GORE® EXCLUDER® AAA Endoprosthesis
ANNUAL CLINICAL UPDATE
2019–2020

Device description

The GORE® EXCLUDER® AAA Endoprosthesis 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 – Overview

This annual clinical update provides a review of the ongoing experience with the GORE® EXCLUDER® AAA Endoprosthesis used in the treatment of abdominal aortic aneurysms. The device has been commercially available in the United States since 2002. In this update more than 20+ years of worldwide commercial experience is presented.

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 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. The low permeability GORE® EXCLUDER® Device is the only commercially available design.

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.

Additional details on the GORE® EXCLUDER® AAA Endoprosthesis can be found in the *Summary of Safety and Effectiveness*.

Table 1 below provides a brief regulatory approval history of the device.

Table 1: Regulatory approval history

Country	Device	First approval
Europe	GORE® EXCLUDER® Device GORE® C3® Delivery System	September 1997 August 2010
Brazil	GORE® EXCLUDER® Device	January 2005
U.S.	GORE® EXCLUDER® Device Low Permeability GORE® EXCLUDER® Device GORE® C3® Delivery System	November 2002 June 2004 December 2010
Japan	GORE® EXCLUDER® Device	January 2007
Canada	GORE® EXCLUDER® Device	October 2008
Australia	GORE® EXCLUDER® Device	December 2008
China	GORE® EXCLUDER® Device	January 2010

Section II – Worldwide device distribution

From September 1997 through June 30, 2020 more than 380,000 GORE® EXCLUDER® Devices have been distributed. This includes more than 16,000 original and modified GORE® EXCLUDER® Devices and more than 370,000 low permeability GORE® EXCLUDER® Devices. Of these, more than 230,000 were deployed using the GORE® C3® Delivery System. Over that same time period, over 620,000, 100,000 and 110,000 contralateral limbs, aortic extenders and iliac extenders have been distributed, respectively.

This *Annual Clinical Update* covers the time period of July 1, 2019 – June 30, 2020, during which more than 100,000 GORE® EXCLUDER® Devices, contralateral limbs, aortic extenders and iliac extenders were distributed.

Section III – Clinical evaluations

There are no current IDE or post market approval clinical evaluations of the GORE® EXCLUDER® AAA Endoprosthesis. A list of the clinical evaluations can be found below while a summary of the results of each can be found in the *Instructions for Use* (IFU).

For full details of clinical pivotal studies 98-03, 99-04 and post approval study 04-04 to evaluate the clinical performance of the low permeability GORE® EXCLUDER® Device reference the GORE® EXCLUDER® Device IFU.

IFU – RLT23, RLT 26, RLT 28

https://eifu.goremedical.com/index.aspx?docid=227

For full details of the 03-02 post approval study that evaluated the clinical performance of the 31 mm Trunk-Ipsilateral Leg and 32 mm Aortic Extender sizes reference the GORE® EXCLUDER® Device IFU.

IFU – PLC, PLA, PLL, RLT31 and RLT35

https://eifu.goremedical.com/index.aspx?docid=226

Section IV – Worldwide recalls, safety communications and field safety notices

From January 2013 to August 5, 2019, Gore received 346 reports of leading end catheter component separations of the GORE® EXCLUDER® AAA Endoprosthesis and GORE® EXCLUDER® Iliac Branch Endoprosthesis. Of the 346 events, 30 reported immediate health consequences and one reported a long-term health consequence (pelvic ischemia). This represents a rate of 0.05% reported complaints of leading end catheter separation events over the last six years.

Gore worked closely with the FDA and executed a corrective action for this Class II recall which included a Medical Device Safety Correction Letter and updated IFU warnings and precautions with no device removal. The *Medical Device Safety Correction Letter* was sent to physicians globally in January 2020.

Section V – Worldwide commercial experience

The data presented in **Table 2** summarize adverse events from worldwide commercial experience that occurred in the past year from July 1, 2019 to June 30, 2020. During this time period, more than 100,000 GORE® EXCLUDER® Devices have been distributed. Adverse event reports presented in **Table 2** are similar or lower than those reported in prior annual clinical updates. Each reported adverse event is not mutually exclusive and may contain multiple adverse events.

