CONFIDENTIALITY STATEMENT

A Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the Ovation™ Abdominal Stent Graft System

Protocol Number 771-0006

NCT Number: NCT01092117

Revision: J (July 7, 2011)

Sponsor Name: TriVascular, Inc.

Address: 3910 Brickway Blvd.
Santa Rosa, CA 95403

Protocol Approval

Reviewed and approved by:

Shari L. Allen
Vice-President, Clinical, Regulatory, and Quality

15 Aug 2011
Date

Protocol Signature Page

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I have read this protocol, including all appendices, and I agree that it contains all necessary details for me and my staff to conduct this study as described. I will personally oversee the conduct of the study as outlined herein, in accordance with FDA regulations 21 CFR 812, Good Clinical Practice (GCP) and the Declaration of Helsinki.

I will provide all study personnel under my supervision with access to this document and all pertinent information provided by TriVascular, Inc. I will discuss this material with them to ensure that they are fully informed regarding the investigational device, the safety and efficacy parameters, and the conduct of the study in general. I understand that I am responsible for providing adequate supervision of those to whom protocol-related tasks are delegated and that I am accountable for regulatory violations from failure to adequately supervise the conduct of the clinical study. I agree to provide all subjects with informed consent forms, as required by government and ICH regulations. I agree to report to TriVascular any adverse experiences in accordance with the terms of this protocol. Furthermore, I am aware that, prior to the commencement of this study, the Institutional Review Board responsible for such matters must approve this protocol for the clinical facility where it will be conducted.

Site Principal Investigator:

_____ _____
Investigator Name (Printed) Signature

_____
Date

TABLE OF CONTENTS

LIST OF APPENDICES

PROTOCOL SUMMARY

Sponsor	TriVascular, Inc.
Protocol Title	A Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the Ovation Abdominal Stent Graft System
Study Description	A prospective, consecutively enrolling, non-randomized multi center clinical evaluation of the safety and efficacy of the Ovation Abdominal Stent Graft System when used in the treatment of patients with AAA.
Study Objectives	The primary objectives of this study are to determine whether the Ovation Abdominal Stent Graft System is a safe and effective method of treating AAA's in those patients considered to be suitable candidates for open surgical repair. The safety of the Ovation Abdominal Stent Graft System will be determined by evaluating the proportion of subjects that experience a Major Adverse Event. The Major Adverse Event rate will be compared to a performance goal. The effectiveness of the Ovation Abdominal Stent Graft System will be determined by evaluating the proportion of subjects that achieve Treatment Success at 12 months post-procedure. The Treatment Success rate will be compared to a performance goal.
Study Primary Endpoints	The primary safety endpoint is defined as the proportion of subjects who experience a Major Adverse Event within 30 days of the initial procedure. The primary effectiveness endpoint is proportion of subjects that achieve Treatment Success. Treatment Success is a composite endpoint assessed at 12 months that requires the following criteria to be met: - Technical Success, defined as successful delivery and deployment of one aortic body and two iliac limbs. - Freedom from Type I & III endoleaks at 12 months - Freedom from stent graft migration at 12 months - Freedom from AAA enlargement at 12 months - Freedom from AAA rupture and conversion to open repair through 12 months

PROTOCOL SUMMARY

Study Secondary Endpoints	The secondary safety endpoints are: • Mortality rates at 30 days and 12 months • AAA related mortality at 30 days and 12 months • Major Adverse Events (MAE) through 12 months • AAA rupture through 12 months • Conversion to open repair through 12 months The secondary effectiveness endpoints will be evaluated through 12 months: • Technical success, defined as successful delivery and deployment of one aortic body and two iliac limbs. • Freedom from Type I & III endoleaks • Freedom from stent graft migration • Freedom from AAA enlargement • Freedom from loss of device integrity The secondary Clinical Utility endpoints will be evaluated: • Blood loss • Duration of procedure • Length of hospital stay • Type of anesthesia • Type of vascular access
Subject Population	Primary Study Phase - 150 subjects Continued Access Phase – 100 subjects
Follow-Up Intervals	Follow up intervals will consist of 1, 6, and 12 months following the initial implant procedure, then annually through 5 years.
Follow- Up Activities	Follow up activities will consist of: • Physical exam • Ankle Brachial Index (ABI) at Hospital Discharge • Contrast Enhanced Spiral Abdominal/Pelvic CT • Abdominal X-ray (KUB), including AP, lateral, left oblique and right oblique views • Device/aneurysm assessment based on imaging • Laboratory Assessment • Assessment of Adverse Events

PROTOCOL SUMMARY

Investigational Sites	Maximum of 40 sites

Anatomic Criteria	Proximal Neck Diameter:	16-30mm (ID)
	Proximal Neck Length:	≥7mm
	Juxtarenal Aortic Angle:	≤ 45 degrees if <10mm neck length
		≤ 60 degrees if ≥10mm neck length
	Iliac Diameter:	8-20mm
	Iliac Length: (Distal Seal Zone)	≥10mm
	Treatment Length:	13-19cm
Principal Investigators:	Dr. Manish Mehta Albany Medical Center	
Data Safety Monitoring Board (DSMB)	Axio Research Acquisition Co. LLC 2601 4th Avenue, Suite 200 Seattle, WA 98121 Phone: 206-547-2829 Fax: 206-547-4671	
Monitoring	TriVascular, Inc. 3910 Brickway Blvd. Santa Rosa, CA 95403	
Electronic Data Capture (Host)	Phase Forward 880 Winter Street Waltham, MA 02451 Phone: 781-890-7878 Fax: 781-890-4848	
Core Lab	M2S, Inc. 12 Commerce Avenue West Lebanon, NH 03784 USA Phone: 603-298-5509 Fax: 603-298-5055	

PROTOCOL

A list of all articles referenced in this protocol is contained in **Appendix I: References**.

1.0 STUDY GOAL

The goal of this study is to evaluate the performance of the Ovation Abdominal Stent Graft System in subjects with Abdominal Aortic Aneurysms. The specific goals of the study are to:

1. Evaluate the safety of the Ovation Abdominal Stent Graft System at 30, 180, 365-days and annually for 5 years post-implant.
2. Evaluate the ability to deliver the Ovation Abdominal Stent Graft System within the abdominal aorta.
3. Evaluate the ability of the Ovation Abdominal Stent Graft to exclude the abdominal aortic aneurysm.

2.0 BACKGROUND AND RATIONALE

Abdominal aortic aneurysms (AAA) are the most commonly encountered aneurysm of the arterial system. Several factors are thought to contribute to the development of AAA's such as: advanced age, gender, previous family history of AAA, chronic obstructive pulmonary disease, hypertension, smoking, connective tissue disorders and atherosclerotic disease. Males are affected by aneurysmal disease more often than females.

The presentation of a AAA usually depends upon whether complications or symptoms have occurred. Many asymptomatic patients are diagnosed with a AAA upon routine examination by a physician for another problem or as a result of increased patient awareness through public screening programs. Symptoms such as acute onset of abdominal, back, or flank pain are a result of expansion of the aneurysm. Such symptoms can be an indication of impending rupture which may follow at a time that is unpredictable. Rupture of a AAA is a life-threatening clinical event necessitating emergent intervention. Many patients with a ruptured AAA die before reaching the hospital. Of the patients that do reach the hospital, about half of those patients survive. Fortunately, the rate of detecting and diagnosing AAA has increased in recent years. Improved imaging techniques and public screening programs for the aging population have contributed to this increase[1].

The overall objective in treating AAA is to prevent rupture and subsequent death. The natural history of untreated AAA is to progressively enlarge and consequently rupture. Although it is difficult to predict, it is generally accepted that the greater the diameter of a AAA, the greater the risk of rupture. According to a study of 300 patients over a 6-year time period, Guirguis et al[2] determined that the risk of rupture of abdominal aortic aneurysms with a diameter less than 5.0 cm is significantly lower than the risk of rupture of AAA's with a diameter of 5.0 cm or more. More recently, Brewster et al[3] reported in 2003 the risk of rupture for females having a 5 cm diameter AAA is equivalent to that of a male having a 6 cm diameter AAA.

2.1 Conventional Treatment of Abdominal Aortic Aneurysm

The current (standard) treatments for abdominal aortic aneurysms include "watchful waiting," surgical repair of the aorta using a fabric substitute, and endovascular repair of the aorta.

2.1.1 Watchful Waiting

If the AAA is small and not causing symptoms, the treating physician may perform a CT or MRI scan every 6 months to assess changes in the size or shape of the aneurysm. This method is usually used for aneurysms that are smaller than about 5 cm in diameter.

If the AAA is large, grows quickly, or is causing symptoms, it will require prompt treatment to prevent rupture. The active treatments for AAA are open surgical aneurysm repair and endovascular stent graft repair.

2.1.2 Open Surgical Repair

Until the early 1990's, open surgical repair was the only standard treatment for AAA. Significant inherent mortality and morbidity risks are associated with open surgical repair due to the invasive nature of this surgery. The standard surgical procedure involves resection of the diseased segment of the aorta and replacement with a synthetic graft. This surgical technique necessitates general anesthesia, aortic cross-clamping, and significant blood loss with associated transfusions.

Improvements in mortality and morbidity rates for open surgical repair have been noted in the last several decades[4]. The rate of early operative mortality for open surgical repair varies

greatly, (between 3-6%) throughout the published literature. In a prior FDA Health Notification, the reported range for early mortality rates in population-based series for elective open surgical repair was between 3-5% at 30 days[1]. In a literature review study conducted in 2001 by Hallin[5], the mortality rate for elective surgical repair was noted to be approximately 5%, and approximately 50% for emergent surgical repair. In a recent multi-center AAA clinical trial evaluation of open versus endovascular treatment conducted by W. L. Gore & Associates, Matusmura[6] reports the rates of major adverse events were significantly lower in the endovascular group (14%) than those in the control group (57%). Patients in the endovascular treatment group experienced less blood loss, a reduction in need for transfusions and a shorter length of hospital stay.

Significant mortality and morbidity have been associated with the surgical repair of AAAs, particularly in elderly patients with multiple comorbid medical conditions. Surgical complications have mainly been associated with the surgical incision, patient co-morbidities, cardiopulmonary bypass, and anticoagulation. Postoperative complications have included bleeding, renal insufficiency, paraplegia, stroke, and the need for prolonged ventilatory support. The literature demonstrates mortality rates for elective surgery to be 0–6.1%, with 2.7% as the average. The following outlines morbidities associated with elective conventional surgery.

Complication	Range	Average*
All Cardiac (includes myocardial infarction, congestive heart failure, and new cardiac arrhythmias)	0.8 – 21%	12%
Pulmonary (includes pneumonia and pulmonary insufficiency, does not include atelectasis)	0 – 23%	8.4%
Renal Failure (chronic and acute)	0 – 9%	4.2%
Cerebrovascular Accident	0 – 11%	1.9%
Paraplegia or Paraparesis	0 – 0.6%	<0.1%
Vascular	0 – 5.7%	1.1%
Thrombotic/embolic	0 – 5.0%	1.8%
Gastrointestinal	0 – 14%	4.2%
Impotence	0 – 1.8%	0.2%
Hematoma	0 – 1.8%	0.2%
Bleeding/coagulopathy	0 – 44%	5.9%
Wound healing/infection	0 – 7.1%	2.2%

*Averages are unweighted from a review of the literature listed in **Appendix II: References Related to Complications**.

2.1.3 Endovascular Stent Graft Repair

Since the early 1990's, endovascular abdominal aortic repair (EVAR) has evolved as an alternative treatment for AAA. In 1991 Parodi was one of the first to introduce endovascular aneurysm treatment as a less invasive procedure. Since that time, systems for performing endovascular repair of AAA have been developed, improved upon, clinically tested, and approved by FDA for commercial use. The availability of this less invasive technique has

afforded the treatment of patients with multiple co-morbidities. These patients may have otherwise been excluded from treatment with open surgical repair[7].

Endovascular grafts, often stented for support, are designed to provide an alternate conduit for blood flow and should exclude the aneurysm from this flow and the associated hemodynamic pressure. Exclusion of the aneurysm is presumed to significantly reduce its potential for rupture.

Endovascular repair of AAA involves the placement of a stent graft at the location of the aneurysm without the need for performing an open surgical procedure. This technique is less traumatic for the patient by eliminating the need for aortic clamping, thereby eliminating or reducing the risks associated with decreased blood flow to vital organs and to the lower extremities. Additionally, anesthetic and ventilation time during these procedures are reduced. An endovascular approach also eliminates a significant amount of postoperative pain and discomfort associated with that of open surgical repair and allows a shorter recovery time for the patient. The length of hospital stay is reduced, thus, allowing patients to more rapidly resume their normal activities of daily living.

