Practicing Outside of IFU – Also an Issue With

New Sac Filling Technologies?

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Disclosure

Speaker name: Matt Thompson, MD

I have the following potential conflicts of interest to report:

☐ Consulting
☒ Employment in industry – Endologix, Inc., Chief Medical Officer
☒ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Introducing a New Therapy
– EVAS is not EVAR

- Therapy NOT product
- Clinical conditions cannot be replicated in vitro
- Realized expectations of therapy
- Failure modes inevitable Understand failure modes and relation to IFU
- Define “sweet spot” of Nellix® – personalized medicine – has led to change in IFU (new IFU 2016)
Evolution in Implant and Procedure

- EVAS conceptually different to EVAR
- Procedure iterated over 3 years
  - Graft placement
  - Manufacture lumens
  - Create effective seal
- Nellix 3.5 launched 2016

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**EVAS FORWARD IDE**

- US FDA Trial
- Enrollment 2014
- 150 patients, 29 sites
  - 26 US, 3 EU
- Core lab adjudicated
- 5 year follow-up

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**EVAS FORWARD GLOBAL REGISTRY**

- Post-market registry
- Enrollment 2013-2014
- 300 patients, 30 sites
  - EU, NZ
- Real world, all comers
- Core lab adjudicated
- 5 year follow-up
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37% of all treated patients had complex anatomy outside of the Nellix IFU

- Neck Length <10mm: 17% (EVAS Global Registry), 2% (ENGAGE Registry), 1.5% (GREAT Registry)
- Neck Angle >60°: 8% (EVAS Global Registry), 6% (ENGAGE Registry), 0% (GREAT Registry)
- Chimney Procedure: 5% (EVAS Global Registry), 0.1% (ENGAGE Registry), 0.5% (GREAT Registry)
- Iliac diameters >25mm: 13% (EVAS Global Registry), 0.6% (ENGAGE Registry), n/r (GREAT Registry)
- EVAR Revision: 2.3% (EVAS Global Registry), 0% (ENGAGE Registry), 0% (GREAT Registry)
- Rupture: 2% (EVAS Global Registry), 0% (ENGAGE Registry), 2% (GREAT Registry)

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Freedom from Type 1a Endoleak

- On-IFU*: 96.9%
- Off-IFU*: 85.6%
- p-value = 0.0008

*Based on previous Nellix IFU

Large proximal necks >28mm
Thrombus-laden necks

Complex Proximal Neck Anatomy
Mid to Late Failure Modes of EVAS

- Physiological stresses on endografts
- Mid to late failure modes of medical devices inevitable
  - Took 20y+ to define mechanisms for EVAR failure
- Mid to late failures EVAS (migration / sac growth)
  - Challenge is to understand late failure modes of EVAS at 2-3y by leveraging clinical data allied to high resolution imaging
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Refinement of the IFU – “Traditional Factors”

1. Proximal Neck Diameter
   - From: 18-32mm
   - To: 18-28mm

2. Neck Diameter Change
   - From: ≤20%
   - To: ≤10%

3. Iliac Artery Luminal Diameter - Unchanged
   - 9-35mm

4. Distal Seal Zone
   - Iliac Artery Inner Wall Diameter: 9-25mm
   - length: ≥10mm

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Refinement of the IFU – “Aneurysm Sac”

Aneurysm Ratio

Max aortic aneurysm dia  
Max aortic blood lumen dia  < 1.4

Aneurysm ratio varies according to proximal seal zone, neck engagement and iliac diameter

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Introducing a Complex Algorithm to IFU – IFU Not Binary

- Format of IFU unchanged for 20y+
- Factors in IFU not regarded as binary
- Clinicians integrate separate factors to estimate outcome
- Complex algorithm more attuned to modern practice
- Computed algorithms used commonly in clinical practice
- Opportunity to set new standard of care

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Max AAA diameter 56mm
Max AAA flow lumen 42mm
Neck length 13mm
Neck diameter 26mm
Neck angle 18%
Max iliac diameter 16mm

- Personalize treatment
- Select graft that provides exceptional outcomes
- Applicable across portfolio
- Timescale

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Freedom from Aortic Events - 2 Year Data – 2016 Binary IFU

Estimated Comparison EVAR
Sac expansion 7.2%
Type 1 endoleak 2%
Migration 2%

Schanzer et al Circulation 2011; 123

96% freedom from migration, Type 1a endoleak or sac enlargement

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Type 2 Endoleak and Biologic Response to Endovascular Repair

Type 2 Endoleak – Global Registry

Persist Incidence

CVM

ACM

99.2%

97.0%

98.5%

89.6%

99% Freedom from Cardiovascular Mortality through 2 Years

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Summary and Conclusions

- Evolution of endovascular surgery for AAA include active management of aneurysm sac
  - Failure modes of EVAS defined by aortic anatomy
  - Refinement of IFU gives excellent results to mid-term
  - Need to consider future of IFU – decision aids
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