NCT Number: NCT02949297

Expanding Patient Applicability with PoLymer SEaling OVATion Alto StEnt Graft IDE Study (ELEVATE IDE Study)

Protocol Number 771-0013

Revision: B (August 23, 2017)

Sponsor Name: TriVascular, Inc. (a wholly owned subsidiary of Endologix, Inc.)

Address: 3910 Brickway Blvd.
Santa Rosa, CA 95403

CONFIDENTIALITY STATEMENT

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Protocol Approval

Reviewed and approved by:

Meredith Huetter
Vice President, Clinical

27NOV2017
Date

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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 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 the study Sponsor. I will discuss this material with them to ensure that they are fully informed regarding the investigational device, the safety 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 trial. I agree to provide all subjects with informed consent forms, as required by International Conference on Harmonization (ICH) regulations. I agree to report to the study Sponsor 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 (IRB)/Ethics Committee (EC) responsible for such matters must approve this protocol for the clinical facility where it will be conducted.

Site Principal Investigator:

Signature:

_____ _____

Investigator, name and signature Date

PROTOCOL SUMMARY

Sponsor	TriVascular, Inc. (a wholly owned subsidiary of Endologix, Inc.) 3910 Brickway Blvd. Santa Rosa, CA 95403 (707) 543-8800
Protocol Title	**E**xpanding Patient Applicability with Po**L**ymer S**E**aling O**VAT**ion Alto St**E**nt Graft IDE Study (**ELEVATE** IDE Study)
Study Description	A prospective clinical evaluation of the effectiveness of the Ovation Alto Abdominal Stent Graft System when used in the treatment of subjects with abdominal aortic aneurysm (AAA)
Study Primary Objective	To evaluate treatment success at 12 months with the Ovation Alto Abdominal Stent Graft System in subjects with AAA. Treatment success will be defined as: • Technical success*; • Freedom from type I & III endoleak at 12 months, to be assessed by an Independent Core Lab; • Freedom from stent graft migration > 10 mm at 12 months (compared to 1-month baseline), to be assessed by an Independent Core Lab; • Freedom from AAA enlargement > 5mm at 12 months (compared to 1-month baseline); • Freedom from AAA rupture through 12 months; • Freedom from conversion to open repair through 12 months; • Freedom from stent graft stenosis, occlusion, or kink requiring secondary intervention through 12 months; • Freedom from thromboembolic event** attributable to stent graft requiring secondary intervention through 12 months, and: • Freedom from stent fracture requiring secondary intervention through 12 months *Technical Success will be a composite endpoint comprised of all of the following: • Successful delivery, (i.e. ability to deliver the implant to the intended location without the need for unanticipated corrective intervention related to delivery, using an adjunctive device outside of the Ovation Alto Abdominal Stent Graft System); • Successful and accurate deployment, defined as: o deployment of the endovascular stent graft in the planned location; o patency of the endovascular stent graft, absence of device deformations (e.g. kinks, stent eversion, mal-deployment, misaligned deployment) requiring unplanned placement of an additional

	device within the endovascular stent graft, and; • Successful withdrawal (i.e. successful withdrawal of the delivery system, without the need for unanticipated corrective intervention related to withdrawal) Note: Unanticipated corrective intervention is unplanned implant of a third party device (outside of the Sponsor's available device platform) to treat/exclude the aneurysm. ** Defined as deep vein thrombosis, pulmonary embolism, embolic stroke, limb ischemia in the presence of occlusion or thrombosis within the stent graft.
Additional Study Evaluation	Additional assessments that will be reported at each follow-up interval include: • Type I, II, III and IV endoleaks and endoleaks of unknown origin, to be assessed by an Independent Core Lab • Stent graft migration > 10 mm (compared to 1-month baseline), to be assessed by an Independent Core Lab • AAA enlargement > 5 mm (compared to 1-month baseline), to be assessed by an Independent Core Lab • AAA rupture • Conversion to open repair • Secondary interventions** • AAA-related mortality** • Device-related AEs & SAEs** • Major Adverse Events (MAE)** • Loss of patency • Stent fracture, to be assessed by an Independent Core Lab • Thromboembolic event (deep vein thrombosis, pulmonary embolism, embolic stroke, limb ischemia) ** MAEs and device-related SAEs will be adjudicated by the Clinical Events Committee (CEC) at 1, 6 and 12 months. MAE is defined as: • All-cause mortality • 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)
Subject Enrollment	Patients with AAA will be prospectively enrolled and treated with the Ovation Alto Abdominal Stent Graft System. Treatment

	success at 12 months will be compared to a performance goal of 80%.
Power Analysis and Sample Size	The sample size for this study was calculated based on the following assumptions: • Estimated treatment success at 12 months: 92.8% • Performance goal: 80% • Confidence interval estimation: One-sided exact 95% confidence limit • Statistical power: 86.1% Based on these assumptions, 60 evaluable patients are required. In order to account for reasonable attrition, the Sponsor plans to enroll up to 75 patients in this study.
Study Follow-Up Intervals	Follow up intervals will consist of 1, 6, and 12 months following the initial implant procedure.
Follow-Up Activities	Follow up activities will consist of: • Physical exam • 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 • Assessment of Adverse Events
Number of Investigational Sites	Up to 16 U.S. clinical study sites
Description of Acceptable AAA Vasculature	Seal Zone: 16-30 mm (ID) at 7 mm below the inferior renal artery Juxtarenal Aortic Angle: $\leq$ 60 degrees if proximal neck is $\geq$ 7 mm and $\leq$ 45 degrees if proximal neck is < 7 mm Iliac Diameter: 8-25 mm Distal Seal Zone: $\geq$10 mm
Principal Investigator:	Sean Lyden, MD Chairman of Department of Vascular Surgery Cleveland Clinic, Cleveland, OH
Data Safety Monitoring Board (DSMB)	To be determined
Core Lab	M2S, Inc. 12 Commerce Avenue West Lebanon, NH 03784 USA Phone: 603-298-5509

	Fax: 603-298-5055
Electronic Data Capture (Host)	IBM Clinical Development eClinicalOS 4000 Aerial Center Pkwy Morrisville, NC 27560 Phone: 866.387.4257 Fax: 919.653.3620

1.0 STUDY GOAL AND OBJECTIVES

The goal of the study is to evaluate the Ovation Alto Abdominal Stent Graft System in subjects with abdominal aortic aneurysm (AAA). The primary study objective is to evaluate treatment success at 12 months in patients treated with Ovation Alto relative to a performance goal of 80%.

