GORE® EXCLUDER®
AAA Endoprosthesis

GORE® EXCLUDER®
Iliac Branch Endoprosthesis

GORE® EXCLUDER®
Conformable AAA Endoprosthesis

The GORE® EXCLUDER® Device family

AN EVAR PORTFOLIO YOU CAN COUNT ON

Together, improving life

GORE® EXCLUDER®
AAA Endoprosthesis

DURABILITY
you can count on

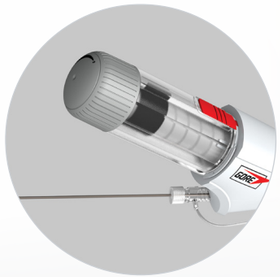
The most-studied EVAR device,* designed to provide an optimal infrarenal seal and reliable results.

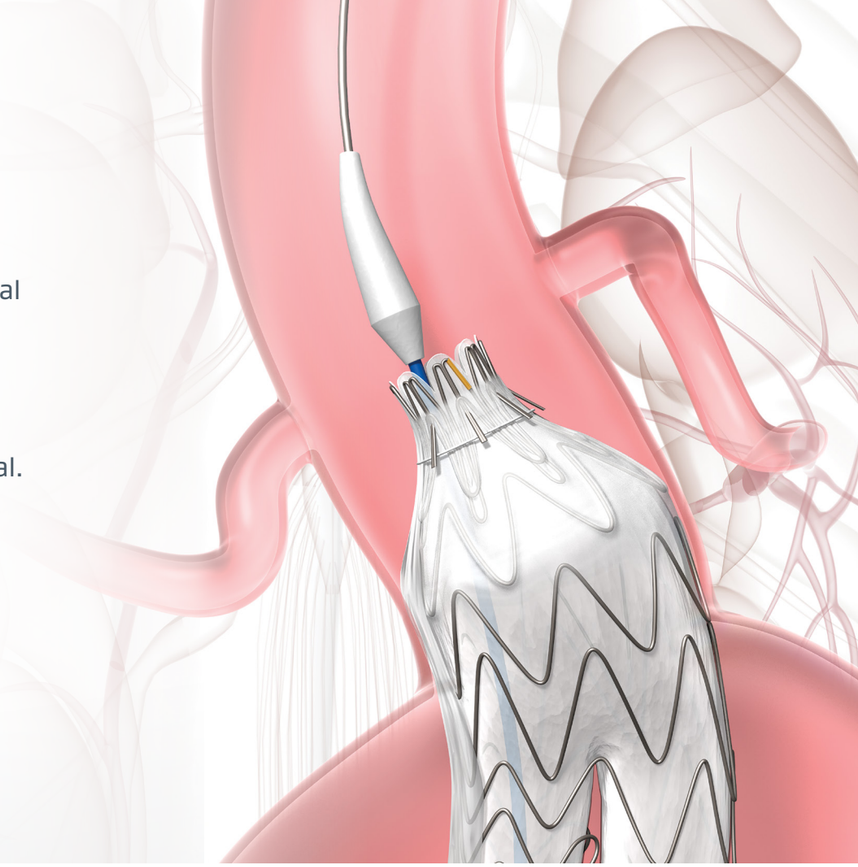
Click to see device animation.

Repositionable to obtain optimal seal.

Unique ability to reconstrain the proximal end and reposition for ideal placement.

More opportunities to maximize infrarenal seal.





3,274 patients through **5 years** of follow-up†

94.7% Freedom from device-related reintervention	**0.2%** Type III endoleak
0.1% Migration	**0.7%** Limb occlusion
1.6% Type I endoleak	**0.4%** Renal complications‡

* Based on company-sponsored trials and registries shown on clinicaltrials.gov for currently available stent grafts.

† Results from the real-world patient population enrolled in the Global Registry for Endovascular Aortic Treatment (GREAT) (n = 3,274). To calculate the overall rates from procedure through end of study period, all subjects who could have had events, regardless of length of follow-up, were included. For outcome data, GREAT only collects site-reported serious adverse events (SAE).

‡ Inclusion for renal complication rate: Subjects with renal complication were identified with MedDRA code. Of those identified with MedDRA code as having a renal complication, only those who showed the SAE occurring within 75 days of the procedure AND were reported by the site/physician as being related to the device or procedure were included in the renal complication rate.

