout all post-treatment visits, including follow-up extending up to 10 years.

This registry has recently completed enrollment and is now in follow-up. The registry was developed to collect patient and device performance outcomes during treatment and throughout all post-treatment visits, including follow-up extending up to 10 years for patients treated with Gore endovascular aortic products. Data were collected from patients enrolled from 110 sites globally, of which 64 were U.S. sites. There were 2,580 patients enrolled in the U.S. and 5,025 patients enrolled worldwide. The sites were to enroll patients with endovascular treatment procedures that were consecutive in nature and not randomized. The patients were not selected based on patient pathologies or co-morbidities, particular treatment, and / or device information, in order to prevent missing or biased data.

This report provides a summary of aggregate data collected from 102 active clinical sites enrolled in GRT 10-11. While 4,623 total patients were enrolled in the study at the time of the September 8, 2017 data evaluation, 14 patients have been enrolled at 10 sites for the treatment of bilateral iliac aneurysms with bilateral IBE placement. There is data available for 11 of these 14 patients.

IceBERG

IceBERG is a European observation registry to collect data on the preservation of the internal iliac artery (hypogastric artery) after treatment for common iliac artery / abdominal aortic aneurysm disease using the GORE® EXCLUDER® Device and IBE (NCT02345005). This study is in two parts:

- A retrospective registry of patients implanted with the IBE from 13 sites in the Netherlands after CE mark was obtained, to get an initial insight on the feasibility and safety of this procedure
- A prospective registry of patients implanted with the IBE from 10 sites in Europe and one site in New Zealand, in order to gain more robust data on the efficacy of the device in maintaining hypogastric artery patency

IceBERG is a nonrandomized, multicenter, single-arm evaluation, which includes patients with bilateral common iliac disease in conjunction with abdominal aortic disease. For the information summarized in this report, the treatment plan required placement of the GORE® EXCLUDER® Device for the abdominal aortic aneurysm along with the IBE to treat bilateral common iliac artery aneurysm.

This report provides a summary of aggregate data collected from the nineteen patients enrolled in IceBERG that have bilateral common iliac artery aneurysm with abdominal aortic aneurysm.

The IBE was CE marked in 2013. The registry is approved under IDE G130038.

Summary of clinical results of bilateral IBE placement

The clinical information below includes the number of patients for whom the data are available procedural data, and similar information presented in the IBE 12-04 through five years of implantation. The following tables include the rates of aneurysm-related mortality, aneurysm rupture, secondary endovascular procedures, conversion to surgical repair, endoleak, aneurysm enlargement, and migration and patency. Reports of losses of device integrity, reasons for conversion, and causes of aneurysm-related death and rupture are described.

Composite tables with results from the IBE 12-04 (bilateral device placement), GREAT, and IceBERG are presented below.

In addition, this clinical update will provide a discussion of any lessons learned from bilateral use of the device.

Summary of patients with available data

The number of patients enrolled in the IBE 12-04, GREAT, and IceBERG studies available for data analysis for this report are included in **Table 10**. Included in this table are the patient counts for the follow-up windows, with and without imaging.

Table 10: Summary of patients available for follow-up, bilateral placement in IBE 12-04, GREAT, and IceBERG

	1 month	6 months	12 months	24 months	36 months
IBE 12-04 Bilateral IBE					
Patients eligible in window	4	4	3	3	1
With any follow-up	4 (100.0%)	4 (100.0%)	3 (100.0%)	2 (66.7%)	0
With imaging follow-up	4 (100.0%)	4 (100.0%)	3 (100.0%)	2 (66.7%)	0
GREAT Registry Bilateral IBE					
Patients eligible in window	14	14	14	6	2
With any follow-up	9 (64.3%)	9 (64.3%)	6 (42.9%)	2 (33.3%)	0
With imaging follow-up	9 (64.3%)	8 (57.1%)	4 (28.6%)	1 (16.7%)	0
IceBERG Registry Bilateral IBE					
Patients in study	19	19	19	19	19
With any follow-up	17 (89.5%)	12 (63.2%)	3 (15.8%)	0	0
With imaging follow-up	14 (73.7%)	12 (63.2%)	2 (10.5%)	0	0

Technical success

As shown in **Table 11**, there were two patients (one each in GRT 10-11 and IceBERG) that could not demonstrate the absence of endoleak (Type I or III). The endoleak found in the GRT 10-11 patient was a Type IA. The patient in IceBERG documented that the residual endoleak was of unknown origin and found at end of procedure. All other measures of technical success were reported as 100% for all three studies.

