Novel Simplified Endograft Device With Off-The-Shelf Potential For Treatment of TAAAs: The Gore TAMBE Device: How It Works And Early Clinical Results

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Clinical research study (Phase I):
"Initial Feasibility Assessment of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) in the Treatment of Crawford Type III & IV and Safi Type V Thoracoabdominal Aortic Aneurysms and Abdominal Aortic Aneurysms Involving the Renal Arteries"

Study Design:
This is a non-randomized, multicenter study designed to assess the initial feasibility of the GORE® EXCLUDER® Juxtarenal and Thoracoabdominal Branched System (TAMBE Device)

Study Objective:
Assess the initial safety of the TAMBE Device implantation procedure in juxtarenal and thoracoabdominal aortic aneurysm subjects

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<th>1 year Follow-Up</th>
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<td>Endoleak/Type</td>
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<tr>
<td>MAE</td>
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<tr>
<td>Treated Branch Patency</td>
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<td>Treated Branch Stenosis/Separation</td>
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<td>Late SCI</td>
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Case 1
- ATS, female, 68y
- Juxtarenal 52mm AAA
- Hypertension
- COPD

Case 2
- LC, male, 56y
- Juxtarenal 55mm AAA
- Hypertension

DISCLOSURE

Pierre Galvagni Silveira, MD, PhD
Research, clinical trial, or drug study funds received from: Boston Scientific Corp., Gore & Associates, Medtronic, Eurocor
Consultant: Gore & Associates, Medtronic
TAMBE Configurations

- First patients were treated using Retrograde configuration
- Focus on Device ease of use (e.g., procedure time). Anatomic applicability
- Antegrade device must be incorporated into trial in 2016

Device Components: Aortic Component

- **Aortic Component:**
  - 26, 31, 37 mm proximal diameter
  - Same oversizing as CTAG
  - Proximal anchors (reconstrainable)
  - 20 mm distal diameter
  - 215 mm length

- SMA & Celiac: 8 mm Antegrade Ports
  - All portals are 10 mm in length

- Renals: 6 mm Retrograde Ports
  - 50 mm seal length
  - 85 mm portal to portal length (outlet to outlet)

TAMBE Device Features

- **Pre-cannulated side branch portals**
  - Tri-lumen catheter to facilitate through-and-through guidewires and prevent entanglement

TAMBE Device Features (Antegrade & Retrograde)

- Multi-stage deployment with proximal, distal, and rotational repositionability to aid in branch vessel access and deployment accuracy
Conformable, kink-resistant side branch components with CBAS® (Heparin Surface)
- GORE® VIABAHN BX Endoprosthesis
- GORE® VIABAHN Endoprosthesis (+7.5cm)

Branch Flow Analyses
- Pre-clinical testing of branch flow using:
  - Computational Fluid Dynamics (CFD)
  - Benchtop pressure drop (ΔP) and volumetric flow rate (Q) measurements
  - Particle imaging velocimetry (PIV)
- Data indicate that for both antegrade and retrograde renal configurations:
  - Pressure drops are well below clinically relevant thresholds
  - Perfusion to the kidneys is maintained throughout the cardiac cycle
  - There is complete “washout” during the cardiac cycle (i.e., there are no flow stagnation zones)
- TAMBE - branch patency and kidney function 1 year FU: no problems related to branch perfusion

Summary
- The use of TAMBE in the first two implants demonstrated safety and efficacy in the exclusion of aneurysm sac and the preservation of visceral and renal arteries.
- The TAMBE device is the only “all in one” pre-cannulated off the shelf system, including aortic component and side branch stent graft.
- The initial results (1 year FU) are promising, longer term outcomes are needed to confirm this early experience.