GORE® EXCLUDER®
Conformable AAA
Endoprosthesis

CONTROL
you can count on

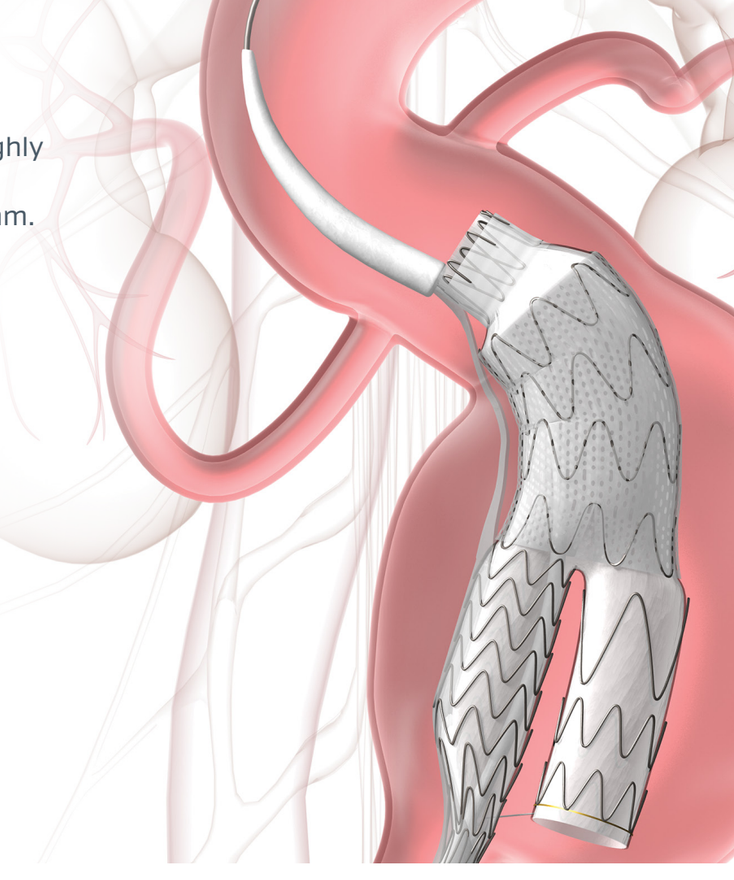
The only EVAR device with angulation control, offering controlled conformability when you need it most.

Click to see device animation.

The only on-label solution for highly angulated aortic necks up to 90° and neck lengths of at least 10 mm.

The conformability to adapt to challenging anatomies.

The capability to reconstrain, reposition and refine angulation in stages.



Patients with neck angles between 60° and 90° outcomes: 1-year follow-up*

97.9%
Technical success

98.9%
Freedom from device-related serious adverse events

ZERO REPORTED
Type III endoleaks
Migrations
Ruptures
Stent fractures

4 Type I endoleaks†

1 Conversion to open repair‡

1 Device occlusion§

Change in AAA diameter‖

26 (34.7%)
≥ 5 mm decrease

48 (64.0%)
NO CHANGE

1 (1.3%)
≥ 5 mm increase

* For these data points, 91 patients were eligible for 1-year outcome analysis.
† Core Lab identified endoleaks. 3 patients with Type 1 endoleaks were resolved at 1-year follow-up, 1 patient died of unrelated causes before 1-year follow-up.
‡ Subject underwent open surgical repair without explant of the EXCLUDER® Conformable Device, was determined the event to be unrelated to the device or the procedure.
§ Same patient that had to convert to open repair.
‖ Change in AAA diameter as identified from baseline imaging taken closest to post-operative day 30 and no later than post-operative day 90.

GORE® EXCLUDER®
Iliac Branch Endoprosthesis

ADVANCES
you can count on

The first FDA-approved iliac branch device and the only all-in-one system. Preservation is the recommended treatment to sustain quality of life.[1-3]

Click to see device animation.

The broadest treatment range for iliac preservation.

The flexibility needed in tortuous iliac anatomy, with proven kink resistance.[4]

The lowest profile (16 Fr) for enhanced vessel access and trackability.

