ENCORE, a Study to Investigate the Durability of Polymer EVAR with Ovation®
A Contemporary Review of 1296 Patients

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Late Failures with EVAR

Late Rupture or Reintervention
5.4% EVAR, 1.4% Open

Early Survival Benefit Lost in Long-Term AAA-Related Death: 5% EVAR, 1% Open

Patel et al. Lancet 2016; 388:2366-2374

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
EVAR Failure Modes

- Loss of proximal seal is the #1 failure mode of EVAR\(^1\)
- EVAR has a 5X increase in AAA-related mortality compared to open repair\(^2\)
- 50% of EVAR patients still alive at 8 years\(^2\)
- Questions remain of sutured graft + materials durability

---

EVAR Durability Data are Limited

- Most studies are underpowered
- No standardized outcomes reporting
- Inconsistent follow-up regimens
- No consensus on how to report superiority
- Quality long-term data lacking

Safety of Device Registries for EVAR: Systematic Review and Meta-regression

147 published studies and 27,058 patients

525 patients required in a registry to show non-inferiority

Only 2 of 147 studies met this requirement

Kent F et al. Safety of Device Registries for EVAR. Eur J Vasc Endovasc Surg 2018; 55:177-183

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Introducing Polymer EVAR

Polymer EVAR
• Low Profile (14F OD)
• Broad IFU Applicability
• Device Deliverability
• Polymer Proximal Sealing

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Ovation Patient Applicability

WITHIN ANATOMIC IFU, ACCESS VESSEL PARAMETERS

M2S Analysis of ~44,000 patients. Applicability based on IFU and access vessel parameters. Ovation iX neck length applicability measured at 13mm. Data on file (MM1660)

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Aortic Neck Dilatation

Traditional EVAR
Neck Dilatation and Events

Kouvelos et al. J Endovasc Ther 2016

Polymer EVAR
No Neck Dilatation

Growth = > 3 mm at 10 mm, 13 mm, and 15 mm IR

The Ovation® Abdominal Stent Graft Platform has not been studied in a head-to-head clinical study against other EVAR devices.

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the "Instructions for Use" for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Do the Clinical Data Establish Durability of Polymer EVAR with Ovation?
The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Study Design and Methodologies

• Pooled, retrospective analysis of 6 prospectively enrolled studies*
• 1,296 patients
  • Treatment from 2009 – 2017
• Global cohort (US, Europe, South America)
• 160 Centers and 339 Investigators
• Standardized variable definitions across each study
• Standardized follow-up intervals across studies for K-M calculations
• Median follow-up across all studies = 1034 days (Range 30d – 5y)

*Retrospective analysis on available variable data includes data cuts available as of April 12, 2018.
Data cuts: Ovation Pivotal Trial Aug 2, 2016 / EU PMR April 12, 2018 / LIFE Registry April 12, 2018 / LUCY Study April 12, 2018
## Patient Demographics

<table>
<thead>
<tr>
<th>DEMOGRAPHICS</th>
<th>RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Y)</td>
<td>73 ± 8</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>Female</td>
</tr>
<tr>
<td>ASA Class*</td>
<td>1/2</td>
</tr>
<tr>
<td></td>
<td>3/4/5</td>
</tr>
</tbody>
</table>

*ASA Class Responses: N=947

<table>
<thead>
<tr>
<th>MEDICAL HISTORY</th>
<th>% Positive</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPD</td>
<td>33%</td>
<td>1034</td>
</tr>
<tr>
<td>Diabetes</td>
<td>22%</td>
<td>1204</td>
</tr>
<tr>
<td>MI</td>
<td>21%</td>
<td>1199</td>
</tr>
<tr>
<td>Family History AAA</td>
<td>12%</td>
<td>842</td>
</tr>
<tr>
<td>CVA (Stroke)</td>
<td>9.3%</td>
<td>975</td>
</tr>
<tr>
<td>CHF</td>
<td>6.0%</td>
<td>1199</td>
</tr>
<tr>
<td>Thoracic Aneurysm</td>
<td>1.5%</td>
<td>980</td>
</tr>
</tbody>
</table>
ENCORE includes results from real-world post market studies. 4% of patients had vascular characteristics beyond FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established.

