Update On The TAMBE Endograft Device (Gore) For Treating Complex AAAs And TAAAs: Current Configuration And Advantages, Technique For Insertion:

Now Approved By The FDA

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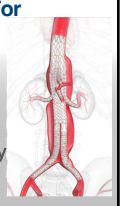
Professor of Surgery



Division of Vascular and Endovascular Surgery
Department of Surgery
UT Southwestern Medical Center

Disclosures

- Honoraria / Consultant / Research
  - Cook Medical Inc
  - W. L. Gore & Assoc
  - Philips Healthcare
- Acknowledgement
  - Gustavo Oderich, MD
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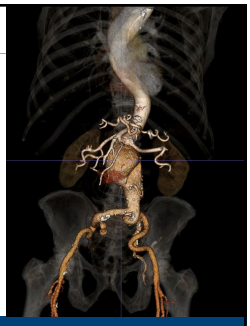
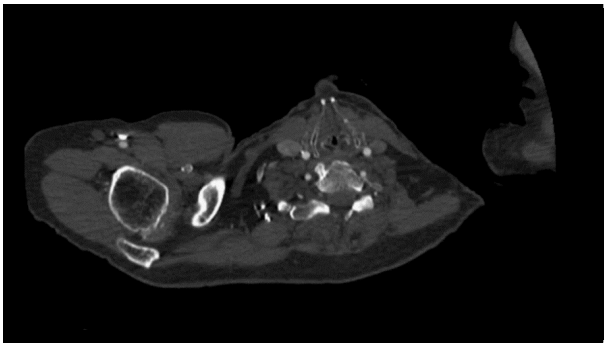
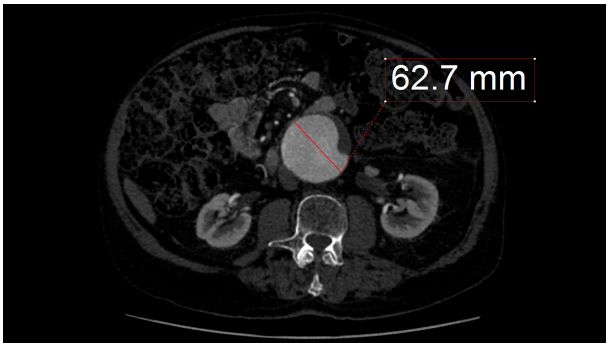
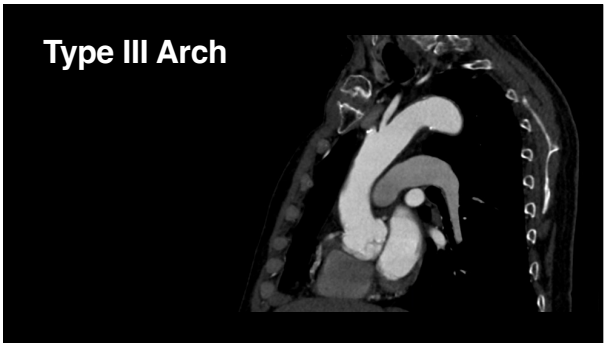
Case presentation

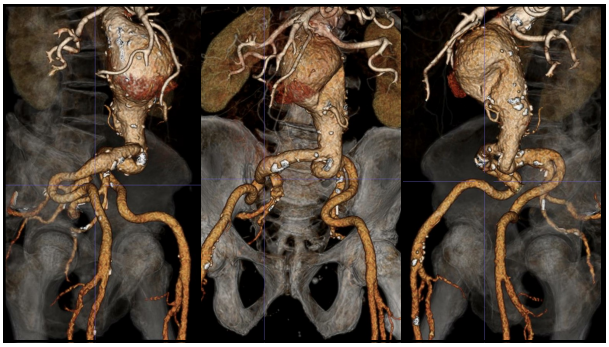
- 84-year-old male
- **Chief Complaint:** Abdominal pain and CT finding of 62 mm Juxtarenal aneurysm





