GORE® EXCLUDER®
Thoracoabdominal Branch Endoprosthesis
(TAMBE)

BRIDGING THE GAP IN THORACOABDOMINAL CARE — EVIDENCE THROUGH 1 YEAR

TAMBE Pivotal Study results through 1 year show:

- Favorable safety and effectiveness
- Low rates of aortic-related mortality and aortic rupture
- Key benefits compared to open surgical repair

The TAMBE Pivotal Study[1]

A multicenter, non-randomized, prospective study (N = 102) evaluating TAMBE in anatomically suitable patients with extent IV thoracoabdominal aortic aneurysms (TAAA) and pararenal aortic aneurysms (PAAA).

Advancing treatment options for complex visceral aortic aneurysms:

100%
freedom from lesion-related mortality (1 year)[2]

94.1%
freedom from all-cause mortality (1 year)[2]

98%
freedom from paraplegia (30 days)[1]

Advancing the evidence base with a first in four-branch repair data:

94.2%
freedom from target vessel instability (1 year)[2]

The first pivotal study for a BEVAR device, providing in-depth subject- and vessel-level data.

See early procedural outcomes
Jump to 1-year results

Together, improving life

High technical success. **Low morbidity.**

Early procedural results support safe delivery and deployment, with a high technical success rate of 99% per SVS reporting standards.[3]

- Median hospital stay following the procedure was 4 days.[1]
- One patient experienced intraoperative aortic rupture due to disruption of a narrow aortic bifurcation during balloon dilatation.[2]
- No additional events of aortic rupture or permanent paraplegia occurred after 30 days and through 12 months.[2]

30-day clinical outcomes (n = 102)[1]	Events (%)
Protocol-defined procedural safety events at 30 days[a,b]	8 (7.8%)
Stented segment aortic rupture	1 (1.0%)
Lesion-related mortality	0 (0.0%)
Permanent paraplegia	2 (2.0%)
Permanent paraparesis	3 (2.9%)[c]
New onset renal failure requiring dialysis	2 (2.0%)
Severe bowel ischemia	0 (0.0%)
Disabling stroke	1 (1.0%)

[a] One patient had two events: paraplegia and stented segment aortic rupture (protocol defined) and intraoperative aortic rupture.

[b] Adjudicated by the clinical events committee. Patients with at least 30-day post-procedure follow-up, or an event.

[c] Two subjects who meet the protocol definition for permanent paraparesis had a full recovery by 6 months after the procedure.

At 30 days, TAMBE was shown to be safe and effective in patients with complex aneurysms involving the visceral aorta — delivering strong technical success, no mortality and low rates of safety events.

See 1-year results

Favorable device-effectiveness. **High-risk anatomy.**

Through 1 year, TAMBE maintained 100% freedom from lesion-related mortality, with 94% freedom from aneurysm growth, zero conversions to open repair and zero reported device migrations.[2]

- Of the 6% (n = 5) with sac enlargement, 1 patient had Type IIIc endoleak, which resolved following angioplasty, and 4 patients had Type II endoleaks (3 resolved via coil embolization, 1 under surveillance). **None of these patients experienced post-operative aneurysm rupture.[2]**
- Branch occlusions occurred in 14 subjects (14.7% of subjects, 4.2% of target arteries).[2] See the target-vessel outcomes.
- Of 22 reinterventions in 15 patients, 6 were classified as major and 16 as minor. Major reinterventions were primarily related to target vessel occlusion (n = 5).[2]

Key 12-month patient-level outcomes[2]	n/N[d] (%)
Clinically significant reintervention[e] through 12 months	25/85 (29.4)
Clinically-indicated condition	6/81 (7.4)
Untreated device seal zone endoleak[f]	0/82 (0)
Target lesion growth > 5mm[f]	5/84 (6.0)
Ruptured	1/94 (1.1)
Compromised device seal zone/integrity[g]	7/94 (7.4)
Total occlusion[g]	14/95 (14.7)
Reintervention-required hospitalization[g]	4/95 (4.2)
Lesion-related mortality[g]	0/94 (0)
Renal function deterioration through 12 months[h,i]	14/74 (18.9)

Abbreviations: n = number of patients with an event; N = number of evaluable patients.

[d] Denominator represents number of patients with at least one appropriate image in the 12-month analysis window (243-546 days) or have an event of interest were included in calculation all endpoint variables listed with exception of all reintervention.

[e] As defined by the protocol: a composite of the following events through the 12 month window (to 546 days): device seal zone endoleak, lesion growth >5 mm, rupture, device effectiveness (seal zone/integrity), total occlusion of the device, and reintervention requiring hospitalization.

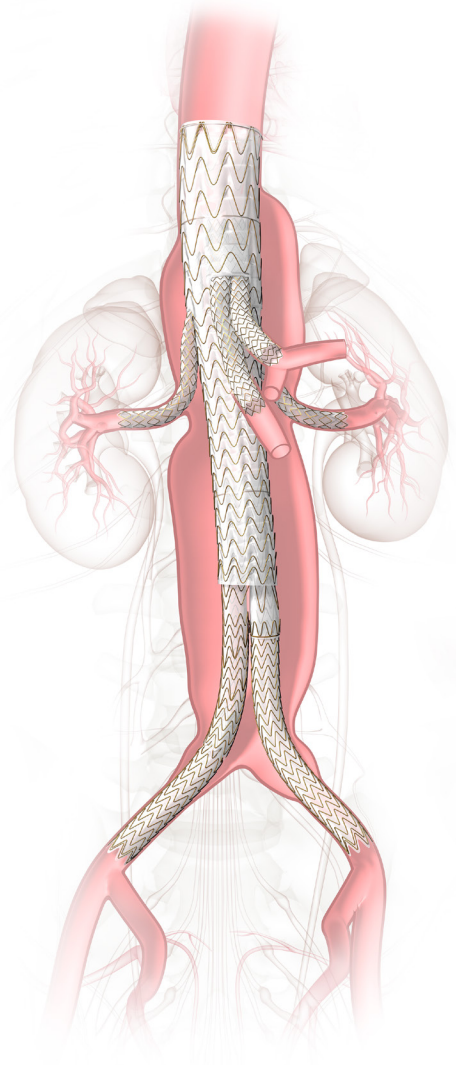
[f] Core lab assessment.