The worldwide commercial experience with the GORE® EXCLUDER® AAA Endoprosthesis has remained consistent with the acceptable performance exhibited in previous years.

Table 2: Summary of GORE® EXCLUDER® Device worldwide performance (July 1, 2019 – June 30, 2020)

Event	Number of events
Aneurysm-related death*	19
Post-procedure aneurysm rupture	12
Aneurysm enlargement†	111
Conversion	45
Migration‡	37
Device occlusion	12
Infection	8
Infolding	4
Type III Endoleaks§	27
Deployment Anomalies	37
Stent Fractures	1

* 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]

† Aneurysm enlargement in this table is defined as any reported enlarging aneurysm with and without endoleak ≥ 5 mm or if no measurement were reported.

‡ During commercial use, migration is defined as any report of post-procedure device movement.

§ Twenty two reported Type IIIa endoleaks (Trunk Ipsilateral Leg/Contralateral Leg Junction (7), Trunk Ipsilateral Leg – Aortic Extender Junction (6), Trunk Ipsilateral Leg – Iliac Extender (1), Contralateral Leg – Contralateral Leg Junction (1), Contralateral Leg–Iliac Branch Endoprosthesis Junction (7)) and 5 Type IIIb endoleaks reported but not confirmed by Gore of which one was a literature report evaluating Type IIIb endoleaks between the years of 2003-2018.

References

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 VI – Explant analysis

The data presented in **Table 3** summarize the reason for explant from July 1, 2019 to June 30, 2020. Of the 43 explants, four were returned to Gore for analysis while five others were evaluated by an independent explant analysis facility.

In one reported event, two years following implantation of the device, the patient reported with a compressed main body and thrombosis of the iliacs. The physician stated that the compressed graft was believed to be due to an acute dissection. The device was explanted and submitted to Gore for analysis. Multiple stent fractures along with two abrasion holes were found on the explant. In the analysis, the wire discontinuities exhibited characteristics consistent with fracture due to cyclic fatigue loading. There was no evidence of corrosion or abnormal abrasion observed on the wire.

Table 3: Primary cause of explant (July 1, 2019 – June 30, 2020)

	Number of occurrences	
Reason for explant	**Original GORE® EXCLUDER® Device**	**Low permeability GORE® EXCLUDER® Device**
Implantation difficulties	0	3
Rupture	0	1
Aneurysm enlargement without endoleak	0	3
Aneurysm enlargement with endoleak	0	14
Endoleak	0	7
Migration	0	2
Infection	0	5
Aortoenteric fistula	0	0
Occlusion	0	4
Incidental autopsy	0	0
Other	0	4
Total cases	**0**	**43**

Section VII – Literature review

The following peer-reviewed literature articles published over the last year describe safety and effectiveness of the GORE® EXCLUDER® AAA Endoprosthesis:

Boutrous ML *et al.,* describes remodeling of the aneurysm sac, particularly as it relates to and influences sac regression, is a complex process after endovascular aneurysm repair.[1] This retrospective study sought to identify factors influencing aneurysm sac shrinkage using a global patient registry. Multivariate analyses reveal that both conical necks and large proximal device diameters were significantly associated with reduction in sac size. On the contrary, older age and larger baseline sac diameter were significantly associated with lower sac shrinkage.

Mwipatayi BP *et al.,* published a retrospective study evaluated patients who were recruited into GREAT and treated for AAA with GORE® EXCLUDER® Device.[2] 3,758 patients (3,220 men and 538 women) were assessed for re-interventions and included in these analyses. On average, women displayed smaller maximum AAA diameters than men. Women also had higher degrees of infrarenal neck angulation than men. Multivariate analyses of risk factors for serious device-related events or device-related reinterventions demonstrated that women have higher rates of both compared to men. Men experienced higher rates of endoleak compared to women during the follow-up period. The rates of freedom from surgical reintervention remained similar between men and women during post-procedure follow-up. The findings of this study reveal that women typically treated for EVAR are of older age and present with more hostile neck anatomy compared to their male counterparts. While mortality rates remain lower in women than men, women experience significantly higher rates of reintervention and morbidity and may benefit from increased surveillance.