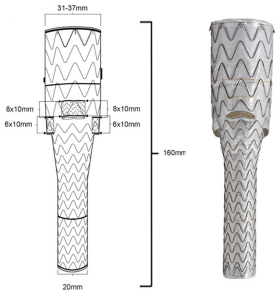


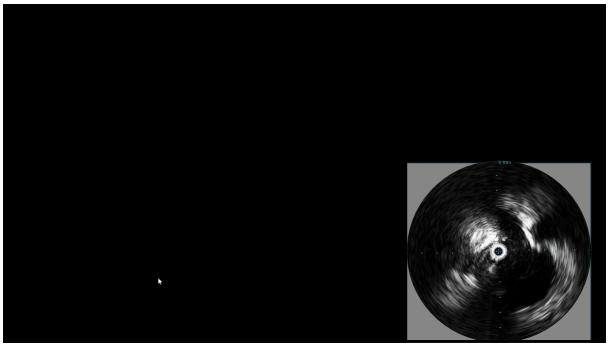


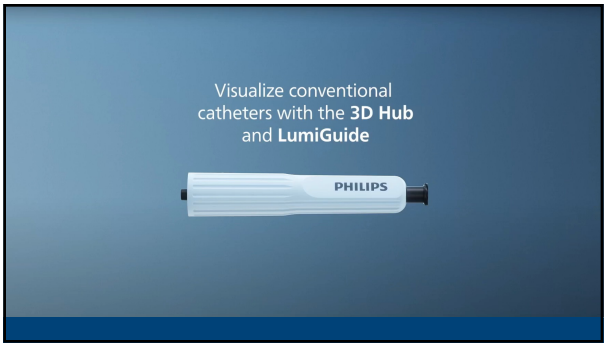


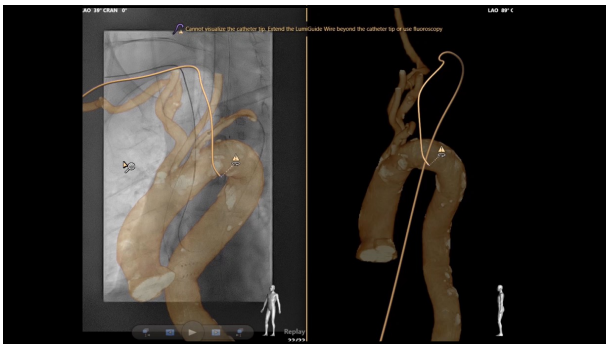
Treatment Plan

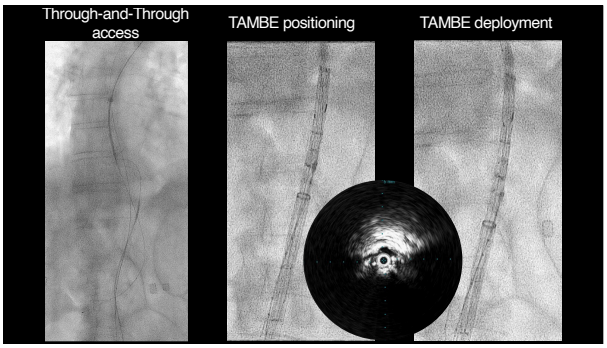
- Branched endovascular aortic aneurysm repair with the Gore® Excluder® Thoracoabdominal Branch Endoprosthesis (TAMBE)