Treatment success will be defined as:

- Technical success*
- Freedom from type I & III endoleaks at 12 months
- Freedom from stent graft migration > 10 mm at 12 months (compared to 1-month baseline)
- Freedom from AAA enlargement > 5mm at 12 months (compared to 1-month baseline)
- Freedom from AAA rupture through 12 months
- Freedom from conversion to open repair through 12 months
- Stent graft stenosis, occlusion or kink requiring secondary intervention through 12 months
- Thromboembolic event** attributable to stent graft requiring secondary intervention through 12 months
- Stent fracture requiring secondary intervention through 12 months

*Technical Success is defined as:

- Successful delivery (i.e. ability to deliver the implant to the intended location site without the need for unanticipated corrective intervention related to delivery, using an adjunctive device outside of the Ovation Alto Abdominal Stent Graft System);
- Successful and accurate deployment, defined as:
    - deployment of the endovascular stent graft in the planned location;
    - patency of the endovascular stent graft, absence of device deformations (e.g. kinks, stent eversion, mal-deployment, misaligned deployment) requiring unplanned placement of an additional device within the endovascular stent graft, and
- Successful withdrawal (i.e. successful withdrawal of the delivery system, without need for unanticipated corrective intervention related to withdrawal).

Note: Unanticipated corrective intervention is unplanned implant of a third party device (outside of the Sponsor's available device platform) to treat/exclude the aneurysm.

** Defined as deep vein thrombosis, pulmonary embolism, embolic stroke, limb ischemia in the presence of occlusion or thrombosis within the stent graft.

Additional assessments that will be reported at follow up include:

- Type I, II, III and IV endoleaks and endoleaks of unknown origin
- Stent graft migration > 10 mm (compared to 1-month baseline; assessed at 6-months)

- AAA enlargement > 5 mm (compared to 1-month baseline; assessed at 6-months)
- AAA rupture
- Conversion to open repair
- Secondary interventions***
- AAA-related mortality***
- Device-related AEs & SAEs***
- Major Adverse Events (MAE)***
- Loss of patency
- Stent fracture
- Thromboembolic event (deep vein thrombosis, pulmonary embolism, embolic stroke, limb ischemia)

***These assessments will be reported at 12 months in addition to the 12-month Primary Effectiveness endpoints listed above. MAEs and device-related SAEs will be adjudicated by the Clinical Events Committee (CEC) at 1, 6 and 12 months.

MAE is defined as:

- All-cause mortality: any death occurring during the study period, regardless of cause
- Myocardial infarction: the presence of raised levels of one or more cardiac biomarkers in comparison to local laboratory reference ranges
- Stroke (excludes TIA) : a sudden development of neurological deficit due to vascular lesions of the brain such as hemorrhage, embolism, or thrombosis that persists for >24 hours
- Renal failure (excludes renal insufficiency): the need for temporary or permanent dialysis
- Respiratory failure (excludes COPD or pulmonary complications): pneumonia or respiratory failure requiring ventilator support beyond 24 hours post-procedure
- Paralysis (excludes paraparesis): paralysis of the lower extremities inclusive of the lower trunk
- Bowel ischemia: the lack of adequate blood flow to the intestines that requires intensification of medical therapy or surgical/endovascular intervention
- Procedural blood loss (≥1,000 mL): estimated blood loss during the index procedure ≥1,000mL

2.0 BACKGROUND AND RATIONALE

Abdominal aortic aneurysm (AAA) is the most commonly encountered aneurysm of the arterial system. Several factors are thought to contribute to the development of AAA such as advanced age, gender, 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 AAA usually depends upon whether complications or symptoms have occurred. 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], and many asymptomatic patients are diagnosed with AAA upon routine examination by a physician for another problem or as a result of increased patient awareness. Symptoms such as acute onset of abdominal, back, or flank pain can be an indication of aneurysm expansion or impending rupture which may follow at a time that is unpredictable. Rupture of AAA is a life-threatening clinical event necessitating emergent intervention. Many patients with ruptured AAA die before reaching the hospital. Of the patients that do reach the hospital, about half of those patients survive.

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 with a AAA diameter less than 5.0 cm is significantly lower than the risk of rupture of AAA with a diameter of 5.0 cm or more. Brewster et al[3] reported 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, MRI, or ultrasound 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 5 cm in diameter.

If the AAA is large, grows quickly, or is causing symptoms, it will require prompt treatment to prevent rupture. Available treatments for AAA requiring intervention 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 requiring intervention. 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 results in 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. The Food and Drug Administration (FDA) reported early mortality rates in population-based series for elective open surgical repair were between 3-5% at 30 days[1]. In a literature review by Hallin[5], the mortality rate for elective surgical repair was noted to be approximately 5%, and approximately 50% for emergent surgical repair.

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.

2.1.3 Endovascular Stent Graft Repair

Since the early 1990's, endovascular aortic repair (EVAR) has evolved into the treatment for AAA at most centers. In 1991, Dr. Juan Parodi was one of the first to introduce EVAR as a less invasive treatment option for AAA. 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 allows the treatment of patients with multiple comorbidities who may have otherwise been excluded from treatment with open repair due to high surgical risk[7].

