TriVascular Ovation Prime®
Abdominal Stent Graft System

Science of the Seal
O-Ring Sealing Technology

O-Ring Sealing in Proven Engineering Solutions

- O-rings are designed to seal by blocking the flow of fluid between two closely spaced surfaces
  - O-rings create a water-tight seal once two surfaces establish intimate contact
  - O-rings are designed to be flexible to accommodate variation in the two surfaces

O-Ring Sealing in Aorta

Ovation Prime O-ring is designed to seal by blocking flow of blood between aortic wall and graft

- Biocompatible polymer delivered to inflate O-ring
- O-ring creates a water-tight seal that provides uniform non-expansive continuous wall apposition
- O-ring designed to conform to irregular luminal surface in aortic neck
- O-ring insulates aortic neck from blood pressure

*water has a lower viscosity than blood and does not clot*
O-Ring Sealing Technology Creates Continuous Wall Apposition

Self Expanding Stent Graft

Wire and fabric grafts create discontinuous points of apposition in irregular and/or tapered anatomy

Ovation Prime Stent Graft

Ovation Prime sealing ring creates uniform continuous wall apposition, even in irregular and/or tapered anatomy

Note: FEA simulations illustrate the spectrum of wall apposition from low (blue) to high (red)
O-Ring Sealing Technology Creates a Custom Seal

Physicians create a customized seal by filling the conformable Ovation Prime O-rings with CustomSeal polymer, effectively completing the last step of the manufacturing process in vivo.

Pre-operative illustration and CT image of an aortic neck with significant calcium and thrombus

17 month follow-up illustration and CT image of an aortic neck with sealing ring conforming to irregular surface, creating a custom seal with no Type 1a endoleak

Images courtesy of Jennifer Ash, MD, Christie Clinic, Champaign, Illinois
Durability of Seal in EVAR

Self Expanding Stent Graft

• Several studies show evidence of aortic neck dilatation with self-expanding EVAR stent grafts\(^1\)

• Aortic neck dilatation can compromise seal and may lead to Type 1 endoleak and/or migration

Ovation Prime Stent Graft

• Ovation\(^\circ\) Global Pivotal Study\(^2\)
  
  • No aortic neck dilatation at 1 and 2 years
  
  • No Type 1 endoleaks and no migration at 1 and 2 years

\(^2\)Mehta et al. J Vasc Surg 2013; 1-9 and Core Lab data on file
Studies Reporting Aortic Neck Dilatation in Self Expanding Stents

Aortic neck dilatation after endovascular abdominal aortic aneurysm repair: A word of caution

Nicolas Diehm, MD,a,b Florian Dick, MD,c Barry T. Katzen, MD,a Juerg Schmidli, MD,c Christoph Kalka, MD,b and Iris Baumgartner, MD,b Miami, Fla; and Bern, Switzerland

- Literature review summarizes current evidence on infrarenal aortic neck dilatation

- Conclusion: “Current evidence on AND (aortic neck dilatation) raises serious concerns about long-term durability of stent graft fixation in the proximal aortic neck”

- Clinical Consequence: “Continuing expansion of aortic necks poses a substantial threat to the mid- and long-term durability of EVAR because proximal fixation is jeopardized once the diameter of the neck exceeds that of the endograft.”

### Table II. Summary of studies reporting neck dilatation in patients undergoing endovascular abdominal aortic aneurysm repair

