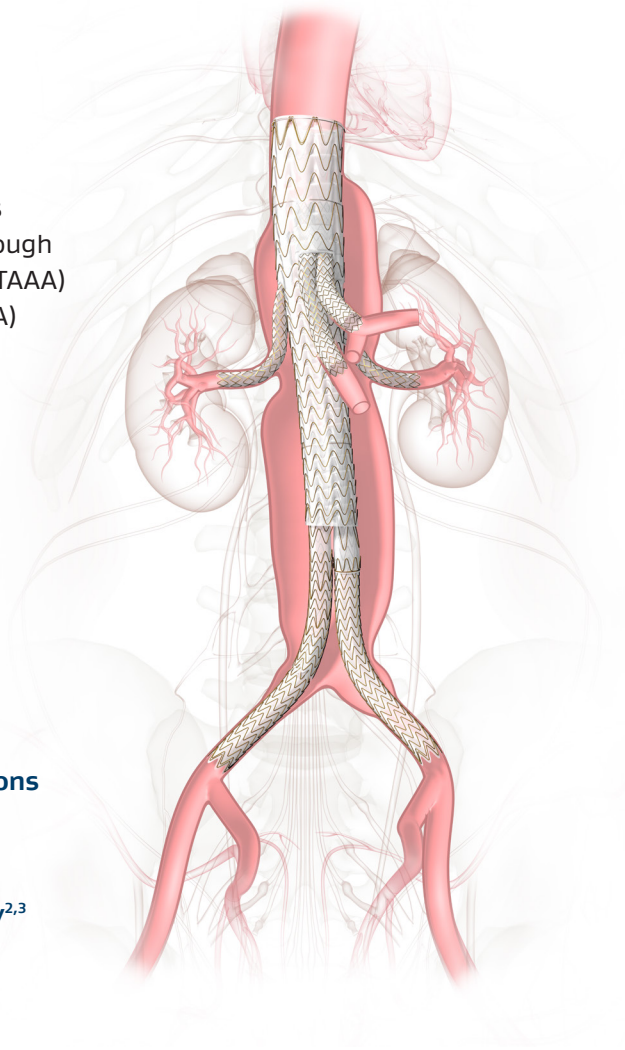
GORE® EXCLUDER®
Thoracoabdominal Branch Endoprosthesis

You advocate for patients. **We're here to help.**



The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) is more than a new option in aortic repair. It's a breakthrough solution in the treatment of thoracoabdominal aortic aneurysm (TAAA) and high-surgical risk pararenal abdominal aortic aneurysm (PAAA) patients with appropriate anatomy.

Until now, there have been limited endovascular options as alternatives to open surgical repair (OSR).

In patients not suited for OSR, physicians have relied on off-label techniques and custom-built devices, which can delay treatment due to manufacturing time:

- Parallel graft techniques
- Custom fenestrated or branched endografts
- Physician-modified endografts (PMEGs)

Key topics for your value analysis committee (VAC) conversations

May reduce overall procedure time vs. off-label endovascular alternatives[2,3]

Supports timely patient treatment[2,3]

Reduces procedure complexity[2,3]

On-label. TAMBE is the only FDA-approved endovascular solution with proven technical and clinical compatibility.

Improved outcomes. Compared to OSR, TAMBE showed reduced risk of mortality and morbidity in the TAMBE Pivotal Study.[1]

Off-the-shelf. All components are available without needing modification, alteration or custom design.

Breakthrough device.* With no approved alternatives, the FDA provided accelerated review for TAMBE to better serve patient needs.

Purpose-built. Modular components designed and tested together.

Contact your Gore Field Sales Associate for more information.

* The FDA Breakthrough Devices Program is a voluntary regulatory review program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. TAMBE received Breakthrough Device designation from the FDA in October 2021.

Together, improving life

References

1. U.S. Food and Drug Administration. Center for Devices and Radiological Health. FDA Summary of Safety and Effectiveness Data. GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE). P230023. Published January 12, 2024. Accessed March 28, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230023B.pdf
2. Mirza AK, Kärkkäinen JM, Tenorio ER, Lima GB, Marcondes GB, Oderich GS. Emergency endovascular repair of symptomatic post-dissection thoraco-abdominal aneurysm using a physician modified fenestrated endograft during the waiting period for a manufactured endograft. *EJVES Vascular Forum* 2020;49:11-15.
3. Gouveia e Melo R, Fernández Prendes C, Caldeira D, *et al*. Systematic review and meta-analysis of physician modified endografts for treatment of thoraco-abdominal and complex abdominal aortic aneurysms. *European Journal of Vascular & Endovascular Surgery* 2022;64(2-3):188-199.

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is indicated for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy as described below: Adequate iliac/femoral access and brachial/axillary access; Proximal (supraceliac) aortic neck treatment diameter range over 2 cm seal zone of 22–34 mm for aneurysms extending up to 6.5 cm or less above the origin of the most proximal branch vessel; Aortic neck angle ≤ 60° at the Aortic Component proximal seal zone; Iliac artery treatment diameter range of 8–25 mm and iliac artery seal zone length of at least 10 mm; Renal artery seal zone diameters between 4.0–10.0 mm; Celiac and superior mesenteric artery seal zone diameters between 5.0–12.0 mm; ≥ 15 mm seal zone length in renal arteries, superior mesenteric artery, and celiac artery; Visceral segment of aorta (3 cm proximal through 9.5 cm distal to the most proximal visceral artery) must be ≥ 20 mm in diameter. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the TAMBE Device materials including ePTFE, FEP, nickel titanium alloy (Nitinol), stainless steel, and gold. Patients who have a condition that threatens to infect the graft. Patients with known hypersensitivity to heparin, including patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II and cannot receive the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. 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. $\mathrm{R}_{\mathrm{X\ Only}}$

Products listed may not be available in all markets.

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