Endovascular grafts, often stented for support, are designed to provide an alternate conduit for blood flow and to exclude the aneurysm from this flow and the associated hemodynamic pressure. Exclusion of the aneurysm significantly reduces 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 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 open surgical repair and allows a shorter recovery time for the patient. The length of hospital stay is reduced, which allows patients to more rapidly resume their normal activities of daily living.

During the last 15 years, systems for performing EVAR have been developed, clinically tested, and approved for use. The Ovation platform is approved for commercial use in approximately 40 geographies, including the United States, Europe and Canada. In addition, there are several devices (Excluder, Zenith, AFX, Powerlink, Talent, AneuRx, Endurant, Endurant II, Aorfix and Ancure) approved for use in the United States, with some also approved in other worldwide geographies.

In a multi-center AAA clinical trial evaluation of open versus endovascular treatment, Matsumura[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 also experienced less blood loss, a reduction in need for transfusions and a shorter length of hospital stay.

The following outlines morbidities associated with EVAR:

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.

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

Less blood loss, fewer days in the ICU, and a shorter hospitalization is generally reported in patients who undergo EVAR when compared to patients in the surgical control groups. On average, patients treated with EVAR are also able to return to their normal activities quicker than those who receive open surgery.

3.0 INDICATIONS

The Ovation Alto Abdominal Stent Graft System is indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with vascular access techniques (percutaneous or femoral cut-down), devices, and/or accessories,
- Proximal aortic landing zone:
  - with an inner wall diameter of no less than 16 mm and no greater than 30 mm at 7 mm below the inferior renal artery, and
  - an aortic angle of $\leq$ 60 degrees if proximal neck is $\geq$ 7 mm and $\leq$ 45 degrees if proximal neck is < 7 mm,
- Distal iliac landing zone:
  -with a length of at least 10 mm, and
  -with an inner wall diameter of no less than 8 mm and no greater than 25 mm.

4.0 DEVICE DESCRIPTION

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

The Ovation Alto Abdominal Stent Graft System includes:

- An Aortic Body Stent Graft and delivery catheter
- Ovation iX Iliac Limb Stent Grafts and delivery catheters*
- Ovation iX Iliac Extension Stent Grafts and delivery catheters, as required*
- Balloon Expandable Stent and delivery catheters, as required
- A Fill Kit*
- An Autoinjector

*Note: These components are currently approved by FDA via PMA P120006.

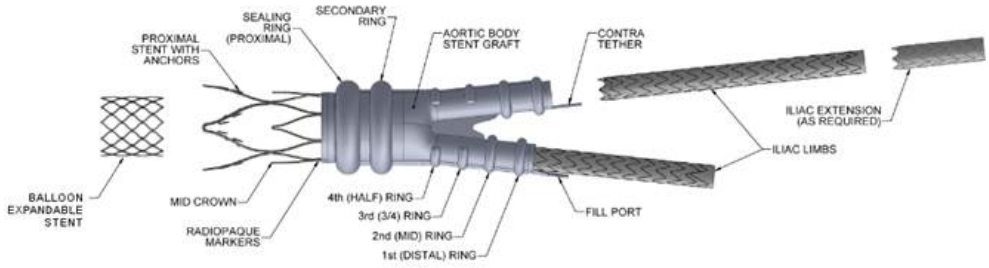

Figure 1. Schematic of Deployed Ovation Alto Abdominal Stent Graft System

The aortic body is comprised of a proximal stent for suprarenal fixation and a low-permeability polytetrafluoroethylene (PTFE) graft. The stent is designed with integral anchors to enable fixation to the aortic wall. For delivery, the stent is in a compressed state within the catheter. When released from the compressed state, the stent expands to engage the vessel wall. The nitinol stent is radiopaque, and radiopaque markers are located adjacent to the graft proximal edge. These radiopaque markers aid placement of the device in its intended location relative to the renal arteries. To seal the proximal end of the graft and to provide support for the aortic body legs into which the iliac limbs are deployed, the graft body contains a network of inflatable rings that are filled with a liquid polymer that solidifies during the deployment procedure. The graft has a fill port that connects the fill network of the graft to the delivery catheter. Figure 2 provides an image of the device with its sealing ring in the aorta.

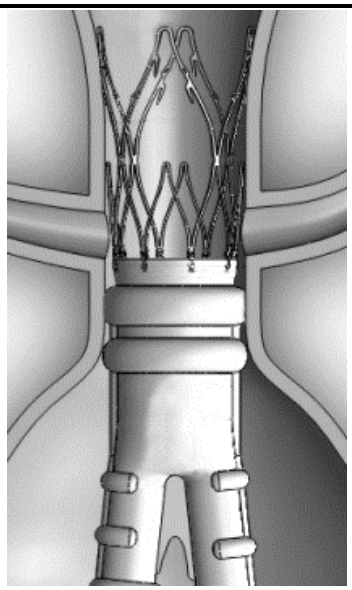

Figure 2. Ovation Alto Aortic Body Stent Graft in aorta

The iliac limbs and extensions are comprised of a nitinol stent encapsulated in low-permeability PTFE. The iliac limbs are deployed into the leg sections of the aortic body. Radiopaque markers enable 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.

The BES implant is a balloon expandable, closed cell design, laser cut stent made from seamless 316LVM stainless steel tubing. The implant is supplied in two nominal lengths, 30mm and 40mm, and is preloaded into a delivery catheter. The implant is designed to expand to a maximum diameter of 30mm. The stainless steel stent is inherently radiopaque which visually aids the placement of the stent graft accessory across the sealing rings of the primary aortic stent graft body as illustrated in Figure 3 below.

