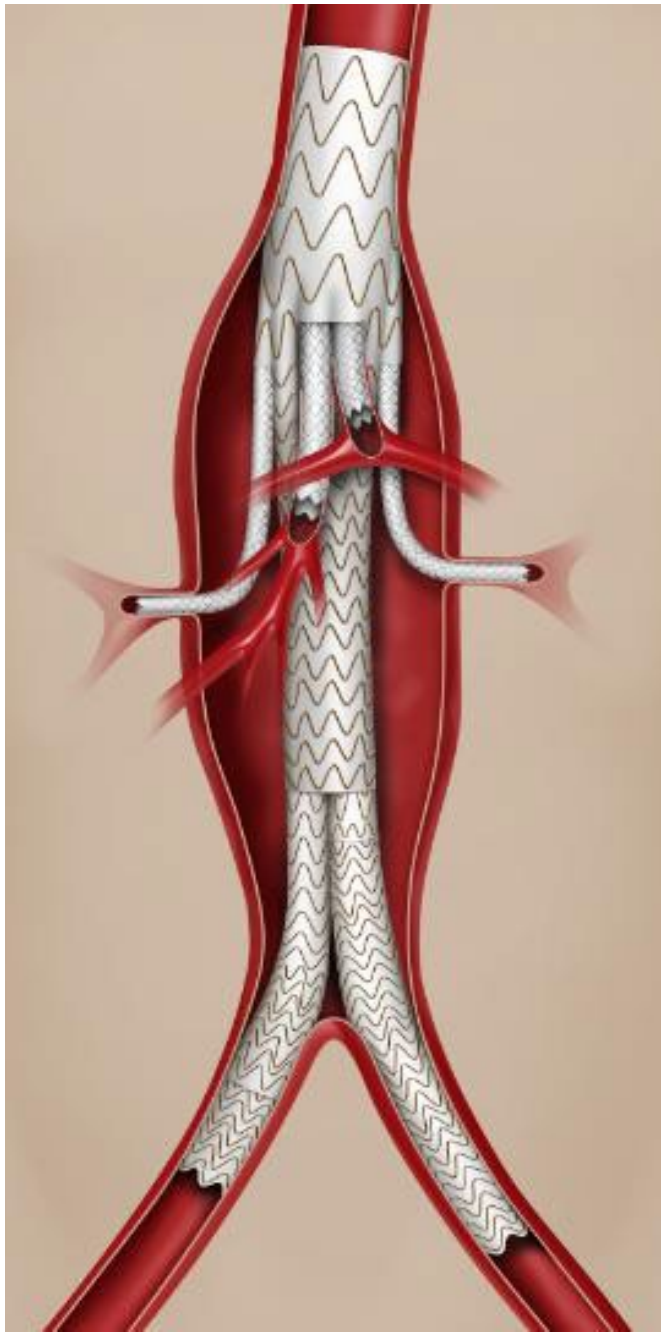
RESTRICTION USING THORACOABDOMINAL BRANCH ENDOPROSTHESIS (TAMBE DEVICE)

Presentation for the March 2024 ICD-10-PCS Coordination and Maintenance Committee



Introduction to the TAMBE Device

- The TAMBE Device is an endoprosthesis that provides endovascular treatment for two types of aortic aneurysms.
- The TAMBE Device is a branched intraluminal device, manufactured integrated system, indicated for use in four or more arteries, using a percutaneous approach. The proximal end is implanted in the thoracic aorta and the distal end in the iliac arteries.
- The TAMBE Device was FDA approved on January 12, 2024, and has Breakthrough Device status.

