GORE® EXCLUDER®
Conformable AAA
Endoprosthesis

ANNUAL CLINICAL UPDATE

July 1, 2023 through
June 30, 2024

Together, improving life

Table of contents

Device description

The GORE® EXCLUDER® Conformable AAA Endoprosthesis is an implantable endoprosthesis that consists of 2 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 1 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 is 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.

Consult Instructions for Use
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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, with the broader indication (≥10 mm aortic neck length and up to 90° aortic neck angle) approved by the FDA in April 2024. 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-Ipsilateral 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 June 30, 2024, a total of approximately 59,628 GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Endoprostheses and GORE® EXCLUDER® Conformable Aortic Extender Endoprostheses have been distributed worldwide. All patients treated with the GORE® EXCLUDER® Conformable AAA Endoprosthesis also require the use of at least 1 GORE® EXCLUDER® Contralateral Limb Endoprosthesis and, if needed, 1 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 2 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 43 sites treating 175 patients with the EXCLUDER® Conformable Device (80 patients in the Short Neck Substudy, 95 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 was completed in 2024. Enrollment in the High Neck Angulation Substudy began in January 2018 and closed in February 2022. Five-year follow-up for the High Neck Angulation Substudy is ongoing and expected to be completed in 2027.

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

175 patients were enrolled at 43 investigational sites.

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 12-month 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 AAA 13-03 subjects within each substudy as of May 9, 2024 through up to 5 years follow-up are presented below in Table 1 and 2.

In the Short Neck Substudy (Table 1), 9 subjects (11.3%) have received reinterventions, including embolization(s) in 8 subjects and additional stenting in 1 subject. One subject received open surgical repair (without device explant) for endotension.

In the High Neck Angulation Substudy (Table 2), 14 subjects (14.7%) have received reinterventions, including embolization(s) in 12 subjects and additional stenting in 3 subjects. Two subjects were converted to open repair due to a stent graft occlusion resulting from a Type A aortic dissection in the thoracic aorta in the first case, and a persistent Type II endoleak in the second.

GORE® EXCLUDER® Conformable AAA Endoprosthesis AAA 13-03

Table 1: Short Neck Substudy (≤ 60°)

		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 subjects	80	80	80	79	79	75	67	62	53	80
Image findings†										
Lumen obstruction (i.e., stenosis)	–	0/2	0/77	0/72	0/68	0/53	0/49	0/47	0/41	0/80
Device compression (i.e., kink)	–	0/2	0/79	0/75	0/73	0/58	0/55	0/51	0/45	0/80
Non-patent component	–	0/2	0/77	0/72	0/68	0/53	0/49	0/47	0/41	0/80
Non-patent Trunk-Ipsilateral Leg	–	0/2	0/77	0/72	0/68	0/53	0/49	0/47	0/41	0/80
Non-patent Contralateral Leg	–	0/2	0/77	0/72	0/68	0/53	0/49	0/47	0/41	0/80
Non-patent Iliac Extension	–	0/1	0/36	0/33	0/30	0/24	0/22	0/21	0/18	0/37
Extrusion/Erosion	–	0/2	0/79	0/75	0/73	0/58	0/55	0/51	0/45	0/80
Wire fracture‡	–	0/1	0/73	0/69	0/71	0/55	0/51	0/45	0/42	0/80
Migration§	–	–	Baseline	0/75	0/73	0/58	0/55	0/51	0/45	0/78
Prosthesis migration ≥ 10 mm	–	–	Baseline	0/75	0/73	0/58	0/55	0/51	0/45	0/78
Intercomponent migration ≥ 10 mm	–	–	Baseline	0/75	0/73	0/58	0/55	0/51	0/45	0/78
Endoleak	–	1/2 (50.0%)	33/75 (44.0%)	25/70 (35.7%)	21/67 (31.3%)	16/53 (30.2%)	13/49 (26.5%)	16/47 (34.0%)	11/41 (26.8%)	37/78 (47.4%)
Type I	–	0/2	0/75	0/70	0/67	0/53	0/49	0/47	0/41	0/78
Type IA	–	0/2	0/75	0/70	0/67	0/53	0/49	0/47	0/41	0/78
Type IB	–	0/2	0/75	0/70	0/67	0/53	0/49	0/47	0/41	0/78
Type II	–	1/2 (50.0%)	31/75 (41.3%)	24/70 (34.3%)	18/67 (26.9%)	16/53 (30.2%)	13/49 (26.5%)	14/47 (29.8%)	10/41 (24.4%)	36/78 (46.2%)
Type III	–	0/2	0/75	0/70	0/67	0/53	0/49	0/47	0/41	0/78
Type IV	–	0/2	0/75	0/70	0/67	0/53	0/49	0/47	0/41	0/78
Indeterminate	–	0/2	3/75 (4.0%)	1/70 (1.4%)	3/67 (4.5%)	1/53 (1.9%)	0/49	2/47 (4.3%)	1/41 (2.4%)	9/78 (11.5%)
AAA expansion ≥ 5 mm§	–	–	Baseline	1/75 (1.3%)	1/74 (1.4%)	5/58 (8.6%)	6/55 (10.9%)	8/51 (15.7%)	5/45 (11.1%)	8/78 (10.3%)
Clinical events‖										
Reintervention	0/80	0/80	1/80 (1.3%)	1/79 (1.3%)	1/79 (1.3%)	4/75 (5.3%)	2/67 (3.0%)	5/62 (8.1%)	0/53	9/80 (11.3%)
Conversion to open repair	0/80	0/80	0/80	0/79	0/79	0/75	0/67	0/62	0/53	0/80
AAA rupture¶	0/80	0/80	0/80	0/79	0/79	0/75	0/67	1/62 (1.6%)	0/53	1/80 (1.3%)
Aneurysm-related mortality	0/80	0/80	0/80	0/79	0/79	0/75	0/67	0/62	0/53	0/80