During the last 10 years, systems for performing endovascular repair of AAA have been developed, clinically tested, and approved for use. At the present time, there are approximately five (Excluder, Zenith, Powerlink, Talent, AneuRx) devices approved for use in the United States, six to eight devices approved for use in Europe, and several devices approved for use in Australia. The following outlines morbidities associated with endovascular repair.

Complication	**Range**	**Average***
All Cardiac (includes myocardial infarction, congestive heart failure, and new cardiac arrhythmias)	0 – 12%	4.9%
Pulmonary (includes pneumonia and pulmonary insufficiency, does not include atelectasis)	0 – 7.7%	2.6%
Renal Failure (chronic and acute)	0 – 6.5%	3.0%
Cerebrovascular Accident	0 – 2.8%	0.3%
Paraplegia or Paraparesis	0 – 0.2%	<0.1%
Access/Deployment Failure	0 – 11%	5.0%
Endoleak	6.5 – 47%	21%
Vascular	0 – 14%	5.1%
Thrombotic/embolic	0.9 – 18%	7.7%
Gastrointestinal	0 – 4.8%	1.4%
Impotence	0%	0%
Hematoma/bleeding/coagulopathy	0 – 24%	5.7%
Wound healing/infection	0 – 14%	3.0%

*Averages are unweighted from a review of the literature listed in **Appendix II: References Related to Complications**.

The literature demonstrates mortality rates for endovascular repair to be 0–7.5%, with 3.4% as the average. This rate is inflated, to some extent, by the utilization of endovascular repair in patients who are not candidates for surgical repair because of co–morbidities that dramatically increase the risk associated with the surgical procedure. For the systemic morbidities (cardiac, pulmonary, renal, cerebrovascular, and gastrointestinal), the rates for endovascular repair appear to be lower than for surgical repair. The statistical significance of this observation, however, has not been assessed.

During the clinical evaluation of the AneuRx Stent Graft System for AAA repair, patients in the endovascular repair group had lower blood loss, fewer days in the ICU, and a shorter hospitalization in comparison to the patients in the surgical control group. The difference for each of these measures was statistically significant. Similarly, the clinical evaluation of the ANCURE System demonstrated that the endovascular repair group experienced a statistically significant lower blood loss and a shorter hospitalization than the patients in the surgical control group.

3.0 INDICATIONS

The Ovation Abdominal Stent Graft System is indicated in subjects diagnosed with an aneurysm in the abdominal aorta having vascular morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with vascular access techniques, devices, and/or accessories,
- Non-aneurysmal proximal aortic neck:
  - with a length of at least 7 mm proximal to the aneurysm,
  - with an inner wall diameter of no less than 16 mm and no greater than 30 mm, 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,
- Non-aneurysmal distal iliac landing zone:
  - with a length of at least 10 mm,
  - with an inner wall diameter of no less than 8 mm and no greater than 20 mm.

4.0 DEVICE DESCRIPTION

The TriVascular Ovation™ Abdominal Stent Graft System is a low-profile endovascular device delivered via catheter to treat abdominal aortic aneurysms (AAAs). The stent graft is designed to reline the diseased vasculature, providing an alternate endovascular blood conduit for isolating the aneurysm from the high pressure flow of blood, thereby reducing or eliminating the risk of rupture. The stent graft is a modular configuration comprised of an aortic body section, iliac limbs, and iliac extensions as required (Figure 1).

The aortic section is comprised of a proximal stent for supra-renal fixation and a low-permeability PTFE graft. The stent is designed with small anchors to enable fixation to the aortic wall. For delivery, the stents are in a compressed state within the catheter. When released from the compressed state, the stent expands to engage the vessel wall. The nitinol stents are radiopaque and the implant contains radiopaque markers adjacent to the graft edges. These markers serve as positioning aids during placement of the device and allow the stent to be located so that it will not obstruct the renal arteries. To seal the proximal end of the graft and to provide support into which the iliac limbs are deployed, the graft body contains a network of inflatable rings that are filled with a liquid polymer which solidifies during the deployment procedure. The graft has a fill port that connects the fill network of the graft to the delivery catheter.

The iliac limbs and extensions are comprised of nitinol stents encapsulated in PTFE. The limbs are deployed into the limb section of the aortic body. Radiopaque markers allow the physician to visualize the appropriate iliac limb - aortic body overlap or iliac extension – iliac limb overlap during a catheter-based deployment. Stent radial force provides both fixation and sealing of the interface between the aortic body and each iliac limb, between the iliac limb and iliac extension, and between the iliac limb/extension and its landing zone in the iliac artery.

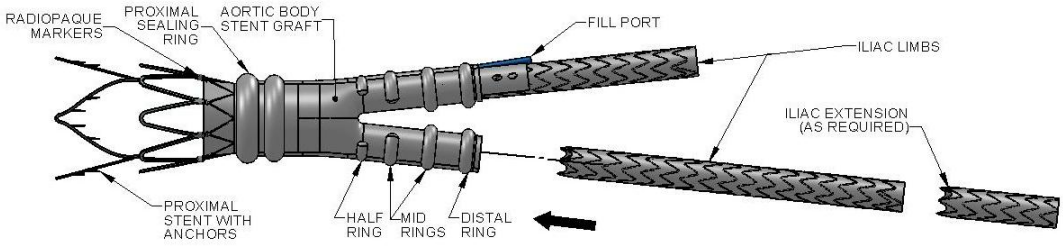

Figure 1. Schematic of Deployed Ovation Abdominal Stent Graft System

To facilitate device introduction into the access vessel, the aortic body, the iliac limbs and the iliac extensions are preloaded into low-profile delivery catheters (14F-15F OD, 13F–15F OD, and 13F-14F OD respectively; Figures 2 and 3). The aortic body is deployed via the aortic body delivery catheter. The aortic body delivery catheter has a lumen that allows for the use of a guidewire to help deliver the stent graft to the deployment site.

During stent graft deployment, the device is positioned and the sheath is retracted. The proximal stent is then deployed using release knobs on the handle. The fill polymer is then delivered through the fill connector port using an auto injector (supplied).

The contralateral and ipsilateral iliac limbs are deployed via iliac limb delivery catheters. After deployment of the aortic body, a guidewire is placed from the contralateral access site into the contralateral distal leg of the aortic body. The contralateral iliac limb is then advanced into position and deployed into the aortic body by retracting the catheter sheath with the catheter in the appropriate location. After the fill material cures within the sealing rings, the aortic body delivery catheter is disengaged from the fill port of the graft and withdrawn from the vasculature. The ipsilateral limb is then advanced over the ipsilateral guide wire and deployed using the method described above for the contralateral limb.

If an iliac extension is required, the delivery system is advanced over the guide wire and deployed using the method described above for contralateral and ipsilateral iliac limbs.

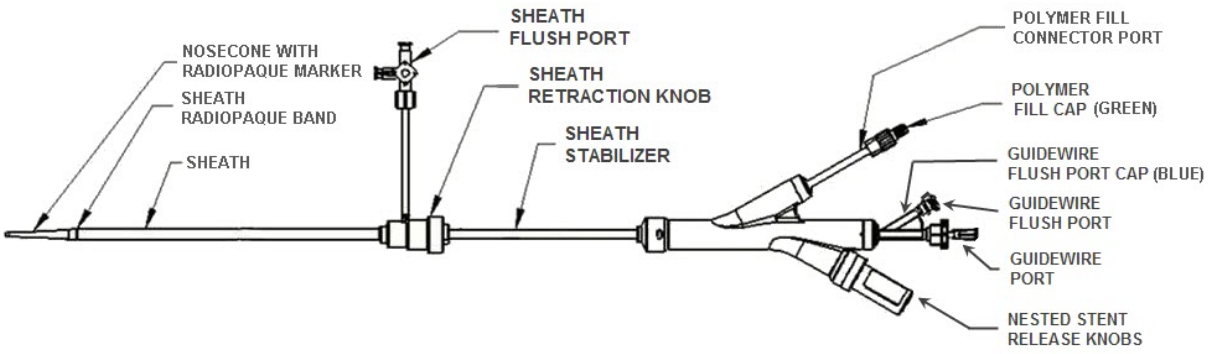

Figure 2. Schematic of TriVascular Ovation Stent Graft aortic body delivery catheter

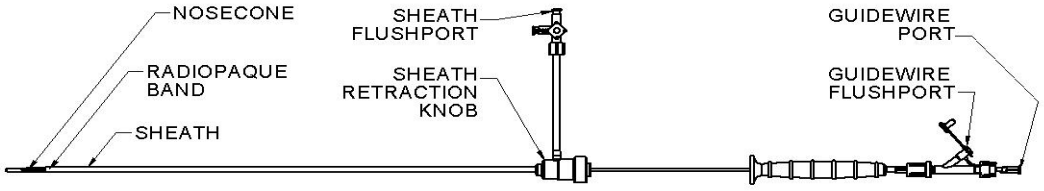

Figure 3. Schematic of TriVascular Ovation Stent Graft iliac limb/extension delivery catheter

The fill polymer is comprised of three components and is supplied in kit form as shown in Figure 4. Upon mixing and injection into the graft, the components form a robust radiopaque polymer network that is durable *in vivo*. Once inside the PTFE channels in the wall of the aortic body graft, the fill polymer forms conformable "gasket-like" sealing rings. The fill polymer radiopacity dissipates over time and may not be visible on fluoroscopy beyond 1-2 months post-implant.

Just prior to use, the two valves on the kit are opened and the fill polymer is mixed by alternately depressing the two syringe plungers for a total of 15 strokes. Thereafter, the full syringe is disconnected from the connection tube, slipped out of the syringe support and connected to the fill polymer injection port on the catheter handle. The syringe plunger is then inserted into the autoinjector (Figure 5) and the syringe given a quarter-turn to lock it in place. The autoinjector applies controlled pressure to inject the fill polymer into the graft without requiring continuous attention from the operator.

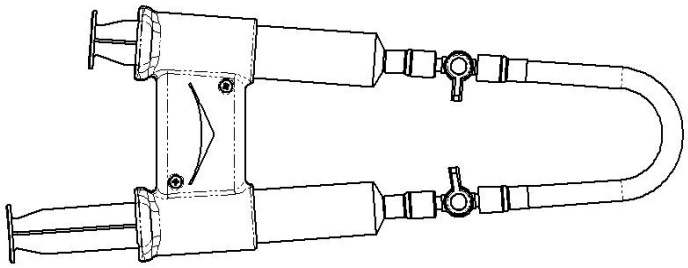

Figure 4 – TriVascular Fill Polymer Kit

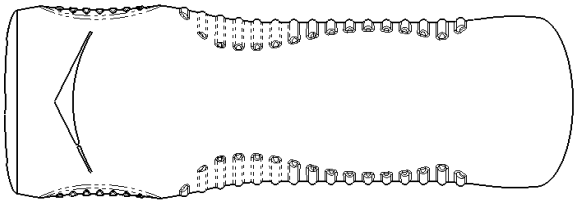

Figure 5–TriVascular Autoinjector

5.0 STUDY DESIGN

This is a Phase II prospective, consecutive enrolling, non-randomized multi-center clinical evaluation of the safety and effectiveness of the TriVascular Stent Graft when used in the treatment of patients with AAA.

A total of 150 subjects will be enrolled during the primary study phase with an additional 100 subjects enrolled during the continued access phase at up to 40 institutions. No one institution may enroll more than 30 subjects.

5.1 Eligibility Criteria

5.1.1 Inclusion Criteria

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

1. Patient is $\geq$ 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; refer to **Appendix III: ASA Classification System**). 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:
   - Abdominal aortic aneurysm $\geq$5.0 cm in diameter
   - Aneurysm has increased in size by 0.5 cm in last 6 months.
   - Maximum diameter of aneurysm exceeds 1.5 times the transverse dimension of an adjacent non-aneurysmal aortic segment
6. Patient has patent iliac or femoral arteries that allow endovascular access with the TriVascular Ovation Abdominal Stent Graft System.
7. Patient has a suitable non–aneurysmal proximal aortic neck length of $\geq$ 7 mm inferior to the most distal renal artery ostium.
8. Patient has a suitable non-aneurysmal distal iliac artery length (seal zone) of $\geq$10 mm. The resultant repair should preserve patency in at least one hypogastric artery.
9. Patient has a suitable non–aneurysmal proximal aortic neck luminal diameter between 16 and 30 mm.
10. Patient has suitable non–aneurysmal distal iliac luminal diameters between 8 and 20 mm.
11. Patient meets the following anatomic criteria: the distance from the most distal renal artery to most superior internal iliac artery measurement is at least 13 cm.
12. Patient has juxtarenal aortic neck angulation $\leq$ 60º if proximal neck is $\geq$10 mm and $\leq$ 45º if proximal neck is <10 mm.
13. Patient must be willing to comply with all required follow-up exams.