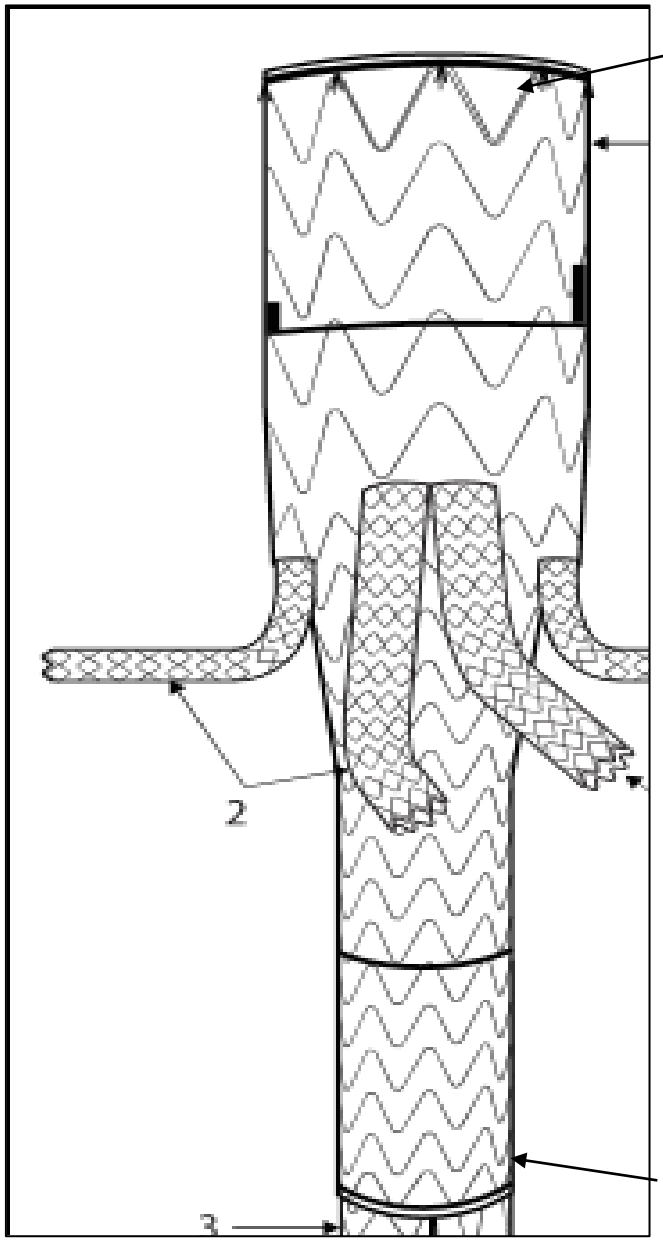
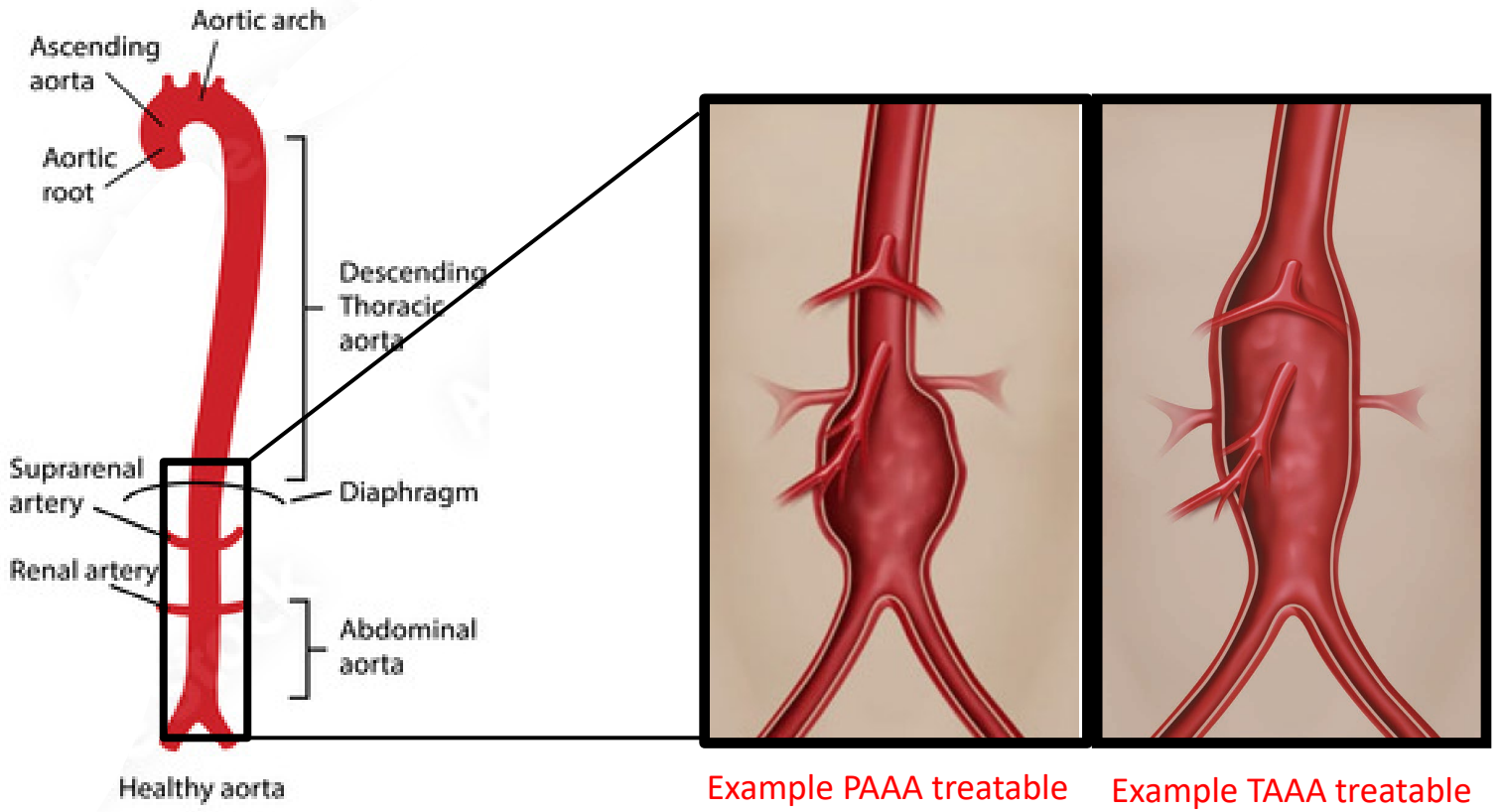


