Two-year outcomes from the European OVATION postmarked registry

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Disclosure

Speaker name: Patrick Peeters, MD

I have the following potential conflicts of interest to report:

- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)

☑️ I do not have any potential conflict of interest
Features of a good endoprothesis

- Treating the infrarenal aneurysm even juxtarenal AAA
- Freedom from type I or III endoleaks
- Freedom from aneurysm expansion
- Freedom from aneurysm rupture
- Need for adequate sealing, fixation
- Need for flexible device for tortuous lesions
- Need for small French size, percutaneous use

Which device complies to this demands?
12F ID/ 14F OD, an ultra-low profile system enables smooth access to the aneurysm.

Staged deployment of suprarenal stent allows simple, precise placement.

Polymer-filled sealing ring creates a custom seal and protects the aortic neck.

Low permeability PTFE enables effective aneurysm exclusion and device patency.

Conformable, kink resistant iliac limbs designed to reduce risk of occlusion.

*The Ovation iX™ features an integrated sheath 12F ID / 14F OD*
O-ring creates a circumferential seal at the midpoint of the sealing ring. This continuous position provides a water-tight seal.
## Instructions for Use (IFU)

### Key Device Indications - OVATION

<table>
<thead>
<tr>
<th>Specification</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal Neck Length</td>
<td>≥ 7mm</td>
</tr>
<tr>
<td>Proximal Neck Angle (Degrees)</td>
<td>&lt;60 if neck length ≥ 10 mm</td>
</tr>
<tr>
<td></td>
<td>≤ 45 if neck length &lt; 10 mm</td>
</tr>
<tr>
<td>Neck Diameter</td>
<td>16-30mm</td>
</tr>
<tr>
<td></td>
<td>Inner Wall</td>
</tr>
<tr>
<td>Iliac Diameter</td>
<td>8-20mm</td>
</tr>
<tr>
<td>Profile OD (main body)</td>
<td>14F-15F</td>
</tr>
<tr>
<td>Sheath Required</td>
<td>No</td>
</tr>
</tbody>
</table>
Ovation Post Market European Registry

- Multicenter, prospective, post-market study
- 501 patients enrolled @ 30 sites across Europe
- Enrolled May 2011 – December 2013
- Safety and Performance Endpoints assessed by Investigator at 1-month, 6-month, and annually to 5 years
- Study Completion: 2019
- Primary Endpoints
  - Technical success
  - Freedom from Type I and III endoleaks, aneurysm rupture, expansion, conversion, occlusion, and migration
- CEC adjudication of device related adverse events
# European Post-Market Registries: Results

<table>
<thead>
<tr>
<th>Safety / Performance Data</th>
<th>1Year Results</th>
<th>2Year Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients Enrolled</td>
<td>501</td>
<td></td>
</tr>
<tr>
<td>Rupture</td>
<td>0.2% (1/501)</td>
<td>0%</td>
</tr>
<tr>
<td>Conversion to Open Repair</td>
<td>0.2% (1/501)</td>
<td>0,4%</td>
</tr>
<tr>
<td>AAA-Related Reintervention</td>
<td>7.0% (35/501)</td>
<td></td>
</tr>
<tr>
<td>Type I Endoleaks</td>
<td>1.9% (7/370)</td>
<td>0,6% (2/337)</td>
</tr>
<tr>
<td>Type III Endoleaks</td>
<td>0.3% (1/370)</td>
<td>0,0% (0/337)</td>
</tr>
<tr>
<td>Migration</td>
<td>0.7% (2/270)</td>
<td>0,4% (1/236)</td>
</tr>
<tr>
<td>AAA Diameter Stable / Decreasing</td>
<td>100.0% (236/236)</td>
<td>93,1% (190/204)</td>
</tr>
</tbody>
</table>

Results as of July 13, 2015 based on investigator reported data. Data collected based on appropriate / available imaging modality. 1-Ns represent the number of completed follow-up visits for 1m, 1yr, and 2yr.
Pre op Aortic Views
Conclusion

• OVATION Post Market Registry has reported encouraging clinical results in a real-world experience

• Safety and Performance outcomes at 2 years are promising, even for more challenging patient anatomies given a broader Indication for Use.
Conclusion

• Over 8,500 patients worldwide have been treated with Ovation Abdominal Stent Graft platform, with over 1,000 subjects in a tightly controlled study or registry.

• Patient demographics, anatomical characteristics, and procedural characteristics indicate a challenging patient cohort.

• These data provide compelling evidence that the Ovation system can expand EVAR access to more patients and improve EVAR outcomes for all patients.