5.1.2 Exclusion Criteria

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

1. Patient has a dissecting aneurysm
2. Patient has an acutely ruptured aneurysm
3. Patient has an acute vascular injury
4. Patient has a need for emergent surgery
5. Patient has a known thoracic aortic aneurysm or dissection.
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 had a myocardial infarction (MI) and/or stroke (CVA) within the past 6 months.
9. Patient has a major surgical or interventional procedure planned ≤30 days of the AAA repair.
10. Patient has history of connective tissue disease (e.g., Marfan's or Ehler's–Danlos syndrome).
11. Patient has history of bleeding disorders or refuses blood transfusions.
12. Patient has dialysis dependent renal failure or baseline serum creatinine level >2.0 mg/dl
13. Patient has a known hypersensitivity or contraindication to anticoagulation or contrast media that is not amenable to pre-treatment.
14. Patient has a known allergy or intolerance to polytetrafluorethylene (PTFE), PEG-based polymers, fluorinated ethylene propylene (FEP) or nitinol.
15. Patient has a body habitus that would inhibit X–ray visualization of the aorta
16. Patient has a limited life expectancy of less than 1 year
17. Patient is currently participating in another investigational device or drug clinical trial
18. 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.

5.2 Study Population

5.2.1 Subject Selection

Adult male and female patients will be consecutively screened for the study. Eligible patients must meet all of the inclusion criteria and none of the exclusion criteria.

The study includes 150 subjects enrolled during the primary study phase with an additional 100 subjects enrolled during the continued access phase.

5.3 Withdrawal and Lost-to-Follow-Up

Subjects may be withdrawn from the study for any of the following reasons:

- Lost-to-follow up despite exhaustive attempts to contact. A minimum of three (3) attempts to contact such subjects must be made. One such attempt must include a registered return receipt requested letter. All attempts to contact the subjects must be documented.

- Subjects may voluntarily decide to withdraw from the study. All reasonable attempts should be made to ascertain the reason for voluntary withdrawal.

All subject withdrawals must be documented on the **Study Completion/Exit Case Report Form (eCRF)**.

5.4 Duration of Study

Subject follow-up visits will occur at one, six, and 12 months post implant procedure then annually through five years. Lifelong follow-up by the physician is required after subjects have completed the study.

6.0 STUDY PROCEDURES

Treatment of subjects enrolled in this study will include tests and procedures listed in **Appendix IV: Schedule of Activities**. Placement of the AAA stent graft will be performed in accordance with the IFU.

6.1 Patient Screening

Prospective candidates are evaluated in a consecutive manner for eligibility for the study at the time they are considered to be candidates for AAA repair. Initial screening may include diagnostic testing (e.g., imaging, angiogram, laboratory testing) performed as part of routine medical care.

The following steps outline the process to determine patient eligibility for enrollment and subsequent shipment of the device(s):

1. Ensure that patient has signed an IRB approved Informed Consent Form, per Institutional policies
2. Complete the Eligibility Verification Worksheet form
3. Complete the AAA Pre-Operative Sizing Worksheet
4. Fax #2 and #3 (above) to TriVascular Clinical Department (888-706-1617)
5. Submit contrasted spiral CT images to Core Lab obtained within 6 months of anticipated treatment.

Refer to Manual of Operations for Core Lab Imaging Guidelines.

6.2 Pre-procedure evaluation

The following assessments will be performed no more than one month prior to the implant/surgical procedure:

- Patient demographics
- Medical/surgical history
- Physical exam
- Ankle-Brachial Index (ABI) measurement
- Laboratory testing, which includes renal and coagulation assessment, as well as serum pregnancy for female patients of childbearing potential.

If the patient is eligible to be enrolled into the study, the results of these screening assessments are recorded on the **Baseline eCRF**. If a patient does not qualify for enrollment into the study, the baseline screening worksheets will be retained, together with the patient's signed/dated consent(s).

6.3 Treatment period (implant/surgical procedure)

The following assessments and data collection will be performed at the time of the implant/surgical procedure:

- Investigational device accountability- documentation of product information (e.g., lot number, serial number, and expiration date).
- Type and length of anesthesia
- Anticoagulation
- Description of delivery system access on both ipsilateral and contralateral sides (e.g. femoral cut down, percutaneous access, closure device)

- Type and volume of contrast used
- Total fluoroscopy time during procedure
- Estimated blood loss and replacement requirements
- Adjunctive procedures (e.g. stent placement)
- Investigator assessment of AAA device performance as it relates to:
    - Access success/failure, delivery/deployment success, evidence of endoleak, device integrity issues
- Procedural times (time of initial arterial access, stent graft deployment start and stop time, polymer mix completion time, delivery system removal time, and time of closure of arterial access)
- Adverse events

6.4 Pre-Discharge

The following assessments and testing will be performed post-procedure, prior to discharge:

- Physical exam
- Ankle-Brachial Index (ABI) measurement
- Laboratory testing, which includes renal and optional coagulation assessment
- Length of hospital stay
- Abdominal X-ray (KUB), including AP, lateral, left oblique and right oblique views. This X-ray will serve as the baseline for all future evaluations of device integrity and can be performed within 7 days following hospital discharge.
- Concomitant medications (anticoagulants, antiplatelets and antibiotics only)
- Adverse events
- Other relevant data as indicated on the CRF, including optional wound assessment.

The above assessments are recorded in the **Hospital Discharge eCRF.** In some instances, subjects may experience a prolonged hospitalization post procedure. In those cases, the above assessments should be performed no more than two (2) weeks post procedure.

6.5 Post-Treatment follow-up period

The following assessments and tests will be performed at the following intervals:

Time period post-treatment	Acceptable visit timeframe allowance
1 Month (30 days)	**± 14 days**
6 Months (180 days)	**± 30 days**
12 Months (365 days)	**± 60 days**
Annually from 2 to 5 years	**± 60 days**

- Physical exam
- Laboratory testing, which includes renal and optional coagulation assessment
- Contrast Enhanced Spiral Abdominal/Pelvic CT
- Abdominal X-ray (KUB), including AP, lateral, left oblique and right oblique views Device/aneurysm assessment based on imaging (endoleak, migration, integrity, patency, AAA dimensions)
- Concomitant medications (anticoagulants, antiplatelets and antibiotics only)
- Adverse events
- Other relevant data as indicated on the CRF including optional wound assessment.

The above assessments are recorded in the appropriate **Follow-up Visit eCRF.** 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.

6.6 Unscheduled Follow-up visits

In the event that a subject visit occurs outside the protocol-specified time frames (i.e., Pre-discharge, 1 month, 6 month, 12 month) sites are required to record data from that visit, if that visit is specifically associated with the device, procedure or aneurysmal disease. Possible reasons for unscheduled visit data collection may be:

- Subject experiences new symptomatology and/or an adverse event
- Surveillance of an existing adverse event

The Unscheduled visit information would be recorded in the **Follow-up Visit eCRF where the reason for the unscheduled visit will be specified.**

If a subject is seen in the office or clinic for other reasons than listed above, information from that visit would be recorded on the next protocol-specified visit in the appropriate **Follow-Up CRF.**

6.7 Annual follow-up visits

Subjects who have completed 12 months of follow-up will continue annual follow-up exams (+/- 2 months) for 5 years.

The following assessments and tests will be performed at annual visits through 5 years:

- Physical exam
- Laboratory testing, which includes renal and optional coagulation assessment
- Contrast Enhanced Spiral Abdominal/Pelvic CT
- Abdominal X-ray (KUB), including AP, lateral, left oblique and right oblique views
- Device/aneurysm assessment based on imaging (endoleak, migration, integrity, patency, AAA dimensions)
- Concomitant medications (anticoagulants, antiplatelets and antibiotics only)
- Adverse events
- Other relevant data as indicated on the CRF, including optional wound assessment.

6.8 Discontinuation from study

Subjects who choose to discontinue participation in the study prior to study completion will be requested to undergo a final assessment by the investigator at the time notification is made of their decision to discontinue. If the subject notifies the clinical site of discontinuation by mail or phone, subject will be requested to have a final assessment by the investigator.

The final assessment will be recorded in the **Follow-up Visit** and **Study Completion/Exit eCRFs.**

7.0 STUDY OBJECTIVES

The purpose of this pivotal clinical trial is to evaluate the safety and effectiveness of the Ovation Abdominal Stent Graft in the treatment of subjects with abdominal aortic aneurysms (AAA).

7.1 Primary Objectives

The primary objective of this study is to determine whether the Ovation Abdominal Stent Graft System is a safe and effective method of treating AAAs in those subjects considered to be suitable candidates for open surgical repair.

The safety of the Ovation Abdominal Stent Graft System will be determined by proportion of subjects with major adverse events.

The effectiveness of the Ovation Abdominal Stent Graft System will be determined by the proportion of subjects that achieve treatment success.

8.0 DEFINITIONS

8.1 Endoleak

Endoleak is defined by the persistence of blood flow outside the lumen of the endovascular graft but within the aneurysm sac and can be classified as:

Type I – Ineffective seal at either the proximal or distal sealing zones

Type II – Retrograde blood flow from lumbar arteries, the inferior mesenteric artery, or other collateral vessels into the aneurysm sac

Type III – A leak caused by fabric tears or disruption, component disconnection, or graft disintegration

Type IV – Blood flow through an intact fabric.

8.2 Migration

Migration is defined as evidence of proximal or distal movement of the stent graft >10mm relative to fixed anatomic landmarks. Spiral CT images will be used to determine migration at regularly scheduled follow-up visits. The 1 month image will be used as the baseline assessment.

8.3 Patency

Patency is defined as the absence of complete occlusion of the treated vessel. This may be evidenced by: CT, angiography, ultrasound or other imaging modality, or pathological analysis.

8.4 Loss of Stent Graft Integrity

The integrity of the stent graft will be evaluated by abdominal x-rays at regularly scheduled follow-up visits. Any fractured stents, and any other issues compromising the integrity of the stent graft will be reported.

8.5 AAA Enlargement

Aneurysm enlargement is defined as a greater than 5 mm (diameter) increase in the aneurysm size. Spiral CT images will be used to determine aneurysm enlargement at regularly scheduled follow-up visits. The 1 month image will be used as the baseline assessment. In addition, aneurysm volume will be assessed by the Core Lab and reported in the data analysis, but diameter is considered the relevant characteristic for the study endpoint evaluations.

8.6 Surgical Conversion

Surgical conversion occurs when a subject implanted with an Ovation Abdominal Stent Graft undergoes open surgical repair with explantation of the stent graft. The follow-up for subjects who are converted to open surgical repair include collection of the following data: Physical Exam and assessment of Adverse Events. The visits are to occur at 1 month post open conversion and 1 year post open conversion.

8.7 Imaging Core Lab

TriVascular will utilize an independent imaging Core Lab to analyze device performance specifically related to study endpoints such as: device integrity, endoleaks, migration, and aneurysm dimensions (e.g., length, diameter, volume). Clinical sites will submit all CT and X-ray images to the Core Lab for all required study visits.

Study Visit	Images* Required to be submitted to Core lab
Baseline (pre-op)	Contrast Enhanced Spiral Abdominal/Pelvic CT
Discharge (post-op)	Abdominal X-rays (AP, lateral, left oblique and right oblique views)
1 month (16 - 44 days)	Abdominal X-rays (AP, lateral, left oblique and right oblique views) Contrast Enhanced Spiral Abdominal/Pelvic CT
6 month (150 - 210 days)	Abdominal X-rays (AP, lateral, left oblique and right oblique views) Contrast Enhanced Spiral Abdominal/Pelvic CT
12 month (305 - 425 days)	Abdominal X-rays (AP, lateral, left oblique and right oblique views) Contrast Enhanced Spiral Abdominal/Pelvic CT

*Refer to **Appendix VI: CT Scanning Techniques** and Manual of Operations for Core Lab imaging requirements.

8.8 Explant Evaluation

TriVascular is committed to understanding the effects of the human *in vivo* environment on the stent graft over time. To this end, all explanted devices should be returned to TriVascular for evaluation by a Pathologist at an independent Explant Laboratory. Refer to **Appendix VII: Explant Procedure** and the Manual of Operations for specific instructions for managing the removal, shipping, and handling of the explanted AAA device.

8.9 Adverse Events

An adverse event is any new, undesirable medical occurrence or change (worsening) of a pre-existing condition that occurs in a subject, whether or not considered to be associated with the product. Elective hospitalizations for pre-existing conditions (e.g., elective cosmetic procedures) are not adverse events.

