

GORE® EXCLUDER® ILIAC BRANCH ENDOPROSTHESIS: The trusted choice for iliac preservation



Trusted for tortuosity

- Proven conformability and kink resistance in challenging iliac anatomies¹⁻³
- Leverages over 25 years of GORE® EXCLUDER® Device family design expertise
- Most studied, all-in-one system^a

Broadest treatment range^b

- Widest internal iliac artery (IIA) and external iliac artery (EIA) diameter range per *Instructions for Use* (IFU)
- Lowest profile for enhanced vessel access and trackability
- Ability to extend above aortic bifurcation
- On-label bilateral use with proven results⁴

EIA seal diameter per IFU:

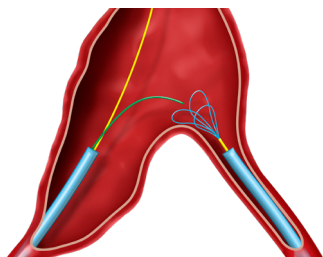
EXCLUDER® IBE	6.5–25 mm
Alternative	8–11 mm

IIA seal diameter per IFU:

EXCLUDER® IBE	6.5–13.5 mm
Alternative	7–10 mm

Device profile per IFU:

EXCLUDER® IBE	16 Fr
Alternative	20 Fr



Designed for ease of use

- Ease of snaring and stability in delivery
- Pre-cannulated internal iliac gate
- Repositionable, two-stage deployment

^a Based on the company-sponsored trials and registries shown on clinicaltrials.gov.

^b Broadest™ determined by cumulative comparison of EIA and IIA seal diameter, EIA seal length, CIA diameter and length, CIA bifurcation diameter, device profile, bilateral treatment and renal-to-hypogastric length. COOK® ZENITH® Iliac Branch (ZBIS) may have broader range for individual factors.

Trust is earned

The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) has proven to have consistently safe, effective and durable outcomes throughout follow-up.



U.S. IDE Trial outcomes^{5,6}

Enrollment: 2013–2016

63 patients through primary enrollment	1 month	5 year
Patency, external iliac artery ^c	100%	100%
Patency, internal iliac artery ^c	95.1%	90.5%
Freedom from IBE-related reintervention	98.4%	95.2%
Freedom from CIAA ^d enlargement (> 5 mm) ^c	baseline	98.3%
Buttock claudication	0%	0%
New onset sexual dysfunction	0%	0%
Type I/III endoleaks ^c	0%	0%
Migrations ^c	0%	0%

IceBERG Iliac Branch Excluder ReGistry⁷

Enrollment: 2015–2018
100 patients
Up to 12-month follow-up

100%

Freedom from AAA-related mortality

97.0%

Freedom from secondary intervention

91.3%

Internal iliac artery primary patency

96.0%

Freedom from Type I/III endoleaks^e

GALIBER GALician IBE Registry⁸

Enrollment: 2017–2022
81 patients
Up to 5-year follow-up

100%

Freedom from aneurysm-related mortality

97.5%

Freedom from IBE-related intervention

98.1%

Internal and external iliac artery patency

98.8%

Freedom from Type I/III endoleaks

GREAT Real-world Registry⁹

Enrollment: 2017–2022
81 patients
5-year follow-up

98.8%

Freedom from aortic rupture

86.4%

Freedom from device-related reintervention^f

90.0%

Decreasing or stable CIAA sac dynamics

0 reported

Migrations or fractures



More than 55,000 IBE implants⁹ to date worldwide
Learn more

^c 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.

^d On the side treated with the IBE.

^e 2/4 Endoleaks were resolved during index procedure via ballooning.

^f There were no conversions to open repair or explant. 7/11 reinterventions required additional grafts, with 2/7 limb-related reinterventions.

⁹ Based on the number of CEBs distributed.

Image: 5-year follow-up; courtesy of Brian Peterson, MD., St. Anthony's Medical Center; St. Louis, Missouri.


References

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Consult Instructions
for Use

eifu.goremedical.com

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

INDICATIONS FOR USE: 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.

Products listed may not be available in all markets.

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