Ovation® Platform: THE WORKHORSE SYSTEM

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Disclosure

Speaker name: Gerard Mertikian, MD

I have the following potential conflicts of interest to report:

- Consulting – TriVascular Medical Educator
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
Limitations of Conventional EVAR\(^1\) = Unmet Clinical Needs

- Nearly 35% of men and 60% of women remain *ineligible* for EVAR
- Limitations based on *narrow* access vessels
- Inadequate neck length was a main driver of ineligibility
- Treatment options limited to surgical repair, fenestrated / branched endografts, off-label EVAR, or watchful waiting

Ovation Abdominal Stent Graft
Tri-modular Design

Suprarenal nitinol stent with Anchors for fixation

Inflatable rings for optimal seal

15F OD Aortic Body
Filled with a low-viscosity, Radiopaque, fill polymer

12-15F OD conformable Iliac limbs

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TriVascular Ovation Primary Seal

Ovation neck length indication > 7mm

Conventional sealing in collar

Water tight seal in ring
Ovation sealing concept

Conventional stentgrafts use wire and fabric to create *discontinuous* points of apposition.

Ovation’s sealing ring provides *continuous* apposition, even in irregular and/or tapered anatomy.

Note: FEA simulations indicate high stress points in pink and red coloring.
Self-Expanding Stent Grafts
Performance in Reverse-Taper Neck

Illustration of Potential Proximal Neck Expansion Over Time

Proximal stent oversized at renals

Neck dilatation

Neck dilatation may result in Type I endoleak and/or migration

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Ovation Platform Protects the Aortic Neck

Ovation Global Pivotal study demonstrates encouraging results with **stable neck diameter** and **durable seal** through 4 years due to the unique sealing ring technology which creates no chronic outward force and insulates the neck from blood pressure.

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Aortic Neck Dilatation Over Time*

*Based on all known peer-reviewed published clinical data with clearly outlined methodology to measure neck dilation in patients with self-expanding AAA stent grafts; measurement methodology in cited studies is comparable to measurement methodology in Ovation Pivotal Trial.²

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4. Neck dilation in proximal neck defined as growth > 3mm at 10mm below renals, 13mm below renals, and 15mm below renals

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Ovation iX™ Abdominal Stent Graft System

Less Invasive

- Ovation iX stands for integrated exchange
- Delivery systems now equipped with an integral, leave behind sheath
  - Minimize vessel trauma
  - Reduce procedural steps and ancillary devices

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Ovation iX Aortic Body

Confidence. Delivered.
• Integrated cross-over lumen facilitates reliable contralateral gate access
• Optional alternative to retrograde cannulation ensures procedural predictability even in challenging anatomies

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Use of Aortic Body Crossover Lumen

• Advance .018” guidewire thru crossover lumen observing under fluoroscopy as it exits the contralateral leg of the iX aortic body
  • Use an introducer tool with the 0.18” wire

Note the wire will exit the lumen between the 2\textsuperscript{nd} and 3\textsuperscript{rd} ring on the contralateral leg of the aortic body
Ovation iX Iliac Stent Graft

Expanded Options

- Broader size matrix enables treatment of a wider range of AAA anatomies
  - Flared limbs up to 28mm diameter
  - Limb lengths up to 160mm
- Profile reduced by 1 Fr for all sizes to improve access

Patency by Design

- Designed to be kink resistant even in the most tortuous iliac anatomy
- 1.2% limb occlusion rate at one year

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Ovation iX Abdominal Stent Graft System

### Aortic Body Sizing

<table>
<thead>
<tr>
<th>Stent Graft Diameter (MM)</th>
<th>Aortic ID (MM)</th>
<th>Max Aortic Vessel Diameter at Anchors (MM)</th>
<th>Inner Diameter</th>
<th>Outer Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>16 – 17</td>
<td>24</td>
<td>12 F</td>
<td>14 F</td>
</tr>
<tr>
<td>23</td>
<td>18 – 20</td>
<td>26</td>
<td>12 F</td>
<td>14 F</td>
</tr>
<tr>
<td>26</td>
<td>21 – 23</td>
<td>29</td>
<td>12 F</td>
<td>14 F</td>
</tr>
<tr>
<td>29</td>
<td>24 – 26</td>
<td>32</td>
<td>12 F</td>
<td>14 F</td>
</tr>
<tr>
<td>34</td>
<td>27 – 30</td>
<td>35</td>
<td>13 F</td>
<td>15 F</td>
</tr>
</tbody>
</table>

### Iliac Stent Graft Sizing

<table>
<thead>
<tr>
<th>Labeled Diameter (MM)</th>
<th>Labeled Lengths (MM)</th>
<th>Native Iliac Vessel ID Range (MM)</th>
<th>Inner Diameter</th>
<th>Outer Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>80 100 120 140 160</td>
<td>8-9</td>
<td>10 F</td>
<td>12 F</td>
</tr>
<tr>
<td>12</td>
<td>80 100 120 140 160</td>
<td>10-11</td>
<td>10 F</td>
<td>12 F</td>
</tr>
<tr>
<td>14</td>
<td>80 100 120 140 160</td>
<td>12-13</td>
<td>10 F</td>
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<td>16</td>
<td>80 100 120 140 160</td>
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<td>11 F</td>
<td>13 F</td>
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<tr>
<td>18</td>
<td>80 100 120 140 160</td>
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<tr>
<td>22</td>
<td>80 100 120 140 160</td>
<td>18-20</td>
<td>12 F</td>
<td>14 F</td>
</tr>
<tr>
<td>28</td>
<td>80 100 120 140 160</td>
<td>21-25</td>
<td>13 F</td>
<td>15 F</td>
</tr>
</tbody>
</table>
OVATION® Post-Market 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
Anatomical Characteristics

