

January 2016
TEVAR



GREAT Objective

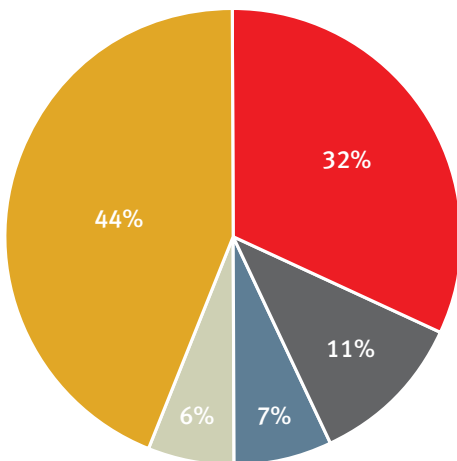
To improve clinical practice and patient outcomes through post-market surveillance and long-term device performance monitoring.

“GREAT demonstrates the collaborative dedication of physicians around the world to advance patient care. We want to ensure that patients are receiving optimal treatment through safe therapies.”

— Piergiorgio Cao, MD, Chief of Vascular Surgery, San Camillo Forlanini Hospital, Rome, Italy

Conformable GORE® TAG® Thoracic Device Designed to Provide Optimal Outcomes in a Wide Range of Pathologies

Thoracic Pathologies Treated in GREAT



- Aortic Aneurysm and Rupture
- Type B Aortic Dissection
- Penetrating Aortic Ulcer and Intramural Hematoma
- Traumatic Aortic Transection
- Other: Coarctation, Fistula

Treatment Performance in All Lesions of the DTA

	PROCEDURE N = 580	ONE MONTH N = 269	ONE YEAR N = 131
Type IA	0.2%	0.4%	0.8%
Migration ¹	0%	0.4%	0%
Compression	0%	0%	0%

Two Year Cumulative Results in the DTA

- 1.7% stroke / TIA²
- 1.2% paraplegia, paraparesis, spinal cord ischemia²
- 0.5% retrograde Type A dissection

“The Conformable GORE® TAG® Thoracic Endoprosthesis is an easy-to-use device designed to treat all lesions of the descending thoracic aorta. The device has strong outcomes in all pathologies, especially in Type B dissection. The device is safe, non-traumatic for the aortic wall, and helps to treat patient with confidence and low rates of complications.”

— Prof. Philippe Piquet, MD, Chief of Vascular Surgery, CHU La Timone, Marseille, France

The Conformable GORE® TAG® Device covers the broadest TEVAR treatment range and is available in a wide range of sizes, including tapered devices

- Only thoracic endograft engineered to perform in 6–33% oversizing conditions: Physician can choose radial force to fit patient anatomy.
- Only five devices needed to treat 16–42 mm treatment range.
- Minimized average number of devices implanted per patient: 1.3 devices per patient in all pathologies.
- Low re-intervention rates on access complications: 0.7%.

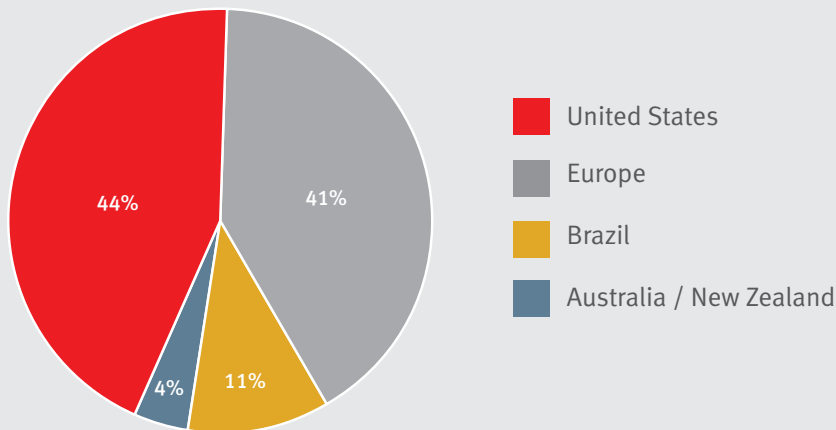
Real World Registry

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.³

Five-year enrollment: More than 3,000 patients, 13 countries, and 98 sites



“GREAT is one way we can serve the global endovascular community by providing this incredibly 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: 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, \geq 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, \geq 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. ^{ix} Only

1. Does not include ‘Device placement at incorrect location’ or similar coded MedDRA term.
2. Only those that meet the ISO definition of a serious adverse event.
3. 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.

W. L. Gore & Associates, Inc. • Flagstaff, AZ 86004 • goremedical.com

Products listed may not be available in all markets.

GORE®, C3®, EXCLUDER®, PERFORMANCE THROUGH DATA, TAG®, and designs are trademarks of W. L. Gore & Associates.
© 2015, 2016 W. L. Gore & Associates, Inc. AU1141-EN1 JANUARY 2016



PERFORMANCE
through data