January 2017
EVAR

GREAT
GLOBAL REGISTRY FOR ENDOVASCULAR AORTIC TREATMENT

Furthering understanding of EVAR outcomes in the female population

438 Women were Successfully Treated with the GORE® EXCLUDER® AAA Endoprosthesis as reported in GREAT

16.6%
of the total population with AAA

50.2%
treated with PEVAR

100%
procedural survival

Anatomical Challenges — In Female Population	
Neck Length < 15 mm	8.7%
Neck angulation > 60°	18.0%
Significant calcium at LZ*	22.4%
Significant thrombus at LZ*	4.1%

* Based on the GRT10-12 module

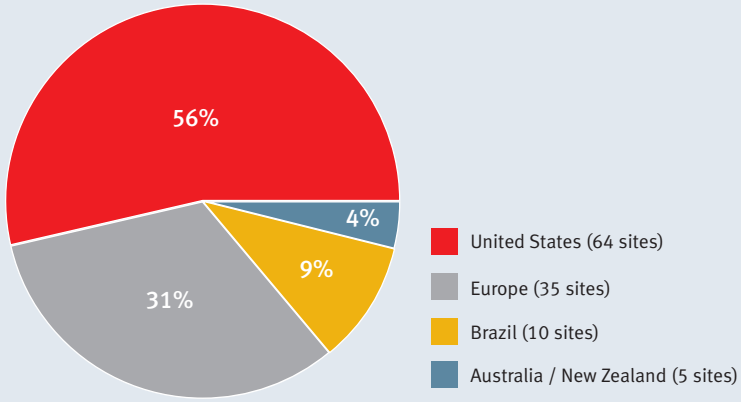
GORE® EXCLUDER® Device — Outcomes in Female Population**	
Description	%
Device-related reinterventions	3.9
Type I endoleak rate	1.6
Type III endoleak rate	0
Migration rate	0
Fractures	0
Rupture rate	0.5
Conversion to open repair	0
Device occlusion rate	0.2
Overall mortality rate	7.5

** All events for all subjects through two years

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

GREAT was initiated in 2010 to evaluate how our family of aortic devices perform in real-world cases and to continue our commitment to advancing patient care in the treatment of aortic disease. Ten-year follow-up is planned for all enrolled patients.

Five-year enrollment: more than 5,000 patients, 13 countries, 114 sites



Females in GREAT (n = 938)

Pathology Treated	%
AAA	57
Isolated iliac aneurysm	1.9
Aorto-iliac aneurysm	2.2
Thoracoabdominal aneurysm	3.8
TAA	17.3
Dissection	6.9
Transection	1.2
Other pathologies	9.7

GREAT
has the largest reported population of females treated with
EVAR and TEVAR
compared to any other company-sponsored registry*

* ENGAGE (Endurant Stent Graft Natural Selection Global Postmarket Registry). 1,262 total patients enrolled, 131 enrolled females.

Stokmans RA, Teijink JA, Forbes TL, *et al.* Early results from the ENGAGE registry: real-world performance of the Endurant Stent Graft for endovascular AAA repair in 1262 patients. *European Journal of Vascular & Endovascular Surgery* 2012;44(4):369-375.

* Medtronic Outcomes of Thoracic Endovascular Repair (MOTHER). 1,010 total patients enrolled, 363 enrolled females.

Patterson B, Holt P, Nienaber C, Cambria R, Fairman R, Thompson M. Aortic pathology determines midterm outcome after endovascular repair of the thoracic aorta: report from the Medtronic Thoracic Endovascular Registry (MOTHER) Database. *Circulation* 2013;127(1):24-32.

"EVAR and TEVAR outcomes may vary by gender, primarily due to anatomic challenges. GREAT, having the largest female cohort, provides a unique opportunity to elucidate outcomes of endovascular management by gender."

— Santi Trimarchi, MD, PhD, Associate Professor of Vascular Surgery, University of Milan, Head, Unit of Vascular Surgery II°, Director, Thoracic Aorta Research Center

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

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Products listed may not be available in all markets.

GORE
Creative Technologies Worldwide