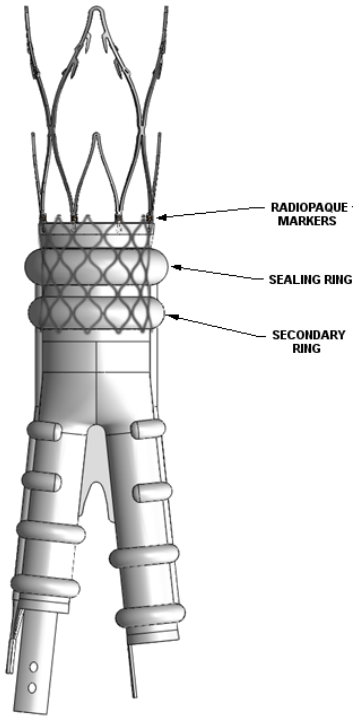

Figure 3. Balloon Expandable Stent in Ovation Alto Stent Graft

To facilitate device introduction into the access vessel, the aortic body, the iliac limbs, the iliac extensions, and the balloon expandable stent are preloaded into delivery catheters, as illustrated in Figures 4-6. The delivery catheters each have a lumen for use with a guidewire to facilitate access and deployment and the outer sheaths are hydrophilically coated. The inner catheter of each delivery system can be withdrawn through the outer sheath, with the outer sheath remaining in the vasculature to facilitate the introduction of ancillary devices.

The aortic body is deployed via the aortic body delivery catheter, which has a connection to the distal legs of the aortic body. During aortic body stent graft deployment, the device is first positioned and the sheath is retracted. The proximal stent is deployed using stent release knobs on the handle, with an integral balloon used to facilitate graft opening. The fill polymer is then delivered through the fill connector port using the Autoinjector.

The contralateral and ipsilateral iliac limbs are each 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 integrated crossover lumen on the aortic body delivery system can be utilized to facilitate the process. The contralateral iliac limb is advanced into position and deployed into the aortic body leg by retracting the catheter sheath with the catheter in the appropriate position. The contralateral limb delivery catheter is then used as an integral sheath (as described above) or withdrawn from the vasculature.

After the fill polymer cures within the sealing rings, the integral balloon of the aortic body delivery catheter can be used to improve seal ring apposition. The catheter is detached from the fill port of the graft and is used as an integral sheath (as described above) or withdrawn from the vasculature.

The ipsilateral iliac limb delivery catheter is advanced over the ipsilateral guidewire and deployed using the method described above for the contralateral limb. The ipsilateral limb delivery catheter is then used as an integral sheath (as described above) or withdrawn from the vasculature.

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

If a balloon expandable stent is required (after removal of the aortic body delivery system), the stent is first positioned across the sealing ring and secondary ring of the previously deployed aortic body stent graft and the sheath is retracted. After sheath retraction, the stent is expanded by inflating the balloon while aligning the proximal crowns of the stent with the aortic body stent graft radiopaque markers. The balloon is then deflated and the delivery catheter is withdrawn from the vasculature.

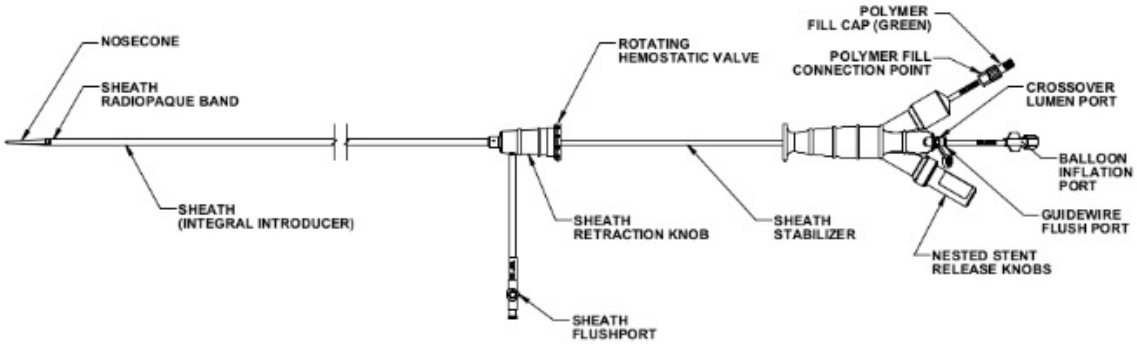

Figure 4. Schematic of Ovation Alto Abdominal Stent Graft System Aortic Body Delivery Catheter

