GORE® EXCLUDER®
AAA Endoprosthesis

ANNUAL CLINICAL UPDATE

July 1, 2020 through
June 30, 2021

Together, improving life

Table of contents

List of Tables

[1] Note that adverse event reporting comprises events associated with GORE® EXCLUDER® Devices that were implanted prior to 2020/2021 commercial distribution.

Overview

This Annual Clinical Update (ACU) provides a review of the ongoing experience with the GORE® EXCLUDER® AAA Endoprosthesis used in the treatment of abdominal aortic aneurysms (AAA). 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 expanded polytetrafluoroethylene (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. First released in the United States in June 2004, the low permeability GORE® EXCLUDER® Device is the only commercially available design.

The GORE® EXCLUDER® AAA Endoprosthesis featuring 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 Endoprosthesis 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.

Consult Instructions for Use
eifu.goremedical.com

INSTRUCTIONS FOR USE

The most up-to-date version of the *Instructions for Use* (IFU) can be found at the web address: https://eifu.goremedical.com and by searching for the device part number or prefix (e.g. "RLT"). Additional details on the GORE® EXCLUDER® AAA Endoprosthesis can be found in the Summary of Safety and Effectiveness Data (SSED) document on the U.S. FDA website at the web address: https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020004B.pdf

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

Table 1: GORE® EXCLUDER® AAA Endoprosthesis regulatory approval history

Country/Region	Approval date
Europe	September 1997
Brazil	January 2005
United States	November 2002
Japan	January 2007
Canada	October 2008
Australia	December 2008
China	January 2010

Worldwide device distribution

From September 1997 through June 2021 more than 420,000 GORE® EXCLUDER® AAA Endoprostheses have been distributed. This includes more than 16,000 original and modified GORE® EXCLUDER® Devices and more than 400,000 low permeability GORE® EXCLUDER® Devices. These devices have been comprised of a total of more than 1.3 million GORE® EXCLUDER® Device components distributed in more than 75 countries around the world.

This ACU covers the time period of July 1, 2020 – June 30, 2021, during which a total of approximately 120,000 GORE® EXCLUDER® Device Trunk-Ipsilateral Limbs, GORE® EXCLUDER® Device Contralateral Limbs, GORE® EXCLUDER® Device Aortic Extenders and GORE® EXCLUDER® Device Iliac Extenders were distributed globally.

Clinical evaluations

There are no active investigational device exemption (IDE) or post market approval clinical evaluations of the GORE® EXCLUDER® Device. A list of prior clinical evaluations can be found below and a summary of the results of each can be found in the *Instructions for Use* (IFU) at the web address https://eifu.goremedical.com and searching for MD175454.

98-03 & 99-04	Pivotal Clinical Studies of the original and modified GORE® EXCLUDER® AAA Endoprosthesis
04-04	Post-approval study evaluating the performance of the low permeability GORE® EXCLUDER® Device
03-02	US IDE Clinical Study of the 31 mm Trunk-Ipsilateral Leg and 32 mm Aortic Extender sizes

Worldwide recalls, safety communications and field safety notices

During the period covered by this annual clinical update, July 1, 2020 – June 30, 2021, there have been no recalls, safety communications or field safety notices associated with the GORE® EXCLUDER® Device.

Worldwide commercial experience

Ongoing post-market surveillance in the form of adverse event and complaint reporting, investigation, tracking and trending is conducted for all markets in which the GORE® EXCLUDER® Device is distributed. The data presented in **Table 2** summarizes the data from adverse events reported to Gore for which investigations were completed between July 1, 2020 and June 30, 2021. During this time, approximately 120,000 GORE® EXCLUDER® Device components were distributed globally. In summary, the quantity of adverse event reports presented in **Table 2** are similar or fewer in quantity than those reported in prior versions of this ACU. Adverse event reports are not mutually exclusive and may contain multiple separate adverse events, all of which are accounted for in the data presented. Additionally, adverse events occurring post-procedurally often occur years following the initial treatment.

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

Table 2: Summary of GORE® EXCLUDER® Device worldwide performance*

Adverse event	Number of events
Aneurysm-related death†	8
Post-procedure aneurysm rupture	10
Aneurysm enlargement‡	107
Conversion	21
Migration§	36
Device occlusion	13
Infection	4
Infolding	1
Type III endoleaks‖	20
Deployment anomalies	23
Stent fractures	3

* Note that adverse event reporting comprises events associated with GORE® EXCLUDER® Devices that were implanted prior to 2020/2021 commercial distribution.

† Aneurysm-related deaths are defined as any deaths within 30 days or due to aneurysm rupture, a primary or secondary procedure, or surgical conversion.

‡ 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.

‖ Seventeen reported Type IIIa endoleaks (Trunk Ipsilateral Leg / Contralateral Leg Junction [two], Trunk Ipsilateral Leg Endoprosthesis -Aortic Extender Junction [two], Contralateral Leg - Contralateral Leg Junction [two], Contralateral Leg-Iliac Branch Endoprosthesis Junction [ten], not reported [one]) two Type IIIb endoleaks, and one Type III endoleak of unspecified origin.

Explant analysis

The data presented in **Table 3** summarize the reason for explant for investigations completed between July 1, 2020 and June 30, 2021. Of the 21 open surgical conversions reported, three explanted devices were returned to Gore for analysis while two others were evaluated by an independent explant analysis facility.

