GORE® EXCLUDER®
Conformable AAA
Endoprosthesis

ANNUAL CLINICAL UPDATE

December 23, 2020 through
October 19, 2021

Together, improving life

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Device description

The GORE® EXCLUDER® Conformable AAA Endoprosthesis is an implantable endoprosthesis which consists of two modular components, the Trunk-Ipsilateral Leg Component and the optional Aortic Extender Component. The EXCLUDER® Conformable Device Trunk-Ipsilateral Leg Component is designed to be used, at minimum, with one commercially available GORE® EXCLUDER® Contralateral Leg Component. Use of an EXCLUDER® Conformable Aortic Extender is optional in the event proximal extension is needed. Additional GORE® EXCLUDER® Contralateral Leg Component(s), Iliac Extender Component(s) and the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) may be used if needed to provide extension and seal into the iliac arteries.

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. ePTFE/FEP primary and secondary sleeves are attached to the endoprosthesis and are used to constrain the endoprosthesis on the leading end of the delivery catheter. Radiopaque markers are attached to the stent graft and delivery system to facilitate fluoroscopic visualization and orientation.

Deployment of both the EXCLUDER® Conformable Device Trunk-Ipsilateral Leg Component and the Aortic Extender Component are achieved using the GORE® ACTIVE CONTROL System. For both components, deployment is initiated by pulling a deployment line that releases the constrained device from the sleeve, allowing the stent graft to expand in vivo. The delivery system of the Trunk-Ipsilateral Leg Component includes a proximal re-constraining fiber and a secondary sleeve that allow for the ability to re-constrain and reposition prior to full deployment, if desired. Additionally, the ACTIVE CONTROL System of both the Trunk-Ipsilateral Leg Component and the Aortic Extender Component features an angulation control knob that may be used to actuate an angulation wire within the delivery catheter to angulate the device, aiding in orthogonal device positioning. This brief description of the device and its construction will facilitate interpretation of the clinical results in this report.

INSTRUCTIONS FOR USE

The most up-to-date version of the *Instructions for Use* (IFU) can be found at https://eifu.goremedical.com and searching for the device part number or prefix (e.g., "CXT"). Additional details on the GORE® EXCLUDER® Conformable AAA Endoprosthesis can be found in the Summary of Safety and Effectiveness Data (SSED) document on the U.S. Food and Drug Administration (FDA) website at the web address: https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200030B.pdf

Overview

This annual clinical update provides a review of the ongoing experience with the GORE® EXCLUDER® Conformable AAA Endoprosthesis used in the treatment of abdominal aortic aneurysms. This device has been commercially available since it was first launched in Europe in September 2018 and has been commercially available in the United States since March 2021. This update provides the most recent results from the pivotal clinical study, Assessment of the GORE® EXCLUDER® Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms, as well as the commercial experience since U.S. regulatory approval.

The GORE® EXCLUDER® Conformable Device is a modular system that includes the GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Endoprosthesis and the GORE® EXCLUDER® Conformable Aortic Extender Endoprosthesis for proximal extension, as needed. The Trunk-Ispilateral Component is intended to be used in conjunction with the GORE® EXCLUDER® Contralateral Leg Endoprosthesis and, if needed, the GORE® EXCLUDER® Iliac Extender Endoprosthesis for distal extension.

The design of the GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg and Aortic Extender Endoprostheses is similar to that of the GORE® EXCLUDER® Device but has been modified to improve the ability of the trunk body to conform to the proximal aortic neck in challenging anatomies. The ACTIVE CONTROL System builds on the GORE® C3® Delivery System of the GORE® EXCLUDER® Trunk-Ipsilateral Leg Endoprosthesis with the addition of an angulation control knob that enables the user to angle the proximal end of both the Trunk-Ipsilateral Leg and Aortic Extender Components to promote orthogonal placement in the patient's aorta. In addition, the delivery system of the Trunk-Ipsilateral Component has been designed to better facilitate repositioning through the inclusion of a secondary deployment sleeve that constrains the trunk portion of the device to approximately 70% of its diameter prior to full deployment.

Worldwide device distribution

As of October 19, 2021, a total of approximately 7,000 GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Endoprostheses and 1,500 GORE® EXCLUDER® Conformable Aortic Extender Endoprostheses have been distributed worldwide. This includes approximately 5,000 device components distributed worldwide since U.S. commercial release in March 2021 following U.S. FDA Approval. All patients treated with the GORE® EXCLUDER® Conformable AAA Endoprosthesis also require the use of at least one GORE® EXCLUDER® Contralateral Limb Endoprosthesis and, if needed, one or more GORE® EXCLUDER® Iliac Extender Endoprostheses. The commercial experience with these additional device components is reported in the GORE® EXCLUDER® AAA Endoprosthesis Annual Clinical Update.