Requirements for reporting AEs are dependent upon the reviewing IRB policy. Adverse events will be reviewed by a Clinical Events Committee (CEC). The CEC will meet periodically, a minimum of annually.

Adverse Event information is recorded in the **Adverse Event eCRF**.
For purposes of this study, the following events are not considered adverse events, because they are expected to occur in conjunction with the index procedure or are associated with customary, standard care of subjects undergoing endovascular AAA repair procedures:

- Early post-operative pain (within 24 hours of index procedure) at the access site and/or related to position on procedure table

- Post-anesthesia/conscious sedation emesis, nausea, or headache (within 24 hours of index procedure)
- Electrolyte imbalance without clinical sequelae following index procedure, even if requiring correction
- Low grade temperature increase (< 101.0 °F)
- Hematocrit decrease from baseline of less than 6 points (2 grams of hemoglobin) that remains above 30% and is not associated with hemodynamic changes and does not require transfusion
- Blood loss not requiring transfusion and not resulting in decreased hematocrit.
- Minor, localized tenderness, swelling, induration, bruising, erythema, hematoma etc. at vascular access site that does not require surgical intervention, evacuation, transfusion, or antibiotics
- Prophylactic administration of atropine
- Prophylactic pacing
- Isolated, non-sustained PVCs/PACs
- Non-sustained, arrhythmia not requiring treatment or intervention
- Hypotension or hypertension not requiring treatment or intervention
- Atelectasis not requiring treatment

The Investigator and/or IRB may require that these events are reported as adverse events. In this case, the Investigator should report these observations based on their medical judgment and requirements of the IRB.

Device-related adverse events should be reported to the sponsor within 24 hours of knowledge of the event.

8.10 Serious Adverse Events (SAE)

A serious adverse event (SAE) defined as one that suggests a significant hazard or side effect, regardless of the investigator or sponsor's opinion on the relationship to the investigational product. This includes, but may not be limited to, any event that:

- Is fatal
- Is life-threatening
- Requires or prolongs (>48 hours) inpatient hospitalization
- Is a persistent or significant disability or incapacity
- Is considered an important medical event

Important medical events may be considered serious by the investigator although they may not be immediately life threatening or result in death or prolong hospitalization. Such important medical events are those that may jeopardize the subject, require intervention to prevent one of the outcomes listed above, or result in urgent investigation. Examples include, but are not limited to, allergic bronchospasm, convulsions, and blood dyscrasias.

Serious Adverse Events will be recorded in the Adverse Event CRF and the event is to be reported by telephone or fax to the Sponsor within 24 hours of knowledge of the event. Sites are also required to adhere to the reviewing IRB requirements for reporting of SAE's.

8.11 Major Adverse Events (MAE)

The following specific events will be considered major adverse events (MAE) for the purpose of evaluating the primary (30 day) and secondary (1 year) safety endpoints:

Major adverse events (MAE) are defined as any one of the following events:

- Death
- Myocardial Infarction
- Stroke (excludes TIA)
- Renal Failure (excludes renal insufficiency)
- Respiratory Failure (excludes COPD or pulmonary complications)
- Paralysis (excludes paraparesis)
- Bowel Ischemia
- Procedural Blood Loss (≥1,000 cc)

A major adverse event (MAE) may or may not be considered related to the device. Mortality will be reported as "all cause" and "AAA related." All deaths occurring in the first 30 days post-index procedure are considered "AAA related."

The Clinical Events Committee (CEC) shall determine which adverse events are considered Major Adverse Events (MAE) for evaluation of the primary (30 days) and secondary (1 year) safety endpoints.

8.12 Unanticipated Adverse Device Effect (UADE)

An unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Unanticipated Adverse Device Effect (UADE) are to be recorded in the Adverse Event CRF and the event is to be reported by telephone or fax (see above contact information) to the Sponsor within 24 hours of knowledge of the event. Sites are also required to adhere to the reviewing IRB requirements for reporting of any UADE.

8.13 Conversion to Open Surgical repair

Conversion to open surgical repair may occur either at the initial implant procedure or subsequent to the initial procedure. Information regarding the surgical conversion will be recorded on the Open Surgical **Conversion eCRF** and the **Adverse Event eCRF**.

In the event that a subject requires conversion from endovascular to open surgical repair, the explanted device should be sent to TriVascular for examination. Refer to the Manual of

Operations for specific instructions for managing the removal, shipping and handling of the explanted device. Explant information will be recorded on the **Explant eCRF**.

Surgical conversions must be reported by telephone or fax to the Sponsor **within 24 hours** of knowledge of the event.

The Follow-up visit schedule for surgically converted subjects is at one month and one year post open conversion.

8.14 Technical Failures

In the event that an AAA stent graft could not be deployed due to a technical failure, contact TriVascular Clinical Affairs to obtain device return information. Device failure information will be captured on the **Device Failure eCRF**.

8.15 Deaths

Any deaths that occur during the conduct of the study must be reported by telephone or fax to the Sponsor **within 24 hours** of knowledge of the event. Sites are also required to adhere to the reviewing IRB requirements for reporting of deaths. In addition, subjects with an implanted device who expire before completing the study should have the device explanted and sent to sponsor whenever possible for examination. Additional information to be submitted to sponsor may include such documents as: death certificate, autopsy report, summary of death report, hospital records, explant reports and copy of IRB notification of the event.

8.16 Explants

Specific instructions for managing the removal, shipping and handling of the explanted device can be found in **Appendix VII: Explant Procedure** and Manual of Operations. Explant information will be recorded on the **Explant eCRF**.

9.0 ENDPOINTS AND TECHNIQUES FOR MEASUREMENT

For the purpose of this study, the information below provides definitions and measurement criteria in determining each endpoint. The endpoints (primary and secondary) specified below and Statistical Considerations outlined in Section 10 may appear in the product labeling to support clinical results. Information not included in the endpoint list below or the statistical considerations will not appear in the labeling to support clinical results.

9.1 Primary Endpoints

9.1.1 Safety

The primary safety endpoint is the rate of major adverse events (MAE) at 30 days post procedure. The following specific events will be considered major adverse events:

Major adverse events (MAE) are defined as any one of the following events:

- Death
- Myocardial Infarction
- Stroke (excludes TIA)
- Renal Failure (excludes renal insufficiency)
- Respiratory Failure (excludes COPD or pulmonary complications)
- Paralysis (excludes paraparesis)
- Bowel Ischemia
- Procedural Blood Loss (≥1,000 cc)

A major adverse event (MAE) may or may not be considered related to the device. Mortality will be reported as "all cause" and "AAA related." All deaths occurring in the first 30 days post-index procedure are considered "AAA related."

9.1.2 Efficacy

The primary effectiveness endpoint is the proportion of subjects that achieve treatment success. Treatment success is a composite endpoint assessed at 12 months that requires all of the following criteria to be met in order for a subject to be considered a treatment success:

- Technical Success, defined as successful delivery and deployment of one aortic body and two iliac limbs.
- Freedom from Type I & III endoleak at 12 months
- Freedom from stent graft migration at 12 months
- Freedom from AAA enlargement at 12 months
- Freedom from AAA rupture and conversion to open repair through 12 months

9.2 Secondary Endpoints

9.2.1 Safety

The following secondary safety endpoints will be assessed:

- All-cause mortality at 30 days and 12 months
- AAA Related Mortality at 30 days and 12 months
- Major Adverse Events (MAE) through 12 months
- AAA rupture through 12 months

- Surgical conversion through 12 months

All deaths that occur in the study will be adjudicated by the CEC. AAA related death is any death determined by the CEC to occur as a result of the initial procedure (first 30 days), AAA rupture, conversion to open surgical repair, or any AAA related secondary intervention.

9.2.2 Stent Graft Efficacy

The following secondary efficacy endpoints will be assessed.

1) Technical Success

The physician was able to insert the delivery catheter and deliver an aortic graft and two iliac limbs to the treatment site.

2) AAA Enlargement

Any increase in aneurysm diameter (>5 mm) from the one month (baseline) post-operative measurement will be considered AAA enlargement, as determined by Core Lab.

3) Migration

Migration is defined as evidence of proximal or distal movement of the stent graft >10 mm relative to fixed anatomic landmarks. Spiral CT images will be used by Core Lab to determine migration from the one month (baseline) CT image.

4) Type I and III Endoleak

Type I and III endoleaks will be assessed by the Core Lab using Spiral CT images.

5) Device Integrity

The integrity of the stent graft will be evaluated from X-ray images by the Core Lab using the discharge X-ray as the baseline. Any fractured stents or other issues compromising the integrity of the stent graft will be reported.

9.2.3 Clinical Utility Assessment

The following secondary endpoints associated with the procedure will also be assessed:

- Procedure time
- Amount of blood loss
- Days spent in hospital
- Type of Anesthesia
- Type of Vascular access

10.0 STATISTICAL CONSIDERATIONS

10.1 Primary Endpoints and Hypotheses

10.1.1 Primary Safety Endpoint and Hypothesis: Major Adverse Event Rates

This study is designed to compare the rate of major adverse events following abdominal aortic aneurysm repair with the Ovation Abdominal Stent Graft System to a target performance goal. The proportion of subjects receiving the Ovation Abdominal Stent Graft who experience one or more events meeting the definition of a major adverse event within 30 days of the initial procedure is the rate of interest. The null and alternative hypotheses are given below:

$$H_0: \pi_T \geq 21\%$$

$$H_1: \pi_T < 21\%, \text{ where}$$

π_T is the expected proportion of subjects undergoing AAA repair with the Ovation Abdominal Stent Graft System who experience a major adverse event at 30 days. The target performance goal rate of 21% is that based on the 11% rate (plus 10% "non-inferiority" margin) of major adverse events at 30 days reported for the Medtronic Talent device (reported in the Medtronic Talent Summary of Safety and Effectiveness Data 2008).

10.1.2 Primary Effectiveness Endpoint and Hypothesis: Treatment Success at 12 Months

Treatment success is the primary effectiveness endpoint for the study. The proportion of subjects who are treatment successes at 12 months is the rate of interest. The null and alternative hypotheses are as follows:

$$H_0: \pi \leq 80\%$$

$$H_1: \pi \geq 80\%, \text{ where}$$

π is the expected rate of treatment success. The Ovation Abdominal Stent Graft is considered to be effective if this study's result verifies that the lower limit of the one-sided 95% confidence interval for π is above 80%.

10.2 Statistical Sample Size Justifications for the Primary Study Phase

Should the rate of major adverse events be 11%, n=150 primary study subjects would provide 96% power to test the primary safety hypothesis at the one-sided 5% significance level.

It is anticipated that attrition through the 12 month visit may be approximately 15%. Hence 150 primary study subjects less 15% attrition would yield approximately 130 subjects with data available to assess the primary effectiveness endpoint at 12 months. Should the rate for the primary effectiveness composite endpoint equal 88.2%, then 130 subjects would provide 80% power to test the primary effectiveness hypothesis at the one-sided 0.05 alpha level. Sample size calculations were performed using the normal approximation in nQuery Advisor 6.02.

10.3 Statistical Methods for Primary Endpoints

10.3.1 Primary Safety Endpoint: Major Adverse Events:

Let n be the sample size and $z_{1-\alpha}$ denote the upper $(1-\alpha)$ quantile of the standard normal distribution. If the upper limit of the one-sided confidence interval for the true rate of Major Adverse Events is less than 21%, then the null hypothesis for safety will be rejected in favor of the alternative hypothesis. Therefore, the primary safety endpoint will be considered met if the upper bound of the 95% confidence interval for the measured value is less than the performance goal (21%), based on the major adverse event rate. An accurate estimate of the upper limit of a binomial proportion is presented by Agresti and Coull (Agresti 1998).[1] The Agresti-Coull upper limit of a one-sided 95% confidence interval for the true rate of major adverse events is estimated by Formula 1, where

Formula 1:

$$U = \frac{(2np + Z_{0.05}^2) + Z_{0.05}\sqrt{Z_{0.05}^2 + 4pn(1-p)}}{2(n + Z_{0.05}^2)}$$, where

p is the observed rate of Major Adverse Events and Z_u is the upper u-th percentile of the standard normal distribution. Hence $Z_{.05} = 1.645$.

10.3.2 Primary Efficacy Endpoint: Treatment Success

Let n be the sample size and $z_{1-\alpha}$ denote the upper $(1-\alpha)$ quantile of the standard normal distribution. If the lower limit of the one-sided confidence interval for the true rate for treatment success is greater than 80%, then the null hypothesis defined in Section 10.1.2 will be rejected in favor of the alternative hypothesis. Using the same approach to calculate the confidence interval as used for the primary safety endpoint, the corresponding formula for the lower limit of the confidence interval is:

Formula 2:

$$L = \frac{(2np + Z_{0.05}^2) - Z_{0.05}\sqrt{Z_{0.05}^2 + 4pn(1-p)}}{2(n + Z_{0.05}^2)}$$, where

p is the observed rate of treatment success and Z_u is the upper u-th percentile of the standard normal distribution. Hence $Z_{.05} = 1.645$.