5-year data from the U.S. IDE clinical trial.*

100%
patency†
External iliac artery

95.2%
Freedom from IBE-related reintervention

ZERO
REPORTED
Buttock claudication‡
New onset erectile dysfunction
Type I/III endoleaks†
Migrations†

95.1%
patency†
Internal iliac artery

98.3%
Freedom from CIAA‡ enlargement†

* U.S. IDE Clinical Trial. 63 subjects with device implanted in initial cohort. 36 patients have completed 5-year follow-up.

† Core Lab reported assessment for patency, endoleak, migration and CIAA enlargement (> 5 mm). Denominator is number of subjects evaluated for primary effectiveness endpoint result with an evaluable result.

‡ On the side treated with the IBE.

DESIGN and MATERIALS

you can count on

Every device in the portfolio is meticulously designed, made from durable materials and exhaustively tested.

25 years
of aortic device experience

525,000
patients treated worldwide*

Most studied†
EVAR device family

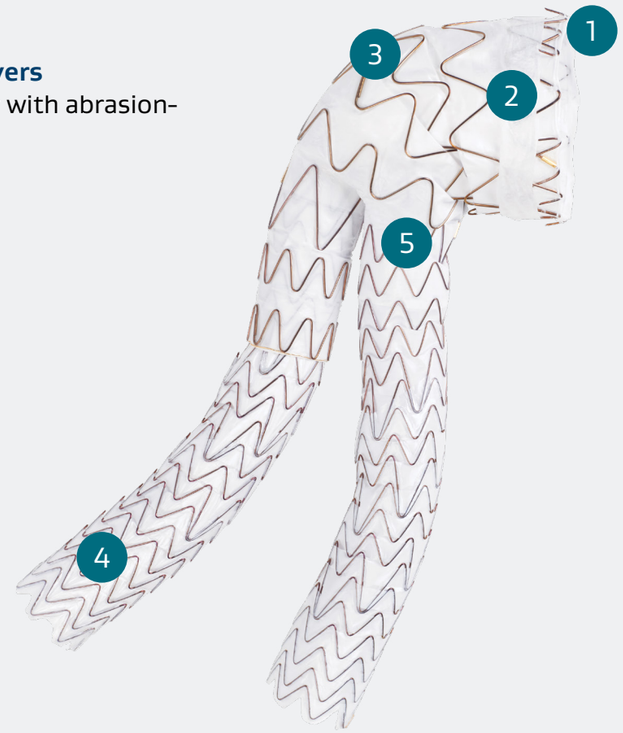
1 **Active infrarenal fixation**
– Anchors are engineered to provide migration resistance with reduced risk of renal impairment

2 **Sealing cuff**
– Engineered to provide an added layer of security against Type 1a endoleaks

3 **Sutureless stent-to-graft attachment**
– Eliminates the risk of graft failure from sutures

4 **Advanced sinusoidal stent design**
– Enhances flexibility and long-term patency

5 **Proprietary ePTFE film layers**
– Provide low permeability with abrasion-resistant properties



* Based on the number of Trunk-Ipsilateral Legs distributed for GORE® EXCLUDER® Device family as of May 2022.
† Based on company-sponsored trials and registries shown on clinicaltrials.gov for currently available stent grafts.

COLLABORATION
you can count on

With the GORE® EXCLUDER® Device family, you get a commitment that goes far beyond products.

Unbiased support

- A non-commissioned sales force — Our focus is on outcomes.
- Committed to supporting physicians in choosing the right product for each patient.

Deep device expertise

- Aortic representatives support hundreds of cases per year.
- Pre-case planning and procedural consultation.

Resources for physician education

- Gore MEDICAL MASTERY Courses — Clinical knowledge through peer-to-peer collaboration.
- Gore Medical Fellows Program — One-stop access to people, training and registration for key events.

A forward-looking legacy

- Multiple clinical and investigational trials in process supporting a robust aortic pipeline.
- Continually advancing aortic treatment capabilities with innovations in device design, deployment and materials.