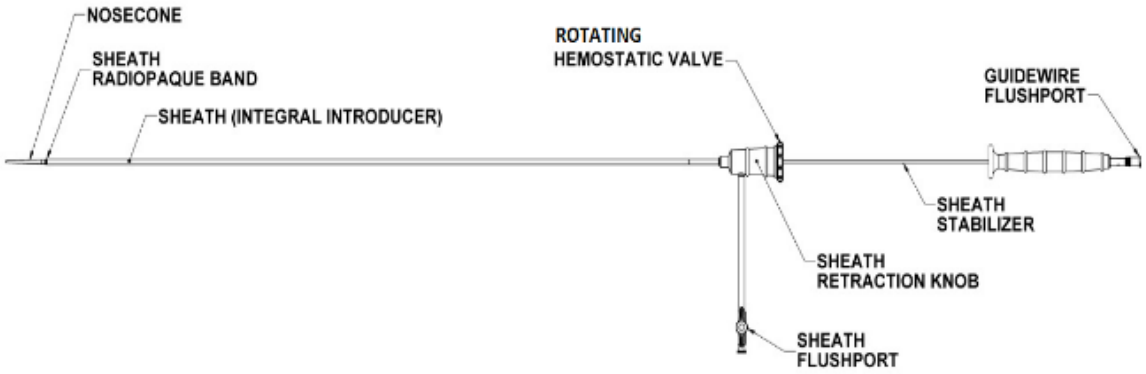

Figure 5. Schematic of Ovation iX Iliac Limb/ Iliac Extension Delivery Catheter

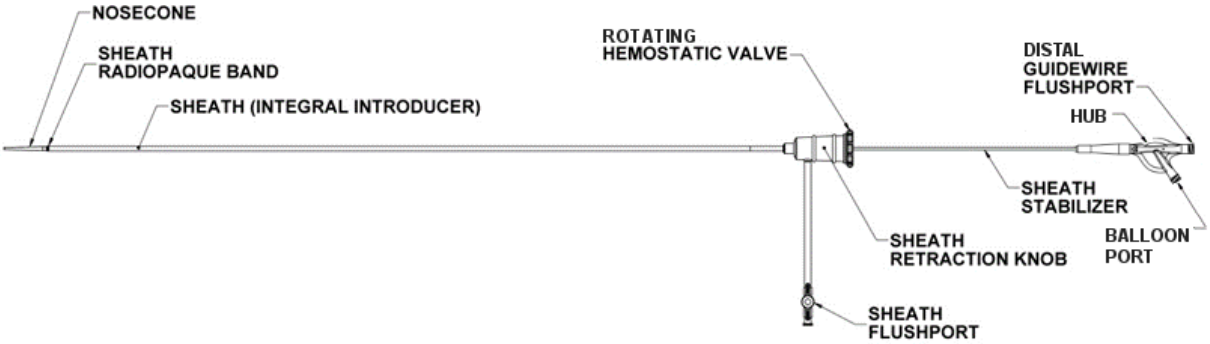

Figure 6. Schematic of Balloon Expandable Stent Delivery Catheter

The Ovation Alto Abdominal Stent Graft System is designed to accommodate various aortic anatomies, including a range of proximal and distal aortic neck diameters and aneurysm lengths. Table 1 summarizes the implant diameters and lengths to be offered for the aortic body and iliac limbs:

Table 1. Device Sizing Matrices

Aortic Body	
Stent Graft Diameter, mm	**Aortic ID, mm***
20	16-17
23	18-20
26	21-23
29	24-26
34	27-30

Iliac Limb / Extension	
Stent Graft Diameter, mm	**Iliac ID, mm**
10	8-9
12	10-11
14	12-13
16	14-15
18	16-17
22	18-20
28	21-25

* At the intended proximal sealing ring location (7 mm below the inferior renal artery). Ensure adequate oversizing of the proximal stent at its anchoring location.

The Fill Kit options are shown in Figure 7 and Figure 8. Figure 7 is the Fill Polymer Kit with 20 minute detach time and Figure 8 is the CustomSeal Kit with 14 minute detach time. The

fill polymer is comprised of three components that are mixed prior to injection. Upon mixing and injection into the graft, the components form a radiopaque polymer that fills the sealing rings in the wall of the aortic body graft and the ribs in the aortic body graft legs. The fill polymer radiopacity dissipates over time and may not be visible on fluoroscopy, X-ray or CT beyond 1-2 months post-implant.

Prior to use, the two valves on the fill kit are opened and the fill polymer is mixed by alternately depressing the two syringe plungers for a minimum of 20 full strokes. Thereafter, the fill syringe is disconnected from the connection tube, slipped out of the syringe support and connected to the fill polymer injection port on the aortic body delivery system. The syringe plunger is then inserted into the Autoinjector (Figure 9), and the Autoinjector is given a quarter-turn to lock it in place. The Autoinjector applies controlled force to the syringe plunger to inject the fill polymer into the graft.

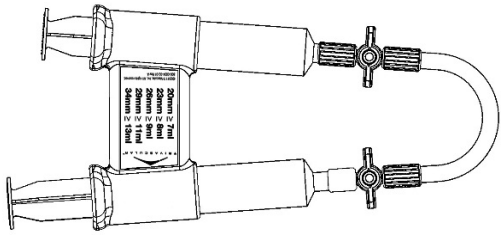

Figure 7. Fill Polymer Kit with 20 minute detach time

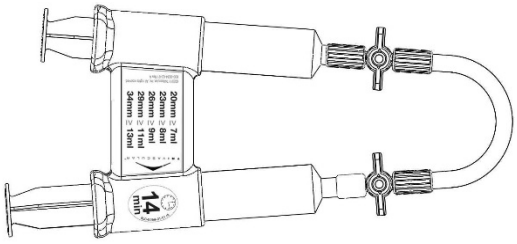

Figure 8. CustomSeal Kit with 14 minute detach time

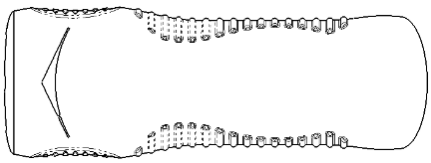

Figure 9. Autoinjector or Autoinjector 2

Table 2. Balloon Expandable Stent sizes

Stent Graft Length, mm	Catheter Working Length, cm	Delivery System Outer Profile, F	Integral Sheath Inner Diameter, F
30	60	12	10
40			

5.0 STUDY DESIGN

The goal of the study is to evaluate the Ovation Alto Abdominal Stent Graft System in subjects with abdominal aortic aneurysm (AAA). This prospective case series will consecutively enroll patients with AAA who will be treated with the Ovation Alto Abdominal Stent Graft System. The primary study objective of the study is to evaluate treatment success at 12 months in patients treated with Ovation Alto. Secondary objectives of this study will include safety and effectiveness assessments of the Ovation Alto device through 12-month follow-up.

Subjects will be screened prior to study entry to determine if they meet the eligibility criteria. Subjects, or, when appropriate, the subject's legal representative, will give informed consent following an explanation by the investigator of the risks and benefits of treatment with the Ovation Alto Abdominal Stent Graft System. A screening log will be maintained of all subjects evaluated for inclusion in this study to document the reasons for non-eligibility. Each study center may enroll and treat up to 20% of the total study population.

