Finally, an ultra-low profile endograft that is not a tradeoff: Deliverability, patency, and durability of the Ovation® platform

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Disclosure

Speaker name:

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
What Determines IFU?

- Preclinical data
  - Biocompatibility
  - Sterility
  - Durability
    - Device fatigue data
    - Metal and Fabric
    - Delivery System
    - 10 million cycles
  - Animal implant data
    - Biocompatibility
    - Thrombogenicity

- Define boundary conditions
  - Inclusion criteria
  - Exclusion criteria

- FDA Safe and Effective
  - At primary endpoint
    - 1 year
  - Followed for 5 years
What Outcome Matters Most?

• IFU
• Result
  – Intra operative
  – 30 Day
  – 1 year
  – 5 year
  – 10 year
• Late Failure Modes
  – Rupture
  – Migration
  – Fracture
  – Endoleak
Treatment Limitations: Challenging Anatomy

30–60% of patients may be excluded from EVAR treatment due to challenging proximal aortic necks\(^1,2\)

Most common reasons for exclusion from EVAR\(^3\)

1. Short infrarenal neck length
2. Proximal neck angulation
3. Shape - Reverse Taper

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Aortic Neck Morphology

- Length
- Angulation
- Shape
- Thrombus
- Calcification
14F ultra low profile enables access to more patients

Staged deployment of suprarenal stent allows precise placement

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

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

Low permeability PTFE enables effective aneurysm exclusion and device patency
Ovation Custom Seals to Each Patient Anatomy

Reverse Taper Neck

Pre-Op

4 Year Follow-Up

Liquid polymer injected to inflate O-ring

Liquid polymer cures to a solid, durable state

No Type 1 Endoleak Stable Neck Diameter
Ovation Well Suited for Challenging Distal Anatomy

Lowest profile of any FDA approved EVAR device

12F ID
ENDOLOGIX
OVATION IX™

Lombard Aorfix™: 22F OD
Addresses 27% of AAA population*

Cook Zenith Flex®: 21F OD
Addresses 36% of AAA population*

Gore Excluder®: 20F OD
Addresses 40% of AAA population*

Endologix AFX™: 19F OD
Addresses 49% of AAA population*

Medtronic Endurant®: 18F OD
Addresses 59% of AAA population*

Endologix Ovation iX™: 14F OD
Addresses 83% of AAA population*

Highly flexible limbs and delivery system

PTFE iliac limbs with helical architecture for exceptional flexibility and minimal luminal encroachment
TriVascular Ovation™ Pivotal
Selected Inclusion Criteria

- AAA ≥ 5.0 cm in diameter or
- AAA ≤ 5.0 cm in diameter:
  - If increased ≥ 5 mm in 6 months
  - If it is 1.5 times normal aortic diameter
- Proximal neck:
  - ≥ 7 mm in length
  - 16 to 30 mm in diameter (ID)
  - ≤ 45° angle (neck < 10 mm)
  - ≤ 60° angle (neck ≥ 10 mm)
- Distal iliac landing zone of:
  - ≥ 10 mm in length
  - 8 to 20 mm diameter (ID)
- Overall length from renal to internal iliac ≥ 130 mm
- 14F OD profile
Anatomical Characteristics

• Over 50% of patients treated had minimum access vessel <7mm in diameter
• Smallest vessel diameter treated = 3.2mm

Minimum Access Vessel Diameter (n=159)*

Aortic Neck Length (n=161)*

• Nearly 1/3 of patients treated had a neck length of <15 mm

*Based on core lab reported measurements
Current IFU Neck Indications

TriVascular Ovation

• Sealing ring @ 13 mm
• Diameter 16-30 mm
• $\leq 60^\circ$ if $\geq 10$ mm neck length
• $\leq 45^\circ$ if $< 10$ mm neck length
# 1 Year Effectiveness

