

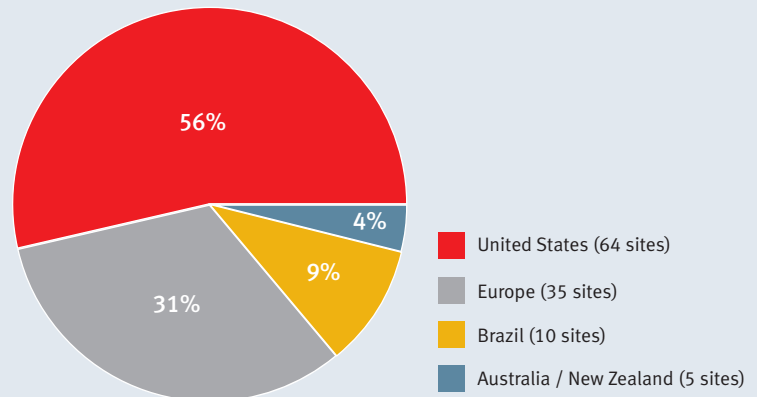
## Real-world data



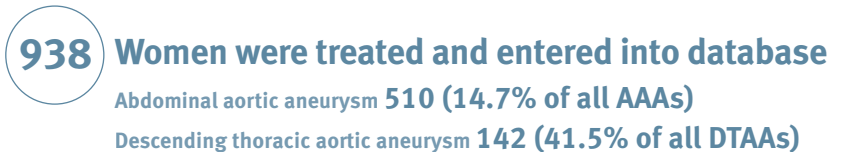
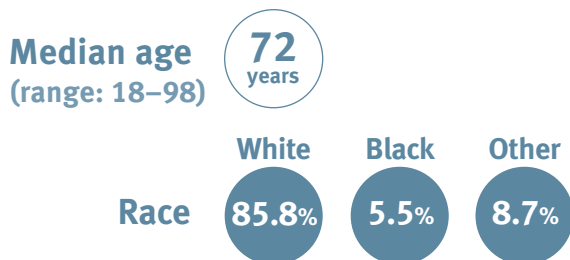
Enrollment completed in largest industry-sponsored global registry of aortic stent-grafts

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



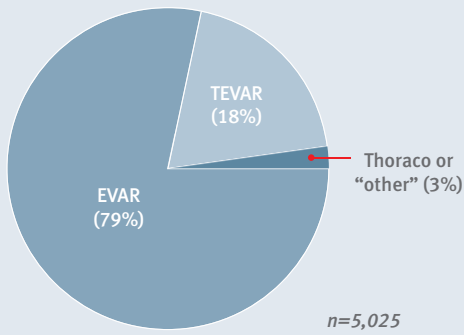
Enrollment resulted in a wide spectrum of demographics, reflecting real-world use.



“Through GREAT, we can take a look at a large number of patients with a broad set of symptoms and treatments to see how a device performs and make a better determination on proper device use in the future. This registry is truly real-world data.” — Fred Weaver, MD

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

DEMOGRAPHICS: GLOBAL ENROLLMENT AS OF OCTOBER 2016



- 28 pathologies treated
  - 92.8% treated for a primary endovascular repair
  - Remaining were reinterventions on previous endovascular and open surgical procedures
- Mean follow-up for all subjects is over one year
- The percent of subjects with any follow-up is 87%
- The procedural survival for the entire cohort is 99.8%

CONFORMABLE GORE® TAG® THORACIC ENDOPROSTHESIS*	
DESCRIPTION	%
Device-related reinterventions including all pathologies treated	6.5
Type I endoleak rate	3.2
Type III endoleak rate	0.6
Migration rate	0.2
Compression rate	0
Rupture rate	0.6
Conversion to open repair	0.7
Stroke rate	1.7
Overall mortality rate	9.0

GORE® EXCLUDER® AAA ENDOPROSTHESIS*	
DESCRIPTION	%
Device-related reinterventions including all pathologies treated	3.5
Type I endoleak rate	1.0
Type III endoleak rate	0.1
Migration rate	0
Compression rate	0
Rupture rate	0.1
Conversion to open repair	0.3
Device occlusion rate	0.3
Claudication rate	0.1
Overall mortality rate	6.3

GORE® EXCLUDER® ILIAC BRANCH ENDOPROSTHESIS* [TREATING ILIAC ANEURYSMS]	
DESCRIPTION	%
Device-related reinterventions including all pathologies treated	3.3
Type I endoleak rate	3.3
Type III endoleak rate	1.1
Migration rate	0
Compression rate	0
Rupture rate	0
Conversion to open repair	0
Device occlusion rate	1.1
Claudication rate	0
Overall mortality rate	0

Conformable GORE® TAG® Thoracic Endoprosthesis has been reported as treating 27 different pathologies, most common being DTAAAs and Type B dissections.

\* All events for all subjects through two years.

For outcome data, GREAT only collects site-reported serious adverse events per the ISO definition.

“Our commitment to the treatment of disease states of the entire aorta will be best informed by these diverse cases over the next decade; we are confident that this data will ultimately translate into better outcomes for patients.” — *Ryan Takeuchi, Gore Aortic Business Leader*

**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 (nickel-titanium alloy), and gold. Patients with a systemic infection who may be at increased risk of endovascular graft infection Refer to *Instructions for Use* at [goremedical.com](http://goremedical.com) for a complete description of all warnings, precautions and adverse events. Rx Only

**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](http://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](http://goremedical.com) for a complete description of all warnings, precautions, and adverse events. Rx Only



W. L. Gore & Associates, Inc. • Flagstaff, AZ 86004 • [goremedical.com](http://goremedical.com)

Products listed may not be available in all markets.

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through data