Disclosure

- Terumo Aortic Arch Branch device is an Investigational Device
- No financial disclosures pertinent to this presentation

Arch Branch Endograft Worldwide Experience (Investigational in US)

- Main commercially manufactured (NOT physician-modified) 2-/3-branch arch systems
  - Cook
  - Terumo-Aortic (formerly Bolton Medical)
- Other manufacturers
  - Medtronic ~10
  - W. L. Gore ~30

Cook Arch Branch

- As of July 2018 (internal company data)
  - 343 device implants
    - 1-branch: 7
    - 2-branch: 311
    - 3-branch: 25

- Total Endovascular Treatment of Aortic Arch Disease Using an Arch Endograft With 3 Inner Branches. J Endovasc Ther 2018;24(4):534-538
- Subsequent Results for Arch Aneurysm Repair with Inner Branched Endografts. Eur J Vasc Endovasc Surg 2016;51(3):380-5

Terumo-Aortic Arch Branch

- As of November 2018 (internal company data)
  - 166 device implants
    - 1-branch: 14
    - 2-branch: 150
    - 3-branch: 2


Terumo-Aortic 3-branch Arch Device

Case 1

- 2009: 59 year old intensivist w/ acute, uncomplicated TBAD ➔ medical mgmt
- 2014: Acute, ruptured type A dissection w/ tamponade and cardiac arrest ➔ ascending graft replacement
- Distal arch dilation to 5.7cm with dual-false lumen in the thoracoabdominal aorta

Under FDA Compassionate Use provision, endovascular arch repair using Terumo Aortic 3-branch Arch Branch device in Dec 2014
- 2 antegrade branches (innominate, L CCA)
- 1 retrograde branch (L SCA) for later access for thoracoabdominal branch device

1 month

- Mid-arch “kink” in unsupported segment ➔ CMD cuff
- Progressive enlargement distal thoracoabdominal aorta ➔ 4-branch CMD TAAA device

10 months
Current Status

- Last follow-up in October 2018 (4 year postop)
- Working full-time
- ABI/WBI >1.0 bilaterally
- Serum creatinine 1.1 mg/dl
- Complete false lumen thrombosis
- All arch branches patent
- All visceral branches patent
  - 1 secondary proc: SMA branch re-stenting

Case 2

- 68 year old man w/ acute type A dissection in 2013
  - Ascending aortic replacement, porcine AVR
  - 6.1 cm arch aortic aneurysm from residual type B aortic dissection
  - Plan A: L carotid-subclavian bypass + TEVAR w/ L CCA chimney stent
  - Plan B: 3-branch Arch Branch repair
    - Upper extremity/antegrade access for future thoracoabdominal branch repair

March 2017

POD 1

- 50 mmHg gradient L>R arm, diminished femoral pulses, oliguria
- Inter-stent kink ➔ Balloon expandable covered stent
Current Status

- **15 months**
  - Recurrent fevers and malaise
  - Multi-focal CVA from septic emboli
  - Positive blood cultures
  - TEE: Valvular vegetations
  - DX: endocarditis

- **18 months**
  - Hospice ➔ Death

Conclusions

- Repair of complex arch pathologies feasible using the Terumo Aortic 3-branch Relay Arch Branch platform
- Experience very limited
- Iterative device improvement needed ➔ nose cone design (for AVR)
- Proper patient selection important
- 3rd antegrade branch useful for descending thoracoabdominal access for future endovascular repairs