Advantages of and Results with the Terumo Aortic Multibranched Device for Treating Aortic Arch Lesions: From the US Multicenter Feasibility Trial

Luis A. Sanchez MD
Gregorio A. Sicard Distinguished Professor of Surgery & Radiology
Chief, Section of Vascular Surgery

Disclosure Statement

• Consultant
• Cook
• Endologix
• Terumo Aortic
• W. L. Gore

Branch Thoracic Endografts

• Aortic Arch Pathologies
  ➢ Aneurysms
  ➢ Penetrating Ulcers
  ➢ Aortic dissections
  ➢ Thoracoabdominal aneurysms

Treatment of Complex Aortic Pathologies

Aortic Arch Pathology

• Increased difficulty as you enter the aortic arch and move to zones 1 & 0
• Open repair
• Hybrid procedures
  ➢ Carotid-subclavian bypass
  ➢ Carotid-carotid bypass
  ➢ Aortic branch stenting
  ➢ Elephant trunk

Aortic Arch Endovascular Branch Devices

• Early branched devices
  ➢ Inoue (1999) – earliest attempts (Japan)
  ➢ Chuter (2005) – early experience (USA)

Thoracic Branched Endovascular Technology
#### Relay NBS Plus Platform Technology used for Relay Branch Technology

- Patented proximal capture technology
- Improved arch conformation and prevention of retroflex deployment
- Self-orienting pre-curved NiTi guidewire lumen
- Dual sheath design facilitates advancement into Zone 0

#### Relay Branch Early Feasibility Study

**STUDY DEFINITION**

Early Feasibility Study of the Relay Branch Thoracic Stent-Graft System in Subjects with Thoracic Aortic Pathologies Requiring Treatment Proximal to the Origin of the Innominate Artery

**STUDY DESIGN**

Prospective, Multicenter, Non-Blinded, Non-Randomized Study

**PATIENTS (Target n=10)**

Enrollment was initiated in January 2018

- 6 patients have been successfully treated, 2 more scheduled

**SITES**

- 4 investigational sites in the United States:
  1. BJH-WUSM, St. Louis, Missouri
  2. Cleveland Clinic Foundation, Cleveland, Ohio
  4. Massachusetts General Hospital, Boston, Mass

**Preliminary results to date**

- 50% males, mean age: 71 years
- 100% technical success
- Mean follow up - 4 months
- No periprocedural mortalities, no major endoleaks, no branch occlusions

#### Terumo Relay Branch Device

**Conclusion**

- This aortic arch multi-branch device is the first on trials in the US.
- The early feasibility experience has been highly encouraging.
- The device tracks well, self-aligns in the arch with minimal manipulation and deploys accurately.
- Based on the European experience and these early results, an international pivotal trial is under development.