

# Trust is Earned



over  
**300,000** Patients  
Treated

**20 Years**  
of Experience

In clinical trials, registries, and site-reported use, the GORE® EXCLUDER® AAA Device has **proven** to be a safe, effective, and durable solution, earning the trust of physicians worldwide. It is also the **most studied\*** of the currently available endografts, and the U.S. **market leader** for EVAR devices.

Contact your local  
**Sales Associate**  
for more information.

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



## GORE® EXCLUDER® AAA DEVICE CLINICAL TRIAL AND REGISTRY DATA

	Low Permeability Post-Approval Study	Global Registry for Endovascular Aortic Treatment (GREAT)	GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) 12-04 Study
Enrollment	2005–2006	2010–2016	2013–2015
Length of follow-up (through)	2 years	3 years	1 year
Number of patients possible	139	3,273	63
Freedom from aneurysm-related mortality	100.0%	98.5%	100.0%
Freedom from reintervention	87.1%	93.4%	93.7%
Freedom from aneurysm enlargement (≥ 5 mm)	95.9%	92.0%	95.7% <sup>1</sup>
Conversion to open	0.7%	0.4%	0.0%
Aneurysm-related rupture	0.0%	0.2%	0.0%
Migration	2.4%	0.0%	0.0%
Type I Endoleak	0.7%	1.2%	0.0%
Type III Endoleak	0.7%	0.2%	0.0%
Limb occlusion	0.7%	0.5%	0.0% <sup>2</sup>

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.

1. For patients presenting with pre-existing AAA, defined as abdominal aorta >50 mm, evaluated by Core Lab.
2. Patency of the common and external iliac arteries on the non-IBE treatment side.

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



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