Table 11: Summary of technical success results, bilateral placement in IBE 12-04, GREAT, and IceBERG

	IBE 12-04 Bilateral IBE	GREAT Bilateral IBE	IceBERG Bilateral IBE
Number of patients	4	14	19
Number of patients with information available	4	11	19
Successful access	4 (100.0%)	11 (100.0%)	19 (100.0%)
Successful deployment of the IBE (and GORE® EXCLUDER® Device) in the intended location	4 (100.0%)	11 (100.0%)	19 (100.0%)
Successful removal of all IBE delivery catheters	4 (100.0%)	11 (100.0%)	19 (100.0%)
Patent IBE (and GORE® EXCLUDER® Device) on completion angiography	4 (100.0%)	11 (100.0%)	19 (100.0%)
Absence of Type I and Type III endoleak on completion angiography	4 (100.0%)	10 (90.9%)	18 (94.7%)
Successful access site closure	4 (100.0%)	11 (100.0%)	19 (100.0%)

Table 12 provides a summary of procedural data for bilateral IBE placement in the 12-04 clinical study. At the time of data evaluation, this was only available from 12-04. Mean procedure time was 310 minutes.

Additional procedures performed during endovascular treatment occurred in one patient (cut-down and patch angioplasty of left common femoral artery).

Table 12: Bilateral IBE 12-04 procedure data (IBE 12-04 only)

	Bilateral IBE Devices
Patients initiating IBE procedure	4
Endovascular access method on IBE side	n = 8
Percutaneous	6 (75.0%)
Cut-down	2 (25.0%)
Cut-down and conduit	0 (0.0%)
Endovascular access method on non-IBE side	
Percutaneous	—
Cut-down	—
Cut-down and conduit	—
Anesthesia method	
General	3 (75.0%)
Regional	1 (25.0%)
Local	0 (0.0%)
Procedure time (minutes)	n = 4
Mean (std dev)	310.8 (116.9)
Median	261
Range	(236,485)
Blood loss (ml)	n = 4
Mean (std dev)	575.0 (695.8)
Median	325
Range	(50,1600)
Transfusion	1 (25.0%)
Heparin administered	4 (100.0%)
Procedure survival	4 (100.0%)
Additional procedures at treatment	1 (25.0%)
Stent	0 (0.0%)
PTA	0 (0.0%)
Thrombectomy	0 (0.0%)
Embolization	0 (0.0%)
Other	1 (25.0%)

Key outcomes: Summary of death, aneurysm rupture, secondary procedure, conversion to surgical repair, endoleak, aneurysm enlargement, migration, loss of patency in device, loss of device integrity

Key outcomes of bilateral IBE placement are summarized below and also in **Table 13**. Information regarding treatment and outcomes is included where available from site. Table denominators include all patients with key outcomes provided by the study sites regardless of the follow-up status.

Death

There was one aneurysm-related death reported in GRT 10-11 due to ruptured abdominal aortic aneurysm. This patient had a Type II endoleak reported POD 78 and aneurysm enlargement reported POD 364. It was reported that the rupture occurred POD 564 and intervention was performed. The patient died POD 566. There were no aneurysm-related deaths reported in IceBERG or 12-04.

Aneurysm rupture

Two total aneurysm ruptures were reported in the registries. One abdominal aortic aneurysm rupture was reported in GRT 10-11. This patient was reported to have a Type II endoleak identified POD 78, with aneurysm enlargement reported POD 364. A surgical conversion was performed on POD 564 to partially remove the endoprosthesis and prosthetic bypass.

It was reported that the patient died on POD 566. One thoracic aorta rupture was reported in IceBERG. The date of rupture was not reported, but it was reported that the patient was treated with a hybrid procedure with visceral debranching and TEVAR.

Secondary procedure

Three total secondary procedures (reinterventions) were reported. One occurred in GRT 10-11 (also reported in the conversion category). This patient had a secondary procedure POD 41 with proximal extension of the endoprosthesis with a chimney in the right renal. Two patients were treated with a secondary procedure in IceBERG. One of the IceBERG secondary procedures was reported at the index procedure and not true reintervention. During the index procedure, a thrombectomy was performed on the external iliac artery to treat thrombus. The second IceBERG report was the thoracic aorta rupture which resulted in a hybrid procedure with visceral debranching and TEVAR.

