

The most-studied*

family of EVAR stent grafts on the market

with over **20 years** of proven performance



GORE® EXCLUDER® AAA Endoprosthesis

	Combined IDE cohort	Low Permeability Post-Approval Study	Global Registry for Endovascular Aortic Treatment (GREAT)*
Enrollment	ent 1998–2002 2005–2006	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 all 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%

See case studies, articles, videos and more at goremedical.com/excluder

GORE® EXCLUDER® Iliac Branch Endoprosthesis

U.S. IDE Clinical Trial for all patients from primary enrollment (n = 63)	6 months	2 years	3 years
Patency — External iliac artery	100%	100%	100%
Patency — Internal iliac artery	95.1%	95.1%	95.1%
Freedom from reintervention	98.4%	93.7%	93.7%
Buttock claudication	0%	0%	0%
New onset erectile dysfunction	0%	0%	0%
Freedom from CIAA enlargement (> 5 mm)	98.3%	98.3%	98.3%

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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 (nickeltitanium alloy), and gold. Patients with a systemic infection who may be at increased risk of endovascular graft infection Refer to instructions for Use at

Products listed may not be available in all markets.

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^{*} GREAT. n = 3,274. 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