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

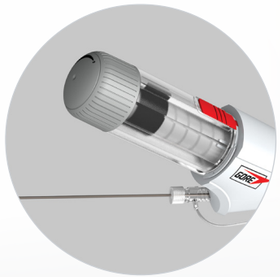
The most-studied EVAR device,* designed to provide an optimal infrarenal seal and reliable results.

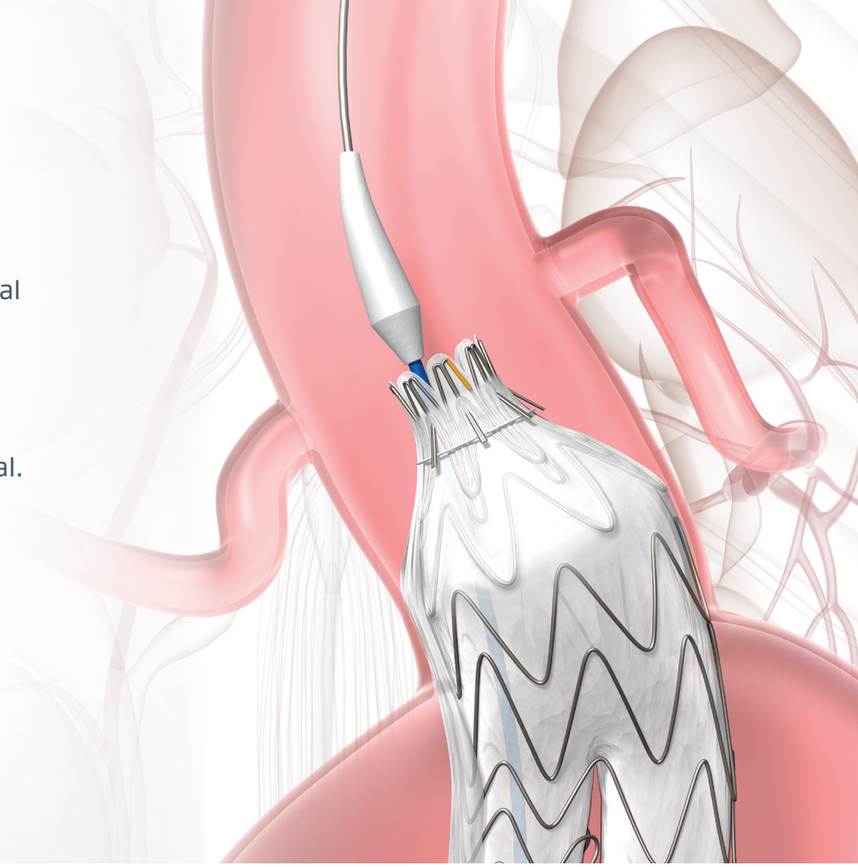
Click to see device animation.

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 **five 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 calculcate 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.

Enhanced device positioning.

Optional angulation control.

Conformable stent graft.

Individual stent rows for flexibility.

Short neck sub-study outcomes. One-year follow-up.*,†

100%

Technical success

Patency

Freedom from device-related serious adverse events

ZERO

Type I and III endoleaks

Migrations

Conversions to open repair

Ruptures

Stent fractures

Limb occlusions

98.6%

Freedom from aneurysm enlargement

* One-year follow-up from short neck sub-study. 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 14, 2022. https://clinicaltrials.gov/ct2/show/NCT02489539

† For these data points, a minimum of 66 patients were eligible for one-year outcome analysis, meeting all follow-up requirements that include contrast enhanced CT scans. More than 66 patients were included in some data points, which can be confirmed in the *Instructions for Use*.

GORE® EXCLUDER®
Iliac Branch Endoprosthesis

ADVANCES
you can count on

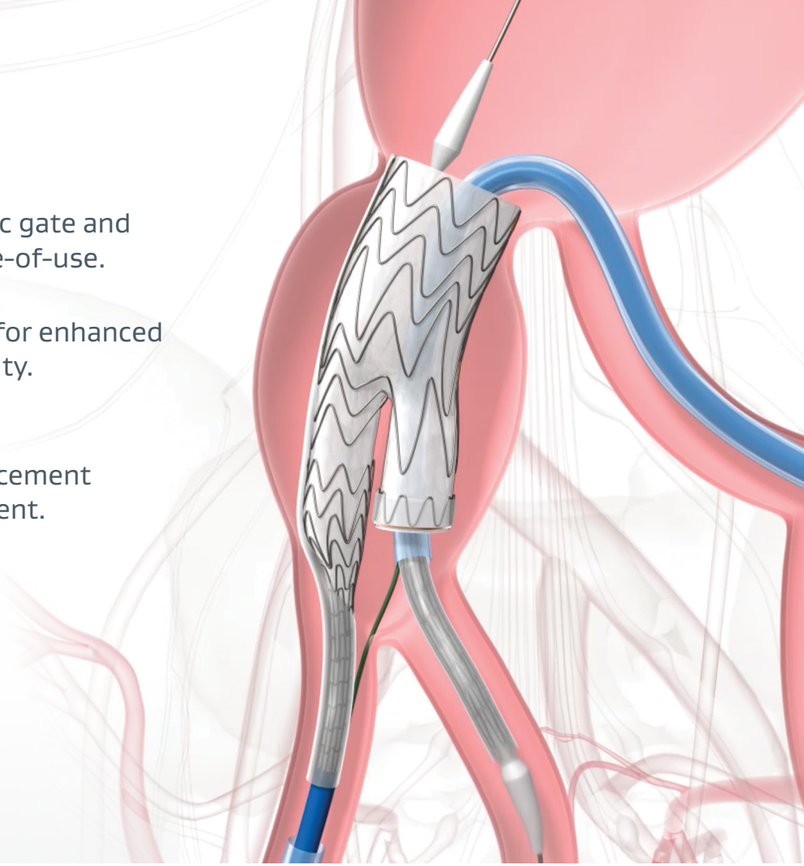
The only off-the-shelf, FDA-approved iliac branch device, and the recommended treatment to sustain quality of life.[1-3]

Click to see device animation.