Conversion to surgical repair

One conversion was reported in GRT 10-11 (also captured under Secondary Procedure). The cause of conversion was ruptured AAA due to Type II endoleak and aneurysm enlargement. The conversion was performed on POD 564, and it was reported that the patient died POD 566.

Endoleak

There were 13 total endoleaks. There was one Type IA endoleak reported in GRT 10-11 (proximal extension with chimney in right renal), one Type IB endoleak reported in IceBERG (external iliac artery), and one indeterminate type of endoleak in IceBERG reported at the end of procedure with no additional follow-up to date. There were 10 reported Type II endoleaks between the three studies. One GRT 10-11 patient with a Type II endoleak had a secondary procedure, aneurysm enlargement, surgical conversion, and death (same patient described in earlier sections). One IceBERG patient with a Type II endoleak noted at six-month follow-up visit had aneurysm enlargement but no secondary procedure.

Aneurysm enlargement

Two patients with aneurysm enlargement (AAA) were noted as described in earlier sections. One occurred in GRT 10-11 on POD 566, and the other in IceBERG, and both were associated with Type II endoleaks.

Migration

No reports of device migration have been reported in any of the three studies.

Patency

No reports of loss of patency in the device have been reported in any of the three studies.

Device integrity

No reports of loss of device integrity have been reported in any of the three studies.

Table 13: Summary of key outcomes, bilateral placement in IBE 12-04 (Core Lab), GREAT, and IceBERG

	IBE 12-04 Bilateral IBE	GREAT Bilateral IBE	IceBERG Bilateral IBE
Number of patients	4	14	19
Number of patients with information available	4	11	17
Follow-up time (median)	548 days	298 days	6 months
Death	1 (25.0%)	1 (9.1%)	0
Aneurysm-related death	0	1 (9.1%)	0
Aneurysm rupture	0	1 (9.1%)	1 (5.9%)
Secondary procedure	0	1 (9.1%)	2 (11.8%)
Embolization	0	0	0
Thrombectomy	0	0	1 (5.9%)
Other	0	1 (9.1%)	1 (5.9%)
Conversion to surgical repair	0	1 (9.1%)	0
Endoleak	3 (75.0%)	3 (27.3%)	7 (41.2%)
Type I	0	1 (9.1%)	1 (5.9%)
Type II	3 (75.0%)	2 (18.2%)	5 (29.4%)
Type III	0	0	0
Indeterminate	0	0	1 (5.9%)
Aneurysm enlargement	0	1 (9.1%)	1 (5.9%)
Prosthesis migration	0	0	0
Loss of patency in device	0	0	0
Loss of device integrity	0	0	0

NOTE: Denominators are number of patients with key outcome information provided by the study sites, regardless of the follow-up status.

Table 14: Change in maximum common iliac artery diameter from baseline (bilateral device placement) – Core lab

	6 months	12 months	24 months	36 months	48 months	60 months
Number of patients with available data[1]	4	3	1	0	0	0
Number of common iliac arteries implanted with IBE[2]	8	6	2	—	—	—
Change in maximum common iliac artery diameter from baseline — Axial						
5 mm decrease	1 (12.5%)	0 (0.0%)	1 (50.0%)	—	—	—
No change	7 (87.5%)	6 (100.0%)	1 (50.0%)	—	—	—
5 mm increase	0 (0.0%)	0 (0.0%)	0 (0.0%)	—	—	—
Change in maximum common iliac artery diameter from baseline — Orthogonal						
5 mm decrease	0 (0.0%)	0 (0.0%)	1 (50.0%)	—	—	—
No change	8 (100.0%)	6 (100.0%)	1 (50.0%)	—	—	—
5 mm increase	0 (0.0%)	0 (0.0%)	0 (0.0%)	—	—	—

Only IBE 12-04 patients with bilateral device placement are included in this table. See Table 6 for IBE 12-04 patients with unilateral device placement.
Study period definitions: 1 month (15-59 days), 6 months (60-242 days), 12 months (243-546 days), 24 months (547-911 days), 36 months (912-1275 days), 48 months (1276-1640 days), 60 months (1641-2006 days). If multiple observations are contained within a single study window, the observation closest to the target study window date is used.
[1] Patients must have a baseline (1 month) and a post-baseline measurement to be available for evaluation.
[2] Each side of the body with an IBE implanted is counted for the denominator.

Further information about common iliac artery diameter changes for patients receiving bilateral IBE in the IBE 12-04 study is reported in **Table 14**. There were no reports of common iliac artery diameter enlargement (> 5 mm) through six months for all four patients.