10.4 Secondary Statistical Endpoints

No hypothesis testing will be performed for secondary endpoints.

10.4.1 Secondary Safety Endpoints

Rates for all-cause mortality, AAA related mortality, major adverse events, AAA rupture, and surgical conversion will all be calculated at 30 days and 12 months. The Kaplan-Meier estimates will be presented with 95% confidence intervals.

10.4.2 Assessment of Clinical Utility

Estimation of Mean Volume of Blood Loss
For each subject, the amount of blood loss is the outcome variable. The mean and standard deviation of blood loss values and 95% confidence intervals will be provided.

Estimation of Mean Duration of Procedure, Overall Hospital Stay
The objective is to estimate mean duration of procedure (minutes), mean time from hospital admission to discharge (days) and duration of anesthesia (minutes). For each outcome the mean, median, standard deviation and 95% confidence interval will be provided.

Anesthesia Type
The objective is to estimate the rate of general anesthesia use.

Vascular Access Type
The objective is to assess the rate of femoral vs. percutaneous access used. The rates will be presented as a percent with 95% confidence interval.

10.4.3 Effectiveness

All secondary effectiveness endpoints are categorical in nature. Technical success is only measured peri-operatively and will be presented as a percent with 95% confidence interval. All the remaining effectiveness endpoints will be presented by visit, as percents with 95% confidence intervals. Endoleak will be reported by type.

10.5 Assumption Verification

Visual inspection and statistical tests will be used to determine if the study variables are consistent with the assumptions of statistical tests proposed. For continuous variables, test of normality will be done by Shapiro-Wilks test or equivalent.

10.6 Study Retention and Handling of Missing Data

Every effort will be made to collect all data points in the study. The sponsor plans to minimize the amount of missing data by appropriate management of the prospective clinical trial, proper screening of study subjects, and training of participating investigators, monitors and study coordinators. Primary analyses will be performed on an intent-to-treat basis. All partial data that is available on subjects who drop out during the course of the study will be included.

In order to evaluate the effect of missing data on the primary outcomes a sensitivity analysis will be performed. The sensitivity analysis will include evaluating the primary outcomes using a best-case scenario (assuming missing data for the subjects are successes) a worse-case analysis (assuming all missing data for the subjects are failures), and a tipping point analysis as described by Yan 2009.[2] A multiple imputation analysis will also be performed using logistic regression to further evaluate the effect of missing data on the primary outcome (Little 2001).[3]

10.7 Poolability

Data will be pooled from multiple study sites for this analysis. The justification for pooling is made on a clinical basis (Meinert, 1986).[4] This study will be conducted such that: 1) the same protocol will be used at each site; 2) site investigators and personnel will receive uniform training; and 3) central data management and monitoring will be applied with equal rigor at all

sites. The diversity of hospital and clinical practice settings will add to the scientific validity and generalizability of the findings**. Rates for the primary efficacy and safety endpoints will also be reported by clinical centers.**

10.8 Subject Populations for Analysis

Primary analysis will be performed on an intent-to-treat basis. The intent to treat group will include all subjects in which the delivery system is inserted into the access vessels.

10.9 Detailed Statistical Analysis Plan

Prior to database lock a detailed statistical analysis plan will be written to provide a detailed description of the statistical analysis to be used in the final analysis. This plan will incorporate lists of relevant variables to be included in multiple imputations analysis and will incorporate any protocol changes that would affect the analysis.

10.10 Statistical References

1. Agresti, A and Coull, B A (1998). Approximate is better than "exact" for interval estimation of bionomial proportions. The American Statistician, 52:119-126.
2. Yan, Xu, Lee, Shiowjen and Li, Ning (2009). Missing Data Handling Methods in Medical Device Clinical Trials. Journal of Biopharmaceutical Statistics, 19: 6, 1085-1098.
3. Little, R. and D Rubin (2001). Statistical Analysis with Missing Data. John Wilen and Sons, New York.
4. Meinert, C. (1986). Clinical Trials: Design, Conduct, and Analysis. Oxford University Press, New York.

11.0 RISK ANALYSIS

Treatment of an AAA with both endovascular and open surgical repair poses significant inherent risks to the subject. The mortality risk of open surgical repair of an AAA is greater for those subjects with significant surgical risk factors, such as age and comorbidities (e.g., cardiac, renal and pulmonary).[1]

Endovascular treatment of a AAA has been shown to be an effective, less invasive procedure that may result in reduced early mortality and factors related to morbidities, reduced time for anesthesia, need for blood products, shorter hospital stays and recovery time, as well as improved quality of life in the early postoperative period.

Risks to subjects are minimized initially by including those patients that are considered to be suitable candidates for open surgical repair and by selecting qualified investigators/institutions with endovascular experience to participate in the study. In order for patients to participate in this study, they must agree to adhere to a strict follow-up schedule to continuously monitor their long term safety.

The risks associated with the use of this study device are not currently known. Although the adverse events associated with the use of the Ovation Abdominal Stent Graft System may be less than for standard open surgical repair, inherent risks exist, as with many medical procedures. However, risks that have been associated with repair of AAAs with this type of device in clinical trials or that are currently marketed include, but may not be limited to:

- Cardiac events such as congestive heart failure (CHF), volume overload, arrhythmias, myocardial infarction (MI), chest discomfort or angina, elevations in creatinine phosphokinase (CPK), hypotension
- Pulmonary events such as pulmonary insufficiency, pneumonia, respiratory depression or failure, pulmonary edema, pulmonary embolism
- Cerebral events such as cerebrovascular accident (hemorrhagic or embolic), reversible ischemic neurologic deficit, transient ischemic attacks (TIA)
- Acute and chronic renal insufficiency or failure, renal microembolism
- Operative and post–operative bleeding disorders, hemorrhage and coagulopathy
- Insertion and other vascular access site complications such as infection, bleeding, delayed healing, hematoma, dehiscence, seroma, nerve injury/damage, neuropathy, neuralgia, vasovagal response
- Vascular injury including damage to blood vessels and surrounding tissues, vessel dissection, perforation, plaque dissection, collateral vessel occlusion, tissue loss, arterial fistula, limb loss, gangrenous disease, worsened or new onset claudication, edema
- Neurological complications, such as paralysis (temporary or permanent), paraplegia, monoplegia, paresis, spinal cord ischemia, hemiplegia, bowel or bladder incontinence
- Multi-system organ failure
- Embolic and thrombotic events such as deep vein thrombosis, thromboembolism, microembolism, thrombophlebitis, phlebothrombosis, pulmonary embolism, air embolism
- Gastrointestinal events such as ischemia, paralytic or adynamic ileus, obstruction, fistulas

- Impotence, erectile dysfunction
- Radiation injury, late malignancy
- Allergic reaction, such as flushing, nausea, vomiting, itching, hives, and/or anaphylactoid response to device materials (including polytetrafluorethylene [PTFE], PEG-based polymers, fluorinated ethylene propylene [FEP] or nitinol) and/or x–ray contrast dye
- Generalized inflammatory response that may be associated with elevated levels of systemic mediators of inflammation, elevated temperature
- General discomfort related to the procedure or tests, sore throat, pain
- Infection–urinary tract, systemic or localized, sepsis, endograft
- Device events such as endograft occlusion, migration, dislodgement, endoleak, and/or stent fracture
- Branch vessel occlusion
- Renal artery occlusion
- Aneurysm rupture
- Conversion to open surgical repair
- Death

Potential benefits of the Ovation Abdominal Stent Graft System compared to open surgical aneurysm repair may include, but are not limited to:

- Not having open surgery;
- Less time under general anesthesia and/or the ability to use other forms of anesthesia that do not require mechanical ventilation;
- Reduction of complications; and
- Reduction in hospitalization and recovery time.

Potential benefits of the Ovation Abdominal Stent Graft System compared to other commercially available endovascular AAA repair devices may include, but are not limited to:

- More robust seal between the graft and aorta, possibly reducing the risk that the graft will develop Type I or III endoleaks or migrate over time and;
- Lower risk of injury to the access vessels due to the low profile and more flexible delivery system compared to the commercially available devices.

12.0 STUDY RESPONSIBILITIES

12.1 Responsibilities of Sponsor

Sponsors are responsible for selecting qualified investigators and providing them with the information needed to properly conduct the investigation, ensure proper monitoring, IRB review and approval are obtained, submitting IDE application to the FDA and ensuring that reviewing IRBs and FDA are promptly informed of significant new information about the study.

The sponsor, the FDA, or other regulatory bodies with responsibilities similar to FDA for clinical sites outside the United States, retain the right to terminate the study and remove all study materials from the investigational site at any time. Specific instances, which may precipitate study termination, are:

- Unsatisfactory subject enrollment with regard to quality and quantity.
- Deviations from protocol, without prior approval from the sponsor.
- Inaccurate, incomplete, and/or untimely data recording on a recurrent basis.
- The incidence and/or severity of adverse experiences in this or other studies indicating a potential health hazard caused by the device.

12.2 FDA and IRB approval

A sponsor shall not begin an investigation until an IRB and FDA have both approved the IDE

12.3 Selection of Investigators

A sponsor shall select investigators qualified by training and experience to investigate the device.

12.4 Selection of Monitors

A sponsor shall select monitors qualified by training and experience to monitor the study in accordance with applicable FDA regulations.

12.5 Accountability and Control of Device

Sponsor shall ship investigational devices only to qualified investigators participating in the study. The investigator shall maintain adequate records of the receipt and disposition of all investigational devices. The investigator shall return any unused devices to sponsor with a completed device disposition record. The disposition record shall include: the devices being returned and the method of return. Devices shall be maintained in a secure, limited–access storage area.

12.6 Obtaining agreements

A sponsor shall obtain a signed agreement from each participating investigator which includes a Curriculum Vitae (CV) with relevant experience, as well as an explanation of any research that was terminated.

12.7 Informing Investigators

A sponsor shall supply all investigators with copies of the investigational plan and inform them of any new relevant safety information obtained during the course of this investigation.

12.8 Monitoring Investigations

Monitoring visits to the clinical sites will be made periodically during the study, to ensure that the clinical trial is being conducted in strict accordance with the protocol/amendment(s) and in compliance with Good Clinical Practice as defined by the Food and Drug Administration (FDA) and by ICH Harmonized Tripartite Guidelines, and that the clinical data can be validated against source documentation at the investigative site. Original source documents will be reviewed for verification of data recorded on the eCRFs and in the electronic database. The Investigator/institution guarantees direct access to original source documents by TriVascular personnel, their designees, and appropriate regulatory authorities. In the event that the original medical record cannot be obtained for a subject that is seen by a non-study physician at a non-study institution, photocopies of the original source documents must be made available for review.

Sponsors may discontinue shipments of devices and terminate the investigator's participation if determination has been made that the investigator is not compliant with the signed agreement, the protocol, conditions imposed by the reviewing IRB, or the applicable FDA regulations.

12.9 Responsibilities of Investigators

An investigator is responsible for ensuring that the study is conducted in accordance with the signed agreement, the protocol, IRB and FDA regulations and requirements. An investigator is also responsible for adhering to regulations associated with obtaining informed consent. An investigator shall permit an investigational device to be used only with subjects under the investigator's supervision. An investigator shall disclose to the sponsor accurate financial information required per 21 CFR, Part 54. Investigator shall return unused devices to the sponsor, or dispose of device as directed by sponsor.

TriVascular Clinical Field Specialists will be in attendance during the implant of the study device to provide technical assistance to the investigators. These field specialists will be supervised by the investigator to eliminate the potential for biasing the outcome of studies, affecting the quality of research data, and/or compromising the rights and welfare of human subjects.

Additionally, investigators are responsible for maintaining accurate, complete and current records pertaining to correspondence, device accountability, each subject case history, including evidence of informed consent. Reports of any IRB withdrawal, unanticipated adverse device effects, deviations from the protocol, use of a device without obtaining subject consent, as well as progress reports to IRB (annually at minimum) are also the responsibility of the investigator.

12.10 Source Documentation

Investigators are responsible for maintaining information in the study subjects' medical records that corroborate data entered into the CRF. The following documents will be maintained and made available as required by the sponsor's designated monitors and/or regulatory inspectors:

1. Medical and surgical history/physical condition of the subject prior to participation in the study in order to verify protocol entry criteria.
2. Dated and signed notes in the subjects' medical record that verify that informed consent was obtained.
3. Dated and signed notes from each subject visit with reference to the data collected.

