GREAT

GLOBAL REGISTRY FOR ENDOVASCULAR AORTIC TREATMENT

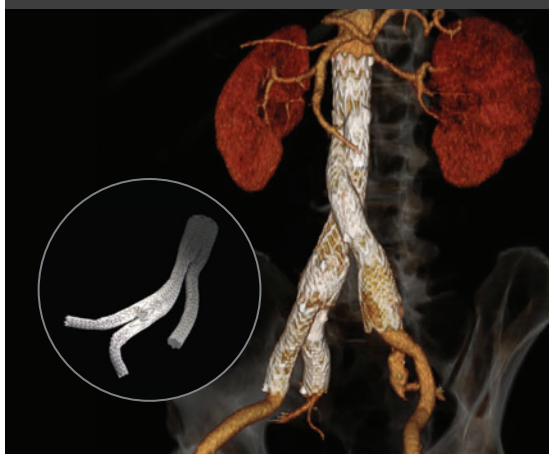
April 2016
EVAR

With more than 1,000 commercial implants worldwide, the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is fully designed to preserve blood flow to external and internal iliac arteries. The IBE is currently commercially available in the United States, Europe, Australia, and Canada.

Since CE Mark approval in 2013, results of 58 IBE implants reported to GREAT have shown:

OUTCOMES AT ONE MONTH (N = 58)	
Technical success[1]	98.3%
Buttock claudication	None reported
Sexual dysfunction	None reported
Patency rate on internal iliac artery	No reinterventions reported
Patency rate on external iliac artery	98.3%
Freedom from reintervention	98.3%
Procedural survival	100%

TWO-YEAR FOLLOW-UP; FIRST CLINICAL USE



Post-operative image courtesy of Brian Peterson, MD., St. Anthony's Medical Center; St. Louis, Missouri.

The iliac branch solution physicians trust and patients count on.

"The GORE® EXCLUDER® Iliac Branch Endoprosthesis offers a sound, complete, and trusted solution to treat complex aorto-iliac aneurysmal disease. The GREAT Registry gives insight in worldwide results of this therapy." — *P. Vriens and J. Heyligers, Vascular Surgery, Elisabeth-TweeSteden Hospital, Tilburg, Netherlands*

GREAT Objective: To improve clinical practice and patient outcomes through post-market surveillance and long-term device performance monitoring.

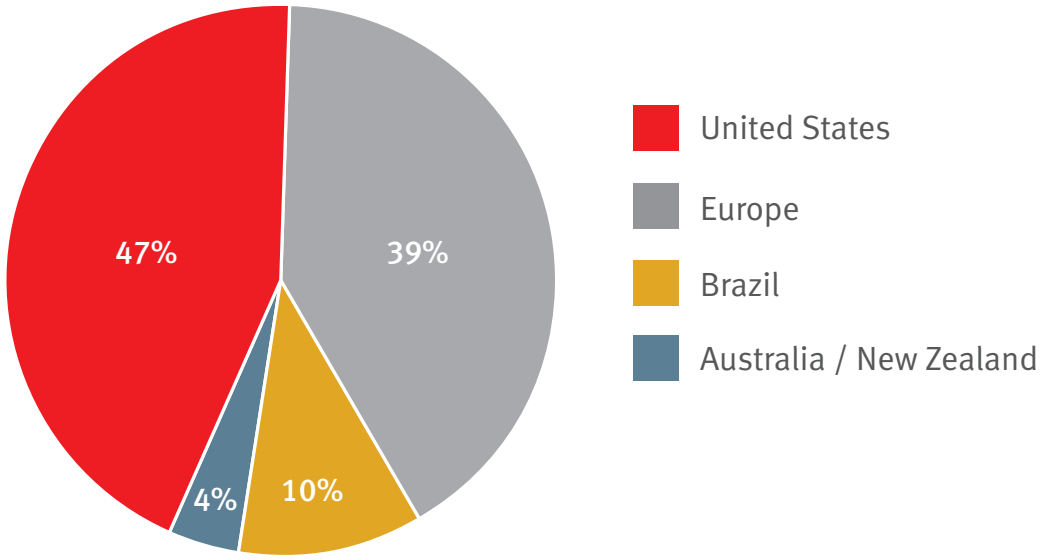
Real World Registry

Design: Prospective, observational, multicenter registry to actively track Gore commercial aortic endovascular device performance and associated patient outcomes in global markets with 10 years of follow-up.

Enrollment: 5,000 consecutive patients from a maximum of 300 worldwide sites with minimal exclusion criteria.

Devices: All commercially available Gore aortic endografts.[2]

Five-year enrollment: More than 4,000 patients, 13 countries, and 111 sites



"GREAT is one way we can serve the global endovascular community by providing this valuable platform for analysis. Improving patient outcomes is at the core of our collaboration with physicians." — *Ryan Takeuchi, Gore Aortic Business Leader*

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 for a complete description of all warnings, precautions and adverse events. ℞ Only

1. Defined as successful implantation with lack of endoleaks
2. GORE® EXCLUDER® AAA Endoprosthesis, GORE® EXCLUDER® AAA Endoprosthesis featuring C3® Delivery System, GORE® TAG® Thoracic Endoprosthesis, Conformable GORE® TAG® Thoracic Endoprosthesis, and GORE® EXCLUDER® Iliac Branch Endoprosthesis.

W. L. Gore & Associates, Inc. • Flagstaff, AZ 86004 • goremedical.com

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Creative Technologies Worldwide

Products listed may not be available in all markets.

PERFORMANCE
through data