Figure : Complete TAMBE Device

1. *Aortic Component*
2. *Branch Components (GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis)*
3. *Distal Bifurcated Component (GORE® EXCLUDER® Iliac Branch Endoprosthesis - Iliac Branch Component)*
4. *Contralateral Leg Component (GORE® EXCLUDER® AAA Endoprosthesis - Contralateral Leg Endoprosthesis and/or GORE® EXCLUDER® AAA Endoprosthesis - Iliac Extender Endoprosthesis)*
5. *Optional DBC Extender component (*GORE® EXCLUDER® AAA Endoprosthesis - Aortic Extender*), not shown*

Anatomic Overview of Aortic Aneurysm & Target for GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis



Gore TAMBE Device Indication for Use:

- The TAMBE Device is indicated for endovascular repair in patients with thoracoabdominal aortic aneurysms (TAAA) and high-surgical risk patients with pararenal abdominal aortic aneurysms (PAAA) who have appropriate anatomy as described below:
  1. Adequate iliac/femoral access and brachial/axillary access
  2. 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
  3. Aortic neck angle ≤ 60° at the Aortic Component proximal seal zone
  4. Iliac artery treatment diameter range of 8-25 mm and iliac artery seal zone length of at least 10 mm
  5. Renal artery seal zone diameters between 4.0-10.0 mm
  6. Celiac and superior mesenteric artery seal zone diameters between 5.0-12.0 mm
  7. ≥ 15 mm seal zone length in renal arteries, superior mesenteric artery, and celiac artery
  8. 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 for use 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

Overview of the TAMBE Device and its Usage:

- The TAMBE Device is a permanent implant that is the first endoprosthesis designed and approved to treat an unmet clinical need for non-invasive endovascular repair of TAAA and PAAA that involves the visceral segment of the aorta while maintaining perfusion of the visceral segment arteries (left and right renal arteries, superior mesenteric artery, and the celiac artery).
  - Since the first TAMBE Device was implanted on Dec 11, 2015, there have been no reported explants of the 171 patients that have been treated to date.
- The TAMBE Device will be implanted as a stand-alone operating room procedure during an inpatient hospital stay and is likely to be mentioned in the surgical notes where the device could be listed as:
  - The Gore TAMBE Device, W. L. Gore thoracic abdominal endoprosthesis device, or Gore multi-branched device.
- Gore does not anticipate that the TAMBE Device will be used in the outpatient setting.
- In terms of adverse events, no new risks or usability aspects have been identified in the clinical data which have not yet been addressed within the risk management process. The anticipated benefits to a patient when using the TAMBE Device outweigh the potential risks of suffering harm due to a residual risk of the device. The TAMBE Device has similar inherent risks as other endovascular devices used in analogous applications.

What Diagnoses are associated with or indicated for use of the TAMBE Device?

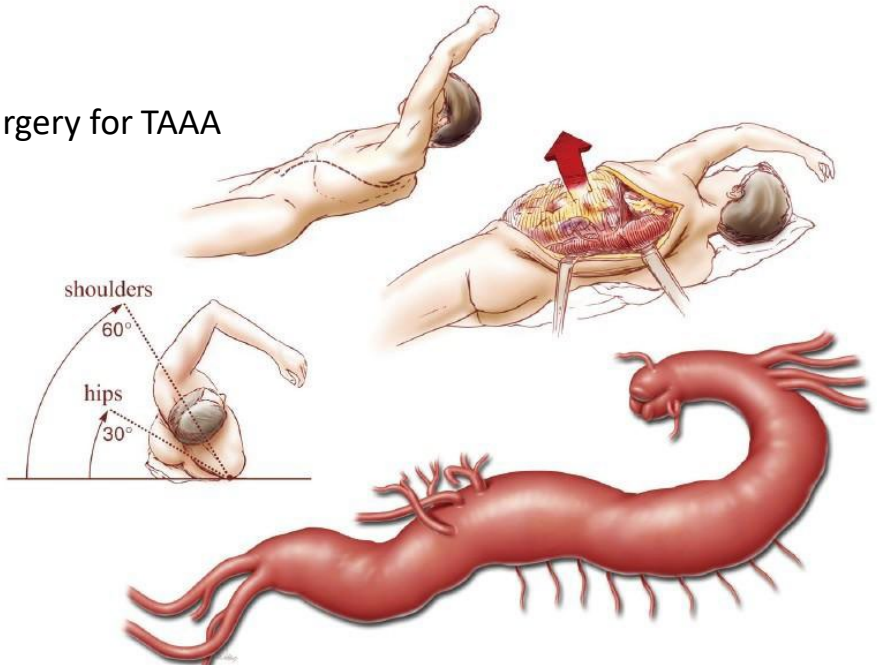
- The TAMBE Device is approved for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal abdominal aortic aneurysms who have appropriate anatomy.
- The associated ICD-10-CM codes:
  - I71.40 Abdominal aortic aneurysm, without rupture, unspecified
  - I71.41 Pararenal abdominal aortic aneurysm, without rupture
  - I71.42 Juxtarenal abdominal aortic aneurysm, without rupture
  - I71.60 Thoracoabdominal aortic aneurysm, without rupture, unspecified
  - I71.61 Supraceliac aneurysm of the thoracoabdominal aorta, without rupture
  - I71.62 Paravisceral aneurysm of the thoracoabdominal aorta, without rupture

How are patients eligible for the TAMBE Device treated now?

The limited options to treat TAAA and PAAA in the U.S. include:

- Medical management for patients who are not candidates open surgical repair,
- Open surgical repair, and Off-label (physician discretion) or
- investigational use of physician modified endovascular graft (PMEG) device combinations.