[g] Adjudicated by Clinical Evaluation Committee.

[h] Site-reported.

[i] Patients with estimated glomerular filtration rate available at 12-month visit window.

TAMBE demonstrated favorable safety and effectiveness outcomes — with no lesion-related mortality reported through 12 months — reinforcing the role of TAMBE for patients with appropriate anatomy.



See target-vessel outcomes

Unique branch insights.
Unmatched clinical oversight.

TAMBE demonstrated freedom from target vessel instability of 94.2% through 1 year (postoperative day 365) and 93.7% through the 12-month analysis window (postoperative day 546).[2]

- The 14.7% patient-level branch occlusion rate through the 12-month window corresponded to a 94.9% target vessel primary patency.[2]

Clinical outcomes by target vessel-level through 12 months[2]

Event, n (%)	Total No. of vessels N = 368[j]	Renal – left n = 90	Renal – right n = 89	Celiac n = 95	SMA n = 94
Any target vessel instability	23 (6.3)	10 (11.1)	9 (10.1)	1 (1.1)	3 (3.2)
Occlusion/stenosis overall	20 (5.4)	8 (8.9)	8 (9.0)	1 (1.1)	3 (3.2)
Occlusion[k]	13 (3.5)	6 (6.7)	6 (6.7)	0	1 (1.1)
Stenosis	7 (1.9)	2 (2.2)	2 (2.2)	1 (1.1)	2 (2.1)
Disconnection/fracture	0	0	0	0	0
Type I and III endoleak[l]	3 (0.8)	2 (2.2)	1 (1.1)	0	0
Type Ia	0	0	0	0	0
Type Ic	2 (0.8)	1 (1.1)	1 (1.1)	0	0
Type IIIa	0	0	0	0	0
Type IIIc	1 (0.3)	1 (1.1)	0	0	0
Rupture	0	0	0	0	0
Death – target vessel-related[k]	1	0	0	0	1
Secondary intervention[m]	14 (3.8)	7 (7.8)	4 (4.5)	1 (1.1)	2 (2.1)

Abbreviations: No. = number; SMA = superior mesenteric artery

[j] At 12 months, 95 patients completed a follow-up with imaging. The denominator for individual vessels and total vessel reflects that in some cases, not all vessels were successfully imaged(eg, unable to visualize vessel) and were, therefore, not included in the count.

[k] One non-aneurysm-related death occurred within 30 days, was previously reported (Farber MA, *et al. J Vasc Surg* 2024:S0741-5214(24)01199-1196), and cause of death was mesenteric ischemia likely related to SMA vessel stent thrombosis.

[l] Site-reported adverse events or as adjudicated by the Clinical Events Committee.

[m] Patency was restored in 4 of 6 renal occluded branches with attempted reinterventions.

Branch complications are a known risk in BEVAR. The assessment of factors impacting renal branch stent outcomes included luminal diameter, branch stent length, and tortuosity as well as renal artery diameter. Among these factors, renal artery diameter was the only statistically significant factor identified.[2]

Kaplan-Meier (KM) analysis demonstrated primary patency of 95.1% for renal arteries > 5 mm, compared to 82.5% for those ≤ 5 mm ($P = 0.004$).[2]

See resources and support

One year in, **TAMBE is delivering.**

With low rates of all-cause mortality and procedural safety events, and promising effectiveness, TAMBE continues to bridge gaps in complex visceral aortic aneurysm care.

- **Strict adherence to the IFU and patient selection criteria** can help optimize both technical success and postoperative outcomes.
- **While renal branch vigilance remains important,** the data transparency and clinical rigor of TAMBE 1-year outcomes help set a new benchmark in complex aortic repair.
- **Close postoperative monitoring** with duplex ultrasonography may help detect early flow issues.

For deployment details and case-planning resources, explore the following:

Deployment sequence wall chart
Case planning and measurement form
Sizing guide (device selection) form

For detailed results and discussion:

Access the 30-day publication
Access the 12-month publication

References

1. Farber MA, Matsumura JS, Han S, *et al*. Early outcomes from the pivotal trial of a four-branch off-the shelf solution to treat complex abdominal and type IV thoracoabdominal aortic aneurysms. *Journal of Vascular Surgery*. 2024;80(5):1326-1335.e4. doi:10.1016/j.jvs.2024.05.020
2. Farber, Mark A. *et al*. 1-year Results from the Pivotal Trial of a 4-Branch Thoracoabdominal Branch Endoprosthesis. *Journal of Vascular Surgery*, Volume 81, Issue 6, e236.
3. Oderich GS, Forbes TL, Chaer R, *et al*. Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries. *Journal of Vascular Surgery*, 2021;73(1S):45-52S.

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 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; and 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 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.

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