Table 2: High Neck Angulation Substudy (> 60° and ≤ 90°)

		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 subjects	95	95	95	95	92	83	63	47	19	95
Image findings†										
Lumen obstruction (i.e., stenosis)	–	0/3	1/83 (1.2%)	0/78	0/73	0/58	0/45	0/29	0/8	1/94 (1.1%)
Device compression (i.e., kink)	–	0/3	1/84 (1.2%)	0/81	0/78	0/63	0/49	0/34	0/9	1/95 (1.1%)
Non-patent component	–	0/3	1/83 (1.2%)	0/78	0/73	0/58	0/45	0/29	0/9	1/94 (1.1%)
Non-patent Trunk-Ipsilateral Leg	–	0/3	1/83 (1.2%)	0/78	0/73	0/58	0/45	0/29	0/9	1/94 (1.1%)
Non-patent Contralateral Leg	–	0/3	1/83 (1.2%)	0/78	0/73	0/58	0/45	0/29	0/9	1/94 (1.1%)
Non-patent Iliac Extension	–	0/1	1/67 (1.5%)	0/64	0/61	0/49	0/37	0/23	0/6	1/77 (1.3%)
Extrusion/Erosion	–	0/3	0/84	0/81	0/78	0/63	0/49	0/34	0/9	0/95
Wire fracture‡	–	0/2	0/81	0/77	0/73	0/58	0/49	0/29	0/9	0/95
Migration§	–	–	Baseline	0/77	0/77	0/63	0/49	0/34	0/9	0/91
Prosthesis migration ≥ 10 mm	–	–	Baseline	0/77	0/77	0/63	0/49	0/34	0/9	0/91
Intercomponent migration ≥ 10 mm	–	–	Baseline	0/77	0/77	0/63	0/49	0/34	0/9	0/91
Endoleak	–	3/3 (100.0%)	43/81 (53.1%)	34/77 (44.2%)	31/73 (42.5%)	21/57 (36.8%)	16/44 (36.4%)	11/29 (37.9%)	4/9 (44.4%)	59/94 (62.8%)
Type I	–	0/3	1/81 (1.2%)	3/77 (3.9%)	0/73	0/57	0/44	0/29	0/9	4/94 (4.3%)
Type IA	–	0/3	1/81 (1.2%)	3/77 (3.9%)	0/73	0/57	0/44	0/29	0/9	4/94 (4.3%)
Type IB	–	0/3	0/81	0/77	0/73	0/57	0/44	0/29	0/9	0/94
Type II	–	3/3 (100.0%)	35/81 (43.2%)	29/77 (37.7%)	29/73 (39.7%)	18/57 (31.6%)	15/44 (34.1%)	8/29 (27.6%)	4/9 (44.4%)	53/94 (56.4%)
Type III	–	0/3	0/81	0/77	0/73	0/57	0/44	0/29	0/9	0/94
Type IV	–	0/3	0/81	0/77	0/73	0/57	0/44	0/29	0/9	0/94
Indeterminate	–	0/3	7/81 (8.6%)	5/77 (6.5%)	2/73 (2.7%)	3/57 (5.3%)	1/44 (2.3%)	3/29 (10.3%)	1/9 (11.1%)	18/94 (19.1%)
AAA expansion ≥ 5 mm§	–	–	Baseline	1/76 (1.3%)	1/75 (1.3%)	12/61 (19.7%)	9/48 (18.8%)	6/33 (18.2%)	1/10 (10.0%)	18/88 (20.5%)
Clinical events‖										
Reintervention	0/95	0/95	2/95 (2.1%)	2/95 (2.1%)	3/92 (3.3%)	5/83 (6.0%)	4/63 (6.3%)	2/47 (4.3%)	1/19 (5.3%)	14/95 (14.7%)
Conversion to open repair	0/95	0/95	1/95 (1.1%)	0/95	0/92	0/83	1/63 (1.6%)	0/47	0/19	2/95 (2.1%)
AAA rupture¶	0/95	0/95	0/95	0/95	0/92	0/83	0/63	0/47	0/19	0/95
Aneurysm-related mortality	0/95	0/95	0/95	0/95	0/92	0/83	0/63	0/47	0/19	0/95

