

Ovation[®]

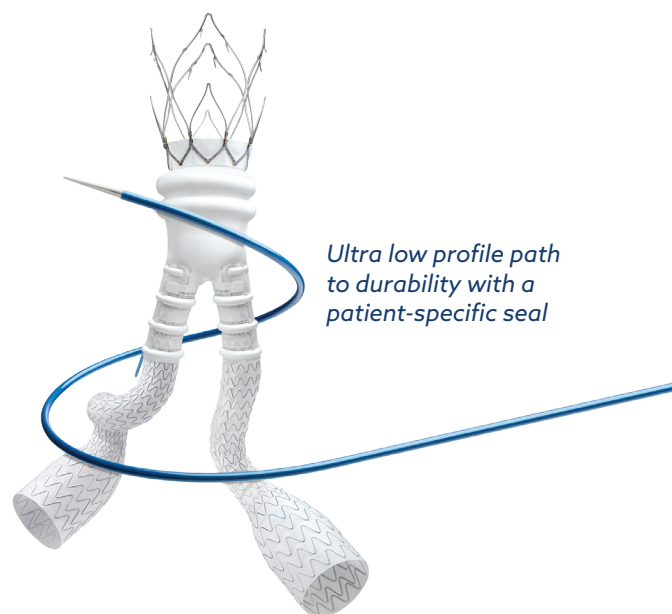
Abdominal Stent Graft System

LUCY Study: Evaluation of Females who are Underrepresented Candidates for Abdominal Aortic Aneurysm Repair

THE FIRST-EVER PROSPECTIVE STUDY TO SPECIFICALLY EVALUATE EVAR IN WOMEN

LUCY Study Design

- Prospective Post-market Registry
- US Multicenter Study: 39 sites actively enrolled
- N = 225 (Female:Male = 1:2)
- Primary Endpoint: MAE rate within 30 days of initial procedure
- Secondary Endpoints: Multiple secondary endpoints will be assessed to demonstrate benefits of EVAR in both the female (treatment arm) and male (control arm)



LUCY STUDY SHOWS SIMILAR 30-DAY OUTCOMES IN BOTH WOMEN AND MEN

Clinical Outcomes (30d)	Female (N=76)	Male (N=149)	P-value
Safety			
Device-Related MAEs*	0%	0%	–
MAEs*	1.3%	1.3%	NS
AAA-Related Mortality	0%	0%	–
Procedural Outcome			
Deployment Success	100%	98.7%	NS

Facts about Women with AAA

- ~1 in 5 AAA patients is female¹
- EVAR Eligibility: 34% women vs. 54% men²
- Perioperative morbidity and mortality after EVAR: higher in women³
- 30d major complications: higher in women (2.9% vs. 1.1%, $p < .001$)⁴
- 30d mortality: higher in women (9.6% vs. 5.8%, $p < .001$)⁴

OVATION IS PROVEN EFFECTIVE, WITHOUT AAA-RELATED SECONDARY INTERVENTION FOR FEMALE PATIENTS

Clinical Outcomes (30d)	Female (N=76)	Male (N=149)	P-value
Effectiveness			
Type Ia Endoleak*	0%	2.0%	NS
Type III Endoleak*	0%	0%	NS
Limb Occlusion	0%	0%	–
AAA-related Secondary Interventions*			
Type Ia Endoleak	0%	1.3%	NS
Type III Endoleak	0%	0%	–
Limb Occlusion	0%	0%	–

Ovation EU PMR 3-Year Results Show Durability in Both Women and Men

Freedom from **AAA-Related Mortality**:
Women **100%** | Men **99%** NS

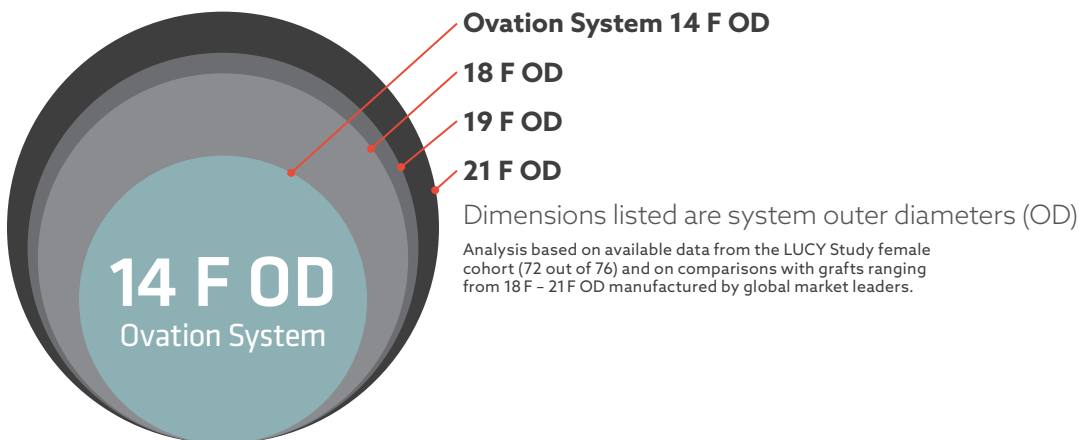
Freedom from **Rupture**:
Women **100%** | Men **99.7%** NS

Freedom from **Reintervention for Type Ia Endoleak**:
Women **96%** | Men **98%** NS

Freedom from **Reintervention for Occlusion**:
Women **96%** | Men **97%** NS

Ovation European Post-Market Registry 3-year results extracted on October 6, 2016. N = 501; Female n = 69 & Male n = 432.

THE OVATION SYSTEM CAN MAKE EVAR A POSSIBILITY FOR 28% - 109% MORE WOMEN WITH ITS ULTRA LOW PROFILE DELIVERY SYSTEM



*CEC Adjudicated NS = Non-significant difference

- Sweet, M. et al. "The influence of gender and aortic aneurysm size on eligibility for endovascular abdominal aortic aneurysm repair." *Journal of Vascular Surgery*. October 2011. *J Vasc Surg* 2011;54:931-7.
- Ulug, P, PhD, et al. "Morphological suitability for endovascular repair, non-intervention rates, and operative mortality in women and men assessed for intact abdominal aortic aneurysm repair: systematic reviews with meta-analysis." *The Lancet*. April 25, 2017
- Lo, R., MD & Marc Schermerhorn, MD. Abdominal aortic aneurysms in women. *J Vasc Surg* 2016;63:839-44.
- Deery, S, MD et al. "Sex differences in mortality and morbidity following repair of intact abdominal aortic aneurysms." *J Vasc Surg* 2017;65:1006-13.

The Ovation® Abdominal Stent Graft System 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.

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