Update On The Nellix Endograft for EVAS: How Has Refinement of the IFU Improved Outcomes: From the EVAS FORWARD IDE Trial

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Disclosure
- Consultant to Endologix

EndoVascular Aneurysm Sealing (EVAS)

- EVAS is not EVAR – It’s a new therapy
- EVAS manages the aneurysm sac using polymer-filled endobags

Early Enthusiasm — Sealing Revolution

EVAS and Active Sac Management

97% 2Y FREEDOM FROM TYPE II EL
99% 2Y FREEDOM FROM Rupture

EVAS and Freedom from Mortality

94% 2Y FREEDOM FROM ALL-CAUSE MORTALITY
99% 2Y FREEDOM FROM CARDIOVASCULAR MORTALITY

2 Year Findings and Root Causes: IDE and Global Registry

**Migration**
- Thrombus plays primary role
- Small blood volumes
- Asymmetric or inadequate endobag filling
- Mechanism is lateral displacement and bending

**Aneurysm Enlargement**
- Original EVAS concept did not require seal zones, "just fill the aneurysm sac"
- Incomplete sealing into the CIA thrombus
- Permits pressure transmission to AAA sac

**Application of Key Learnings and Path Forward**

**Refined Anatomic IFU**

**Standardized Procedure**

- migrated

**EVAS FORWARD IDE: 3 Year Results**

**Refined IFU – ON and OFF Target**

**EVAS Path Forward**

**Refined Anatomic IFU**

**Standardized Procedure**

- Disciplined Approach
  - Incorporated Lessons Learned
  - Focused Investigator Training
  - Rigorously Trained Case Support
  - Peer-to-Peer Case Review
- EVAS-Experienced Proctors
MW13 Suggest adding to the prior slide - one slide with 3 side-by-side KM curves, or 3 separate slides with one KM curve on each.

Mary Wheeler, 10/24/2018
Conclusions

- Active Sac Management
  - FF Type II endoleak
  - FF All-Cause and CV mortality
- Evolution of New Therapy
  - IFU and Procedure Refinements
  - Gen2 Nellix Device
  - 3y FF adverse events encouraging, on-label, with adequate procedure
- EVAS2 Confirmatory Study