Worldwide Update On The Nellix Endograft For EVAS: From The GLOBAL 2 Registry And EVAS IDE 2 Trial: Both Assess New Improvements in the Device and its IFU

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Relevant Disclosures

- Dr Holden is a Clinical Investigator and Medical Advisory Board Member for Endologix
- No other relevant disclosures

PROMISING RESULTS, DESPITE PUSHING IFU (GLOBAL REGISTRY)

FF TYPE II ENDOLEAK, RUPTURE, ARM, ACM

2015 - 2018-2019

2017

M A T R I Y

TIME

2020-2022

GLOBAL REGISTRY: N=300, ALL-COMERS (37% OFF-IFU)

IDE: N=333, CONTROLLED

2013-2014

ROOT CAUSE ANALYSES

Clinical
Imaging
Engineering
Statistical

1Y FREEDOM FROM ENDOLEAK, REINTERVENTION, RUPTURE

2Y EVENTS

TYPE IA ENDOLEAK

MIGRATION

SAC GROWTH

EVAS EVOLVED

ChEVAS IDE

NEXT GEN EVAS

ACM/CVM

IFU/PROCEDURE REFINED

PREDICTABLE OUTCOMES

96% FF MIGRATION, TYPE IA, SAC GROWTH

Important perspectives but includes cases early in the learning curve


Revised Anatomic IFU for Most Predictable Outcomes

96% 2 YEAR FREEDOM FROM TYPE IA ENDOLEAK, MIGRATION, OR SAC GROWTH

Several Publications have not shown a significant impact of the revised 2016 IFU on outcomes

IFU Impact on Longer Term Data

Several Publications have not shown a significant impact of the revised 2016 IFU on outcomes

The modified IFU has significantly reduced morphological applicability


Several Publications have not shown a significant impact of the revised 2016 IFU on outcomes

IFU Impact on Longer Term Data

The impact of procedural and device refinement is difficult to assess

Many of these cases were performed with earlier versions of the device and before ongoing device and procedural refinement

Anatomic applicability reduced from 63% to 18%
Anatomic applicability reduced from 75% to 34%
**EVAS Therapy: Device Evolution**

- Global Endovag attachment
- Strategic angiography holes
- Longer stents
- Greater conformability
- Ability to exchange
- Single-pull reusable design

*Images courtesy of Endologix, Inc., Irvine, CA*

**EVAS Therapy: Procedural Evolution**

- Unfurling of endobag before stent deployment allows optimum endobag conformability
- Angioplasty balloons left up during endobag filling optimizes position
- Endobags pre-fill after stent deployment with dilute contrast saline allows optimum positioning and calculation of endobag fill volume

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**IFU Impact on Longer Term Data**

**IFU Refinement and Type IA Endoleak**

- Single Centre audit of 115 consecutive cases
- Auckland Hospital
- Minimum follow up 2 years
- Mean follow up 3.5 years

Significantly lower TI AEL incidence with IFU compliance, \( p = 0.036 \)

**IFU Refinement and Composite Endpoint**

Freedom from TI AEL, sac expansion > 5mm, reintervention

Significantly lower composite endpoint incidence with IFU compliance, \( p = 0.018 \)

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**EVAS2 Confirmatory Studies**

- 300 patients, 5y follow-up
- Confirmatory study
  - IFU Refinement
  - Late Migration
- Enrollment Status
  - 45 patients, 10 centers (EU, NZ)
  - Mean follow up 257 days (range 21, 600)
  - No rupture, death, conversion or MAE

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**EVAS FORWARD 2 Global Registry**

- 300 patients, 5y follow-up
- Confirmatory study
  - IFU Refinement
  - Late Migration
- Enrollment Status
  - 45 patients, 10 centers (EU, NZ)
  - Mean follow up 257 days (range 21, 600)
  - No rupture, death, conversion or MAE

*EVAS FORWARD2 Global Registry 16 July 2018*
**NZ Experience: Results on Revised IFU, Procedural Best Practices**

- Review of consecutive cases with at least 1 year follow up
- All cases anatomically within 2016 revised IFU
- All cases using Nellix 3.5 device with endobag attached proximally and distally
- All cases performed with unfurling, endobag pre-fill, angioplasty balloons up, secondary fill if necessary

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**NZ Experience: Results on Revised IFU, Procedural Adequacy**

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*SAC Growth: CIA proximal diameter >20mm and >10mm length, but distal CIA 20-25mm and continued to dilate both treated with embolisation and limb extensions into EIA.

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**NZ Experience: Results on Revised IFU, Procedural Best Practices**

- 20 Patients
- 2014: 55.2mm
- 2017: 52.8mm
NZ Experience: Results on Revised IFU, Procedural Best Practices

Active Sac Management

99% Freedom from Cardiovascular Mortality through 2 Years

98.5%
97.4%
89.1%

Continued EVAS Therapy Evolution

Conclusions

• Endovascular sealing with Nellix has faced challenges with durability, particularly around device migration, aneurysm sac growth and type 1 endoleak
• The combination of revised IFU, procedural and device evolution does appear to have favourably impacted on outcomes although the extent is still unclear
• The favorable ACM and CVM data seen in the EVAS trials is driving ongoing interest in active sac management
• Next generation EVAS is an important development in the journey of minimally invasive aneurysm intervention

Nellix and EVAS2 is not approved in any geography for sale or investigation. Safety and effectiveness of all next gen products have not been assessed or approved.


NELLIX 3.5
CHEVAS IDE
NEXT GEN EVAS
NEXT GEN EVAS PIVOTAL
2018
2019
2020-2022
2018

APPROVAL TARGET
FIH

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