<table>
<thead>
<tr>
<th>First author</th>
<th>N</th>
<th>Neck measurement specifications</th>
<th>Definition of AND</th>
<th>Follow-up</th>
<th>Graft type</th>
<th>Quantification of AND</th>
<th>Clinical impact of AND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simpkins20</td>
<td>144 CTa</td>
<td>Relative diameter increase, 10%</td>
<td>Median 257 days (AnconRx), 629 days (AnconRx)²</td>
<td>100% SXS</td>
<td>10% increase at 2 years in 36.1% (AnconRx) and in 33.5% (Ancon); 15% increase at 2 years in 12.4% (AnconRx) and in 9.1% (Ancon)</td>
<td>No correlation with early or late endoleak.</td>
<td></td>
</tr>
<tr>
<td>Wever21</td>
<td>83 CT²</td>
<td>Absolute change, % surface area</td>
<td>Median 12 months</td>
<td>100% SXS</td>
<td>10.3% surface area increase at 6 months; 15.6% surface area increase at 1 year; Cumulative incidence: 21.8%; 12% at 1 year, 33% at 2 years</td>
<td>No correlation with early or late endoleak.</td>
<td></td>
</tr>
<tr>
<td>Napoli22</td>
<td>90 CT and DUS³</td>
<td>2.5 mm diameter increase</td>
<td>Mean 15 months</td>
<td>1.1% BES; 98.9% SXS</td>
<td>4 mm diameter increase; 0.09 ± 1.1 mm/y at 2 years for asymptomatic, 2.61 ± 3.3 mm/y at 2 years for those treated for rupture: 24.9% of patients at 2 years; 38.1% of patients at 4 years</td>
<td>35.3% of patients with AND had distal migration. Graft migrations were associated with AND in asymptomatic patients as well as in patients with ruptured AAA.</td>
<td></td>
</tr>
<tr>
<td>Badger²³</td>
<td>161 CT³</td>
<td>Absolute change, mm</td>
<td>Up to 2 years</td>
<td>100% SXS</td>
<td>24.9% of patients at 2 years; 38.1% of patients at 4 years</td>
<td>No correlation with early or late endoleak.</td>
<td></td>
</tr>
<tr>
<td>Diehm²⁴</td>
<td>6383 CTa</td>
<td>Relative change, ≥ 15% diameter increase</td>
<td>Mean 21 months</td>
<td>3% BES; 97% SXS</td>
<td>28% of patients at 2 years; 50% of patients at 4 years; 1.65-mm increase at 25 months; 8.6% increase at 2 years, 10.3% increase at 4 years</td>
<td>Late repeat intervention associated with AND (p&lt;0.0001).</td>
<td></td>
</tr>
<tr>
<td>Cao²⁵</td>
<td>280 CT³</td>
<td>4 mm diameter increase</td>
<td>Median 24 months</td>
<td>100% SXS</td>
<td>4 mm diameter increase; 0.7 ± 2.1 mm/y</td>
<td>No correlation with early or late endoleak.</td>
<td></td>
</tr>
<tr>
<td>Sonesson²⁶</td>
<td>54 CT³</td>
<td>Relative change, % diameter, mm</td>
<td>Mean 25 months</td>
<td>100% SXS</td>
<td>4 mm diameter increase; 0.7 ± 2.1 mm/y</td>
<td>No correlation with early or late endoleak.</td>
<td></td>
</tr>
<tr>
<td>Badran²⁶</td>
<td>73 CT³</td>
<td>Relative change, % diameter, mm</td>
<td>Mean 26 months</td>
<td>4% BES; 96% SXS</td>
<td>4 mm diameter increase; 0.7 ± 2.1 mm/y</td>
<td>No correlation with early or late endoleak.</td>
<td></td>
</tr>
<tr>
<td>Matsumura²⁷</td>
<td>59 CT³</td>
<td>Absolute change, mm</td>
<td>Mean 27 months</td>
<td>100% SXS</td>
<td>2.5 mm diameter increase; 0.7 ± 2.1 mm/y</td>
<td>No correlation with early or late endoleak.</td>
<td></td>
</tr>
<tr>
<td>Makaron²⁸</td>
<td>314 CT³</td>
<td>Absolute change, % surface area</td>
<td>Up to 3 years</td>
<td>100% SXS</td>
<td>20% surface area increase at 2 years; 30% surface area increase at 3 years</td>
<td>Migration in 1 patient associated with AND.</td>
<td></td>
</tr>
<tr>
<td>Prinsen²⁹</td>
<td>87 CT³</td>
<td>Relative change, % surface area</td>
<td>Up to 3 years</td>
<td>100% SXS</td>
<td>20% surface area increase at 2 years; 30% surface area increase at 3 years AND in 20% of patients after 2 years</td>
<td>AND significantly influenced incidence of late type I endoleaks (p=0.001).</td>
<td></td>
</tr>
<tr>
<td>Dillavou²⁰</td>
<td>729 CT³</td>
<td>3 mm diameter increase</td>
<td>Up to 5 years</td>
<td>4.3% BES; 95.7% SXS</td>
<td>20% surface area increase at 2 years; 30% surface area increase at 3 years AND in 20% of patients after 2 years</td>
<td>AND significantly influenced incidence of late type I endoleaks (p=0.001).</td>
<td></td>
</tr>
</tbody>
</table>

AAA, Abdominal aortic aneurysm; AND, aortic neck dilatation; EVAR, endovascular aneurysm repair; NS, not specified; BES, balloon expandable stent graft; SXS, self-expandable stent graft; CT, computed tomography; DUS, duplex ultrasound.
Type 1 Endoleak and Migration in Patients with Aortic Neck Dilatation

Predictive factors and clinical consequences of proximal aortic neck dilatation in 230 patients undergoing abdominal aorta aneurysm repair with self-expandable stent-grafts

