3-years results of the OVATION PMR registry

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Conflict of interest

- have the following potential conflicts of interest to report:
  - 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
35% men and 60% women remain not feasible for EVAR
- narrow access vessels
- Inadequate neck length

Urgent call for new generation endoprothesis

Database of 11 East US clinical sites with 14800 patient with untreated AAA

Ultra Low Profile with a Patient-Specific Seal system

**Ovation®**
Abdominal Stent Graft System

14F ultra low profile enables access to more patients

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

Staged deployment of suprarenal stent allows 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
You Do Need an “Aortic Neck” to Achieve Seal

**CONVENTIONAL NECK REQUIREMENT**
- Based on **neck length** ≥ 10mm or ≥15mm of parallel vessel

**OVATION NECK REQUIREMENT**
- 13mm below inferior renal (IR) artery: sealing zone
- **neck diameter** ≥16 mm and ≤30 mm

Parallel vessel along 10 to 15mm in length

Circumferential seal occurs at midpoint of sealing ring at IR+13
Liquid polymer injected to inflate O-ring

Liquid polymer adapts to the configuration of the neck and gives the seal

**Ovation Platform Custom Seals to Each Patient Anatomy**

### Reverse Taper Neck
- **Pre-Op**
- **4 Years**

### Calcified Neck
- **Pre-Op**
- **4 Years**

- *No Type 1 Endoleak*  
  *Stable Neck Diameter*
Ovation Abdominal Stent Graft

Sealing ring creates no chronic outward force and insulates the neck from blood pressure, resulting in a stable neck diameter.

Aortic Neck Dilatation Over Time

2. Neck dilation = growth > 3mm at 10mm, 13mm, and 15mm below renals
A Systematic Review of Proximal Neck Dilatation After Endovascular Repair for Abdominal Aortic Aneurysm

George N. Kouvelos, MD, Kyriakos Oikonomou, MD, George A. Antoniou, MD, Eric L. G. Verhoeven, MD, PhD, and Athanasios Katsargyris, MD

Meta-analysis

Increased size of aorta

Neck Dilation

24.6% incidence of clinical events with dilation

Type Ia endoleak, migration, and reintervention

26% vs 2% Without dilation

SELF EXPANDING STENT GRAFT

Chronic outward force from stent, combined with blood pressure, can result in aortic neck dilatation. 1

Ovation  
Abdominal Stent Graft System
Ovation and Challenging Distal Anatomy

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

Tight Access Vessels

5.3 mm  3.2 mm
Pre-Op  5 Year

Tortuous Iliacs

4 Year

Courtesy Thomas Noite, MD, Bad Bevenson, Germany

Courtesy Francisco Valdes, MD, Santiago, Chile
OVATION® EUROPEAN POST MARKET REGISTRY

- Multicenter, prospective
- 501 patients, 30 EU sites
- Enrolled May 2011 – December 2013
- 5 year follow-up
- CEC adjudication of device-related adverse events
- Primary Endpoints
  - Technical success
  - Freedom from Type I/III endoleak, rupture, sac expansion, conversion, occlusion, and migration
Patient demographics and comorbid risk factors indicate a **typical AAA patient** cohort.

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<tr>
<td><strong>Age (mean)</strong></td>
<td>$73 \pm 8$</td>
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<tr>
<td><strong>Male Gender</strong></td>
<td>$432 (86.2%)$</td>
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<tr>
<td><strong>ASA Class III/IV</strong></td>
<td>$244 (48.7%)$</td>
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<td><strong>Coronary artery disease</strong></td>
<td>$40.9% (205/501)$</td>
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<td><strong>Hypertension</strong></td>
<td>$69.1% (346/501)$</td>
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<td><strong>Hyperlipidemia</strong></td>
<td>$47.9% (240/501)$</td>
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<tr>
<td><strong>Smoking</strong></td>
<td>$47.7% (239/501)$</td>
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<tr>
<td><strong>COPD</strong></td>
<td>$22.8 (114/501)$</td>
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1/3 of patients had **Severe Morphology**

Data provided by site imaging. Severe morphology based on SVS/AAVS anatomic scoring.

Procedural Outcomes

Technical Success (successful deployment of device) 99.8%
Polymer leak with anaphylactic shock 0.2%
Anesthesia Time (mean) 150 minutes
Procedure Time (mean) 118 minutes
Fluoroscopy Time (mean) 22.2 minutes
Major Adverse Event @ 30 Days 3.3% (3/92)
99% Freedom from AAA-Related Mortality through 3 Years

99% Freedom from AAA Related Mortality
88% Freedom from All causes Mortality
Freedom from Rupture and Conversion through 3 Years

99% Freedom from Rupture

One contained rupture, day 30, from Type Ib endoleak. Treated with hypogastric occlusion and iliac limb extension.

99% Freedom from Conversion

Three conversions: day 88 due to aortic occlusion, day 449 due to Type I/II endoleak, and 477 due to aorto-enteric fistula.
Type I/III Endoleak Through 3 Year

97% Freedom from Type I/III Endoleak
Freedom from Occlusion, Migration, and AAA Growth through 3 Years

98% Freedom from Loss of Patency

99% Freedom from Migration

93% Freedom from Sac Growth >5mm

Seven total occlusions: 4 early, 3 between 6mo and 1 yr

Four site-reported migrations associated with Type Ib endoleak. All successfully reintervened with stent graft extension.
Adjunctive Procedures for Type Ia Endoleak

CASE EXAMPLE
- Palmaz stent used to address intraoperative Type Ia endoleak due to undersized graft.
- 3 year follow-up shows no neck dilatation. Palmaz stent and sealing ring maintain wall apposition.
Freedom from Secondary Intervention

- 97% freedom for Type I Endoleak
- 95% freedom for Type II Endoleak
- 97% freedom for Occlusion
The Ovation Alto™ is not approved in any market; Ovation Alto is an investigational device in the United States, limited by federal (or United States) law to investigational use only.

**Ovation Alto™**
Abdominal Stent Graft System

**Next Generation Design**

1. Elevated Sealing Ring
   ~ 7 mm IR

2. Webbing at bifurcation to facilitate cannulation

3. Offset aortic body legs for improved visualization

4. Ultra-low profile for small access and tortuous anatomy
10. We Have Listened to Clinical Feedback

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EXPANDING PATIENT APPLICABILITY WITH POLYMER SEALING OVATION ALTO STENT GRAFT

ELEVATE IDE
US FDA Pivotal Trial
75 patients / Up to 12 Centers
Enrollment to begin Q1 2017

ELEVATE2
EU Post Market Registry
300 patients / Up to 30 Centers
Enrollment to begin Q3 2017

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