4. Description of device implantation procedure (date, time, medications, AEs, duration of procedure, etc)
5. Notations on abnormal lab results and their resolution.
6. Dated printouts of diagnostic reports of assessments (CT, X-ray, etc)
7. Adverse event reporting and follow-up of the AE.
8. Subjects condition upon completion of or withdrawal from the study.

12.11 Maintaining Records

TriVascular will maintain hard or electronic copies of correspondence, data, shipment of devices, adverse device effects, and other records related to the clinical trial. All Core Labs and clinical sites will maintain study records for two (2) years after study completion.

It is the responsibility of the investigator and the study staff to maintain a comprehensive and centralized filing system of all relevant study documentation which may include:

- Subject Files – which substantiate the data entered in the electronic Case Report Forms for all required tests and procedures.
- Subject Identification Log – a list correlating all subject names, appropriate identifying information, etc., to the TriVascular assigned subject number.
- Screening Log – which should reflect the reason any subject was screened for the study and found to be ineligible.
- Monitoring Visit Log – which lists dates of monitor/sponsor visits.
- IRB Correspondence – includes approval letter(s), and any adverse event reporting or other correspondence with the IRB.
- Sponsor Correspondence –letters, e-mails, or faxes sent to the investigator or study coordinator at the investigational site.
- Site Correspondence – letters or fax sent to the sponsor from the investigator or study coordinator at that site.
- Signed Informed Consent for each subject
- Informed Consent Log – lists version of consent(s) signed by each subject screened and enrolled into the study
- Device Inventory Log – includes a list of any devices received by the site, used in a case and/or returned to the sponsor.

All Study Documentation pertaining to the conduct of the study must be kept on file by the investigator for a minimum of two (2) years after being notified by the sponsor of either PMA approval or discontinuation of the Sponsor's IDE.

In compliance with current regulatory guidelines regarding the monitoring of clinical studies, it is requested that the investigator permit the study monitor to review and duplicate information in the subject's medical record that is directly related to the study. This information may include relevant study documentation, including the subject's medical history, to verify eligibility, laboratory test results to verify transcription accuracy, x–ray reports, admission and discharge summaries for hospital or outpatient admissions occurring while the subject is participating in the study, charges and billing, and autopsy reports for deaths occurring during the study (if available).

As part of the required content of informed consent, the subject must be informed that his/her medical record will be reviewed and, possibly, duplicated by the sponsor, or the sponsor's

authorized representative or government regulatory authorities. Should access to the medical record require a separate waiver or authorization, it is the investigator's responsibility to obtain such permission from the subject in writing before the patient subject is entered into the study.

12.12 Study Deviations

A study deviation is defined as an event where the investigator or site personnel did not conduct the study according to the investigational plan, protocol or the investigator agreement. Investigators shall be required to obtain prior approval from TriVascular clinical study management before initiating deviations from the protocol, except where necessary to protect the life or physical well being of a subject in an emergency. Such approval shall be documented in writing and maintained in clinical study management and investigator files. Prior approval is generally not expected in situations where unforeseen circumstances are beyond the investigators control (e.g., missed visits or tests); however, the event is still considered a deviation and will be collected on the **Deviation eCRF**. Investigators are responsible for reporting deviations in accordance with the reviewing IRB policies.

FDA regulations require that investigators maintain accurate, complete, and current records, including documents showing the dates of and reasons for each deviation from the protocol. The following information outlines requirements for the reporting of protocol deviations:

Type of Deviation	Investigator to notify:	Reporting timeline
Emergency procedures to protect the life or physical well-being of a subject	TriVascular and reviewing IRB	Within 5 days of event
Changes in or Deviations from the investigational plan	Prior approval from: TriVascular, IRB and FDA	Prior to use
Non-urgent protocol deviation	TriVascular, IRB (if required)	Upon CRF completion. Deviations directly related to the study endpoints will be summarized and submitted in an annual report to the FDA

12.13 Termination of Study

The sponsor or the FDA retains the right to terminate the study and remove all study materials from the investigational site at any time. Specific instances, which may precipitate study termination, are:

1. Unsatisfactory subject enrollment with regard to quality and quantity.
2. Deviations from protocol, without prior approval from the sponsor.
3. Inaccurate, incomplete, and/or untimely data recording on a recurrent basis.

4. The incidence and/or severity of adverse experiences in this or other studies indicating a potential health hazard caused by the device.
5. Submission of fraudulent data.

13.0 STUDY COMMITTEES

13.1 Data Safety Monitoring

A Data Safety & Monitoring Board (DSMB) committee shall be used to review the progress of the clinical study. The committee will be responsible for reviewing the data associated with the device and the subjects. It will provide independent recommendations to the sponsor based on its review of the data and input from the Clinical Events Committee (CEC). The DSMB shall meet annually, at a minimum.

13.2 Clinical Events Committee

The Clinical Events Committee (CEC) shall be used to review and adjudicate all device related adverse events (AE) and all serious adverse events (SAE) regardless of the relatedness to the device. The CEC shall also determine which adverse events are considered Major Adverse Events (MAE) for evaluation of the primary (30 days) and secondary (1 year) safety endpoints. The committee shall consist of at least three (3) physicians representing multiple specialties familiar with abdominal aortic aneurysm repair. The CEC will provide their review to the DSMB and shall meet annually, at a minimum.

14.0 TRAINING

TriVascular will provide technical training and support. Physician training may involve a didactic review of the research team's study responsibilities and hands on device implantation in a simulated anatomic model. The emphasis during physician training will include: protocol and study compliance, compliance with applicable regulations, subject selection criteria, sizing of the stent graft, mechanics of the Ovation Abdominal Stent Graft System and its deployment, as well as the essential ancillary equipment necessary to perform the implant procedure with the device.

15.0 INFORMED CONSENT

All subjects must provide written informed consent in accordance with the reviewing IRB policy and procedures. The process of obtaining informed consent must be documented in the subject's medical record. If changes to the TriVascular informed consent template are to be made, these changes must be submitted and approved by TriVascular prior to IRB submission. Each clinical site must provide TriVascular with a copy of the IRB approval letter, which states the study name, protocol revision being approved as well as the approval date. A copy of the approved informed consent must also be submitted to TriVascular. A template for the Informed Consent is provided in **Appendix V: Informed Consent Template**. Clinical sites are responsible for maintaining annual approval (as appropriate) and submitting the annual approval letters to TriVascular.

APPENDIX I: REFERENCES

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4. Menard, M. T., Chew, D. K.W., Chan, R. K., Conte, M. S., Donaldson, M. C., Mannick, J. A., Whittemore, A. D., Belkin, M. Outcome in Patients at high risk after open surgical repair of abdominal aortic aneurysm. J Vascular Surgery 2003; 37:285-292.

5. FDA Public Health Notification: Updated Data on Mortality Associated with Medtronic AVE AneuRx® Stent Graft System. December 17, 2003

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8. Lavori, P.W., Dawson, D., Shera, D. “A Multiple Imputation Strategy for Clinical Trials with Truncation of Patient Data.” Statistics in Medicine, Vol 14, (1995):1913-1925.]

APPENDIX II: REFERENCES RELATED TO COMPLICATIONS

1) AbuRahma, A. F., Robinson, P. A., Boland, J. P., Lucente, F. C., Stuart, S. P., Neuman, S. S., Hall, M. D., Hoak, B. A.. Elective resection of 332 abdominal aortic aneurysms in a southern West Virginia community during a recent 5-year period. Surg 1991; 109 (3) Part I: 244-251.
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3) Brewster, D. C., Geller, S. C., Kaufman, J. A., Cambria, R. P., Gertler, J. P., LaMuraglia G. M., Atamian S., Abbott W. M. Initial experience with endovascular aneurysm repair: Comparison of early results with outcome of conventional open repair. J Vasc Surg 1998; 27 (6): 992-1005.
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5) Chuter, T. A., Risberg, B., Hopkinson, B. R., Wendt, G., Scott, A. P., Walker, P. J., Viscomi, S., White, G. Clinical experience with a bifurcated endovascular graft for abdominal aortic aneurysm repair. J Vasc Surg 1996; 24 (4): 655-666.
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APPENDIX III: ASA CLASSIFICATION SYSTEM

American Society of Anesthesiologists Classification System

The American Society of Anesthesiologists (ASA) presents a graded scale assessing a patient's risk of undergoing anesthesia. The scale represents the significance of the patient's underlying illnesses prior to anesthesia.

The following provides a description of the four grades of the ASA scale:

ASA I
Healthy individual *without any systemic disease*, undergoing elective surgery. Patient not at extremes of age. *(Note: Age is sometimes ignored as affecting operative risk; however, patients at either extreme of age are thought to represent increased risk.)* Some examples are a fit man with an inguinal hernia, and a fibroid uterus in an otherwise healthy woman.

ASA II
Individual *with one system, well-controlled disease*. Disease does not affect daily activities. Other anesthetic risk factors, including mild obesity, alcoholism, and smoking can be incorporated here. Examples include non-limiting or only slightly limiting organic heart disease, essential hypertension, anemia, or mild diabetes.

ASA III
Individual *with multiple system disease or well controlled major system disease*. Disease does limit daily activities. No immediate danger of death from any individual disease. Examples include severe organic heart disease, severe diabetes with vascular complications, moderate to severe degrees of pulmonary insufficiency, angina or healed myocardial infarction.

ASA IV
Individual in imminent danger of death. Surgery is viewed to be last resort at salvaging life. Individual not expected to live through the next 24 hours. In some cases, the individual may be healthy prior to catastrophic event that led to the current medical condition. Examples include ruptured abdominal aortic aneurysm with profound shock, major cerebral trauma with rapidly increasing intracranial pressure, massive pulmonary embolus.

Reference: Composite from different editions of: Sabiston, DC, Textbook of Surgery. Philadelphia: W.B. Saunders Company

APPENDIX IV: SCHEDULE OF ACTIVITIES

Procedure	Baseline	Treatment	Discharge	1 Month Follow-Up	6 Month Follow-Up	12 Month Follow-Up	Annual Follow-Up
Medical/Surgical History	X[3]						
Physical Exam	X[3]		X	X	X	X	X
ABI	X		X				
Spiral Contrast Enhanced CT	X[4]			X	X	X	X
Abdominal X-ray[1]			X	X	X	X	X
Laboratory Assessment (BUN, creatinine, PT, PTT, INR)[2]	X[3]		X	X	X	X	X
Adverse Event Assessment		X	X	X	X	X	X
Concomitant Medication Assessment (anticoagulants, antiplatelets, antibiotics only)	X	X	X	X	X	X	X
Device/aneurysm assessment based on imaging (endoleak, migration, integrity, patency)		X[5]		X	X	X	X

[1]X-ray images should include: AP, lateral, left oblique and right oblique views.
[2]PT, PTT and INR are optional after Baseline.
[3]Baseline med/surg history, physician exam/ABIs, and laboratory assessments performed no more than one month prior to the implant/surgical procedure. Serum pregnancy HCG required for females of child-bearing potential only.
[4]Baseline contrast enhanced CT must be obtained within 6 months of anticipated treatment date.
[5]Only the device will be assessed at discharge as no CT is performed at that visit.

APPENDIX V: INFORMED CONSENT TEMPLATES

DRAFT SCREENING INFORMED CONSENT

Study Title: A Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the Ovation Abdominal Stent Graft System

Trial Number: **771-0006**

Researcher: Investigator Name
Site Name
Site Address
Site Address
Investigator Telephone:

Sponsor: **TriVascular, Inc.**
3910 Brickway Blvd.
Santa Rosa, CA 95403
Telephone: +1 707.543.8811

Patient Name: _____

I, _____, an adult, voluntarily consent to release my medical records for screening evaluations for possible participation in a clinical research study sponsored by TriVascular, Inc. The TriVascular Pivotal Clinical Study is to evaluate the Safety and Effectiveness of the Ovation Abdominal Stent Graft System for the treatment of abdominal aortic aneurysms.

I understand that in order to determine my eligibility to participate in the study, medical information from my CT scans and/or x-rays whichever is deemed appropriate and available, will be evaluated by the study sponsor and an independent laboratory appointed by the study sponsor, who will read the scans/x-rays and take anatomical measurements.

I have been informed that my name may appear on the films (x-rays) that will be sent to the sponsor. All personal information taken and recorded will be treated in strict confidence. I understand that my personal identity will not be used by the sponsor for any public disclosure.

I understand that my consent is for screening only and is not my consent to participate in the study. I understand that the CT scans or x-rays are part of the standard evaluation for abdominal aortic aneurysms and are not taken specifically for research study purposes.

