The LUCY Study
The First Prospective Study Evaluating Endovascular Aneurysm Repair in a Female Population

TriVascular Evaluation of Females who are Underrepresented Candidates for Abdominal Aortic Aneurysm Repair
STUDY RATIONALE

Women are under-represented in EVAR clinical trials which prevents the generalization of clinical findings to the broader female population with AAA requiring intervention. Consequently there is a lack of information for these patients and their physicians regarding risks and benefits of EVAR.

The TriVascular Ovation® system can accommodate small diameter access vessels and challenging aortic necks, suggesting this endograft may be particularly well-suited to the study of EVAR in women.

CASE STUDY

An 84-year-old woman presented with a AAA and challenging aortic anatomy (Figures 1 and 2A). After being treated with the TriVascular Ovation System, the completion angiography confirmed accurate endograft placement, exclusion of the AAA, and no endoleaks (Figure 2B). The patient was followed-up at 1 month, 6 months, and 1 year with no evidence of any endoleaks or sac enlargement.

*Images courtesy of Syed Hussain, MD and Jennifer Ash, MD at Christie Clinic in Champaign, IL
STUDY DESCRIPTION

The LUCY Study is a prospective, consecutively enrolling, non-randomized multi center post-market registry to evaluate the ultra low profile (14F) Ovation System when used in the endovascular treatment of AAA in female patients.

STUDY DESIGN

Study will enroll up to 225 subjects (75 females in the Treatment Group and 150 males in the Control Group) in up to 45 sites in the U.S. Study results will provide a comparison of female and male patient outcomes.

PRIMARY ENDPOINT

The primary endpoint is the Major Adverse Event (MAE) rate within 30 days of the initial procedure. MAEs will be adjudicated and reported based upon an independent Clinical Events Committee (CEC).

SITE SELECTION CRITERIA

- Site has participated in a clinical research study in the past
- Site has a research coordinator available to support the study
- Site commitment to perform at least 5 study cases

Site selection questions can be directed to Kaleigh Bulloch Whitehall (kbulloch@trivascular.com).
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 $\leq 60$ degrees if proximal neck is $\geq 10$ mm and $\leq 45$ 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 with your TriVascular representative to confirm product availability.

CE marked. Please refer to current product Instructions for Use.

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