Open Surgery for TAAA



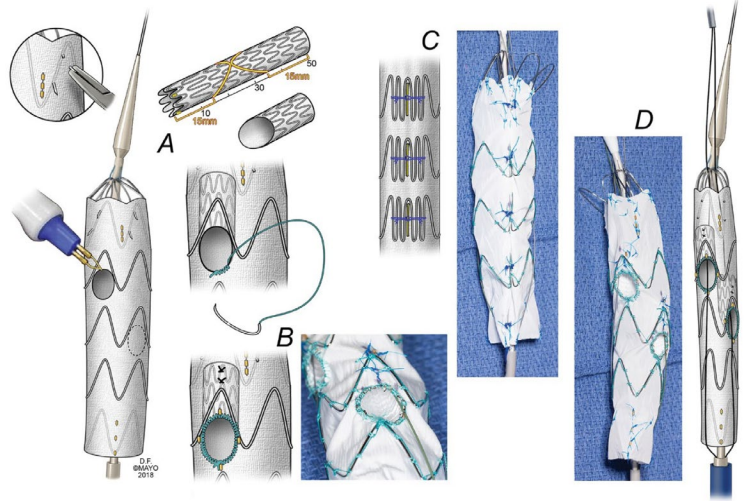
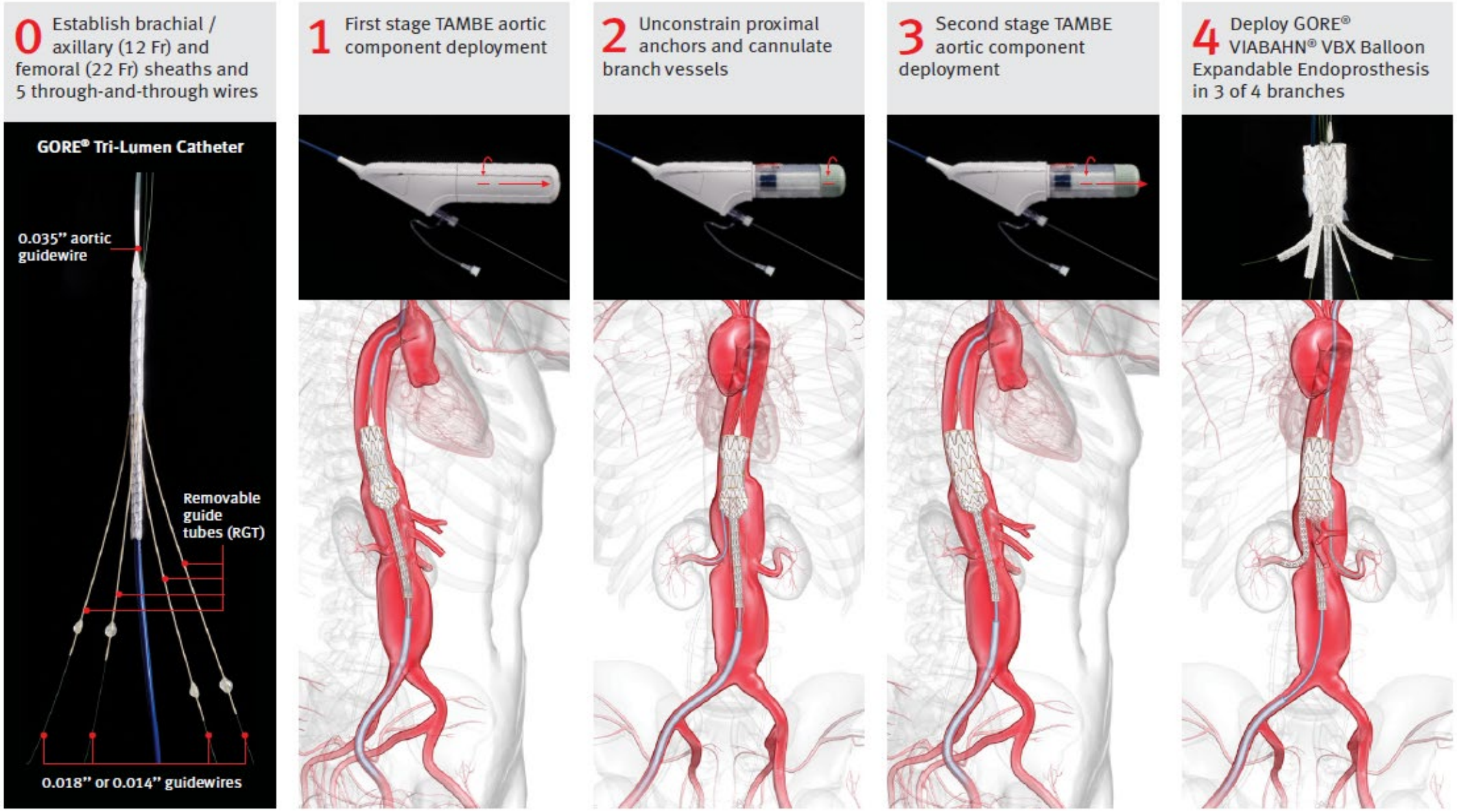