Pre-cannulated internal iliac gate and bi-femoral delivery for ease-of-use.

Low profile (16 Fr) delivery for enhanced vessel access and trackability.

Two-staged repositionable deployment for precise placement of the Iliac Branch Component.



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

100%
patency†
External iliac artery

95.2%
Freedom from IBE-related reintervention

ZERO
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. Sixty-three subjects with device implanted in initial cohort. Thirty-six 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

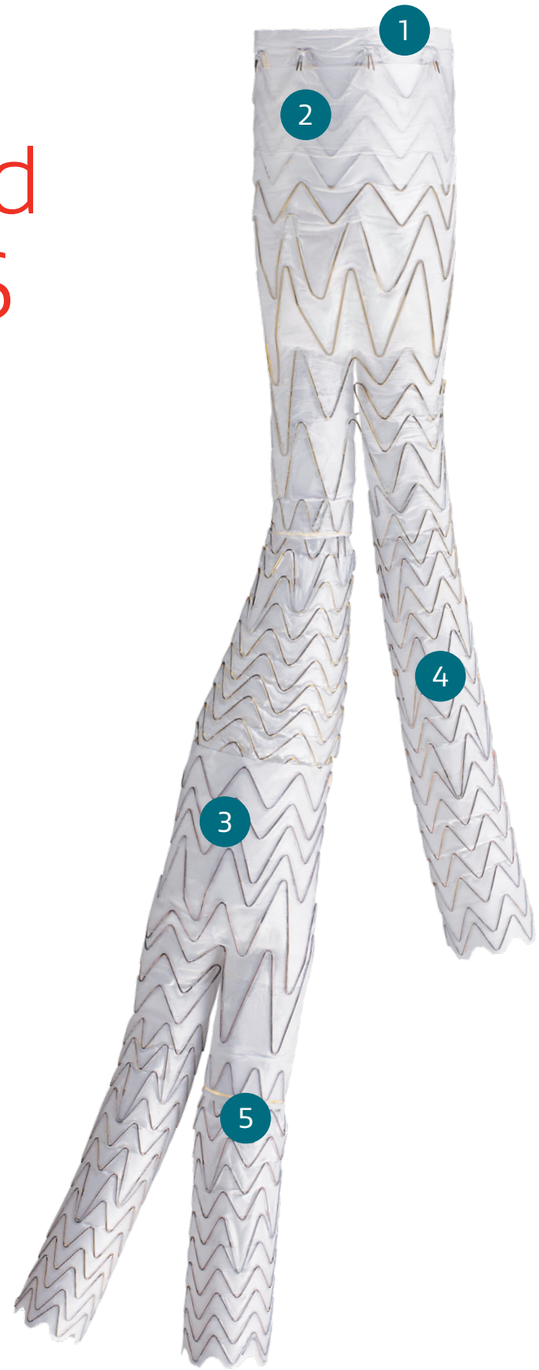
you can count on

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

25 years
of aortic device experience

450,000+
patients treated worldwide*

Most studied†
EVAR device family



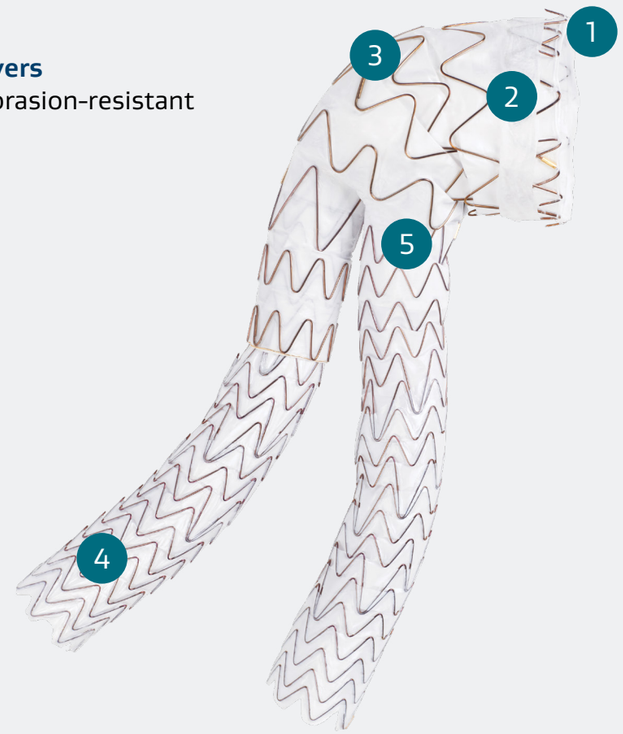
1 **Active infrarenal fixation**
– Anchors for active fixation are engineered to provide migration resistance

2 **Sealing cuff**
– Engineered to provide security against endoleaks

3 **Sutureless stent-to-graft attachment**
– ePTFE graft technology on luminal and abluminal surfaces

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

5 **Proprietary ePTFE film layers**
– 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 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.

Consult Instructions for Use
eifu.goremedical.com

GORE® EXCLUDER® AAA Endoprosthesis: INDICATIONS FOR USE IN THE U.S.: 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. 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 **GORE® EXCLUDER® Conformable AAA Endoprosthesis**: **INDICATIONS FOR USE IN THE U.S.:** 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. The GORE® EXCLUDER® Conformable Aortic Extender Endoprosthesis (Aortic Extender) is intended to be used after deployment of the GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Component. The Aortic Extender is 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. **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. 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 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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