STUDY DESCRIPTION

The LIFE Study is a prospective, consecutively enrolling, non-randomized multi center post-market registry to evaluate the ultra low profile (14F) Ovation Prime® Abdominal Stent Graft System when used in the Percutaneous Endovascular Aneurysm Repair (P-EVAR) treatment of patients with AAA using a Fast-Track EVAR protocol.

STUDY OBJECTIVES

The primary objectives of the LIFE Study are to demonstrate the clinical and cost benefits associated with using the Ovation Prime Abdominal Stent Graft System under the least invasive conditions defined in the Fast-Track EVAR protocol. The key elements of the Fast-Track EVAR protocol include:

- Appropriate patient selection (i.e. candidate for Ovation Prime device, Inclusion/Exclusion criteria)
- Bilateral percutaneous access
- No general anesthesia (e.g. local or conscience sedation)
- No ICU admission post procedure
- Next day discharge (one midnight stay)
# SCHEDULE OF ACTIVITIES

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1. Creatinine and serum pregnancy HCG required no more than 30 days prior to the implant/surgical procedure. Note: the serum pregnancy is required for females of child-bearing potential only.

2. Baseline medical/surgical history performed no more than 30 days prior to the implant/surgical procedure.

3. Baseline contrast enhanced CT must be obtained within 6 months of anticipated treatment date.

4. Note that in the event the subject is unable to tolerate a contrast-enhanced spiral CT, a duplex ultrasound and non-contrast spiral CT should be completed as an alternative assessment.

5. Quality of Life (QOL) assessment via the EuroQol Group’s EQ-5D form.

INCLUSION CRITERIA

All patients must meet ALL of the following inclusion criteria to be eligible for enrollment into this study:

1. Patient is > 18 years of age.
2. Patients who are male or non-pregnant female (females of child bearing potential must have a negative pregnancy test prior to enrollment into the study).
3. Patient has signed an Institutional Review Board (IRB) approved Informed Consent Form.
4. Patient is considered by the treating physician to be a candidate for elective open surgical repair of the AAA (i.e., category I, II, or III per American Society of Anesthesiology (ASA) classification). ASA category IV patients may be enrolled provided their life expectancy is greater than 1 year.
5. Patient has an infrarenal abdominal aortic aneurysm that meets at least one of the following:
   a. Abdominal aortic aneurysm > 5.0 cm in diameter
   b. Aneurysm has increased in size by 0.5 cm in last 6 months.
   c. Maximum diameter of aneurysm exceeds 1.5 times the transverse dimension of an adjacent non-aneurysmal aortic segment
6. Patient has suitable anatomy that allows use of the TriVascular Ovation/Ovation Prime Abdominal Stent Graft System:
   a. Iliac or femoral arteries that allow endovascular access with the TriVascular Ovation/Ovation Prime Abdominal Stent Graft System (14F OD).
   b. Proximal aortic neck 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.
   c. Distal iliac artery landing zone length (seal zone) of ≥10 mm. The resultant repair should preserve patency in at least one hypogastric artery.
d. Distal iliac artery landing zone an inner wall diameter of no less than 8 mm and no greater than 20 mm.

e. Distance from the most distal renal artery to most superior internal iliac artery measurement is at least 130 mm.

f. Aortic angle of $\leq 60$ degrees if proximal neck length is $\geq 10$ mm and $\leq 45$ degrees if proximal neck length is $<10$ mm.

7. Patient has suitable femoral arteries at the percutaneous access site that allow use of the Perclose ProGlide Suture-Mediated Closure (SMC) System via the pre-close technique, including:

a. $\geq 5$ mm in diameter.

b. At least 2 cm segment for access, 10 mm above the origin of the profunda femoris branch and 10 mm below the lower margin of the inferior epigastric artery as determined on preoperative contrast-enhanced CT, angiography, or ultrasound.

c. No calcification on the anterior wall or circumferential (> 50%) calcification on the posterior wall.

d. No prior groin incision, hematoma, or significant scarring.

e. No prior clip or collagen based vascular closure device placement within 90 days of procedure.

f. No prior femoral artery needle puncture within 30 days of procedure.

g. No current active localized groin infection, traumatic vascular injury, femoral artery aneurysm, arteriovenous (AV) fistula, or pseudoaneurysm.

8. Patient must be willing to comply with all required follow-up exams.
EXCLUSION CRITERIA

Patients who meet ANY of the following are not eligible for enrollment into the study:

1. Patient has a need for emergent surgery.
2. Patient has a dissecting aneurysm.
3. Patient has an acutely ruptured aneurysm.
4. Patient has an acute vascular injury.
5. Patient has had a previous repair of the abdominal aortic aneurysm or the iliac artery.
6. Patient has a mycotic aneurysm or has an active systemic infection.
7. Patient has unstable angina (defined as angina with a progressive increase in symptoms, new onset at rest or nocturnal angina, or onset of prolonged angina).
8. Patient has unstable peripheral artery disease with critical limb ischemia (CLI).
9. Patient has congestive heart failure (CHF).
10. Patient has had a myocardial infarction (MI) and/or stroke (CVA) within the past 3 months.
11. Patient requires use of techniques (e.g. Chimney graft) that would cover the renal arteries.
12. Patient requires planned adjunctive devices (e.g. renal stents) to complete the procedure.
13. Patient has a major surgical or interventional procedure planned during or within ±30 days of the AAA repair.
14. Patient has history of connective tissue disease (e.g., Marfan’s or Ehler’s–Danlos syndrome).
15. Patient has history of bleeding disorders or refuses blood transfusions.
16. Patient has dialysis dependent renal failure or baseline serum creatinine level >2.0 mg/dl
17. Patient has a known hypersensitivity or contraindication to anticoagulation or contrast media that is not amenable to pre-treatment.

18. Patient has a known allergy or intolerance to polytetrafluoroethylene (PTFE), PEG-based polymers, fluorinated ethylene propylene (FEP) or nitinol.

19. Patient is on home oxygen.

20. Patient is morbidly obese (BMI ≥40 kg/m²).

21. Patient was admitted from a skilled nursing facility.

22. Patient has a limited life expectancy of less than 1 year.

23. Patient has an inability to be discharged within 1 day (one midnight stay) of the procedure. Examples include, but are not limited to, comorbid conditions, unable to admit the day of procedure, live too far away from treatment center, or insufficient post-operative family support.

24. Patient is currently participating in an investigational device or drug clinical trial.

25. Patient has other medical, social or psychological conditions that, in the opinion of the investigator, preclude them from receiving the pre-treatment, required treatment, and post-treatment procedures and evaluations.
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.

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