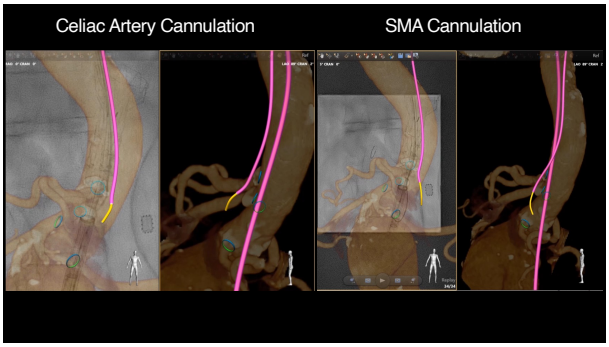


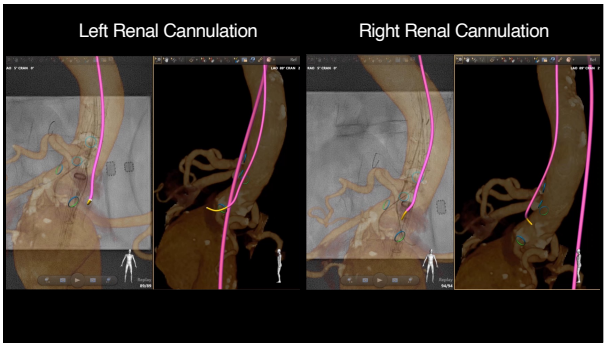


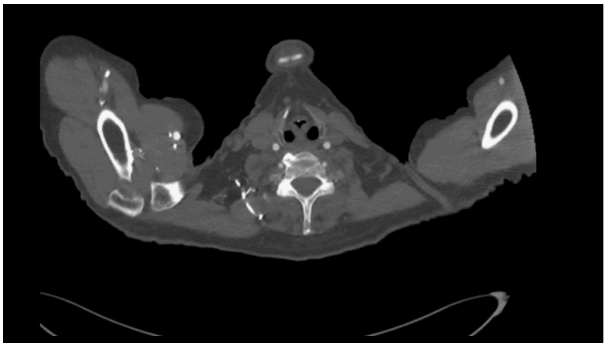


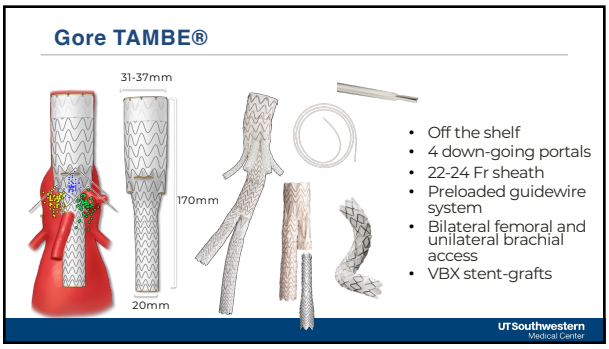





Celiac Artery Cannulation
SMA Cannulation


Left Renal Cannulation
Right Renal Cannulation




Gore TAMBE®
31-37mm
170mm
20mm
Off the shelf
4 down-going portals
22-24 Fr sheath
Preloaded guidewire system
Bilateral femoral and unilateral brachial access
VBX stent-grafts
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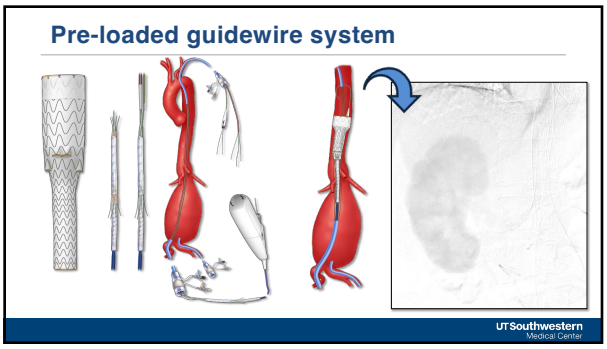
Pre-loaded guidewire system
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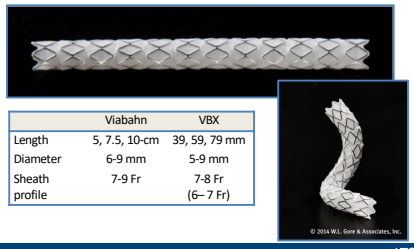
VBX® Balloon Expandable Stent



	Viabahn	VBX
Length	5, 7.5, 10-cm	39, 59, 79 mm
Diameter	6-9 mm	5-9 mm
Sheath profile	7-9 Fr	7-8 Fr (6– 7 Fr)

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VBX® for directional branches

Appealing qualities

- Low profile (7-8 Fr)
- Good visualization with precise deployment
- Flexible
- Flaring to 16mm
- High radial force
- Excellent trackability on tortuous anatomy

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GORE TAMBE®

FDA-approved in January 2024

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Early outcomes from the pivotal trial of a four-branch off-the shelf solution to treat complex abdominal and type IV thoracoabdominal aortic aneurysms

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J Vasc Surg 2024; 80:1326-35

Mark Farber, MD
National PI

Department of Surgery

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Study overview

Study objective:

- Assess the safety and effectiveness of the TAMBE Device in the treatment of thoracoabdominal and pararenal aortic aneurysms

Study design:

- Prospective, non-randomized, multicenter study

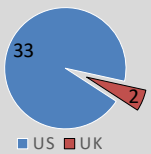
102
Patients enrolled in primary arm

44 sites in the U.S. and U.K.

35 sites with enrolled, implanted Subjects

Median Patients/Site: 2

Implanting Site Location



Screen Failure Rate: ~75%

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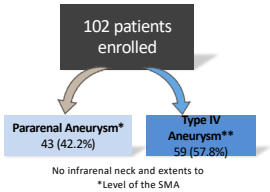
Aneurysm Characteristics



No infrarenal neck and extents to
*Level of the SMA
**≤ 6.5 cm above the CA

Number of Subjects	102
Size: Extent IV TAAA, n (%)	59 (57.8)
<5.0 cm	0
≥5.0 to <5.5 cm	10/59 (16.9)
≥5.5 to <6.0 cm	27/59 (45.8)
≥6.0 cm	22/59 (37.3)
Size: PRAA, n (%)	43 (42.2)
<5.0 cm	1/43 (2.3)***
≥5.0 to <5.5 cm	11/43 (25.6)
≥5.5 to <6.0 cm	16/43 (37.2)
≥6.0 cm	15/43 (34.9)

***Saccular

Mean maximum diameter: 59.4±7.8 mm

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Gore TAMBE Early Results

- Pivotal trial – 35 sites
- 102 patients with SR AAAs and t… AAs
- Technical success, 99%
- No 30-day or in-hospi… y
- No type I or III … at 30 days
- CA and SM… y, 100% (1 & 1 occlusions)
- Left … patency, 96% (6 occlusions)
- … al art patency, 99% (8 occlusions)
- … e stroke, 2 paraplegia

High-surgical risk patients with pararenal aortic aneurysms & type IV TAAAs

Reinterventions

12 reinterventions occurred in 9 (9.4%) patients through the 30-day follow-up window of which three patients had two reinterventions each.

Reinterventions

- Primarily balloon angioplasty with additional stent placement (n=7)
- Angioplasty alone (n=1)
- Total occlusions (n=2)
- Embolization coils (n=1)
- Control of retroperitoneal bleeding vessels (n=1).

Conclusions

- The TAMBE device has been shown to be safe and effective at 30 days in treating patients with complex aneurysms involving the visceral aorta.
- Outcomes demonstrate a high technical success rate, no 30-day mortality, and a low rate of safety events within 30 days of the index procedure.
- Procedure is not without risks, including paraplegia, renal failure, and the need for adjuvant stenting to resolve complications both intraoperatively and in follow-up.
- Long-term data will help determine where this treatment strategy will fit in the management of patients with TAAA and PRAA.