First in Human Trial of the 
Mona LSA 
Branched Thoracic Stent Graft: An Early 
Feasibility Device Trial in the FDA’s New 
Innovation Pathway 

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CAUTION – Investigational Device. Limited by Federal (or United States) law to investigational use.
Disclosures

Medtronic: Investigator/Consultant
17- 43% of patients undergoing TEVAR have planned coverage of LSA

where achievement of a proximal seal necessitates coverage of the left subclavian artery, we suggest that revascularization should be individualized and addressed expectantly on the basis of anatomy, urgency, and availability of surgical expertise (GRADE 2, level C). (J Vasc Surg 2009;50:1155-8.)
Coverage of LSA without revascularization is single most important predictor of post TEVAR stroke

- Spinal cord ischemia 4%
- Arm ischemia 6%
- Death 6%

Valiant Mona LSA Stent Graft System

- **Diameter**: 30-46mm
- **Length**: 15cm
Valiant Mona LSA Delivery

- Flexible cuff “volcano” on main body
- Two wire system
  - Main system wire
  - LSA branch thru & thru wire
- Pre-cannulated LSA cuff
- Tip capture
**LSA Thoracic Branch Stent Graft**

- Nitinol helical stent / polyester fabric
- Distal flare
- 10, 12 and 14 mm diameters
- 40 mm length
- 15 Fr profile, femoral access

Proximal | Distal
Innovation Pathway
Guidance from FDA - CDRH

• New program by FDA to bring first-in-the-world technology to U.S. patients
• Clinical investigation – generally < 10 subjects
• Device early in development, for specific indication
• Proof of principle and initial clinical safety data
Key Principles of the Guidance

• Early Feasibility Study (EFS) appropriate:
  • Nonclinical testing not adequate to advance development
  • Clinical experience is necessary
• EFS must be justified by
  • risk-benefit analysis
  • adequate human subject protection
• FDA approval of EFS IDE application may be based on less nonclinical data than expected for a traditional feasibility or a pivotal study
Medtronic Early Feasibility Study
Valiant Mona LSA Thoracic Stent Graft System

- 7 subjects at 2 sites
- **Goal:**
  - Validate procedure in humans
  - Assess safety and performance acutely and 30 days
  - Collect imaging data to augment current understanding
Initial Cases

Case 1: Eric E. Roselli, MD
Case 2,3: Frank R. Arko, III, MD
70 y/o female, DTA 55mm

• Measurements
  • Proximal sealing zone
    • Between LSA and LCC: 27.2mm
    • Length: 21.0mm
  • Distal landing zone: 31.7mm
  • LSA: 6.6 – 9.9mm

• Planned Treatment with:
  • 34mm MSG (15cm length)
  • 12mm BSG (4cm length)
  • 34 and 36mm Distal Extension to celiac a.
Access –

Rt femoral and Lt brachial
Delivery and Deployment
Completion Angiogram
81 y/o female, DTA 5.7cm

- **Measurements**
  - **Proximal Seal zone**
    - Between LSA and LCC: 35.7mm
    - Beginning of Proximal Neck: 37.5mm
  - **Distal Seal zone:** 41.6mm
  - **LSA:** 8.0 - 9.0mm
- **Planned Treatment with:**
  - 46mm MSG (15cm length)
  - 10mm BSG (4cm length)
  - 46mm Distal Extension to diaphragm
MSG Deployment
BSG Deployment
Pre and Post Fluoro Images

Distal device placed first
78 y/o male, PAU near LSA

- **Measurements**
  - **Proximal landing zone**
    - Between LSA and LCC: 33.0mm
    - Length: 20.0mm
  - **Distal landing zone**: 30.8mm
  - **LSA**: 10.0 - 11.2mm

- **Planned Treatment with single system**:
  - 36mm MSG (15cm length)
  - 12mm BSG (4cm length)
Pre-Op CT
MSG Deployment
BSG Deployment
Pre and Post Angiograms
Better disease specific devices are needed

- New FDA Innovation Pathway
  - Rapid development and approval process for novel devices in the U.S. is underway

- LSA preservation during TEVAR with the Mona LSA system is feasible