Limitations Of Nellix EVAS And What Precautions Must Be Taken When Using It

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Vascular Medicine
Predictors of Abdominal Aortic Anomalous Sac Enlargement After Endovascular Repair

Endovascular sac sealing concept: will the Endologix Nellix™ device solve the deficiencies?
A. Holden

Nellix Global Registry
37% Off IFU

50% reduction in endoleaks and reinterventions compared to EVAR

<table>
<thead>
<tr>
<th>Device</th>
<th>30 Days</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zenith IDE</td>
<td>3.0%</td>
<td>6.1%</td>
<td>11.0%</td>
</tr>
<tr>
<td>Excluder IDE</td>
<td>7.0%</td>
<td>9.2%</td>
<td>11.5%</td>
</tr>
<tr>
<td>Endurant IDE</td>
<td>4.3%</td>
<td>9.8%</td>
<td>6.7%</td>
</tr>
</tbody>
</table>

1-Year results for commercially available devices shown per the respective US FDA Summary of Safety and Effectiveness Data (SSED) and peer-reviewed publications of trial results. Mortality rates for days 31-365.

Short Neck – Type 1a Endoleak
Small Flow Lumen and Large Thrombus Burden

Wide Neck
Small Flow Lumen / Large Thrombus Burden

Baseline
Migration at 2 Years

Aneurysm Growth with Partial CIA Exclusion

Post-Op
Partial CIA Exclusion

2 Years
Sac Change
52.6 mm to 59.6 mm
Complete seal
No endoleak
Coil embolization and covered stent ext.

IFU Refinements - Validation for Path Forward

2 Yr Freedom from Core Lab-Reported Migration >5mm, Type 1a Endoleak, or Sac Enlargement >5mm

On IFU
96.1%
Off IFU
81.1%

Patent Lumbars / IMA

Patent Lumbars / IMA
EVAS for EVAS Repair
Caudal Migration at 2 years
Nellix-in-Nellix Extension with Renal Stents

Potential Biological Benefits of EVAS

No type II Endoleak, potentially ablative to ILT
Shuts down pro-inflammatory activity of ILT
No concentrated force at proximal and distal seal zones
Minimizes local pro-inflammatory response
No sideways movement
Prevents introduction of new mechanical forces

Conclusions
• EVAS designed to solve EVAR deficiencies
• Updated indications will optimize outcomes
  • Proximal necks ≤ 28mm diameter
  • Aortic diameter/lumen ration of ≥ 1.4
• Best clinical outcomes, on-IFU
  • 50% lower endoleaks and reinterventions compared to EVAR
  • 96% freedom from T1A endoleaks, migration and sac enlargement at 2 years
• EVAS remains an important tool for aortic specialists