August 2016
TEVAR

GREAT
GLOBAL REGISTRY FOR ENDOVASCULAR AORTIC TREATMENT

Delivering confidence for all clinical challenges

The Conformable GORE® TAG® Thoracic Endoprosthesis demonstrates reliable perioperative outcomes in arch anatomy (GREAT one-month outcomes in Zones 2–3).*

Zone 2 N = 179	Zone 3 N = 246
Occurrence of Type 1 Endoleaks	
1.3%	0.9%
Occurrence of Device Migration	
0%	0%
Freedom from Device-Related Reintervention**	
98.3%	98.8%

* For outcome data, GREAT only collects site-reported serious adverse events. Based on one-month follow-up data (0–59 days), all pathologies.

** Device-related reinterventions include any invasive or minimally invasive measure related to a deficiency of the device(s) implanted into the aorta performed at any time following the initial procedure.

GREAT Zone 1 experience has demonstrated 0% endoleaks and 0% migrations with a 91.9% freedom from device-related reintervention (N = 37). The Conformable GORE® TAG® Device has not been evaluated for safety and effectiveness in Zone 1.

> ***The ideal condition is to devise an endograft that conforms to the vessel and does not deform the aorta.***
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> – A. Lumsden, J. Bismuth, What exactly is radial fit? *Endovascular Today* 2012:4-6

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

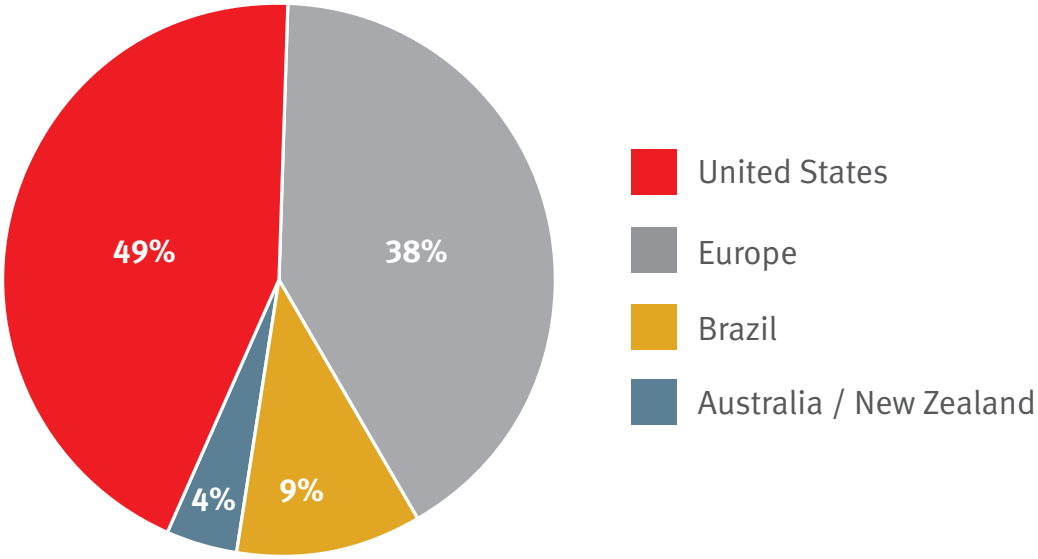
Real-world Registry Overview

Design: Prospective, observational, multicenter registry to actively track Gore commercial aortic endovascular device performance and associated patient outcomes in global markets with 10 years of follow-up.

Enrollment: 5,000 consecutive patients from a maximum of 300 worldwide sites with minimal exclusion criteria.

Devices: All commercially available Gore aortic endografts.[1]

Five-year enrollment: More than 4,500 patients, 13 countries, and 113 sites



"GREAT is one way we can serve the global endovascular community by providing this valuable platform for analysis. Improving patient outcomes is at the core of our collaboration with physicians." — *Ryan Takeuchi, Gore Aortic Business Leader*

INDICATIONS FOR USE IN THE US: The GORE® TAG® Thoracic Endoprosthesis is intended for endovascular repair of all lesions of the descending thoracic aorta, including: Isolated lesions in patients who have appropriate anatomy, including: adequate iliac / femoral access, aortic inner diameter in the range of 16–42 mm, ≥ 20 mm non-aneurysmal aorta proximal and distal to the lesion; Type B dissections in patients who have appropriate anatomy, including: adequate iliac / femoral access, ≥ 20 mm landing zone proximal to the primary entry tear; proximal extent of the landing zone must not be dissected, diameter at proximal extent of proximal landing zone in the range of 16–42 mm. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials; patients who have a condition that threatens to infect the graft. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions, and adverse events. **INDICATIONS FOR USE UNDER CE MARK:** The GORE® TAG® Thoracic Endoprosthesis is indicated for endovascular repair of the descending thoracic aorta. **CONTRAINDICATIONS:** 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 goremedical.com for a complete description of all warnings, precautions, and adverse events. ℞ Only

1. GORE® EXCLUDER® AAA Endoprosthesis, GORE® EXCLUDER® AAA Endoprosthesis featuring C3® Delivery System, GORE® TAG® Thoracic Endoprosthesis, Conformable GORE® TAG® Thoracic Endoprosthesis, and GORE® EXCLUDER® Iliac Branch Endoprosthesis.

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Products listed may not be available in all markets.

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PERFORMANCE
through data