Ovation™ Prime Stent Graft System can be used for challenging anatomy in EVAR cases

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Disclosure slide

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☐ I 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
Problems with Commonly Used Stent Grafts for AAA

Narrow and tortuous iliac arteries preclude access to treatment area

Hostile necks, thrombus and calcium prevent an effective seal
Ovation™ Prime Stent Graft System

• Appears to be a compelling therapy option for EVAR

The ultra low profile (14F OD) and novel sealing technology expands the treatable pool of patients on label

The pre-market clinical data (CE and FDA) are very encouraging

• But can excellent Clinical Trial Results be mirrored in our Clinical Practice
14F OD Ovation™ Abdominal Stent Graft System

Suprarenal nitinol stent with integral anchors for fixation

Tri-modular design
Low-viscosity, radiopaque, fill polymer

13-14F OD conformable iliac limbs

14F OD main body
Inflatable rings for optimal seal
Novel Design Paradigm

Robust and Conformable Seal

Other stent grafts use wire and fabric to create points of apposition.

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

Note: FEA simulations indicate elevated stress points in pink and red coloring.

The Ovation Prime components deliver:
1. Suprarenal secure the
2. Biocompatible for a robust

14Fr OD Ovation Prime Stent Graft
EU Postmarket Ovation™ REGISTRY

INCLUSION criteria

- Subject > 18 years
- Intention to electively implant the Ovation SG
- Treatment of AAA in accordance with IFU of Ovation SG
- Subject signs Informed Consent Form
- Subject has the willingness to comply with follow-up exams
- Subject does not participate in a concurrent RCT
- Subject does not have a serum creatinine > 2.5 mg/dl
- Subject has a life expectancy > 1 year

INSTRUCTIONS for Use

- Adequate iliac/femoral access
- Non-aneurysmal proximal aortic neck > 7mm proximal to AAA - inner wall diameter 16 to 30mm - with aortic angle < 60° if proximal neck > 10mm and < 45° if proximal neck < 10mm

- Adequate distal iliac landing zone - length of > 10mm - with inner wall diameter 8 to 20mm

Two challenging cases in our center

Rejected by commonly used company
Case 1 (#006 Registry)

Preoperative

Post Operative

AAA diameter at baseline: 90 mm
Preop aortic views

RPO  PA  LPO  LLat
Preop angio-CT
Proximal Neck

Calcium present in perirenal neck. At 15 minutes post mix time perform angio to evaluate proximal seal. Treat if necessary with compliant balloon.

Also note calcium @ IR20 and 2 left renal arteries with common origin.
Highly calcified bilateral common iliac arteries. Advancing a 14Fr dilator through commons to sac might help. Dilatation with PTA balloon may be necessary to allow delivery catheter to advance. Prepare kissing post deployment 12x40 PTA from flow divider, through native bifurcation to end of grafts.
RESULT

Post-Operative

Anterior  Left  Posterior  Right
RESULT

1 year follow up

AAA diameter at follow up: 60 mm
Case 2 (#320 Registry)
Preop
Proximal Neck

Thrombus present in perirenal neck. Pull stiff guidewire back during polymer fill. Ease tension on delivery catheter if present. Suggest angio at 15 minute mix time to assess seal. Treat with compliant balloon if needed.

- Heavy thrombus and circumferential calcium in the aortic neck down to the native bifurcation.

- Narrow flow lumen at IR+80 (~18.6mm in diameter).

- Juxtarenal angulation of 51 degrees (apex @~IR+16).
Bilateral stents in common iliacs as well as a stent in the right external iliac.

Suggest kissing balloons post deployment 12x40 PTA from Aortic Body overlap through native bifurcation.

Iliac Landing Zone
Ovation Stent Graft continues to show excellent results in the treatment of AAA. The unmatched low profile delivery system offers reliable options also in patients with challenging anatomies.

**Aortoiliac Characteristics**

1/4 of treated aortic necks were shorter than 15 mm
- 53% had moderate/severe calcification
- 63% had moderate/severe thrombus

1/3 of treated patients had access vessels < 7 mm

**Clinical Outcomes**

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<th>PERFORMANCE</th>
<th>30 Day (N=250)</th>
<th>6 months (N=150)</th>
<th>1 Year (N=50)</th>
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<tbody>
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<td>Technical Success</td>
<td>100%</td>
<td>N/A</td>
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<td>Freedom from Type I and III Endoleaks</td>
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<td>Freedom from Migration</td>
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<td>Freedom from Conversion to Open Repair</td>
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<tr>
<td>Freedom from Occlusion</td>
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**ANEURYSM ASSESSMENT**

| Enlargement >5mm                                | Baseline 2.7% (3/112) | 5.3% (2/38) |
| No change                                       | Baseline 80.3% (90/112) | 68.4% (26/38) |
| Reduction >5mm                                  | Baseline 17% (19/112) | 26.3% (10/38) |
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SUMMARY

- 14F OD has enabled or simplified treatment of patients with narrow and calcified vessel
- The polymer filled sealing rings increased confidence in patients with calcified or thrombus filled necks
- Expanded our ability to treat more challenging anatomies on-label (IFU)
- Encouraging results from the tightly controlled clinical study appear to be confirmed in broader use in the context of a post market registry
- Additional follow-up will be evaluated to confirm these early results