Together, improving life

FOR IMMEDIATE RELEASE

GORE® TAG® THORACIC BRANCH ENDOPROSTHESIS (TBE) NOW APPROVED IN US AND CANADA 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. (September 19, 2025) — W. L. Gore & Associates' medical business (Gore) has announced FDA approval and Health Canada licensing of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE) for use in Zones 0 and 1 of the aortic arch.

A proven solution for Zone 2 repair, TBE is now the first off-the-shelf, single-branch thoracic endoprosthesis indicated across Zones 0, 1 and 2, expanding its indication for endovascular repair of all lesions in the aortic arch and descending thoracic aorta while preserving flow to a single branch vessel.

First approved for Zone 2 in the U.S. in May 2022 and licensed in Canada in June 2024, TBE reinforces Gore's continuing commitment to advancing minimally invasive care for complex aortic disease.

"With broader indications, we can confidently address a wider range of complex arch pathologies using a trusted solution that streamlines procedure planning," 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% 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."

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

"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 Product Division, "The expanded indication equips physicians with a versatile solution for the challenges of treating aortic arch pathologies."

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

For complete indications and other important safety information for Gore commercial products referenced herein, refer to the applicable *Instructions for Use* (IFU).

INDICATIONS FOR USE: 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.