Footnotes for Table 1 and Table 2

* No study visit was required in the Post-Procedure Analysis Window (Day 1-14).

† Imaging findings are reported by an independent Core Lab. Denominators are number of subjects with an evaluable result for specified parameter. Per protocol, imaging findings for subjects who are post-conversion to open repair (as adjudicated by CEC) are not included. Numerators report any scan in window with a device event.

‡ 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.

§ Subject must have a post-operative baseline and post-baseline image to be evaluable.

‖ Clinical events are site-reported adverse events adjudicated by an independent Clinical Events Committee. Denominator is the number of subjects at risk in window, inclusive of subjects who are post-conversion to open repair (as adjudicated by CEC).

¶ AAA rupture may be reported by either Core Lab imaging evaluation or by site-reported, CEC-adjudicated adverse event.

Study period definitions: Procedure (0 days); Post-procedure (1-14 days); 1 month (15-59 days); 6 months (60-242 days); 12 months (243-546 days); 24 months (547-911 days); 36 months (912-1275 days); 48 months (1276-1640 days); 60 months (1641-2006 days); Total (0-2006 days).

Worldwide recalls, safety communications and field safety notices

During the period covered by this annual clinical update, July 1, 2023 – June 30, 2024, 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 July 1, 2023, to June 30, 2024. During this time period, a total of approximately 23,437 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 (July 1, 2023 – June 30, 2024), there were 14 reported surgical conversions and explant of a GORE® EXCLUDER® Conformable Endoprosthesis. There was 1 explanted GORE® EXCLUDER® Conformable Device returned to Gore for analysis. An examination of this device showed the presence of fracture in the stent wire.

Literature review

There were 9 peer-reviewed literature articles published during the report time-period describing the safety and effectiveness of the GORE® EXCLUDER® Conformable AAA Endoprosthesis. These peer-reviewed publications demonstrate that the GORE® EXCLUDER® Conformable Device continues to show acceptable safety and effectiveness profile in the longer term. The GORE® EXCLUDER® Conformable Device remains a safe and effective device for the treatment of AAA disease.

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[†]	2
Post-procedure aneurysm rupture	5
Aneurysm enlargement[‡]	15
Conversion[§]	14
Migration[‖]	12
Device occlusion	1
Infection	2
Infolding	3
Type III endoleaks	11
Deployment anomalies	38
Stent fractures	1

* Data from adverse events reported to Gore for which investigations were completed from July 1, 2023 to June 30, 2024.

† 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.

§ Three reports of surgical conversion intra-procedure, 2 due to positioning complications and 1 for access complications. 11 reports of surgical conversion post-procedure, 6 for enlargement with endoleak, 1 each for unsuitable anatomy, infection, positioning difficulties, and 2 for unspecified reasons.

‖ 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 demonstrate 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 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 10 mm
  - Proximal aortic neck angulation ≤ 90°
  - 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

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Consult Instructions for Use
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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 10 mm; Proximal aortic neck angulation ≤ 90°; 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. All components of the GORE® EXCLUDER® Conformable Endoprosthesis contain expanded polytetrafluoroethylene (ePTFE), fluorinated ethylene propylene (FEP), nitinol (nickel-titanium alloy) and gold. Patients with 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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