

# ZONE 0/1 PIVOTAL TRIAL<sup>1</sup> Clinical Overview

Total enrolled in Zone 0/1 arm: N = 77

## Delivering results you expect

6.5%

6.5% device  
reintervention rate  
through 12 months.<sup>1</sup>

98.6%

98.6% Side Branch  
patency through  
12 months.<sup>1</sup>

Zone 0: n = 0 occlusions  
Zone 1: n = 1 occlusion<sup>a</sup>  
<sup>a</sup> Did not require  
intervention.

7.8%

7.8% disabling  
stroke rate through  
12 months.<sup>1</sup>

ZERO

Zero reported  
device migration,  
zero wire fractures  
through 12 months<sup>1</sup>

100%

100% freedom from  
permanent paraplegia,  
paraparesis through  
30 days.<sup>1</sup>

62.5%

62.5% proximal  
landing zone in  
open surgical graft  
(dissection cohort).<sup>1</sup>

## Contact your Gore representative for additional details

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](http://eifu.goremedical.com) for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. <sup>1</sup> 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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