ZONE 2 PIVOTAL TRIAL[1] Clinical Overview

Total enrolled in Zone 2 arm: N = 238

Delivering results you expect

2.9%

2.9% device reintervention rate through 12 months.[1]

99.2%

99.2% LSA branch patency through 12 months. [a,1]

2.9%

2.9% disabling stroke rate through 12 months.[1]

ZERO

Zero device migration, zero wire fracture through 12 months[1]

99%

99% freedom from permanent paraplegia, paraparesis through 30 days.[1]

18.9%

18.9% proximal landing zone in open surgical graft (dissection cohort).[1]

Contact your Gore representative for additional details

[a] 100% freedom from reintervention due to loss of LSA patency.

1. GORE® TAG® Thoracic Branch Endoprosthesis [Instructions for Use] W. L. Gore & Associates; 2025. MD205141

Consult Instructions for Use eifu.goremedical.com

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

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.

Products listed may not be available in all markets.

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