Clinical evaluations

The Assessment of the GORE® EXCLUDER® Conformable Device in the Treatment of Abdominal Aortic Aneurysms clinical study (AAA 13-03; IDE G150057; NCT 02489539) is a prospective, nonrandomized, multicenter study with two parallel substudies to assess the safety and effectiveness of the GORE® EXCLUDER® Conformable Device for treatment of patients with infrarenal abdominal aortic aneurysms.

SHORT NECK SUBSTUDY

Subjects with abdominal aortic aneurysms having aortic neck angulation ≤ 60˚ and infrarenal aortic neck length ≥ 10 mm.[1]

HIGH NECK ANGULATION SUBSTUDY

Subjects with abdominal aortic aneurysms having aortic neck angulation > 60˚ and ≤ 90˚ and infrarenal aortic neck length ≥ 10 mm.[2]

The AAA 13-03 study is a multicenter study with a maximum of up to 56 sites and up to 190 patients treated with the EXCLUDER® Conformable Device. (80 patients in the Short Neck Substudy, 110 patients in the High Neck Angulation Substudy).[3] Short Neck Substudy enrollment began in December 2017 and closed in February 2019. Five-year follow-up for the Short Neck Substudy is expected to be completed in 2024. Enrollment in the High Neck Angulation Substudy is ongoing and, as such, the data is not yet available.

Details of clinical pivotal study AAA 13-03 Short Neck Substudy[3]

Eighty patients were enrolled at 31 investigational sites in the Short Neck Substudy.

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

- Death
- Stroke
- Myocardial infarction
- Bowel ischemia
- Paraplegia
- Respiratory failure
- Renal failure
- Blood loss > 1000 ml
- Thromboembolic events (including limb occlusion and distal embolic events)

The primary effectiveness endpoint was treatment success, defined as technical success (successful access and deployment of all required GORE® EXCLUDER® Conformable Device Components) and freedom from the following events:

- Type I endoleak
- Type III endoleak
- Migration (10 mm or more)
- AAA enlargement ≥ 5 mm with or without intervention
- AAA rupture
- Conversion to open repair

Data from the AAA 13-03 Short Neck Substudy subjects as of October 26, 2021 through up to four-years follow-up are presented below in Table 1. All eligible subjects have reached the two-year study window, and a majority have completed follow-up within the three-year study window.

Six subjects (7.5%) have received reinterventions. Five subjects have received embolization for Type II endoleak or aneurysm sac expansion and one received an additional stent for iliac limb stenosis distal to the implanted endograft.

Although the Short Neck Substudy enrollment included patients with infrarenal neck length ≥ 10 mm in length, the U.S. FDA indication is currently limited to patients with neck length ≥ 15 mm.

Table 1: AAA 13-03 Clinical Trial through 5 Years of follow-up — Short Neck Substudy[*, 1]

	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total
Subjects eligible for follow-up	80	79	79	75	67	27	0	80
Subjects discontinued or lost to follow-up	1	0	4	8	2	0	0	15
Aneurysm-related mortality	0/80	0/79	0/79	0/74	0/54	0/1	-	0/80
Aneurysm rupture	0/80	0/79	0/79	0/74	0/54	0/1	-	0/80
Conversion to open repair	0/80	0/79	0/79	0/74	0/54	0/1	-	0/80
Type I endoleak	0/75	0/70	0/67	0/51	0/42	0/1	-	0/78
Type Ia endoleak	0/75	0/70	0/67	0/51	0/42	0/1	-	0/78
Type Ib endoleak	0/75	0/70	0/67	0/51	0/42	0/1	-	0/78
Type II endoleak	31/75 (41.3%)	24/70 (34.3%)	18/67 (26.9%)	14/51 (27.5%)	10/42 (23.8%)	1/1 (100.0%)	-	35/78 (44.9%)
Type III endoleak	0/75	0/70	0/67	0/51	0/42	0/1	-	0/78
Type IV endoleak	0/75	0/70	0/67	0/51	0/42	0/1	-	0/78
Indeterminate endoleak	3/75 (4.0%)	1/70 (1.4%)	3/67 (4.5%)	0/51	0/42	0/1	-	6/78 (7.7%)
Aneurysm enlargement ≥ 5 mm	Baseline	1/74 (1.4%)	1/73 (1.4%)	4/55 (7.3%)	5/48 (10.4%)	1/1 (100.0%)	-	5/77 (6.8%)
Prosthesis migration ≥ 10 mm	0/79	0/75	0/73	0/56	0/49	0/1	-	0/80
Intercomponent migration ≥ 10 mm	0/79	0/75	0/73	0/56	0/49	0/1	-	0/80
Occlusions								
Trunk-Ipsilateral Leg	0/77	0/72	0/68	0/51	0/43	0/1	-	0/80
Contralateral Leg	0/77	0/72	0/68	0/51	0/43	0/1	-	0/80
Iliac Extender	0/35	0/33	0/30	0/24	0/19	-	-	0/37
Wire fracture[†]	0/73	0/69	0/71	0/54	0/46	0/1	-	0/80
Extrusion/Erosion[‡]	0/79	0/75	0/73	0/56	0/49	0/1	-	0/80
Lumen obstruction (i.e., stenosis)	0/77	0/72	0/68	0/51	0/43	0/1	-	0/80
Device compression (i.e., kink)	0/79	0/75	0/73	0/56	0/49	0/1	-	0/80