Lessons learned from IBE bilateral device use

Patients with bilateral common iliac artery aneurysms are eligible for bilateral placement of IBE if anatomical requirements are met on both sides. Treatment diameters are identical for bilateral IBE placement compared to unilateral IBE, though the minimum total treatment length requirement on the ipsilateral side should be longer than the contralateral side (see IFU). Use of the IBE in bilateral configuration is similar to that with unilateral placement. Both IBE components (Iliac Branch Component and Internal Iliac Component) are implanted prior to placement of the GORE® EXCLUDER® Device.

Additional extended follow-up information (unilateral and bilateral IBE placement)

Post-approval study data will consist of the extended follow-up data out to five years for patients enrolled in the IBE 12-04 clinical study, which was initiated prior to device approval. This will include data from the pivotal study and continued access cohorts in accordance with the previously approved Investigational Device Exemption protocol.

The data will 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, migration and patency, and loss of device integrity.

Summary of adverse events

From October 2013 through May 15, 2017 more than 5,000 IBEs have been distributed worldwide. The data presented in **Table 15** summarize adverse events from worldwide commercial experience that occurred in the past year from May 15, 2016 to May 15, 2017. From May 15, 2016 to May 15, 2017, more than 2,900 GORE® EXCLUDER® Iliac Branch Endoprostheses have been distributed.

Table 15: Summary of GORE® EXCLUDER® Iliac Branch Endoprosthesis worldwide performance

Aneurysm-related death[a]	0
Post-procedure aneurysm rupture	0
Infection	0
Device integrity observation	0
Aneurysm enlargement[b]	2
Conversion	4
Device occlusion	10

[a] Aneurysm-related deaths are defined as any deaths within 30 days or due to aneurysm rupture, a primary or secondary procedure, or surgical conversion[1].
[b] Aneurysm enlargement in this table is defined as any reported enlarging aneurysm with and without endoleak.

Aneurysm-related death

No aneurysm-related deaths have been reported worldwide in patients treated with the IBE within the past year from May 15, 2016 to May 15, 2017. Causes of aneurysm-related deaths are shown in **Table 16**.

Table 16: Aneurysm-related death[a]

Procedure-related	**0**
Non-aneurysm aortic ruptures	0
Non-aneurysm iliac ruptures	0
Other complications	0
Comorbidity[b]	**0**
Aneurysm rupture	**0**
Occlusion	**0**
Total	**0**

[a] Aneurysm-related deaths are defined as any deaths within 30 days or due to aneurysm rupture, a primary or secondary procedure, or surgical conversion[1].
[b] Aneurysm-related death attributed to comorbidity is defined here as death that occurs within 30 days of a primary or secondary procedure; such death cannot be linked directly to the use of the device, but may be related to complications arising from the procedure.

[1] Chaikof EL, Blankensteijn JD, Harris PL, *et al*; Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of The Society for Vascular Surgery/American Association for Vascular Surgery. Reporting standards for endovascular aortic aneurysm repair. *Journal of Vascular Surgery* 2002;35(5):1048-1060.

Section II – Worldwide commercial experience

Post-procedure aneurysm rupture

There have been no commercial post-procedure aneurysm ruptures reported among patients treated with the IBE within the past year from May 15, 2016 to May 15, 2017. Post-procedure aneurysm rupture causes are shown in **Table 17**.

Table 17: Post-procedure aneurysm rupture[a]

Aneurysm enlargement with endoleak	0
Aneurysm enlargement without endoleak	0
Total	**0**

[a] Other less-frequent events that have contributed to post-procedure aneurysm rupture include post-procedure conversion and the disease state of the patient's aorta.

Aneurysm enlargement

There were two aneurysm enlargements (defined as enlargement ≥ 5 mm with and without endoleak) reported in patients treated worldwide within the past year with the IBE from May 15, 2016 to May 15, 2017, as shown in **Table 18**. One patient had reported aneurysm enlargement during follow up, but the enlargement was small (<2 mm) and resolved itself. This report of enlargement may be a result of core lab measurement variation. The second reported event was a result of a distal Type I endoleak due to insufficient covereage distally into the internal iliac artery at the time of the original procedure.

Table 18: Aneurysm enlargement

With endoleak	1
Without endoleak	1
Total	**2**

Conversion

Conversion to open surgical repair has been reported in four patients treated with the IBE worldwide within the past year from May 15, 2016 to May 15, 2017.