Piergiorgio Caò, MD, Fabio Verzini, MD, Gianbattista Parlani, MD, Paola De Rango, MD, Basso Parente, MD, Giuseppe Giordano, MD, Stefano Mosca, MD, and Agostino Maselli, MD, Perugia, Italy

- Aortic neck dilatation, defined as diameter growth >3mm, occurred in 28% of patients at a median follow-up of 24 months
  - Type 1 endoleak occurred in 9% of patients with neck dilatation and 1% of patients with no neck dilatation
  - Migration >10mm occurred in 27% with neck dilatation

- Late repeat intervention was more frequently necessary in patients with aortic neck dilatation

Fig 1. CT scans obtained at 1 month (top) and 24 months (bottom) after endograft placement show aortic neck dilatation of 6.6 mm.
Aortic Neck Dilatation Risk Factor for Type 1 Endoleak and Migration

Is Neck Dilatation After Endovascular Aneurysm Repair Graft Dependent?

Results of 4 US Phase II Trials

Ellen D. Dillavou, MD, Satish Muluk, MD, FACS, and Michel S. Makaroun, MD, FACS, Pittsburgh, PA

Conclusions

The incidence of neck dilatation ≥ 3 mm approaches 20% regardless of the endograft used. For most endografts, neck dilatation was a significant risk factor for endograft migration and late proximal endoleak but did not influence AAA sac behavior. Small necks at the time of EVAR appear to be at higher risk for subsequent dilatation than those over 25 mm.

- 729 Patients with follow up of at least 24 months
- Type 1 endoleak occurred in 4.1% of patients with aortic neck dilatation. Rates similar among graft types
- Aortic neck dilatation associated with migration in Ancure and Gore Excluder
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

Sealing in Reverse-Taper Neck

Self Expanding Stent Graft

- Longitudinal seal created by chronic outward force across 10 or 15mm in length
- Proximal stent significantly oversized at renals and immediately below renals in order to seal at 10-15mm

Ovation Prime Stent Graft

- Circumferential, non-expansive seal at midpoint of sealing ring at 13mm
- Collar designed to transmit longitudinal force between graft and suprarenal stent, not radial force

IR = Inferior Renal
**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

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Blood Pressure ➔ Aneurysm

Blood Pressure ➔ Stent Outward Radial Force ➔ Contributes to Neck Dilatation

Minimal Blood Pressure ➔ NO Stent Outward Radial Force ➔ No Neck Dilatation
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
Core lab data
Ovation System Protects the Neck

Aortic Neck Dilatation Over Time

Ovation Prime sealing ring creates no chronic outward force and insulates the neck from blood pressure, resulting in no neck dilatation and no late Type 1 endoleaks at 3 years\(^3,4\)

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\(^1\) Monahan JVS 2010: 52: 303-7 N=46. Devices: Cook Zenith
\(^3\) Neck dilatation in proximal neck defined as growth > 3mm at 10mm below renals, 13mm below renals, and 15mm below renals; measurement methodology in Ovation Pivotal Trial similar to measurement methodology in cited studies
\(^4\) Ovation Global Pivotal Trial N=131
Case Studies From Ovation Global Pivotal Study Demonstrate Stable Aortic Neck Diameters

**Straightforward**
*No aortic neck growth at 4 years*

**Reverse Tapered Neck**
*No aortic neck growth at 2 years*

**Heavy Calcification**
*No aortic neck growth at 2 years*
Long-Term Data on O-Ring Sealing Technology

Professor John P. Fletcher
University of Sydney, Department of Surgery, Westmead Hospital, Sydney, Australia

- 12 patients followed for mean of 8 years and 2 months
- No AAA related deaths
- 3 deaths (25%) 54 to 93 months after EVAR from cancer, cardiac and respiratory failure
- No late Type I Endoleaks

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February 2013 Poster Presentation
Conclusion

• Ovation O-Ring Sealing Technology
  • Provides a water tight seal in aorta
  • Creates uniform continuous wall apposition, even in irregular and/or tapered anatomy
  • Molds and conforms to aorta, offering a customized seal
  • Non-expansive circumferential wall apposition of sealing ring creates no chronic outward radial force and no aortic neck dilatation

• Ovation Global Pivotal study demonstrates encouraging results with stable neck diameter and durable seal in 3 year follow up
INDICATIONS FOR USE: The TriVascular Ovation/Ovation Prime Abdominal Stent Graft Systems are 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 20 mm.

The Ovation Prime Abdominal Stent Graft System with the Ovation iX Iliac Stent Graft are indicated as stated above with a distal iliac landing zone inner wall diameter no greater than 25 mm.

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.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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

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

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