5.1 Eligibility Criteria

The inclusion/exclusion criteria in this study are identical to the Ovation Abdominal Stent Graft System IDE G090239, with the exception of Inclusion Criteria 7, 8, and 10 below, which are specific to the Ovation Alto Abdominal Stent Graft System device sizing.

5.1.1 Inclusion Criteria

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 Ethics Committee/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:

   (a) Abdominal aortic aneurysm $\geq$5.0 cm in diameter,

(b) Aneurysm that has increased in size by 0.5 cm in last 6 months*,

(c) Maximum diameter of aneurysm exceeds 1.5 times the transverse dimension of an adjacent normal aortic segment*.

*As part of the ELEVATE IDE Study, abdominal aortic aneurysms that are less than 5 cm in diameter may be treated, if at least one of the following anatomical criteria is met:

-Aneurysm has increased in size by at least 0.5 cm in the last 6 months
- Aneurysm is no less than 4 cm in diameter and exceeds 1.5 times the transverse dimension of the an adjacent normal aortic segment, as demonstrated on the screening CTA, performed within 6 months of anticipated treatment.

6. Patient has patent iliac or femoral arteries that allow endovascular access with the Ovation Alto Abdominal Stent Graft System.
7. Patient has a proximal aortic landing zone with an inner wall diameter of no less than 16 mm and no greater than 30 mm at 7 mm below the inferior renal artery.
8. Patient has an adequate distal iliac landing zone with an inner wall diameter of no less than 8 mm and no greater than 25 mm.
9. Patient has an adequate distal iliac landing zone with a length of at least 10 mm. The resultant repair should preserve patency in at least one hypogastric artery.
10. Patient meets the following anatomic criteria: the distance from the most distal renal artery to most superior internal iliac artery measurement is at least 125 mm.
11. Patient has juxtarenal aortic neck angulation $\leq 60^{o}$ if proximal neck is ≥ 7 mm and ≤ 45 degrees if proximal neck is < 7 mm.
12. Patient must be able and 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 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 prior and 30 days post procedure 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 polytetrafluoroethylene (PTFE), polyethylene glycol (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 an 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.

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 the Study

Subject follow-up visits will occur at 1, 6, and 12 months post implant procedure.

5.5 Conduct of the Study

5.5.1 Schedule of Activities

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

5.5.1.1 Patient Screening

Prospective subjects are consecutively evaluated for study eligibility at the time they are considered 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/EC approved Informed Consent Form, per Institutional policies
2. Submit contrasted spiral CT images of slice thickness ≤3 mm to the Sponsor obtained within 6 months of anticipated treatment.

5.5.1.2 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)
- Laboratory testing, which includes renal assessment and 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 is not enrolled into the study, the baseline screening worksheets will be retained, together with the patient's signed/dated consent(s).

5.5.1.3 Treatment Period (implant/surgical procedure)

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

- Device accountability- documentation of product information (e.g., lot number, serial number, and expiration date).
- Type and length of anesthesia
- Type of vascular access (e.g. femoral cut down or percutaneous)
- Estimated blood loss
- Adjunctive procedures (e.g. stent placement)
- Investigator assessment of AAA device performance as it relates to delivery/deployment/required interventions, endoleak, and device integrity issues
- Procedural times (total device and procedure)
- Fluoroscopy time

- Contrast medium volume
- Adverse events
- The above assessments are recorded in the **Procedure eCRF.**

5.5.1.4 Pre-Discharge

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

- Physical exam
- Length of hospital stay
- ICU stay
- Adverse events
- KUB X-ray (AP, lateral, left oblique and right oblique views)

The above assessments are recorded in the **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.

5.5.1.5 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**

- Physical exam
- Laboratory test, which includes renal assessment at 1-month follow-up visit
- Contrast Enhanced Spiral Abdominal/Pelvic CT and X-ray (KUB), to be evaluated by Independent Core Lab
- Adverse events

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.

5.5.1.6 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 months, 12 months) 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 Unscheduled **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 Visit eCRF.**

5.5.1.7 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.**

6.0 DEFINITIONS

The outcomes defined below will be collected by the study sites and evaluated by the Independent Core Lab as specified.

6.1 Endoleak

Endoleak is evaluated by the Independent Core Lab and 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 IA* – Ineffective seal at the proximal sealing zone
  - *Type IB* – Ineffective seal at the distal sealing zone
- *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 IIIA* - Junctional leak or component disconnection
- *Type IIIB* - Midgraft hole
- *Type IV* – Blood flow through an intact fabric.
- *Unknown endoleak* - Endoleak present but unable to assess type
  Endoleak will only be evaluated as an adverse event or serious adverse event if it is present at the 30-day follow-up visit or if a post-index procedure re-intervention occurs.

6.2 Migration

Migration is evaluated by the Independent Core Lab and 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.

6.3 Patency

Patency is defined as the absence of complete occlusion (100%) of the device or native vessel. Patency can be either within the device (device patency) or the native vessel outside the device (vessel patency). This may be evidenced by: CT, angiography, ultrasound or other imaging modality, or pathological analysis.

6.4 Thrombosis

Thrombosis is defined as complete occlusion (100%) of the device or native vessel. Thrombosis can be either within the device (device thrombosis) or the native vessel outside the device treatment area (vessel thrombosis). This may be evidenced by: CT, angiography, ultrasound or other imaging modality, or pathological analysis.

6.5 Stenosis

Stenosis is defined as narrowing of the blood flow lumen that is less than 100% occlusion. Stenosis can be either within the device (device stenosis) or the native vessel outside the device treatment area (vessel stenosis). This may be evidenced by: CT, angiography, ultrasound or other imaging modality, or pathological analysis.

6.6 Loss of Stent Graft Integrity

The integrity of the stent graft is evaluated by the Independent Core Lab via 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.