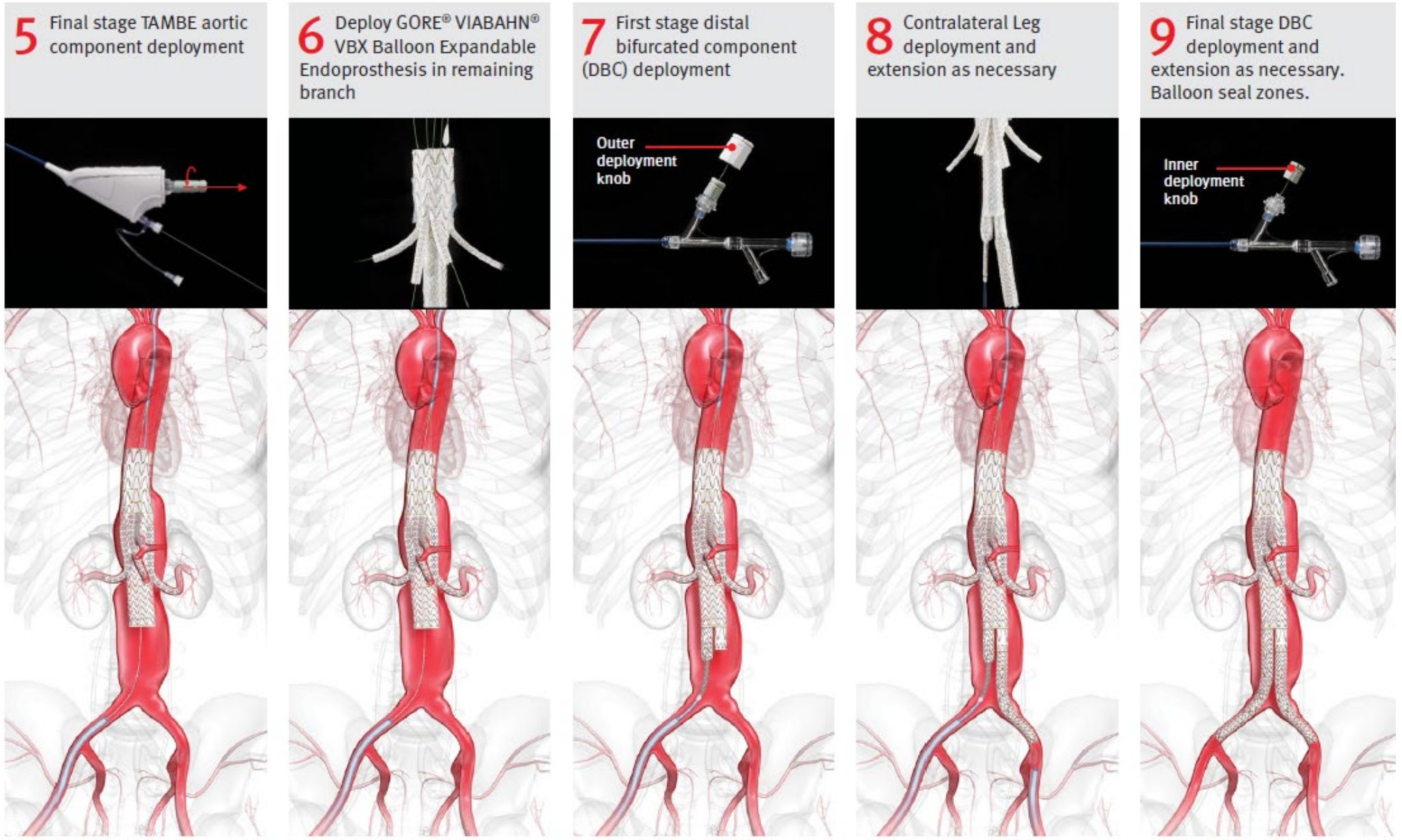
Illustration of an Off-Label Endovascular Graft Construct*