The primary cause of conversion was positioning complications during implantation and unsuitable anatomy (categorized as "other" in **Table 19** below). In both reports of unsuitable anatomy, the physician was aware of anatomical restrictions that might lead to complications and in one case it was reported that the device was used outside the indications for use.

Table 19: Conversion

Aneurysm rupture post-procedure	0
Aneurysm enlargement	0
Implantation difficulties[a]	2
Other[b]	2
Total	**4**

[a] Any problems associated with implantation of any component during the procedure.
[b] Cause of conversion was unsuitable anatomy.

Device occlusion

There were 10 occlusions reported in patients treated with the IBE worldwide within the past year from May 15, 2016 to May 15, 2017 (**Table 15**). All reported occlusions occurred in patients with unilateral IBE placement. Primary reasons for occlusion include implanting devices outside indications for use, unintentional coverage of an internal iliac branch and vessel tortuosity. The majority of device occlusions occurred within the Internal Iliac Component.

Section III – Explant analysis and device durability

Explant analysis

There was one IBE explanted and returned to Gore from worldwide commercial experience within the past year from May 15, 2016 to May 15, 2017. The device was explanted secondary to occlusion of one of the GORE® EXCLUDER® Device contralateral limbs. Analysis indicated no device integrity observations with this device.

Section IV – Summary and conclusions

Overview

There have been more than 5,000 IBEs distributed worldwide, beginning in October 2013 through May 15, 2017. Early results from the prospective, controlled clinical data and three years of worldwide commercial experience continue to support the safety and effectiveness for treatment of common iliac or aortoiliac artery aneurysms with the IBE.

Summary of clinical experience

Early clinical data and commercial results presented in this report indicate that the IBE offers a safe and effective therapy option in the treatment of patients diagnosed with common iliac or aortoiliac artery aneurysms.

The new aspects of the EVAR procedure associated with implantation of IBE do not introduce new safety concerns compared to EVAR and open surgical repair. Clinical results evaluating IBE have demonstrated high patency rates, low reintervention rates, and low aneurysm enlargement rates.

Conclusions

The clinical study results presented demonstrate high patency rates, low reintervention rates, and low buttock claudication rates for patients treated with the IBE. Worldwide commercial experience corroborates the low adverse events identified in the IBE clinical trial data. These early results from clinical and commercial evaluations support that the IBE can be used as a safe and effective treatment for patients presenting with common iliac or aortoiliac artery aneurysms.

Section V – Patient selection and follow-up

Regular follow-up of all patients treated with this device is required. Worldwide commercial experience and clinical data demonstrate that some adverse events may become apparent over time. As stated in the IFU, regular and consistent follow-up is a critical part of ensuring continuing safety and efficacy of aortic endovascular repair and patients with specific clinical findings such as endoleak and / or aneurysm enlargement should receive enhanced follow-up. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient.

As outlined in the IFU, critical factors for successful clinical outcomes include:

- Appropriate patient selection, including:
  - adequate iliac / femoral access
  - minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE
  - external iliac artery treatment range of 6.5 – 25 mm and seal zone length of at least 10 mm
  - internal iliac artery treatment 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
- Device selection in accordance with the IFU
- Device deployment in accordance with the IFU
- Appropriate and timely patient follow-up

Adverse event reporting

Any adverse event involving the IBE should be reported to Gore immediately. To report an event in the U.S., call 800.437.8181. Outside the U.S., contact your local Gore technical associate.

Section V – Patient selection and follow-up

INDICATIONS FOR USE IN THE US

The GORE® EXCLUDER® Iliac Branch Endoprosthesis 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.

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.

WARNINGS AND PRECAUTIONS

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

PATIENT SELECTION, TREATMENT AND FOLLOW-UP

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

POTENTIAL DEVICE OR PROCEDURE RELATED ADVERSE EVENTS

Table 20 includes adverse events may occur and / or may require intervention. These adverse events include, but are not limited to:

Table 20: Adverse events listed In alphabetical order

- 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 and surrounding vasculature
- edema
- endoleak
- endoprosthesis:
  - improper component placement
  - incomplete component deployment
  - component migration
  - separation of graft material from stent
  - improper component placement
  - occlusion
  - infection
  - stent fracture
  - graft material failure
  - dilatation
  - erosion
  - puncture
  - perigraft flow
- 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 (e.g., infection, dehiscence)
- vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, seroma, bleeding, rupture, death)

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