Table 3: Primary cause of explant

	Number of occurrences (July 1, 2020 – June 30, 2021)	
Reason for explant	**Original GORE® EXCLUDER® Device**	**Low permeability GORE® EXCLUDER® Device**
Implantation difficulties	0	3
Rupture	0	1
Aneurysm enlargement without endoleak	0	1
Aneurysm enlargement with endoleak	0	9
Endoleak	0	2
Migration	0	0
Infection	0	5
Aortoenteric fistula	0	0
Occlusion	0	0
Incidental autopsy	0	0
Other	0	0
Total cases	0	21

Of the five explanted devices available for analysis, one was explanted during the primary procedure following an iliac artery rupture. The remaining four were in-life for an average of 3,206 days (between 1,473 and 4,013 days). One of these devices exhibited a single fatigue-induced wire fracture with no associated graft disruptions. Another device, explanted for endoleak of unknown origin after 3,637 days, exhibited multiple abrasion holes and two wire fractures in a tortuous region of overlapping iliac limb components.

Literature review

The following peer-reviewed literature articles published between July 1, 2020 and June 30, 2021 describe the safety and effectiveness of the GORE® EXCLUDER® Device:

Bogdanovic, et al., report on the clinical outcomes related to limb graft occlusion (LGO) following endovascular aneurysm repair (EVAR) in 924 patients treated at five Swedish vascular surgery centers from 2012 – 2018. Patients were treated with COOK® ZENITH® ALPHA SPIRAL-Z® Endovascular Leg (n = 315, Z1SL limbs), GORE® EXCLUDER® Device (n = 152, PLC/PXC limbs), MEDTRONIC ENDURANT® II AAA Stent Graft System and MEDTRONIC ENDURANT® IIs AAA Stent Graft System (n = 457, ETLW/ETEW limbs). Median follow-up was 37 months for all subjects with a total of 55 limb occlusions (5.9%); 39 with COOK® ZENITH® ALPHA SPIRAL-Z® Endovascular Leg (12.4%), one with GORE® EXCLUDER® Device (0.7%), and 15 with MEDTRONIC ENDURANT® II AAA Stent Graft System and MEDTRONIC ENDURANT® IIs AAA Stent Graft System (3.3%). Independent risk factors for LGO were use of the COOK® ZENITH® ALPHA SPIRAL-Z® Endovascular Leg device (OR 5.31, 95% CI 1.97 - 14.3), landing in the external iliac artery (OR 5.91, 95% CI 1.30 - 26.7) and external iliac artery diameter < 10 mm (OR 4.99, 95% CI 1.46 - 16.9).[1]

Charlton-Ouw, et al., report on data collected in Gore's GREAT to evaluate the impact of endograft proximal and distal oversizing on endoleak, reintervention and mortality. Of the 3,607 participants, 53% were within IFU for oversizing, 22% were oversized, 15% were undersized and 10% had both oversized and undersized components. Undersizing of the proximal graft was associated with endoleak (Hazard Ratio [HR], 1.8) and an increased risk of aortic (HR, 65.7) and all-cause mortality (HR, 18.0). Under sizing of the iliac limbs was associated with endoleak (HR, 1.5) and increased risk of device-related reintervention (HR, 1.3). Proximal and distal oversizing were not associated with adverse outcomes.[2]

Piazza, et al., report on the early and long-term outcomes of EVAR with the GORE® EXCLUDER® Device in young and low surgical risk patients from the Gore GREAT. Of the 3,217 patients included in the analysis, 182 (6%) were < 60 years old, 956 (30%) had a low surgical risk, 1,561 (49%) had an average risk and 700 (22%) had high surgical risk. A longer infrarenal neck and lower neck angulation were present in young compared with old patients. Low-risk patients had significantly lower early mortality compared with average and high-risk patients. At six years, lower-risk patients had significantly decreased aorta-related mortality (0% vs. 2%, $P = .04$) and reintervention rates (6% vs. 11%, $P = .007$). Similar rates of aorta-related mortality and reintervention were observed between young and old patients.[3]

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.

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 safe and effective 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 exceeding 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. Bogdanovic M, Stackelberg O, Lindstrom D, *et al*. Limb Graft Occlusion Following Endovascular Aneurysm Repair for Infrarenal Abdominal Aortic Aneurysm with the Zenith Alpha, Excluder, and Endurant Devices: a Multicentre Cohort Study. *European Journal of Vascular and Endovascular Surgery* 2021; 62(4):532-539.
2. Charlton-Ouw KM, Ikeno Y, Bokamper M, *et al*. Aortic endograft sizing and endoleak, reintervention, and mortality following endovascular aneurysm repair. *Journal of Vascular Surgery* 2021;74(5):1519-1526.
3. Piazza M, Squizzato F, Colacchio C, Grego F, Trimarchi S. Early and Long-Term Outcomes of Endovascular Aortic Repair in Young and Low-Surgical-Risk Patients in the Global Registry for Endovascular Aortic Treatment. *Journal of Vascular Surgery* 2020;72(1):e103-e104.

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INDICATIONS FOR USE: Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components. The GORE® EXCLUDER® AAA Endoprosthesis 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. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components.** 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. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

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