* Denominators used in calculation of percentages are number of subjects at risk (for aneurysm related mortality, aneurysm rupture and conversion to open repair) or with an evaluable result (for all other outcomes which are derived from Core Lab assessment of imaging). 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)

† Wire fracture was considered assessed and included in denominator if any fracture was present or at a minimum the non-overlap areas of investigational device could be assessed.

‡ Extrusion/Erosion of the metal frame through the full thickness of the vessel wall.

Worldwide recalls, safety communications and field safety notices

During the period covered by this Annual Clinical Update, December 23, 2020 – October 19, 2021, there have been no recalls, safety communications or field safety notices associated with the GORE® EXCLUDER® Conformable AAA Endoprosthesis.

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® Conformable AAA Endoprosthesis is distributed. The data presented in Table 2 below summarizes the data from adverse events reported to Gore for which investigations were completed from the date of U.S. FDA approval, December 22, 2020, to October 19, 2021. During this time period, a total of approximately 5,000 GORE® EXCLUDER® Conformable AAA Endoprosthesis Components were distributed globally. Adverse event reports are not mutually exclusive and may contain multiple separate adverse events, all of which are accounted for in the data presented.

Explant analysis

In the period covered by this update (December 23, 2020 – October 19, 2021), there was one reported surgical conversion and explant of a GORE® EXCLUDER® Conformable Endoprosthesis. There were no device integrity observations reported. There have been no explanted GORE® EXCLUDER® Conformable Devices returned to Gore for analysis.

Literature review

There were no peer-reviewed literature articles published over the last year describing the safety and effectiveness of the GORE® EXCLUDER® Conformable AAA Endoprosthesis when used on-label according to U.S. FDA approval.

Conclusion

Based on available clinical study data and worldwide clinical experience to date, endovascular treatment with the GORE® EXCLUDER® Conformable AAA Endoprosthesis is a viable treatment option for the treatment of abdominal aortic aneurysms.

Table 2: Summary of worldwide performance[*,1]

	Number of events
Aneurysm-related death[†]	0
Post-procedure aneurysm rupture	0
Aneurysm enlargement[‡]	1
Conversion	1[§]
Migration[‖]	1[§]
Device occlusion	0
Infection	0
Infolding	0
Type III endoleaks	0
Deployment anomalies	7
Stent fractures	0

* Data from adverse events reported to Gore for which investigations were completed from the date of U.S. FDA Approval to October 19, 2021.

† 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.

§ One report of surgical conversion 8 days post-op secondary to proximal migration of the device.

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

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® Conformable AAA 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 with endovascular devices demonstrates that some adverse events may become apparent over time. 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 U.S. IFU, critical factors for successful clinical outcomes include:

- Appropriate patient selection, including:
  - Adequate iliac/femoral access
  - Infrarenal aortic neck treatment diameter range of 16–32 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. Rhee R, Peterson B, Moore E, Lepore M, Oderich G. Initial human experience with the GORE EXCLUDER conformable AAA endoprosthesis. *Journal of Vascular Surgery Cases & Innovative Techniques* 2019;5(3):319-322.
2. W. L. Gore & Associates. Evaluation of the GORE® EXCLUDER® Iliac Branch Endoprosthesis for the Treatment of Common Iliac Artery Aneurysms or Aorto-iliac Aneurysms. NLM Identifier: NCT01883999. Published June 21, 2013. Updated November 2, 2021. Accessed June 7, 2022. https://clinicaltrials.gov/ct2/show/NCT01883999
3. W. L. Gore & Associates. Assessment of the GORE® EXCLUDER® Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms. NLM Identifier: NCT02489539. Published July 3, 2015. Updated May 2, 2022. Accessed June 7, 2022. https://clinicaltrials.gov/ct2/show/NCT02489539

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components. The GORE® EXCLUDER® Conformable 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 16 – 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® Conformable AAA Endoprosthesis. These extensions are intended to be used when additional length and / or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Conformable 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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