I hereby authorize my physician to release the information from my CT scans or x-rays to the study sponsor and the independent core laboratory to evaluate and determine my eligibility to participate in research.

_____

Participant's (or representative) printed full name

_____ __ __ / __ __ / __ __ __ __

Participant's (or representative) signature — Date (dd/mm/yyyy) (written by the participant or his/her representative)

_____

Impartial witness (full name) (Witness signature required only in the event the patient cannot read and/or sign the Informed Consent; for instance, if the patient is illiterate or blind)

_____ _____

Signature of the impartial witness (if required) — Date (dd/mm/yyyy) (written by the witness)

_____ __ __ / __ __ / __ __ __ __

Principal Investigator or Authorized Designee — Date (dd/mm/yyyy)

DRAFT INFORMED CONSENT

Study Title:	A Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the Ovation Abdominal Stent Graft System
Trial Number:	**771-0006**
Researcher:	Investigator Name Site Name Site Address Site Address Investigator Telephone:
Sponsor:	**TriVascular, Inc.** 3910 Brickway Blvd. Santa Rosa, CA 95403 Telephone: +1 707.543.8620

Patient Name: _____ **Patient #:** _____

WHAT IS INFORMED CONSENT?

When researchers ask for your consent, they are asking for your voluntary agreement to take part in a test, procedure, or clinical research trial. Informed consent means more than signing a printed consent form. To be informed, you need to know about benefits and risks of the clinical research trial and how it may affect you, your family, and society. The following document is called a consent form and describes the clinical research trial and what your role will be as a study participant.

This consent form may contain words that you do not understand. Please ask the doctor in charge of the study, your own doctor, or the staff involved with the clinical research trial to explain any words that you do not understand before signing this form. You may also contact the organizations listed in the Section below entitled "Persons To Contact For Research Questions" for any questions you may have regarding this research study. You will be given a copy of the signed consent form.

PURPOSE OF THE STUDY

You have been asked to consider participating in a clinical research study designed to determine the safety and effectiveness of the Ovation Abdominal Stent Graft System, an investigational device used in the treatment of abdominal aortic aneurysms (AAA). This study will be conducted at approximately 40 clinical sites and will enroll up to 150 subjects during the initial study phase with an additional 100 subjects enrolled during the continued access phase.

An abdominal aortic aneurysm is a bulge in the aorta (the main artery leaving the heart) caused by a weakening in the artery wall. If left untreated, this bulge may continue to grow larger and ultimately rupture (break open), resulting in serious internal bleeding. The information collected

from this study will be used to evaluate how well patients do when treated with the Ovation Abdominal Stent Graft System both immediately after surgery and over a long period of time. If you decide to participate in this study, your medical condition will be carefully monitored.

Treatment of your AAA with the Ovation Abdominal Stent Graft System involves the placement of specially designed grafts (fabric tubes) in your aorta. The main graft looks like a pair of pants with very short legs. The top of the pants will be placed in your aorta. Then, two or more smaller grafts are used to extend from the main graft into your iliac arteries (the main arteries supplying blood to your abdomen and legs) to form the legs of the pair of pants. Each graft is enclosed in a small catheter (a long, flexible tube) that is inserted into your aorta through the femoral artery in your groin (top of your leg). The grafts are then placed in the correct position in your aorta by releasing them from the catheters. Once the grafts are attached inside your aorta, they will reinforce the area of your aorta that is weakened and bulging from your aneurysm. This procedure is called an endovascular aneurysm repair because the grafts are delivered through your blood vessels.

In standard surgical aneurysm repair, the surgeon makes a large incision in your abdomen and actually cuts into your aorta and sews a graft in place. There are other endovascular AAA repair devices that are approved for use by the Food and Drug Administration (FDA) in the United States (U.S.). You have the choice of having your treatment with the investigational Ovation Abdominal Stent Graft System or with any other AAA repair device which is already FDA approved. You also have the choice of having your treatment with standard surgery or choosing to have no treatment for your aneurysm.

EXPLANATION OF PROCEDURES

In preparation for this research study, you will have a physical examination by the study doctor, an evaluation of your medical history and any risk factors, and a check of the blood pressures in your arms and legs. You will also have approximately 2 tablespoons, or 30 milliliters, of blood drawn from a vein using a needle, so that tests of your kidney function and your body's blood-clotting abilities can be performed. If you are a female with child bearing potential, you will also have a blood pregnancy test performed to make sure you are not pregnant. Since your doctor has already diagnosed your aneurysm, you may have already had a special x-ray, called a CT scan. If you have not had a CT scan, or if the CT scan information is not detailed enough to let your doctor evaluate your aneurysm, you will be required to have a CT scan. These same tests would be done if you were scheduled to undergo standard surgery to repair your aneurysm or if you were going to have an endovascular AAA repair using another device.

As the procedure begins, you will receive a drug in your hand or arm to help sedate you, or you might receive general anesthesia depending upon your particular circumstance. Your surgeon will clean your skin and shave hair around the place where the device will be inserted through a catheter (flexible tube) into your body. Your surgeon will then make an incision (cut) into the skin in order to get access to the femoral artery in your groin (top of leg). Your surgeon will then thread a very thin wire into your artery to guide it to the aneurysm. Because you have no nerve endings inside your arteries, you will not feel the wires or catheters as they move through your body. You may feel a slight pressure or a sensation of mild tugging during this part of the procedure.

The main catheter containing the first piece of the graft will be advanced through your femoral artery up to a level in the aorta above the aneurysm, but below the arteries that go to your kidneys. The graft will be released from the catheter and the catheter will be pulled away. A special material will be inserted into tubes inside the wall of the main graft to ensure it is tight against the artery wall. Then, catheters are used to place the two or more smaller grafts into your iliac arteries to complete the procedure. All the catheters will be removed leaving the graft in place inside your aorta. The incisions in your groin arteries and in your skin will be closed by your doctor.

After the procedure has been completed and you have had time to recover from the sedation, you will be kept in the hospital until your doctor allows you to go home. Prior to your discharge from the hospital, you will have physical examinations, the blood pressure in your arms and legs will be checked, an X-Ray of your abdomen and you will have blood tests that will require approximately 2 tablespoons, or 30 millimeters, of blood to be drawn.

FOLLOW-UP EVALUATIONS

If you decide to participate in this research study, you will be required to return to your doctor for follow-up evaluations at one (1) month, six (6) months, and twelve (12 months) after the procedure, as well as every year thereafter until five (5) years after the procedure.

At each of the follow-up visits, you will have a physical exam, CT scan, X-Ray of your abdomen, and blood tests that will require approximately 2 tablespoons, or 30 millimeters, of blood to be drawn. If you experience any problems with your grafts, your physician may ask to see you more frequently and additional tests may be done.

It is very important to complete these follow-up visits even if you are feeling well and not having any symptoms. These visits are important for documenting how well the treatment has worked. It is also very important that you contact your doctor if you have any symptoms that may be related to the treatment that you received so that your condition can be properly checked.

ALTERNATIVE TREATMENTS

Alternative procedures to repair your AAA include standard surgical aneurysm repair and endovascular repair using a commercially available endovascular AAA repair device. In standard surgical aneurysm repair, the surgeon makes a large incision in your abdomen and actually cuts into your aorta and sews a graft in place. The procedure with a commercially available endovascular AAA repair device is very similar to the procedure with the Ovation Abdominal Stent Graft System, by placing the device through your groin (femoral) arteries.

RISKS

The risks associated with the use of this study device are not currently known. Although the adverse events associated with the use of the Ovation Abdominal Stent Graft may be less than for standard open surgical repair, inherent risks exist, as with many medical procedures. However, risks that have been associated with repair of AAAs with this type of device in clinical trials or that are currently marketed include, but may not be limited to:

- hematoma (deep bruise) or lymphatic problems (infection) at the access sites in the groin;
- damage to the iliac or femoral arteries during device deployment;

- fracture of the metallic components of the implant;
- endoleak (leakage of blood around the graft into the aneurysm sac and/or blood flow into the aneurysm sac from vessels connected to the aorta);
- continued enlargement of your aneurysm;
- failure to deploy the graft resulting in the need to stop the procedure and/or convert to open surgical repair;
- twisting of the implanted graft;
- migration of the some or all of the device parts;
- separation of implant parts;
- aortic occlusion (blockage or the blood flow in your aorta) from blood clots;
- kinking or twisting of the graft and iliac artery occlusion (blockage of blood flow in the blood vessels that supply blood to your legs) from blood clots, kinking or twisting of the legs of the graft; and
- allergic reaction to the device fill material, if injected into the bloodstream, as well as device materials.

Complications common to all patients undergoing standard surgical aneurysm repair or endovascular repair include, but may not be limited to:

- allergic reaction to x-ray contrast dye;
- procedural bleeding;
- post-procedure bleeding;
- hematoma (deep bruise);
- bleeding disorders;
- respiratory failure;
- pneumonia;
- pulmonary embolism (blood clots in the lung);
- myocardial infarction;
- congestive heart failure;
- irregular heart beat requiring therapy;
- kidney failure; wound infection;
- bowel complications such as paralysis of the bowel; blockage of the bowel; or decreased blood flow to the bowel tissue;
- mild or severe blockage of blood flow to your legs or arms due to blood clots or damage to the blood vessels;
- amputation;
- stroke;

- impotence;
- blood clots or infection in the graft; graft dilatation (stretching);
- development of a hole between the aorta and the intestines or the aorta and the vena cava (major blood vessel carrying blood to the heart);
- separation of the walls of the aorta;
- a false aneurysm developing at the fixation point of the graft;
- re-operation (additional surgery); and
- death.

Your doctor will make every effort to minimize the risks and discomforts of the procedures. Most of the complications and discomforts listed above can be treated with medications or surgery that can be given to you if your doctor feels it is needed. In the event of a serious complication or injury, it may be necessary to surgically remove the study device. In that case, TriVascular requests that the removed study device be returned to them for examination.

POTENTIAL BENEFITS

Potential benefits of the Ovation Abdominal Stent Graft System compared to open surgical aneurysm repair may include, but are not limited to:

- Not having open surgery;
- Less time under general anesthesia and/or the ability to use other forms of anesthesia that do not require mechanical ventilation;
- Reduction of complications; and
- Reduction in hospitalization and recovery time.

Potential benefits of the Ovation Abdominal Stent Graft System compared to other commercially available endovascular AAA repair devices may include, but are not limited to:

- More robust seal between the graft and your aorta, possibly reducing the risk that the graft will develop leaks or move over time and;
- Lower risk of injury to the vessels in your legs because this catheter is smaller and more flexible than the commercially available devices.

Any potential benefits cannot, however, be guaranteed. There may be no direct benefit to you from your participation in this study, but it is hoped that the information gained from your participation in this study may benefit others with a condition similar to yours.

CONFIDENTIALITY

The information obtained about you due to taking part in this study will be kept confidential to the extent allowed by law. Total confidentiality cannot be guaranteed. However, all medical records and research materials that would identify you will be held confidential. Your identity will remain confidential unless the law requires disclosure. By signing this consent, you grant permission for medical information about you obtained during this study to be made available to

authorized representatives of the FDA and other government agencies. You also grant permission for this medical information to be made available to the following people:

- TriVascular, the Sponsor—the manufacturer of the Ovation Abdominal Stent Graft System and the company funding the Study, and its employees (e.g., Clinical Field Specialists who are in attendance during the procedure to provide technical assistance to your physician) who are involved in the conduct of the study.
- Employees of a Contract Research Organization, a company contracted by TriVascular to supervise/validate the clinical information obtained in the Study.
- The local Institutional Review Board (IRB).

The results of this research study may be published or used for teaching purposes; however, patients will not be identified by name in those publications or teaching materials. You will be assigned a special study code that will not reveal your name or personal identity.

You will be asked to review and sign a special document, along with this informed consent form, that describes the privacy law, Health Insurance Portability and Accountability Act (HIPAA), so that the researchers can use or disclose your protected health information for research purposes.

RIGHT OF REFUSAL AND STUDY TERMINATION

Your participation in this study is voluntary. Your refusal to participate will not prejudice your future treatment or benefits. You are free to stop participation in the study at any time without fear of penalty or loss of medical care. You will be asked to come in for a final study visit.

Your doctor may also terminate your participation in this study, if in his or her medical judgment it is in your best interest not to continue. You will be informed, if important new findings develop during the study that may affect your willingness to continue.

COSTS OF TREATMENT AND STUDY PARTICIPATION

You and/or your third party payer (Medicare or other health insurance company) will be responsible for the costs of your treatment procedures and follow-up examinations which are considered standard of care for endovascular AAA repair. The cost of any test or examination which is not considered standard of care or reimbursable by your third party payer (insurance) will be covered by the study sponsor.