Oliveira-Pinto J *et al.,* describes a retrospective study to assess long-term clinical outcomes of patients treated for AAA with the MEDTRONIC ENDURANT® Abdominal Stent Graft or GORE® EXCLUDER® Device.[3] At seven-year follow-up, primary clinical success was 58.1% for GORE® EXCLUDER® Device. The freedoms from neck-related events was 78.8% for GORE® EXCLUDER® Device at seven-year follow-up. Overall rates of survival was 50.3% for GORE® EXCLUDER® Device at seven-years. The findings of this study reveal the similar, durable long-term outcomes are achieved with either MEDTRONIC ENDURANT® Device or GORE® EXCLUDER® Device.

Pujari A *et al.,* published a retrospective study aims to compare postoperative outcomes of patients treated for EVAR with infrarenal or suprarenal fixation.[4] 5,534 patients treated for EVAR were grouped into normal, moderate or severe kidney disease and assessed for postoperative renal complications. The most commonly used devices were GORE® EXCLUDER® Device, MEDTRONIC ENDURANT® Device, and Cook Zenith AAA Endovascular Graft (version not described in the article). In unadjusted analyses, the GORE® EXCLUDER® Device was not significantly associated with postoperative renal complications. Subgroup analyses revealed that patients with moderate kidney dysfunction experienced higher rates of renal complications. In comparing renal outcomes of patients treated with suprarenal versus infrarenal devices, postoperative elevation of creatinine above baseline was a driving differentiator (0.6% versus 0.2%, $P = 0.03$). Patients treated with suprarenal devices experienced 2.6 times higher rates of renal complications compared to patients treated with the GORE® EXCLUDER® Device. Patients who presented with ruptured aneurysms were independently associated with higher rates of renal complications after EVAR while obesity was associated with reduced rates. Overall, patients treated with suprarenal fixation devices were associated with higher rates of renal complications compared to treatment with infrarenal fixation devices.

Tsolakis IA *et al.,* describes a retrospective study were to compare outcomes of patients treated with the original GORE® EXCLUDER® Device or with the repositionable GORE® EXCLUDER® Device featuring the GORE® C3® Delivery System.[5] 313 patients were included in these analyses, with 174 receiving the original or 139 receiving the GORE® EXCLUDER® Device. Patients treated with the original GORE® EXCLUDER® Device had higher rates of the primary compositive outcome (intraoperative misdeployment or endograft migration) compared to patients treated with the GORE® EXCLUDER® Device (10.9% versus 3.6%, respectively). Significant predictors identified upon Cox univariate analysis were: female sex, failure to cannulate, the primary outcome measure and absence of dyslipidemia. However, device type was not identified as a significantly predictive factor. Overall, the GORE® EXCLUDER® Device featuring the GORE® C3® Delivery System has comparable long-term safety and effectiveness compared to the original GORE® EXCLUDER® Device.

These peer-reviewed publications demonstrate that 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 VIII – Conclusion

Conclusion

Based on available clinical study data and world-wide clinical experience to date, endovascular therapy with the GORE® EXCLUDER® Device continues to be a viable treatment option for the treatment of AAA disease.

Adverse event reporting

The accurate and timely reporting of adverse events by users is critical for monitoring device performance and detection of device-related safety issues. 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.

Patient follow-up and selection:

Regular follow-up of all patients treated with this device is required. Worldwide commercial experience and clinical data over the last 20 years demonstrate that some adverse events may become apparent over time, however, Gore's post market surveillance program monitors complaints for frequency and severity to determine potential impact on safety. 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

