First-in-Human Experience with Endovascular Aneurysm Repair Using the Ovation ALTO Stent Graft

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Ovation Stent Graft System and Ovation Alto

Ovation Stent Graft System (Ovation iX)
- Polymer sealing ring at 13mmf

Design Goals of Ovation Alto
- Treat more patients on IFU

Differentiating Features:
- Elevated polymer sealing ring (7mm)
- Integrated balloon
- Gate cannulation easier
- Improved visualization
Ovation ALTO Delivery System

- Integrated crossover port for simplified contralateral limb cannulation
Ovation ALTO Case Example

- 57mm AAA
- Approximately 10mm long neck below renal arteries
Ovation ALTO Case Example

- Device introduced, orientated, and positioned relative to renal arteries and mid crown of proximal stent deployed
Ovation ALTO Case Example

- Compliant balloon inflated
Ovation ALTO Case Example

- Final re-positioning if necessary
Ovation ALTO Case Example

- Angiographic catheter withdrawn and proximal crown of stent then deployed
Ovation ALTO Case Example

- Polymer rings then filled
Ovation ALTO Case Example

- Contralateral limb cannulated
Ovation ALTO Case Example

- Limb lengths planned, deployed and post-dilated
Ovation ALTO Case Example
Ovation ALTO
Auckland, NZ Experience

- 7 cases, August 2016 to February 2017
- 100% Technical success
- 30d CT Follow-Up (7/7)
- No T1 or T3 endoleak
- 2 T2 endoleak
Early Observations

- 4 patients with 6 month follow-up
- No T1 or T3 endoleak
- Sac stable or smaller in all cases (2 with significant sac shrinkage)
- One persistent T2EL
EXPANDING PATIENT APPLICABILITY WITH POLYMER SEALING OVATION ALTO STENT GRAFT

US FDA Pivotal Trial
75 patients / Up to 15 Centers
Enrollment near complete

The Ovation Alto is not approved in any market
Ovation ALTO
Cleveland Clinic Experience

- 5 cases, 2017
- 100% Technical success
Conclusions

• Ovation Alto moves the sealing ring to closer to the renal arteries IR 7 from IR 13
• Gate cannulation is improved
• Integral Balloon is helpful
• Short term outcomes are good
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