

Trust is earned



over
350,000 patients
treated*

over
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 the number of Trunk-Ipsilateral Legs distributed

† Based on company-sponsored trials and registries shown on clinicaltrials.gov for currently available stent grafts



GORE® EXCLUDER® AAA Device Clinical Trial and Registry data

	Combined IDE Cohort	Low Permeability Post-Approval Study	Global Registry for Endovascular Aortic Treatment (GREAT)
Enrollment	1998–2002	2005–2006	2010–2016
Length of follow-up (through)	5 years	2 years	5 years
Number of patients possible	565	139	3,274
Freedom from aneurysm-related mortality	98.2%	100.0%	98.8%
Freedom from reintervention	82.3%	87.1%	92.0%
Freedom from device-related reintervention	N/A	N/A	94.7%
Freedom from aneurysm enlargement (≥ 5 mm)	67.3%	95.9%	87.9%
Conversion to open	2.5%	0.7%	0.8%
Aneurysm-related rupture	0.2%	0.0%	0.3%
Migration	0.5%	2.4%	0.0%*
Type I endoleak	4.9%	0.7%	1.6%
Type III endoleak	1.3%	0.7%	0.2%
Limb occlusion	0.5%	0.7%	0.7%

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 5 years.

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 $\leq 60^\circ$; 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 for a complete description of all warnings, precautions and adverse events. Rx only



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