References

1. Boutrous ML, Peterson BG, Smeds MR. Predictors of aneurysm SAC shrinkage utilizing a Global Registry. *Annals of Vascular Surgery*. In press.
2. Mwipatayi BP, Anwari T, Wong J, *et al.,* Sex-related outcomes after endovascular aneurysm repair within the global registry for endovascular aortic treatment. *Annals of Vascular Surgery* 2020;67:242-253.e4.
3. Oliveira-Pinto J, Oliveira NFG, Bastos-Gonçalves FM, *et al*., Long-term results after standard endovascular aneurysm repair with the Endurant and Excluder stent grafts. *Journal of Vascular Surgery* 2020;71(1):64-74.
4. Pujari A, Ramos CR, Duwayri Y, *et al.,* Influence of baseline kidney dysfunction on perioperative renal outcomes after EVAR with suprarenal fixation. *Journal of Vascular Surgery*. In press.
5. Tsolakis IA, Kakkos SK, Papageorgopoulou CP, *et al*., Improved effectiveness of the repositionable GORE EXCLUDER AAA endoprosthesis featuring the C3 delivery system compared with the original GORE EXCLUDER AAA endoprosthesis for within the instructions for use treatment of aortoiliac aneurysms. *Journal of Vascular Surgery* 2019;69(2):394-404.

Device description

The GORE® EXCLUDER® Iliac Branch Endoprosthesis (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 (IBC) and the Internal Iliac Component (IIC). 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 ePTFE and 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 – Overview

This annual clinical update provides a review of the ongoing experience with the GORE® EXCLUDER® Iliac Branch Endoprosthesis used in the treatment of CIAA and AIA. In this update, five years of IDE clinical data and seven years of worldwide commercial experience is presented.

The GORE® EXCLUDER® Iliac Branch Endoprosthesis is comprised on an implantable endoprosthesis which consists of two modular components and a delivery system. The two primary components are the IBC and the IIC. The graft material is ePTFE and 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 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.

Table 1: Regulatory approval history

Country	First approval
Europe	October 2013
U.S.	February 2016
Canada	February 2016
Australia/New Zealand	January 2015
Japan	November 2017
Brazil	August 2019

The GORE® EXCLUDER® Iliac Branch Endoprosthesis was released in Europe in October 2013. The device was approved for commercial distribution in the U.S. in February 2016.

The most up-to-date version of the IFU can be found at https://eifu.goremedical.com/index.aspx?docid=224. Additional details on the GORE® EXCLUDER® Iliac Branch Endoprosthesis can be found in the *Summary of Safety and Effectiveness* (SSED).

Table 1 below provides a brief regulatory approval history of the device.

Section II – Worldwide device distribution

From November 2013 through June 30, 2020 almost 20,000 GORE® EXCLUDER® Iliac Branch devices have been distributed worldwide. Over that same time period, over 18,000 internal iliac components have been distributed.

This ACU covers commercial distribution between July 1, 2019 – June 30, 2020, during which more than 9,000 GORE® EXCLUDER® iliac branch components (IBC) and internal iliac components (IIC) were distributed worldwide.

Section III – Clinical evaluations

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 CIAA or AIA.

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. Five-year follow-up is expected to be completed in 2021.

Details of the clinical pivotal study IBE 12-04 can be found at https://clinicaltrials.gov/ct2/show/resultsNCT01883999?term=IBE+12-04&draw=2&rank=1&view=results.

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 primary safety endpoint was a composite of the following events through 30 days post-treatment:

- Death
- Stroke
- Myocardial Infarction
- Bowel Ischemia
- Paraplegia
- Respiratory failure
- Renal failure
- Conversion to open surgical repair

The primary effectiveness endpoint was 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 1B or Type III endoleak as determined by the 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 laboratory
- 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

Data from the IBE 12-04 study subjects as of September 22, 2020 through up to five years follow-up are presented in **Table 2**. All eligible subjects have reached the five-year study window, and a majority have completed follow-up within the five-year study window.

