GORE® EXCLUDER®
AAA Endoprosthesis

TRUST IS EARNED

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.

20+ years
of worldwide experience

400,000+
patients treated†

An EVAR market leader

Most EVAR device STUDIED*

* Based on company-sponsored trials and registries shown on clinicaltrials.gov for currently available stent grafts.
† Based on the number of Trunk-Ipsilateral Legs distributed.

Together, improving life

GORE

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%	0.1%
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.

Contact your local Field Sales Associate for more information.

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE: Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components. The GORE® EXCLUDER® Conformable 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 16 – 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® Conformable AAA Endoprosthesis. These extensions are intended to be used when additional length and / or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Conformable AAA Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials; Patients with a systemic infection who may be at increased risk of endovascular graft infection. 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

Products listed may not be available in all markets.

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