6.7 AAA Enlargement

Aneurysm enlargement is evaluated by the Independent Core Lab and 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 Independent Core Lab and reported in the data analysis, but diameter is considered the relevant characteristic for the study endpoint evaluations.

6.8 Surgical Conversion

Surgical conversion occurs when a subject implanted with an Ovation Alto 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. The patient will remain enrolled in the study until 30 days after the conversion procedure or the discharge date of the conversion procedure, whichever occurs later.

6.9 Imaging Assessment

The Sponsor 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 X-ray (KUB) and CT images to the Core Lab for all required study visits.

Study Visit	Images* Required to be submitted to Sponsor
Baseline	Contrast Enhanced Spiral Abdominal/Pelvic CT
Pre-Discharge	X-ray (KUB) (AP, lateral, left oblique and right oblique views)
1 month	Contrast Enhanced Spiral Abdominal/Pelvic CT X-ray (KUB) (AP, lateral, left oblique and right oblique views)
6 month	Contrast Enhanced Spiral Abdominal/Pelvic CT X-ray (KUB) (AP, lateral, left oblique and right oblique views)
12 month	Contrast Enhanced Spiral Abdominal/Pelvic CT

	X-ray (KUB) (AP, lateral, left oblique and right oblique views)

*Refer to **Appendix V: CT Scanning Techniques** for imaging requirements.

6.10 Explant Evaluation

The study Sponsor 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 the study Sponsor for evaluation by a Pathologist at an independent Explant Laboratory. Refer to **Appendix VI: Explant Procedure** for specific instructions for managing the removal, shipping, and handling of the explanted AAA device.

6.11 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. The following events are to be captured in this study:

- Adverse Events, regardless of device relationship
- Serious Adverse Events, regardless of device relationship
- All Deaths
- Unanticipated Adverse Device Effects

Requirements for reporting AEs are dependent upon the reviewing IRB/EC 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 subjects undergoing customary, standard of care 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
- Prolonged hospitalization due to logistical delays relating to discharge to a skilled nursing facility, care facility, rehabilitation center, etc.

The Investigator and/or IRB/EC 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/EC.

Device-related adverse events should be reported to the study Sponsor as soon as possible (24 hours recommended), but no more than 10 working days after the date the site becomes aware of the event.

Device-Related: Event is caused or contributed by any component of the device during delivery, deployment or while the device is in situ post-operatively

- "Caused or Contributed" means that an injury was or may have been attributed to the study device, or that the study device was or may have been a factor in an injury, including events occurring as a result of:
  - Any event resulting from intervention on the AAA or device
  - Any device failure, malfunction, inadequacy, including operator error

Procedure-Related: Event is caused or contributed by the initial study device implantation (index) procedure, up to 30 days, unless a different etiology can be identified

6.12 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 should be reported to the study Sponsor as soon as possible (24 hours recommended), but no more than 10 working days after the date the site becomes aware of the event.

Sites are also required to adhere to the reviewing IRB/EC requirements for reporting of SAE's.

6.13 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.

6.14 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 protocol 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 eCRF and the event is to be reported to the Sponsor within 24 hours of knowledge of the event. Sites are also required to adhere to the reviewing IRB/EC requirements for reporting of any UADE.

6.15 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 Procedure eCRF (if at initial implant) or Follow Up eCRF (after implant) , and the **Adverse Event eCRF/ Secondary Intervention eCRF**.

In the event that a subject requires conversion from endovascular to open surgical repair, the explanted device should be sent to the Sponsor for examination. Refer to **Appendix VI** for specific instructions for managing the removal, shipping and handling of the explanted device. Explant information will be recorded on the **Secondary Intervention eCRF under Adverse Event eCRF**.

Surgical conversions must be reported by telephone, email or EDC system by noting an Adverse event/secondary intervention to the study Sponsor **within 24 hours** of knowledge of the event.

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

6.16 Technical Failures

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

6.17 Deaths

Any deaths that occur during the conduct of the study must be reported to the study Sponsor **within 24 hours** of becoming aware of the event. Sites are also required to adhere to the reviewing IRB/EC 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 the Sponsor whenever possible for examination. Additional information to be submitted to the Sponsor may include such documents as: death certificate, autopsy report, summary of death report, hospital records, explant reports and copy of IRB/EC notification of the event. Patient death will have only one corresponding adverse event with outcome of "Death", entered for the most proximal cause of death. Upon entry of the death into the **Study Exit eCRF,** every patient death will be determined to be "AAA-Related", or "Non-AAA-Related".

6.18 Explants

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

7.0 ENDPOINTS

7.1 Primary Endpoint

The primary objective of this study is to evaluate treatment success at 12 months with the Ovation Alto Abdominal Stent Graft System in subjects with AAA.

Treatment success will be a composite endpoint comprised of all of the following:

- Technical success*;
- Freedom from type I & III endoleak at 12 months, to be assessed by an Independent Core Lab;
- Freedom from stent graft migration > 10 mm at 12 months (compared to 1-month baseline) , to be assessed by an Independent Core Lab;
- Freedom from AAA enlargement > 5mm at 12 months (compared to 1-month baseline);
- Freedom from AAA rupture through 12 months;
- Freedom from conversion to open repair through 12 months;
- Freedom from stent graft stenosis, occlusion, or kink requiring secondary intervention through 12 months;
- Freedom from thromboembolic event attributable to stent graft requiring secondary intervention through 12 months, and:
- Freedom from stent fracture requiring secondary intervention through 12 months

*Technical Success will be a composite endpoint comprised of all of the following:

- Successful delivery, defined as ability to deliver the implant to the intended location without the need for unanticipated corrective intervention related to delivery, using an adjunctive device outside of the Ovation Alto Abdominal Stent Graft System;
- Successful and accurate deployment, defined as:
    - deployment of the endovascular stent graft in the planned location
    - patency of the endovascular stent graft, absence of device deformations (e.g. kinks, stent eversion, mal-deployment, misaligned deployment) requiring unplanned placement of an additional device within the endovascular stent graft, and;
    - successful withdrawal of the delivery system without the need for unanticipated corrective intervention related to withdrawal