Section III – Clinical evaluations

Table 2: Summary of IBE 12-04 Clinical Study through five-year follow-up

	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total
Subjects eligible for follow-up	98	98	94	90	80	74	68	98
Subjects discontinued or lost to follow-up	0	4	4	10	6	6	9	39
Aneurysm related mortality	0/98	0/98	0/91	0/85	0/76	0/68	0/52	0/98
Aneurysm rupture	0/91	0/85	0/78	0/69	0/58	0/50	0/33	0/96
Conversions	0/98	0/98	0/91	0/85	1/76 (1.3%)	0/68	0/52	1/98
Type I endoleak	0/89	0/81	0/78	0/70	0/58	0/50	0/33	0/95
Type Ia endoleak	0/89	0/81	0/78	0/70	0/58	0/50	0/33	0/95
Type Ib endoleak	0/89	0/81	0/78	0/70	0/58	0/50	0/33	0/95
Type III endoleak	0/89	0/81	0/78	0/70	0/58	0/50	0/33	0/95
Diameter enlargement ≥ 5 mm (Core Lab orthogonal view)								
Common Iliac Artery[1]	—	0/81	0/78	1/68 (1.5%)	0/56	0/48	0/33	1/84 (1.2%)
Abdominal aorta	—	0/84	2/80 (2.5%)	4/70 (5.7%)	5/59 (8.5%)	10/51 (19.6%)	8/33 (24.2%)	14/87 (16.1%)
Prosthesis migration	0/92	0/88	0/83	0/72	0/60	0/51	0/34	0/96
Occlusions								
Iliac Branch Component	1/91 (1.1%)	0/85	0/78	0/69	0/58	0/50	0/33	1/96 (1.0%)
Internal Iliac Component	5/91 (5.5%)	4/85 (4.7%)	3/78 (3.8%)	2/69 (2.9%)	0/58	0/50	0/33	5/96 (5.2%)
Fracture	0/44	1/43 (2.3%)	0/34	0/32	0/27	1/23 (4.3%)	1/16 (6.3%)	1/60 (1.7%)

Denominators used in calculation of percentages are number of subjects at risk (for aneurysm related mortality and conversion) or with an evaluable result (for all other outcomes which are derived from Core Lab assessment of imaging in effectiveness eligible subjects)

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), Total (15-2006 days)

1. Denominators for subjects with unilateral IBE device placement, assessing diameter change of common iliac artery on IBE side

Twelve subjects (12.2%) have received reinterventions. Six subjects have received embolization for Type II endoleak, three received additional stents, two received thrombectomy, and one subject had conversion to open repair due to an infection.

Bilateral IBE placement

In order to supplement the information about bilateral IBE placement, IBE 12-04 bilateral device placement study results (n = 4) are presented alongside results from the subsets of bilateral placement patients enrolled in GREAT (GRT 10-11) (n = 15) and IceBERG (n = 28) as shown in **Tables 3 and 4.**

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).

Table 3: Summary of technical success, bilateral IBE placement in 12-04 study, GREAT and IceBERG

	IBE 12-04 Bilateral IBE	GREAT Bilateral IBE	IceBERG Bilateral IBE
Number of patients	4	15	28
Number of patients with information available	4	12	28
Successful access	4 (100.0%)	12 (100.0%)	28 (100.0%)
Successful deployment of the IBE (and GORE® EXCLUDER® Device) in the intended location	4 (100.0%)	12 (100.0%)	28 (100.0%)
Successful removal of all IBE delivery catheters	4 (100.0%)	12 (100.0%)	28 (100.0%)
Patent IBE (and GORE® EXCLUDER® Device) on completion angiography	4 (100.0%)	12 (100.0%)	28 (100.0%)
Absence of Type I and Type III endoleak on completion angiography	4 (100.0%)	11 (91.7%)	27 (96.4%)
Successful access site closure	4 (100.0%)	12 (100.0%)	28 (100.0%)

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 11 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

Table 4: Summary of key outcomes, bilateral IBE placement in 12-04 clinical trial (core lab), GREAT and IceBERG

	IBE 12-04 Bilateral IBE	GREAT Bilateral IBE	IceBERG Bilateral IBE
Number of patients	4	15	28
Number of patients with information available	4	12	27
Follow-up time (median)	1,486 days	1,093 days	24 months
Death	1 (25.0%)	2 (16.7%)	0
Aneurysm-related death	0	1 (8.3%)	0
Aneurysm rupture	0	1 (8.3%)	1 (3.7%)
Secondary procedure	0	2 (16.7%)	2 (7.4%)
Embolization	0	0	0
Thrombectomy	0	0	1 (3.7%)
Other	0	1 (8.3%)	1 (3.7%)
Conversion to surgical repair	0	1 (8.3%)	0
Endoleak	3 (75.0%)	5 (41.7%)	14 (51.9%)
Type I	0	3 (25.0%)	1 (3.7%)
Type II	3 (75.0%)	4 (33.3%)	11 (40.7%)
Type III	0	0	0
Indeterminate	0	0	2 (7.4%)
Aneurysm enlargement	0	5 (41.7%)	2 (7.4%)
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.