PAYMENT FOR STUDY PARTICIPATION

You will not be compensated or paid for your participation in this study. Any reasonable costs you incur traveling to your physician for required follow-up visits will be reimbursed by the sponsor, TriVascular, Inc., if agreed to in advance of your visit. Please contact _____, the Research coordinator for this study at _____ <*insert institution name*> to arrange for reimbursement.

RESEARCH RELATED INJURIES

If physical injury occurs that is directly related to your involvement in this research, you will receive any medical treatment that is necessary to assist your recovery from the injury. The costs of medical care associated with injuries related to your participation in this study will be provided by the sponsor, TriVascular, Inc, provided that the injury is a <u>direct</u> result of the use of

the investigational device in accordance with the Protocol. You will not receive any compensation for this injury. This agreement to provide free medical treatment does not include treatment for any illness you might experience during the course of this study if the illness is not the result of direct participation in the research study.

PERSONS TO CONTACT FOR RESEARCH QUESTIONS

If you have any questions about the research or experience an adverse reaction (any unusual symptoms) or injury, and if emergency medical treatment is required, you should immediately contact your study doctor, Dr. _____ at _____.

If you have questions about your rights as a research participant at this institution, you may call the Institutional Review Board at _____*<insert contact information for IRB>*.

STUDY PARTICIPANT'S BILL OF RIGHTS

Persons who participate in a medical experiment are entitled to certain rights. These rights include but are not limited to the subject's right to:

- Be informed of the nature and purpose of the experiment;
- Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- Be given a description of any attendant discomforts and risks reasonably to be expected;
- Be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- Be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, their relative risks, and benefits;
- Be informed of the avenues of medical treatment, if any, available to the subject after the investigational procedure if complications should arise;
- Be given an opportunity to ask questions concerning the experiment or the procedures involved;
- Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- Be given a copy of the signed and dated consent form; and
- Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

CONSENT AND SIGNATURES

PATIENT OR LEGALLY AUTHORIZED REPRESENTATIVE

I voluntarily consent to participate in this study. The purpose and procedures of this study have been fully explained to me by the study investigator listed above. All of my questions about the study have been satisfactorily answered. I am free to not participate in this research study or to withdraw at any time, and that my current medical care will not be affected by this decision.

I agree that my primary physician will be informed of my participation in this trial. I authorize the release of my medical records to TriVascular, agents of TriVascular, the Food and Drug Administration in the United States, other governmental agencies, and the (Insert name of IRB/EC).

By signing and dating this consent form, I have not waived any of the legal rights that I would have if I were not a participant in a clinical research study. I will receive and may keep a copy of this signed and dated consent form.

_____
Participant's (or representative) printed full name

_____ __ __ / __ __ / __ __ __ __
Participant's (or representative) signature — Date (dd/mm/yyyy) (written by the participant or his/her representative)

_____
Impartial witness (full name) (Witness signature required only in the event the patient cannot read and/or sign the Informed Consent; for instance, if the patient is illiterate or blind)

_____ _____
Signature of the impartial witness (if required) — Date (dd/mm/yyyy) (written by the witness)

_____ __ __ / __ __ / __ __ __ __
Principal Investigator or Authorized Designee — Date (dd/mm/yyyy)

AUTHORIZATION OF USE AND DISCLOSURE

PROTECTED HEALTH INFORMATION
FOR RESEARCH PURPOSES
(Sample HIPAA authorization)

The privacy law, Health Insurance Portability & Accountability Act (HIPAA), requires me to sign an agreement called an Authorization so that the researchers can use or disclose my protected health information for research purposes.

I authorize Dr. *<insert name>* and his research staff, and the Sponsor of this study, TriVascular, Inc., to use and disclose my protected health information for the purposes described below in the study titled, "A Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the Ovation Abdominal Stent Graft System".

I authorize the following individuals or groups to use or disclose my Protected Health Information:

- *<Insert Name of Hospital>;*
- My doctor(s) who care for me during this research. These doctors include my primary care doctor and other doctors who may take care of me while I am part of this research.

The health information that may be used and disclosed includes:

- All information collected during the research described in the Informed Consent Form; and
- Health information in my medical records that is relevant to the research described in the Informed Consent Form.

The Researchers may:

- Use and share my health information to conduct the research;
- Disclose my health information to the Sponsor of the research, TriVascular, Inc. and its agents;
- Disclose my health information as required by law;
- Disclose my health information to representatives of government organizations and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research; and
- Remove from my health information my name and other information that could be used to identify me.

TriVascular, Inc. may:

- Use and share my health information to conduct the research;
- Use my health information for additional purposes, such as other medical research, development of other study protocols, development of new medical products or procedures, system analysis and other business purposes, except where prohibited by law;

- Disclose my health information as required by law;
- Disclose my health information to representatives of government organizations and other persons who are required to watch over the safety and effectiveness of medical products and therapies, and the conduct of research; and
- Remove from my health information my name and other information that could be used to identify me.

The Researchers may share my health information with:

- *<Insert Name of Institutional Review Board>;*
- *<Insert Name of Hospital Clinical Research Department>;*
- Government representatives, when required by law;
- *<Insert any names of hospital representatives, as applicable>;*
- TriVascular, Inc., as the Sponsor of the study, or its agents, such as data management groups, research monitoring groups, or contract research organizations;
- *<Insert>* Other medical centers/institutions/Investigators outside of the name of hospital;
- Your health insurer or payer, if necessary, in order to secure their payment for any covered treatment not paid for through the research.

Once my health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure. The Researchers and TriVascular agree to protect my health information by using and disclosing it only as permitted by me in this Authorization and as directed by state and federal law. Once information that could be used to identify me has been removed, the information that remains is no longer subject to this Authorization and may be used and disclosed by the Researchers and TriVascular as permitted by law. No publication about the research will reveal my identity without my specific written permission.

I do not have to sign this Authorization. If I decide not to sign the Authorization:

- It will not affect my treatment or my eligibility for health benefits.
- I will not be able to participate in the research study.

After signing the Authorization, I can change my mind and:

- Not let the Researcher disclose or use my protected health information (revoke the Authorization), except for the information already collected for the study.
- If I wish to revoke the Authorization, I will send a written letter to _____<*insert Name and address of Investigator*>.
- If I revoke the Authorization, I can no longer participate in the study.

Expiration:

This Authorization expires at the conclusion of all work related to this research study, which could be as long as six years or until the study is completed, whichever is longer.

If I have not already received a copy of the Notice of Privacy Practices, I may request one. If I have questions or concerns about my privacy rights, I should contact <*insert name and contact information for this person*>.

Authorization:

I have read this information, and I will receive a copy of this form after it is signed.

_____

Patient's Printed Name

_____ _____

Patient's Signature **Date**

APPENDIX VI: CT SCANNING TECHNIQUES

Reminders:

- TriVascular requires contrast enhanced Spiral CT data for reconstruction.
  - Data must be uncompressed DICOM
  - Patient motion should be avoided during scan. If possible, avoid scanning non-patient objects in field of view. Do not change patient position, table height, or field of view during scan. If patient moves, repeat the study in its entirety.
- Entire Exam sent to M2S via: Direct transfer of data via FTP or on optical disc sent via a traceable method.

	Minimum Protocol (Required)	**High Resolution Protocol (Recommended)**
Scan Mode	Helical	Helical
Scan Parameters	110-140kVp, Auto mAs or 170-400 mA scan time of 0.5sec	110-140kVp, Auto mAs or 170-400 mA scan time of 0.5sec
Slice Thickness	3mm	0.625 – 2mm
Slice Interval	3mm	0.625 – 2mm
Pitch	0.984:1	0.984:1
Superior Extent AAA	2 cm above celiac artery origin	2 cm above celiac artery origin
Inferior Extent AAA	Pre-op: Lesser trochanter of femurs to include femoral bifurcations Post-op: At least 2cm distal to the lowest hypogastric artery origin	Pre-op: Lesser trochanter of femurs to include femoral bifurcations Post-op: At least 2cm distal to the lowest hypogastric artery origin
Contrast	Standard per Radiology Department	Standard per Radiology Department
Volume	80ml contrast with 40ml saline flush or Standard Contrast Volume with Saline Flush per Radiology Department	80ml contrast with 40ml saline flush or Standard Contrast Volume with Saline Flush per Radiology Department
Rate	4 ml/sec	4 ml/sec
Scan Delay	ROI – threshold 90-100 HU in aorta	ROI – threshold 90-100 HU in aorta
Field of View	Large Body	Large Body
Reconstruction Algorithm	Standard	Standard

APPENDIX VII: EXPLANT PROCEDURE

Explant During Surgical Conversion

The objective of device removal is to minimize trauma or damage to the device at the time of surgical excision from the subject, while maintaining the subject's safety. It is also important to minimize surrounding tissue disturbance so that a thorough pathological evaluation can be made.

1. If possible, a swab should be used to obtain material for microbial culture prior to removal of the explant.
2. Attempt to identify all components including their orientation so that they may be maintained in the same relative position as they were *in situ*.
3. Attempt to remove the specimen en bloc from superior to the proximal stent to inferior to the distal stent.
4. The residual blood should be rinsed from the explant surfaces utilizing physiological solutions such as Ringer's lactate or normal saline avoiding disturbance to the inside surface of the explant.
5. All samples should be fixed in 10% neutral buffered formalin.
6. Prior to the explant, please contact TriVascular to obtain shipping instructions.
7. Please alert the sponsor within 24-hours of the explant and the shipment of the device.
8. Explant case report forms should be completed at this time
9. An operative report and a separate report from the examining pathologist should be sent to the sponsor, if available.

Explant During Autopsy

The objective of device removal is to excise en bloc from superior to the proximal stent to inferior to the distal stent. The abdominal aorta and iliacs should not be opened nor should any endovascular device manipulation be done. Photos should be taken in anterior-posterior as well as oblique and lateral views. The external characteristics and the relationship to surrounding viscera should be noted based on the guidelines on the case report forms. Adhesions to viscera as well as evidence of fistula formation by erosion of the endograft through the arterial wall should be noted. Any problems or abnormalities of this type should be photographed *in situ*, if possible.

1. If possible, a spiral CT scan with 3-D reconstruction should be obtained of the endograft prior to explantation of the device. Spiral CT should be performed before immersion of the specimen in fixative.
2. Attempt to identify all components including their orientation so that they may be maintained in the same relative position as they were *in situ.*
3. Attempt to remove the specimen en bloc from superior to the proximal stent to inferior to the distal stent.
4. All samples should be fixed in 10% neutral buffered formalin.
5. Prior to the explant, please contact TriVascular to obtain shipping instructions.
6. Please alert the sponsor within 24-hours of the explant and the shipment of the device.
7. An autopsy report and a separate report from the examining pathologist should be sent to the sponsor, if available.

*These guidelines have been furnished by the Lifeline Registry of Endovascular Aneurysm Repair.

Revision History

Rev	DCO #	Date	Description of Change	Initiator
A	2176	18Nov09	Initial Version of Document	L. Mack
B	2311	07Jan10	Revision of Juxtarenal aortic neck length from 7-9 mm to <10 mm.	L. Mack
C	2350	21Jan10	Addition of Protocol Signature Page, Clinical Utility endpoint, and Revision of Statistical Section 10.0.	L. Mack
D	2412	10Feb10	Addition of Protocol Approval Page; deletion of references to "roll-in patients"; revisions to Imaging Core Lab and Schedule of Activities tables to be consistent with schedule of procedures discussed in body of protocol; clarification of visit timeframe allowances; correction of protocol title on screening informed consent and informed consent templates; specification of number of patients and exit visit procedure on informed consent template; and minor spelling corrections.	L. Mack
E	3238	13Aug10	Update verbiage based on DSMB's request in response to UADE.	M. Carr
F	3551	20Oct10	Clarification of allowable window for baseline procedures; incorporation of suggested investigator responsibilities as per "Guidance for Industry: Investigator Responsibilities" issued by the FDA in October of 2009. Update PI and product name. Added optional wound assessment at FU. Removed ABI after Hospital Discharge. Made coagulation labs optional after Baseline. Requested site notification within 24 hours of device-related AEs. Modifications in response to FDA Conditional Approval letter dated 30 July 2010.	L. Mack
G	3732	22Nov10	The Device Description and Patient Informed Consent were revised to include the use of iliac extensions.	C. Campbell
H	3759	23Nov10	Minor change to rename Section 1.0 of Protocol – Study Goal	L. Mack
I	3917	10Jan11	Revise to incorporate provisions for the continued access phase.	C. Campbell
J	4759	15Aug11	Revise number of additional subjects, modify follow-up periods, clarify sample size justification and remove DSMB wording added in previous revision.	J German