*D'Oria M, Mirza AK, Tenorio ER, Kärkkäinen JM, DeMartino RR, Oderich GS. Physician-Modified Endograft With Double Inner Branches for Urgent Repair of Supraceliac Para-Anastomotic Pseudoaneurysm. *Journal of Endovascular Therapy*. 2020;27(1):124-129.

The TAMBE Device Deployment Steps



The TAMBE Device Deployment Steps, Cont'd



If the technology is a device or implant, is only one device/implant routinely inserted or can multiple devices/implants be utilized?

- Only **one** TAMBE Device is implanted per patient; however, the number of components used will vary according to the extent of the patient's aneurysm and the medical judgement of the clinician.
- The average patient requires 11.3 components within the integrated TAMBE Device as observed in the clinical study.
- Some patients require multiple branch components implanted in sequence down a visceral vessel due to a long aneurysm.

ADDITIONAL SLIDES

What are the procedural steps involved?

Following standard clinical practice, arterial access is gained via bi-lateral iliac/femoral and brachial/axillary vascular access with five through-and-through guidewires.

- The TAMBE Device Aortic Component (AC) has four removable guidewire tubes to facilitate pre-cannulation of guidewires through the portals.
- The TAMBE Device AC on the delivery catheter is tracked via femoral / iliac access through a 22 Fr sheath and positioned with portals in proximity to the target branch vessels (celiac, superior mesenteric, and renal arteries). With the AC positioned in the aorta at a level where the outlet of the proximal portals is 1 to 3 cm above the origin of the most proximal visceral artery, deployment initiates from the leading end and proceeds toward the trailing end of the delivery system.
- Removing the white outer knob of the delivery system deploys the AC to approximately 50% of the final diameter while the proximal fixation anchors remain constrained. At this time position can be adjusted. Once the desired position is confirmed, the gray nut on the delivery system is rotated counter-clockwise to unconstrain the anchors. From the upper extremity access, target branch vessels are sequentially cannulated from their respective pre-cannulated portal guidewires. Once all branch vessels are cannulated with appropriate wires exchanged and final positioning confirmed, the constraining system, which includes the secondary sleeve, can be removed. This is done by sliding the red safety lock on the delivery system back and rotating the secondary deployment knob counter-clockwise.
- The Branch Components are introduced through each AC portal into its target branch vessel and deployed.
- Once three of the four branches are deployed, the distal sleeve of the AC can be deployed to fully deploy the distal end of the TAMBE Device AC. This is accomplished by rotating the gray deployment knob counterclockwise and pulling back.
- Once the final stage of the TAMBE Device AC is deployed, the delivery catheter may be removed, and the final branch may be deployed.
- The Distal Bifurcated Component, which bifurcates the TAMBE Device, is introduced into the distal portion of the TAMBE Device AC and deployed.
- Deployment of the Contralateral Leg Components and any necessary limb extensions complete the TAMBE Device by mating with the Distal Bifurcated Component and sealing in the common iliac arteries. To complete the procedure, all component seal zones and junctions are ballooned with appropriate balloon catheters. A final angiogram may be performed to confirm exclusion of the aneurysm and device seal integrity.

Note: See final Instructions for Use for complete information

Questions and Answers

- When additional devices are required to treat disease in the more proximal thoracic aorta and/or or the more distal iliac arteries, are these included in the TAMBE Device?
  - No, additional devices used to treat disease proximal or distal to the TAMBE treatment would be reported utilizing current coding guidelines.
- Are all parts of the TAMBE Device required for all patients?
  - Yes, the complete TAMBE device is always used as a unit.
- Are extensions into visceral arteries part of the TAMBE Device?
  - Yes, because each patient's anatomy and aneurysm disease is unique, some patients may require extensions into a branch visceral artery to create a proper endograft seal. These are part of TAMBE deployment.