Together, improving life

FOR IMMEDIATE RELEASE

GORE® TAG® THORACIC BRANCH ENDOPROSTHESIS (TBE) NOW INDICATED FOR ZONE 0 AND ZONE 1 AORTIC ARCH REPAIRS

The first off-the-shelf, on-label branched endovascular device for Zones 0, 1 and 2.

FLAGSTAFF, Ariz. (Month XX, 2025) — W. L. Gore & Associates Medical Products (Gore) today announced that the GORE® TAG® Thoracic Branch Endoprosthesis (TBE) is now FDA approved for use in Zones 0 and 1, expanding its indication for the endovascular repair of lesions in the aortic arch and descending thoracic aorta while preserving flow to a single aortic arch branch vessel.

The device — a proven solution for Zone 2 repair — becomes the first off-the-shelf, single-branch thoracic endoprosthesis indicated across Zones 0, 1 and 2, enabling or expanding minimally invasive aortic repair of all lesions involving the arch.

"With broader indications, we can confidently address a wider range of complex arch pathologies using a trusted solution that streamlines procedure planning and — critically — helps improve patient outcomes," said Michael Dake, M.D., National Co-Principal Investigator of the GORE TAG Thoracic Branch Endoprosthesis Clinical Trial. "Of the 77 patients enrolled in the Zone 0/1 pivotal trial, more than 90 percent were treated in Zone 0 with no instances of device migration or wire fracture through 12 months, as well as low rates of Type I and III endoleaks."

For Zone 0 and 1 procedures, TBE provides an on-label alternative to open surgical repair and reduces the overall impact of procedures like sternotomy, cardiopulmonary bypass and circulatory arrest.

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Michael Dake, M.D.
Tucson, Arizona

Media contact

Jessica Moran
External Affairs
jmoran@wlgore.com

"We've seen firsthand how this technology can transform patient care," said Himanshu Patel, M.D., National Co-Principal Investigator. "With a less invasive approach, we can reduce a significant procedural burden on patients."

For Gore's Jason Belzer, Americas Business Leader, Medical Products Division, "The expanded indication equips physicians with a versatile solution for the challenges of treating aortic arch pathologies — with the backing of rigorous data and a track record of procedural success. We are excited that more patients will have access to this technology."

First approved in the U.S. in May 2022, this new indication for the use of TBE in Zones 0/1 further demonstrates how Gore is advancing the care of complex aortic disease with minimally invasive approaches for patients.

Medical Products

Gore engineers medical devices that treat a range of cardiovascular and other health conditions. With more than 55 million medical devices implanted over the course of more than 45 years, Gore builds on its legacy of improving patient outcomes through research, education and quality initiatives. Product performance, ease of use and quality of service provide sustainable cost savings for physicians, hospitals and insurers. Gore is joined in service with clinicians and through this collaboration we are improving lives. For more information, visit goremedical.com

About Gore

W. L. Gore & Associates is a global materials science company dedicated to transforming industries and improving lives. Since 1958, Gore has solved complex technical challenges in demanding environments — from outer space to the world's highest peaks to the inner workings of the human body. With approximately 13,000 Associates and a strong, team-oriented culture, Gore generates annual revenues of $5 billion. gore.com

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Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the aortic arch and descending thoracic aorta, while maintaining flow into a single aortic arch branch vessel in patients who have: **Adequate iliac/femoral access; Proximal Aortic Landing Zones:** For Isolated Lesion Patients: Proximal landing zone cannot be aneurysmal, dissected, heavily calcified or heavily thrombosed; For Dissection Patients: Primary entry tear must be distal to the target branch vessel and the proximal extent of the landing zone must not be dissected; Aortic inner diameter range 16-42 mm; Proximal segment length (length from distal edge of target branch vessel to the midpoint of any proximal branch vessel) of at least 2.0-4.0 cm, depending on Aortic Component selection; Proximal covered length (measured from distal edge of target branch vessel to the distal edge of any proximal branch vessel) of at least 15–36 mm, depending on Aortic Component selection; For patients with prior ascending aorta or aortic arch repair with surgical graft: at least 2 cm landing zone proximal to the distal anastomosis; **Target Branch Vessel Landing Zone:** Landing zone cannot be aneurysmal, dissected, heavily thrombosed and severely tortuous (180 degree turn within the treated length); Target branch vessel inner diameter of 6–18 mm, depending on Side Branch Portal diameter selected; Target branch vessel minimum length of 2.5–3.0 cm, depending on Side Branch Portal diameter selected. **Distal Landing Zone (Isolated Lesion Patients only):** Outer curve length must be ≥ 2 cm proximal to celiac artery; Aortic inner diameter range 16-42 mm; Cannot be aneurysmal, dissected, heavily calcified or heavily thrombosed; Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft. **CONTRAINDICATIONS:** The GORE® TAG® Thoracic Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials [ePTFE (polytetrafluoroethylene), FEP (fluoroethylpropylene), Nitinol (nickel, titanium), Gold, SB Component only - Heparin (CBAS® Heparin Surface)]; Patients who have a condition that threatens to infect the graft; Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.