<table>
<thead>
<tr>
<th>EFFECTIVENESS</th>
<th>30 Day</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success*</td>
<td>100%</td>
<td>N/A</td>
</tr>
<tr>
<td>Freedom from Type I and III Endoleaks¹</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Freedom from Migration</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Freedom from Rupture*</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Freedom from Conversion to Open Repair*</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ANEURYSM ASSESSMENT</th>
<th>30 Day</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enlargement &gt;5mm</td>
<td>Baseline</td>
<td>0.7%</td>
</tr>
<tr>
<td>No change</td>
<td>Baseline</td>
<td>67.3%</td>
</tr>
<tr>
<td>Reduction &gt;5mm</td>
<td>Baseline</td>
<td>32.0%</td>
</tr>
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</table>
**O-Ring Seals Without Exerting Chronic Outward Radial Force**

**Self Expanding Stent Graft**

*Seal created by chronic outward force with discontinuous points of wall apposition across a minimum 10-15 mm length*

Chronic outward radial force from stent may result in aortic neck dilatation to the nominal diameter of the stent

**Ovation Prime Stent Graft**

*Water-tight seal created by O-ring provides uniform continuous wall apposition*

Non-expansive circumferential apposition from sealing ring creates no chronic outward radial force and no aortic neck dilatation*

*Neck dilatation in proximal neck defined as growth > 3mm at 10mm below renals, 13mm below renals, and 15 mm below renals*
O-Ring Insulates Aortic Neck

**Untreated Aneurysm**
Blood pressure results in a bulge in aortic wall where tissue is weak.

**Self Expanding Stent Graft**
Oversized wire and fabric graft allows transmission of blood pressure, and exerts pressure of its own.

**Ovation Prime Stent Graft**
Polymer-filled O-ring insulates aortic neck from blood pressure.

- **Blood Pressure** → **Aneurysm**
  - Blood Pressure + Stent Outward Radial Force → Contributes to Neck Dilatation
  - Blood Pressure + NO Stent Outward Radial Force → No Neck Dilatation
No Aortic Neck Dilatation through 5 Years


Core Lab evaluation, Ovation Global Pivotal Trial. N=94. Data as of Aug 2, 2016  Neck dilation = growth > 
3mm at 10mm, 13mm, and 15mm below renals
## Safety and Effectiveness

**Lowest Reported MAE Rate Across IDE Trials for FDA-Approved AAA Devices**

<table>
<thead>
<tr>
<th></th>
<th>Ovation IDE</th>
<th>Endurant IDE</th>
<th>Zenith IDE</th>
<th>Excluder IDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients Enrolled</td>
<td>161</td>
<td>150</td>
<td>200 / 100 Std Risk / High Risk</td>
<td>565</td>
</tr>
<tr>
<td>ASA Class III/IV</td>
<td>60% / 7%</td>
<td>49% / 0%</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>30d / 1 Yr Major Adverse Events</td>
<td>2.5% / 3.8%</td>
<td>4.0% / 6.5%</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>5-Yr Freedom from AAA-Related Mortality</td>
<td>99%</td>
<td>99%</td>
<td>99% / 94%</td>
<td>98%</td>
</tr>
<tr>
<td>5-Yr Freedom from All-Cause Mortality</td>
<td>75%</td>
<td>83%</td>
<td>83% / 58%</td>
<td>70%</td>
</tr>
<tr>
<td>5-Yr Freedom from Rupture</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
</tr>
<tr>
<td>5-Yr Freedom from Conversion</td>
<td>100%</td>
<td>100%</td>
<td>98%</td>
<td>97%</td>
</tr>
<tr>
<td>5-Yr Freedom from Migration &gt;10mm</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>99%</td>
</tr>
</tbody>
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Results for EVAR commercially available devices shown per the respective US FDA Summary of Safety and Effectiveness Data (SSED) and Annual Clinical Reports.
5 Year Freedom from Mortality

98% Freedom from ARM
75% Freedom from ACM
5 Year Freedom from Reintervention

97% for type I endoleak
97% for occlusion
90% for type II endoleak
Conclusions

• Ovation provides durable repair of AAAs
• High degree of freedom from
  • Migration
  • Endoleak
  • Aneurysm related mortality
  • Open Conversion
  • Fracture
  • Limb occlusions
• Other low profile devices have failed to do this
Finally, an ultra-low profile endograft that is not a tradeoff: Deliverability, patency, and durability of the Ovation® platform

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