References

1. Chaikof EL, Dalman RL, Eskandari MK, *et al.* The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *Journal of Vascular Surgery* 2018;67(1):2-77.e2.
2. Moll FL, Powell JT, Fraedrich G, *et al*. European Society for Vascular Surgery. Management of abdominal aortic aneurysms clinical practice guidelines of the European Society for Vascular Surgery. *European Journal of Vascular & Endovascular Surgery* 2011;41(Supplement 1):S1-S58.
3. Schneider DB. One-year U.S. results of GORE® EXCLUDER® Iliac Branched Endograft: Advantages and limitations. Presented at the 42nd Annual Symposium on Vascular and Endovascular Issues, Techniques, Horizons, (VEITHsymposium); November 17-21, 2015; New York, NY.
4. Simonte G, Parlani G, Farchioni L, *et al*. Lesson learned with the use of iliac branch devices: single centre 10 year experience in 157 consecutive procedures. *European Journal of Vascular & Endovascular Surgery* 2017;54(1):95-103.

Consult Instructions for Use
eifu.goremedical.com

GORE® EXCLUDER® AAA Endoprosthesis

INDICATIONS FOR USE: Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis. 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 and Iliac Extender Endoprosthesis.** 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.

GORE® EXCLUDER® Conformable AAA Endoprosthesis

INDICATIONS FOR USE: 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 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.

GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE)

INDICATIONS FOR USE IN THE U.S.: Iliac Branch and Internal Iliac Components. The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is intended to be used with the GORE® EXCLUDER® AAA Endoprosthesis or the GORE® EXCLUDER® Conformable Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: Adequate iliac/femoral access; Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE; External Iliac artery treatment diameter range of 6.5–25 mm and seal zone length of at least 10 mm; Internal iliac artery treatment diameter range of 6.5–13.5 mm and seal zone length of at least 10 mm; Adequate length from the lowest major renal artery to the internal iliac artery to accommodate the total endoprosthesis length, calculated by adding the minimum lengths of required components, taking into account appropriate overlaps between components. **GORE® EXCLUDER® Components used in conjunction with GORE® EXCLUDER® Iliac Branch Endoprosthesis: Trunk-Ipsilateral Leg Component.** The Trunk-Ipsilateral Leg is intended to provide proximal seal and fixation for the endovascular repair of the aneurysm. For more information on the Trunk-Ipsilateral Leg Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis or the GORE® EXCLUDER® Conformable Endoprosthesis *Instructions for Use*. Contralateral Leg Endoprosthesis Component. The Contralateral Leg Endoprosthesis is intended to bridge the GORE® EXCLUDER® Device Trunk-Ipsilateral Component to the GORE® EXCLUDER® Iliac Branch Endoprosthesis following deployment of the GORE® EXCLUDER® Iliac Branch Endoprosthesis. Additionally, the Contralateral Leg Endoprosthesis is intended to be used for distal extension of the Iliac Branch Component in the external iliac artery. The Iliac Branch Component can treat external iliac artery diameters up to 13.5 mm. This ability to extend the Iliac Branch Component distally with any Contralateral Leg Endoprosthesis expands the external iliac artery treatment range up to 25 mm. For more information on the Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis *Instructions for Use*. **Aortic Extender and Iliac Extender Components.** The Aortic and Iliac Extender Components can be used after deployment of the GORE® EXCLUDER® Iliac Branch and GORE® EXCLUDER® AAA Endoprostheses or the GORE® EXCLUDER® Conformable Endoprosthesis. These extensions are used when additional length and/or sealing for aneurysmal exclusion is desired. For more information on Aortic Extender and Iliac Extender indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis or the GORE® EXCLUDER® Conformable Endoprosthesis *Instructions for Use*. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is contraindicated in: patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), the GORE® EXCLUDER® AAA Endoprosthesis and GORE® EXCLUDER® Conformable Endoprosthesis contain ePTFE, FEP, nitinol (nickel-titanium alloy) and gold. Patients with a systemic infection who may be at increased risk of endovascular graft infection.

INDICATIONS FOR USE IN CANADA: The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is intended to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: Adequate iliac/femoral access, Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE, External Iliac artery treatment diameter range of 6.5 – 25 mm and seal zone length of at least 10 mm, Internal iliac artery treatment diameter range of 6.5 – 13.5 mm and seal zone length of at least 10 mm.

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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