- 41% of patients treated had minimum access vessel less than 7mm in diameter
  - Smallest vessel diameter treated was 2.9mm

- 21% of treated aortic necks were shorter than 15mm
  - 42% had moderate/severe calcification (N=440)
  - 49% had moderate/severe thrombus (N=434)

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Investigator reported measurements.
# OVATION Post-Market Registry 2-Year Results

## Technical Success

<table>
<thead>
<tr>
<th></th>
<th>All N=501</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful, delivery and deployment of one aortic body and two iliac limbs</td>
<td>99.8%</td>
</tr>
</tbody>
</table>

## Safety

<table>
<thead>
<tr>
<th></th>
<th>0 to 30 Days N=501</th>
<th>31 to 365 Days N=499</th>
<th>366 to 730 Days N=469</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rupture</td>
<td>0.2%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Conversion to Open Repair</td>
<td>0%</td>
<td>0.2%</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

## Performance

<table>
<thead>
<tr>
<th></th>
<th>30 Day</th>
<th>1 Year</th>
<th>2 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I Endoleaks</td>
<td>0.9% (4/432)</td>
<td>1.6% (6/377)</td>
<td>0.6% (2/337)</td>
</tr>
<tr>
<td>Type III Endoleaks</td>
<td>0.5% (2/432)</td>
<td>0.3% (1/377)</td>
<td>0.0% (0/337)</td>
</tr>
<tr>
<td>Migration</td>
<td>Baseline</td>
<td>0.7% (2/273)</td>
<td>0.4% (1/236)</td>
</tr>
<tr>
<td>AAA Diameter Stable / Decreasing</td>
<td>Baseline</td>
<td>99.6% (237/238)</td>
<td>93.1% (190/204)</td>
</tr>
</tbody>
</table>

Results as of January 8, 2016 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.

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OVATION Post Market Registry Summary

• 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.
Data
Hietzing Hospital

• 39 patients (35 male / 4 female)
• ø 71.3 yrs. (58.4-87)
• 6 Ovation / 31 Ovation Prime / 2 Ovation iX
• 37 AAA / 1 PAU / 1 CIA-Aneurysm
Data
Hietzing Hospital

• Aneurysm diam. Ø 58,4 mm (35-79)
• 28/39 > 90° Thrombus
• 31/39 Ca^{+2}
• Neck diam. at 13mm Ø 23,3 mm (17-30)
Data
Hietzing Hospital

- Hypertension 74.36% (29/39)
- Hyperlipidemia 76.9% (30/39)
- CHD 56.4% (22/39)
- Nicotine 56.4% (22/39)
- PAD 35.9% (14/39)
- Diabetes mellitus 20.5% (8/39)
- COPD 28.2% (11/39)
- CAD 30.8% (12/39)
- CRF 23% (9/39)
Data
Hietzing Hospital

- 75/78 PEVAR (Prostar XL/Proglide)
- 28/39 G.A./epidural (71.8%)
- 11/39 L.A. (28.2%)
- 39/39 technical success (100%)
- EL 14/39 (35.9%)
- 11/39 EL IIa/b (78.6%/28.2%)
- 4/11 EL II-Resolution (36.4%)
- 2/19 EL Ia (14.3%/5%)
- 1/39 EL III (7.1%/2.6%)
- 30/36 aneurysm sack stable or shrinking (83.3%)
- 2/36 sack enlargement
- 3/39 lost to follow up
- 5/39 deceased (unrelated causes)

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Adverse Events

• 5/75 surgical repair of puncture site
• 1/39 toe gangrene
• 1/39 blue toe syndrome (resolved)
• 1/39 kidney infarction (GFR>60)
• 2/39 limb occlusion (1 lysis + stent/ 1 surg. Thrombectomy + stent)
• 1/39 occlusion of comm. fem. at access site
• 1/39 sealing ring broke upon premature inflation
Secondary interventions

- Stent sup. mesenteric artery (weight loss)
- Renal stent
- Broken sealing ring – Palmaz Stent
- EL Ia – embolization (Coils and Onyx)
- EL Ia – Palmaz Stent
- EL IIb – embolization (Glue and Onyx)
- EL III – overstenting
Hostile necks
Hostile necks
Type Ia
Failed BES
Type I a
7/12 Follow-up CT
Type III EL
Type III EL

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Type III EL

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Conclusion

Ovation Platform:

• renders EVAR possible in difficult anatomy (tortuous, small calibre access vessels)

• expands the indications for EVAR in hostile necks, while staying within IFU

• is ideally suited for PEVAR

• enables EVAR in L.A.

• low profile platform, without compromising material thickness

• shows good clinical results

• and is a reliable workorse!
Thank you for your attention!
INDICATIONS FOR USE: The TriVascular Ovation platform (including Ovation, Ovation Prime and/or Ovation iX Abdominal Stent Graft Systems) is indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair, including:

- adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories;
- proximal aortic landing zone: with an inner wall diameter of no less than 16 mm and no greater than 30 mm at 13 mm below the inferior renal artery, and with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm; distal iliac landing zone: with a length of at least 10 mm, and with an inner wall diameter of no less than 8 mm and no greater than 25 mm (no greater than 20 mm for Ovation/Ovation Prime).

CONTRAINDICATIONS: The systems are contraindicated for use in patients who have a condition that threatens to infect the graft and in patients with known sensitivities or allergies to the device materials (including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, fluorinated ethylene propylene [FEP] or nitinol). Also consider the information in Section 4 Warnings and Precautions of the systems’ Instructions for Use.

Refer to Instructions for Use at TriVascular.com for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

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NOTE: Not all product components are available in every country. Please consult with your TriVascular representative to confirm product availability.

CE marked. Please refer to current product Instructions for Use.
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