

Durable outcomes.  
Proven performance.

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GORE® EXCLUDER®  
AAA Endoprosthesis

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GORE® EXCLUDER® Iliac  
Branch Endoprosthesis



# GORE<sup>®</sup> EXCLUDER<sup>®</sup> AAA Endoprosthesis

## The most-studied\* EVAR stent graft designed for durable outcomes.

The trusted performance of the GORE<sup>®</sup> EXCLUDER<sup>®</sup> Device is paired with the intuitive GORE<sup>®</sup> C3<sup>®</sup> Delivery System to provide optimal infrarenal seal and reliable results, even in more challenging anatomies.

### Proven Performance.

## Results from the Global Registry for Endovascular Aortic Treatment (GREAT)

**3,273** Patients through 3 years of follow-up\*\*

**96.0%** Freedom from device-related reintervention

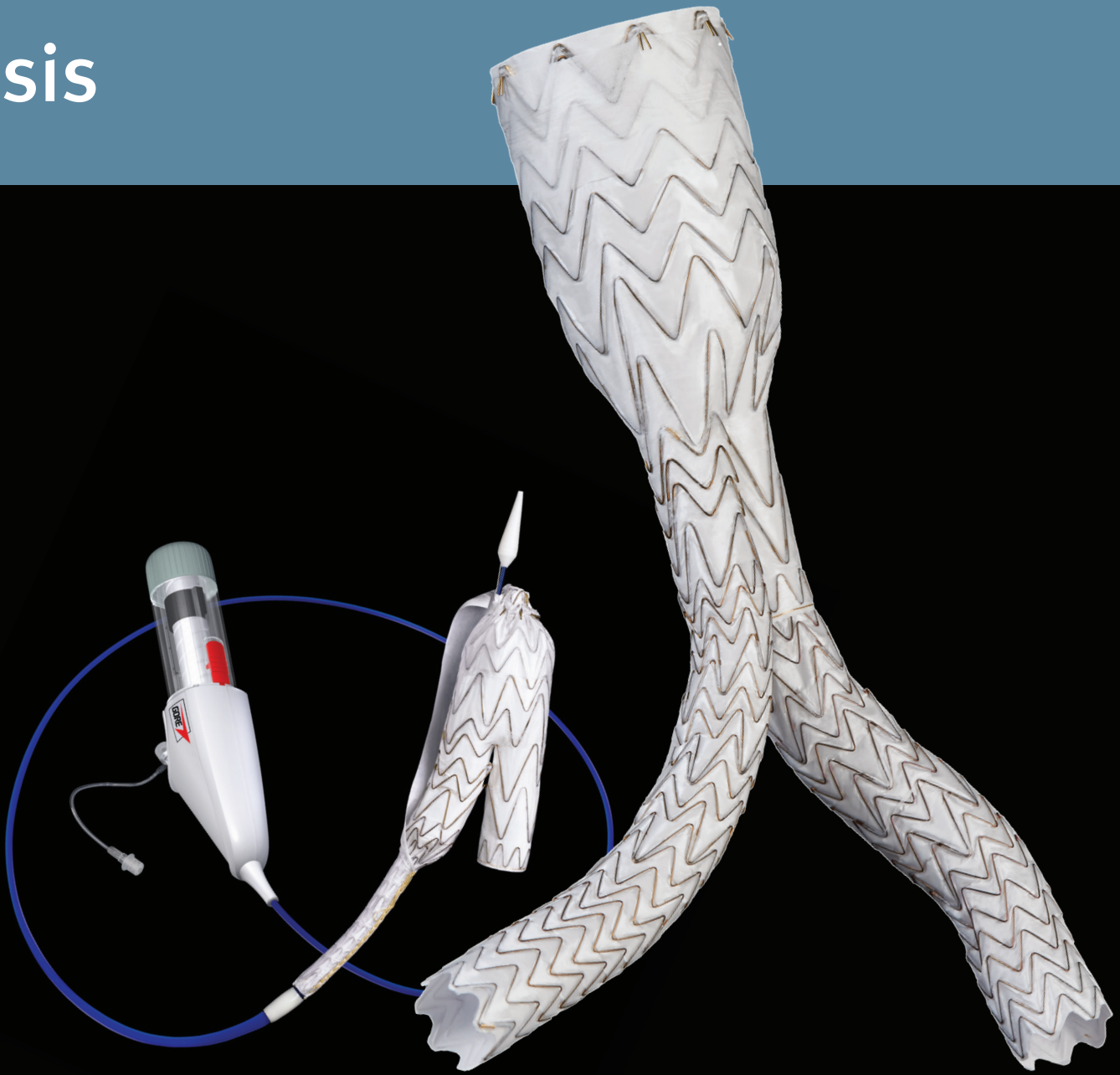
**93.4%** Freedom from all reintervention