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>MEAN ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck Length (mm)</td>
<td>24.1 ± 12.2</td>
</tr>
<tr>
<td>Max Neck Dia IR (mm)</td>
<td>22.5 ± 3.2</td>
</tr>
<tr>
<td>Max Neck Dia IR+13 (mm)</td>
<td>23.6 ± 3.5</td>
</tr>
<tr>
<td>Juxtarenal Neck Angulation (°)</td>
<td>19 ± 19</td>
</tr>
<tr>
<td>Max AAA Dia (mm)</td>
<td>53.9 ± 9.1</td>
</tr>
<tr>
<td>Common Iliac Artery Dia (mm)</td>
<td>13.7 ± 3.5</td>
</tr>
<tr>
<td>External Iliac Artery Min Dia (mm)</td>
<td>8.0 ± 2.0</td>
</tr>
</tbody>
</table>
## Vascular Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck length &lt;10mm</td>
<td>7%</td>
</tr>
<tr>
<td>Neck width &gt;28mm</td>
<td>4%</td>
</tr>
<tr>
<td>Reverse taper ≥ 10%</td>
<td>28%</td>
</tr>
<tr>
<td>Neck angle &gt;60°</td>
<td>1%</td>
</tr>
<tr>
<td>EIA &lt;6mm</td>
<td>14%</td>
</tr>
<tr>
<td>Off-IFU</td>
<td>4%*</td>
</tr>
</tbody>
</table>

46% of patients had one or more challenging baseline anatomic characteristics.

*ENCORE includes results from real-world post market studies. 4% of patients had vascular characteristics beyond FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used off-IFU have not been established.

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the "Instructions for Use" for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Early Postoperative Outcomes

• Procedural
  • Technical Success 99.8%*
  • Procedural stenting to achieve seal 2.6%
  • Polymer leaks 0.2%, no clinical sequela

• 30 days
  • Major Adverse Events 1.3%†
  • AAA-Related Mortality 0.2%
  • One Rupture
  • One Conversion

* 1135/1137 from Pivotal Trial, EU PMR, LIFE, and LUCY. Pivotal CAP and Pivotal De Novo studies did not study technical success as per the respective protocols.
† 8/636 from Pivotal Trial, LIFE, and LUCY. Pivotal CAP, Pivotal De Novo, and EU PMR studies did not study MAEs as per the respective protocols.
Freedom from Mortality

98.9% FF AAA-Related Mortality

78.9% FF All-Cause Mortality

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the "Instructions for Use" for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Freedom from Rupture, Conversion

99.5% FF Rupture
99.2% FF Conversion

Three (3) Ruptures
Day 29, Type Ib EL with contained iliac artery rupture, treated with bypass and limb extension
Day 1486, Rupture, death due to COPD, renal failure
Day 1497, Contained rupture with hematoma, death due to COPD

Six (6) Conversions
One aortic body thrombosis, one AEF, two Type Ia, one Type II endoleak, one sac expansion

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the "Instructions for Use" for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Freedom from Endoleak

99.2% FF Type III Endoleak
98.9% FF Type Ib Endoleak
95.9% FF Type Ia Endoleak

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Freedom from Aneurysm Enlargement

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
Freedom from Reintervention

97.2% for Occlusion
92.6% Device-Related
Freedom from Reintervention

97.6% Freedom from Reintervention for Type Ia Endoleak

<table>
<thead>
<tr>
<th>All Type Ia endoleak</th>
<th>39</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated</td>
<td>19</td>
</tr>
<tr>
<td>Untreated</td>
<td>20</td>
</tr>
<tr>
<td>Resolved</td>
<td>6</td>
</tr>
<tr>
<td>Persistent</td>
<td>9</td>
</tr>
<tr>
<td>Refused Tx, Died, Exited Study</td>
<td>5</td>
</tr>
</tbody>
</table>

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. The Ovation® Abdominal Stent Graft Platform and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. MM1892 Rev 02
INDICATIONS FOR USE: The Ovation® iX Abdominal Stent Graft System 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.

CONTRAINDICATIONS: The system is 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).

Rx only.

Note: Endologix products and associated components are not available in all countries or regions. Please consult with your Endologix representative for details regarding product availability.

The Ovation® iX System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.

CE marked. Please refer to current product instructions for use.

Endologix is a registered trademark of Endologix, Inc. in United States, Europe and Japan and Ovation is a registered trademark of Endologix, Inc. and its subsidiaries in United States, Brazil, Canada, China, Europe, India, Mexico, and Japan. All other trademarks are the property of their respective owners.

© 2018 Endologix, Inc. All rights reserved.
Additional Disclosures

The ENCORE analysis includes results from 1 real-world post market study of Ovation in patients with AAA. 4% of total patients included in the study had vascular characteristics beyond the FDA-approved anatomic Indications for Use. Safety and effectiveness of Ovation when used outside the Indications for Use have not been established.

The long-term performance of the Ovation iX implant has not been established.

The ENCORE analysis has not been submitted to FDA.

All patients treated with this device must undergo periodic imaging to evaluate stent graft integrity and position, aneurysm size, and potential endoleaks and/or, occlusion of vessels in the treatment area. Significant aneurysm enlargement, a persistent endoleak, the appearance of a new endoleak, device migration, reduced blood flow through the graft, and/or decrease in renal function due to renal artery occlusion should prompt further investigation into the need for further patient treatment, including additional intervention or surgical conversion. Additional patient imaging follow up should be considered for patients with devices that have effectiveness issues.