Section IV – Worldwide recalls, safety communications and field safety notices

From January 2013 to August 5, 2019, Gore received 346 reports of leading end catheter component separations of the GORE® EXCLUDER® AAA Endoprosthesis and the GORE® EXCLUDER® Iliac Branch Endoprosthesis. Of the 346 events, 30 reported immediate health consequences and one reported a long-term health consequence (pelvic ischemia). This represents a rate of 0.05% reported complaints of leading end catheter separation events over the last six years.

Gore worked closely with the FDA and executed a corrective action for this Class II recall which included a Medical Device Safety Correction Letter and updated IFU warnings and precautions with no device removal. The *Medical Device Safety Correction Letter* was sent to physicians globally in January 2020.

Section V – Worldwide commercial experience

The data presented in **Table 5** summarize adverse events from worldwide commercial experience that occurred in the past year from July 1, 2019 to June 30, 2020. During this time period, more than 9,000 GORE® EXCLUDER® Iliac Branch Devices have been distributed. Adverse event reports presented in **Table 5** are similar or lower than those reported in prior annual clinical updates. Each reported adverse event is not mutually exclusive and may contain multiple adverse events. Since IBE is used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis, adverse events unique to IBE and not related to the AAA device are called out in parenthesis ( ).

The worldwide commercial experience with the GORE® EXCLUDER® Iliac Branch Endoprosthesis has remained consistent with the acceptable performance exhibited in previous years.

Table 5: Summary of GORE® EXCLUDER® Iliac Branch Endoprosthesis worldwide performance (July 1, 2019 – June 30, 2020)

	Number of events
Aneurysm-related death*	2 (2 unique)
Post-procedure aneurysm rupture	2 (1 unique)
Aneurysm enlargement†	4 (0 unique)
Conversion	5 (2 unique)
Migration‡	0
Device occlusion	9 (7 unique)
Infection	1 (0 unique)
Infolding	0
Type III Endoleak§	11 (5 unique)
Deployment Related Events	16 (16 unique)
Stent Fracture	0

* 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]

† Aneurysm enlargement in this table is defined as any reported enlarging aneurysm with and without endoleak ≥5 mm or if no measurement is reported.

‡ During commercial use, migration is defined as any report of post-procedure device movement.

§ The majority of Type III endoleaks reported occurred at the junction of the proximal portion of the IBE and bridging contralateral leg component.

Section VI – Explant analysis

The data presented in **Table 6** summarize the number of IBE explants and the corresponding reason for explant from July 1, 2019 to June 30, 2020. Of the four explants, none were returned to Gore for analysis. There were no device integrity observations reported in any of the explants.

Table 6: Primary cause of explant (July 1, 2019 – June 30, 2020)

Reason for explant	Number of occurrences
Implantation difficulties	0
Rupture	0
Aneurysm enlargement without endoleak	0
Aneurysm enlargement with endoleak	1
Endoleak	0
Migration	0
Infection	1
Aortoenteric fistula	0
Occlusion	1
Incidental autopsy	0
Other	1
Total cases	**4**

Section VII – Literature review

There were no peer-reviewed literature articles published over the last year describing the safety and effectiveness of on label use of the GORE® EXCLUDER® Iliac Branch Endoprosthesis.

Section VIII – Conclusion

Based on available clinical study data and world-wide clinical experience to date, endovascular therapy with the GORE® EXCLUDER® Iliac Branch Endoprosthesis continues to be a viable treatment option for the treatment of aneurysmal disease associated with the iliac arteries.

Adverse event reporting

The accurate and timely reporting of adverse events by users is critical for monitoring device performance and detection of device-related safety issues. Any adverse event involving the GORE® EXCLUDER® Iliac Branch Endoprosthesis should be reported to Gore immediately. To report an event in the U.S., call 800 437 8181.

Patient follow-up and selection

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
  - 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

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