Endologix Nellix: Can Nellix Repair All Para-renal Aneurysms?

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Disclosures

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For the 12 months preceding this CME activity, I disclose the following types of financial relationships:

Honoraria received from: Nil

Consulted for:
  Abbott Vascular Laboratories
  Endologix Inc
  Cook Medical Systems
  480 Biomedical

Held common stock in: Nil
Nellix Endovascular System

A radically different endovascular system for AAA repair
Nellix Endovascular System

- Introduce both catheters over .035” wires
- Balloon expand both stents (Chromium Cobalt)
- Fill with Polymer using pressure monitoring

• Designed to fill and seal the entire aneurysm sac and target the direct causes of secondary interventions
• Endobags filled with biostable polymer seal anatomy from renals to hypogastrics
Nellix Endovascular System Delivery System

- Ergonomic Handles
- .035” Guidewire Lumen
- 17 Fr OD Catheter
- Console Quick Connects with Access Ports
- Angio-Tip (Hand or Power Contrast Injections)
Nellix Endovascular System Operator Console
Nellix Endovascular System
In-line Pressure Monitor

- Sterile pressure transducer
- In-line design
- Integrated display
- Real time monitoring
Step 1: Introduce Devices

0915 hours
Step 2: Withdraw Sheaths
Step 3: Confirm Device Position
Step 4: Deploy Stents
Step 5: Fill Endobags with Polymer
Step 5: Polymer Fill

- In-line pressure monitor
- Aim for endobag pressure 180mmHg
Step 6: Device Removal
Nellix Endovascular System

Pre-contrast

Post-contrast

Thrombus, endobags (arrows) and stents easily seen
Can Nellix Repair All Para-renal Aneurysms?
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No!
Unique Nellix Features

Motivation for Endovascular Aneurysm Sealing

• Address Challenging Proximal Neck Anatomies
  • Shorter lengths (<10mm)
  • Irregular (reverse conical)
• Treat Iliac Aneurysm Disease
  • Avoid IIA occlusion or IBDs
Short Infra-renal Neck

5mm long neck
Because the endobags are sealing the aneurysm, short and adverse neck anatomies can be treated.
Note the superb apposition of endobags to the dangerous posterior bulge in the infra-renal neck.
Reverse Conical Neck
Unique Nellix Features

Motivation for Endovascular Aneurysm Sealing

- Address Challenging Proximal Neck Anatomies
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- Treat Iliac Aneurysm Disease
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Common Iliac Artery Aneurysms may be treated with an iliac extender, avoiding hypogastric artery embolization or IBD.
Nellix Endovascular System

- Endovascular Aneurysm Sealing Technology should minimize the risk of all forms of endoleak (including type 2) and graft migration
- This could have a major impact on:
  - Secondary intervention rate
  - Frequency of surveillance
  - Procedural cost
Prevention of Type 2 Endoleaks
### NELLIX GLOBAL CLINICAL EXPERIENCE – RESULTS

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>30 Days (N = 47)</th>
<th>6 Month (n = 46)</th>
<th>1 YR (n = 32)</th>
<th>2 YRS (n = 23)</th>
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</thead>
<tbody>
<tr>
<td>Rate of Secondary Procedures</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4.3% (1)</td>
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<tr>
<td>(Endoleaks)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Aneurysm Rupture</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>Device Migration</td>
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<td>0</td>
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<tr>
<td>Sac Expansion</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Endoleak – Type 1A</td>
<td>2.1% (1)</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Endoleak – Type 1B</td>
<td>2.1% (1)</td>
<td>2.2% (1)</td>
<td>3.1% (1)</td>
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</tr>
<tr>
<td>Endoleak – Type II</td>
<td>2.1% (1)</td>
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<tr>
<td>Endoleak – Type III/IV</td>
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<td>Stent Occlusion</td>
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<td>Fracture or Fatigue</td>
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</tbody>
</table>

- **Type 1A Endoleak resolved spontaneously within 60 days**
- **Type 1B Endoleak was due to improper device sizing (too short). A limb extension was added at 15 months which resolved the endoleak**
- **Type II Endoleak due to undersized endobag - resolved spontaneously within 60 days**
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The Future?
Chimneys and Snorkels

- The endobag concept works could easily accommodate chimneys and snorkels
- Nellix concept could extend to the thoracic aorta
Branch Nellix Device

- Modified endobags with large fenestrations for branch arteries
- Stents extend from the aortic lumen to the branch lumen to maintain patency
The Future is Here!!