**0.0%<sup>†</sup>** Migration

**1.4%** Type I / III endoleak

**0.5%** Limb occlusion

# thesis



## GORE® C3® Delivery System

- Repositionable to obtain optimal seal
- Unique ability to reconstrain the proximal end and reposition for ideal placement
- More opportunities to maximize infrarenal seal

# GORE<sup>®</sup> EXCLUDER<sup>®</sup> Iliac Branch En

U.S. IDE Clinical Trial now has 2-year follow-up data for all patients from primary enrollment (n = 63).

## 2-year data

**100%** Patency — External iliac artery

**95.1%** Patency — Internal iliac artery

**93.7%** Freedom from reintervention

**0%** Buttock claudication

**0%** New onset erectile dysfunction

**98.3%** Freedom from CIAA enlargement (> 5 mm)

**152 minutes**

Procedure time



**114 ml**

Contrast used



**40 minutes**

Fluoro time



**95.2%**

Technical success<sup>‡</sup>



# doprosthesis

We designed this all-in-one system exclusively for use in the iliac arteries. It is the only FDA-approved, off-the-shelf iliac branch solution.

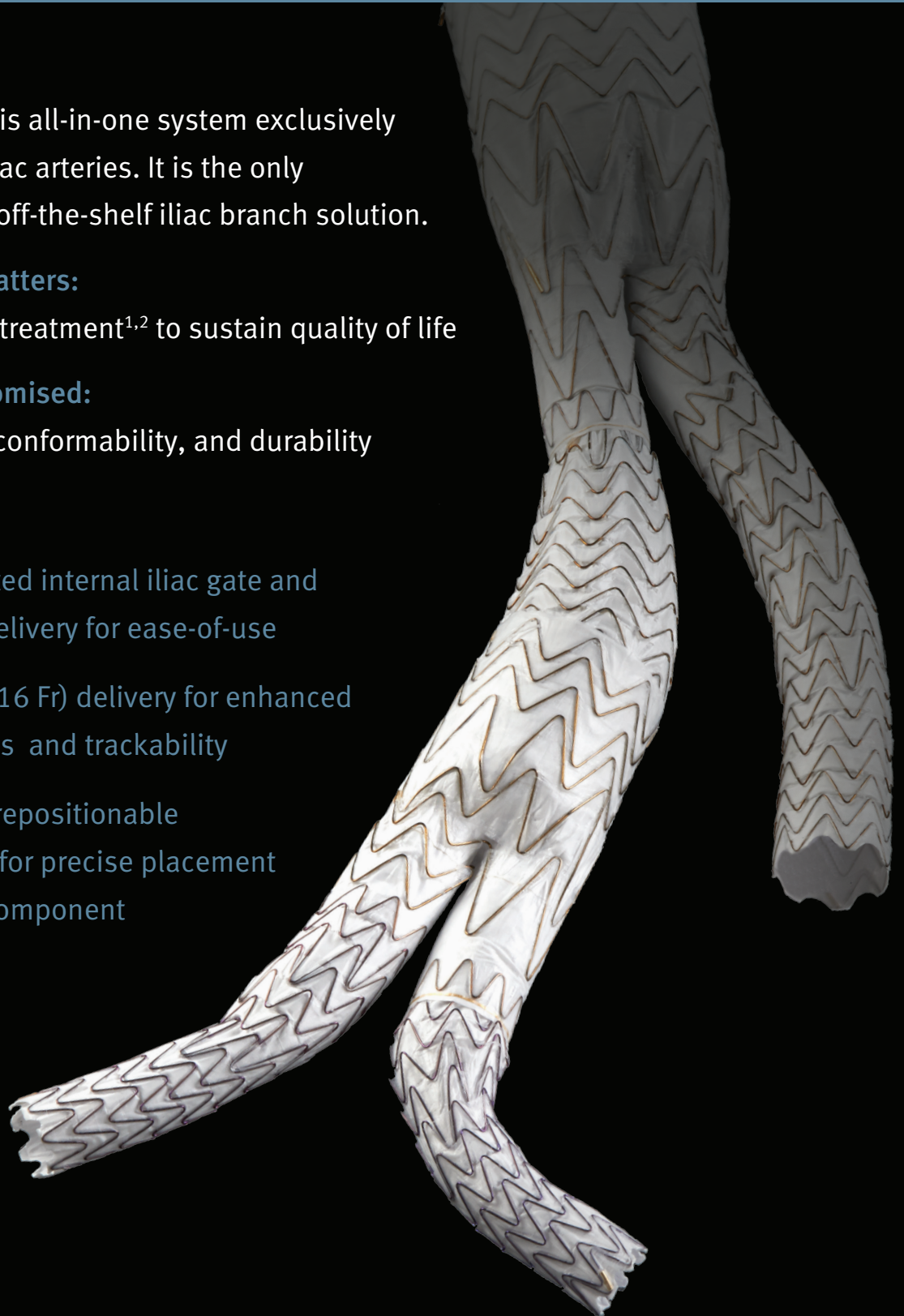
## Preservation matters:

Recommended treatment<sup>1,2</sup> to sustain quality of life

## Performs as promised:

High patency<sup>3</sup>, conformability, and durability

- 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 component



# Trusted design. Trusted legacy.

The GORE® EXCLUDER® Device family has evolved based on what we have learned from over 20 years of experience in EVAR.

## Worldwide experience

- More than 350,000 patients treated with GORE® EXCLUDER® AAA Endoprosthesis<sup>§</sup>
- More than 10,000 patients treated with GORE® EXCLUDER® Iliac Branch Endoprosthesis<sup>||</sup>

## Durability

- 1 **Sutureless construction**
  - Expanded PTFE graft technology on luminal and abluminal surfaces
- 2 **Advanced sinusoidal stent design**
  - Enhances flexibility and long-term conformability
- 3 **Proprietary ePTFE film layers**
  - Low permeability with abrasion-resistant properties
  - Conformability in tortuous anatomies
- 4 **Sealing cuff**
  - Engineered to provide security against endoleaks
- 5 **Active infrarenal fixation**
  - Anchors for active fixation are engineered to provide migration resistance

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# Physician collaboration and unwavering commitment.

When we join with our partners in the medical community, we work together to advance patient care. With the only FDA-approved iliac branch solution, and durable outcomes with more than 20 years of EVAR experience, the GORE® EXCLUDER® Device family offers solutions physicians trust and patients count on.

Learn more at [goremedical.com/aortic](http://goremedical.com/aortic)

The GORE® EXCLUDER® Iliac Branch Endoprosthesis is to be used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis and is not intended to be used on its own.

\* Based on company-sponsored trials and registries shown on [clinicaltrials.gov](http://clinicaltrials.gov) for currently available stent grafts.

\*\* GREAT. n=3,273. To calculate the overall event 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.

† One peri-procedural migration reported. Zero migrations reported during follow-up through 3 years.

‡ Defined as successful implantation with lack of endoleaks.

§ Based on the number of Trunk-Ipsilateral Legs distributed.

|| Based on the number of Iliac Branch Components distributed.

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 F.L., Powell J.T., 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 D. B. 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.

**INDICATIONS FOR USE IN THE US: Iliac Branch and Internal Iliac Components.** The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is intended to be used with the GORE® EXCLUDER® AAA 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® AAA Endoprosthesis 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. **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. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components:** The Aortic and Iliac Extender Endoprostheses can be used after deployment of the GORE® EXCLUDER® Iliac Branch Endoprosthesis and GORE® EXCLUDER® AAA Endoprosthesis. These extensions are used when additional length and / or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Iliac Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis and the GORE® EXCLUDER® AAA 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 [goremedical.com](http://goremedical.com) for a complete description of all warnings, precautions and adverse events. <sup>Rx</sup> Only

Products listed may not be available in all markets.

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