7.2 Additional Study Evaluation

Additional assessments that will be reported at each follow-up interval include:

- Type I endoleak, to be assessed by an Independent Core Lab
- Type III endoleak, to be assessed by an Independent Core Lab
- Stent graft migration > 10 mm (compared to 1-month baseline), to be assessed by an Independent Core Lab
- AAA enlargement > 5 mm (compared to 1-month baseline)
- Loss of patency
- Stent fracture, to be assessed by an Independent Core Lab
- AAA rupture
- Conversion to open repair

- Secondary interventions
- AAA-related mortality
- Adverse events, including:
    - Serious adverse events
    - Major adverse events
    - Procedure-related adverse events
    - Device-related adverse events
    - All adverse events, regardless of seriousness or cause

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.

8.0 DATA ANALYSIS

8.1 Analysis Population

Primary analyses will be performed on a modified intent-to-treat basis. The modified intent-to-treat group includes all subjects in which the delivery system was inserted into an access vessel. All subjects who achieve technical success and remain free of all other elements of the composite effectiveness endpoint at 12 months will be considered treatment successes. All subjects who fail based on any element of the composite effectiveness endpoint, and all subjects who deemed treatment successes will be included in the denominator. Only subjects with readable imaging during each respective follow-up interval will be included in the denominator for relevant effectiveness endpoints. Subjects not counted as failures, but with incomplete data to assess all the composite elements will be treated as missing data points.

8.2 Analysis Windows

Safety and effectiveness data will be categorized into discrete, contiguous analysis windows to ensure that all available data are included in analyses. The analysis windows around each follow-up visit are: 1 month (0-90 days), 6 months (91-304 days), and 12 months (305-547 days).

8.3 Analysis Methods

Baseline patient characteristics will be summarized with standard descriptive statistics. Categorical variables will be described with percentages and counts. Continuous variables will be described with means, standard deviations, medians, and ranges.

For evaluation of treatment success at 12 months, all subjects with technical success and freedom from all other elements of the composite endpoint will be considered treatment successes. Subjects who fail based on any element of the composite endpoint, and all subjects deemed treatment successes will be included in the denominator. Subjects not counted as failures due to meeting any element of the composite, but who have incomplete data to assess all the composite elements will be treated as missing data points. Only subjects with readable imaging during each respective follow-up interval will be included in the denominator for relevant effectiveness endpoints. Sensitivity analyses will be performed to assess the impact of missing data on the primary endpoint.

Complete data analysis methods will be prospectively defined in a Statistical Analysis Plan.

8.4 Study Hypotheses

Treatment success at 12 months in subjects treated with the Ovation Alto will be compared to a performance goal of 80%.

The primary effectiveness hypotheses are defined as:

- H_0: $\pi \leq 80\%$
- H_1: $\pi > 80\%$, where

π is the expected treatment success rate at 12 months in subjects treated with the Ovation Alto. The primary effectiveness endpoint will be met if the lower limit of the one-sided 95% confidence interval for π is greater than 80%.

Additional outcomes in this study will be reported descriptively, with no hypothesis testing.

8.5 Power Analysis and Sample Size

The sample size for this study was calculated based on the following assumptions:

- Estimated treatment success at 12 months: 92.8%
- Performance goal: 80%
- Confidence interval estimation: One-sided exact 95% confidence limit
- Statistical power: 86.1%

The power analysis assumptions are based on the following rationales:

- Estimated treatment success at 12 months of 92.8% was derived by retrospectively applying the treatment success definitions in this study to the data observed in Ovation Abdominal Stent Graft System IDE G090239. Given the similarities in device attributes and that no impacts on device effectiveness are anticipated between IDE G090239 and the current study, it is reasonable to assume the same adjusted treatment success rate observed in IDE G090239.
- The performance goal of 80% is a common standard for comparing 12-month effectiveness outcomes in EVAR IDE trials. The pivotal study for the Ovation stent graft utilized the same performance goal. The performance goal may be somewhat more conservative in the current study given the comparatively broader definition of 12-month treatment success.
- A one-sided 95% confidence limit is appropriate since the 12-month treatment success rate with the Ovation Alto would not reasonably be expected to be lower than the 80% performance goal. Therefore, protection against a type I error on that side of the hypothesis is not considered.

Based on these assumptions, 60 evaluable patients are required. In order to account for reasonable attrition, the Sponsor plans to enroll up to 75 patients in this study.

9.0 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 Alto 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:

- Acute and chronic renal failure, renal microembolism, renal insufficiency, renal artery occlusion, contrast toxicity;
- Allergic reaction and/or anaphylactoid response to x–ray contrast dye, anti-platelet therapy, device materials;
- Anesthetic complications and subsequent attendant problems (aspiration);
- Aneurysm enlargement or rupture;
- Blood or bleeding events such as anemia, gastrointestinal bleeding, retroperitoneal bleeding;
- Bowel events such as bowel ischemia, infarction, bowel necrosis, colon ischemia, paralytic or adynamic ileuses, obstruction, fistulas;
- Cardiac events and subsequent attendant problems such as congestive heart failure, volume overload, arrhythmias, myocardial infarction, chest discomfort or angina, elevations in creatinine phosphokinase (CPK), hypotension, hypertension;
- Cerebral events (local or systemic) and subsequent attendant problems such as change in mental status, cerebrovascular accident (hemorrhagic or embolic), reversible ischemic neurologic deficit, nerve injury, transient ischemic attacks, paraplegia, paraparesis, paralysis;
- Death;
- Device events such as deployment or device malfunction, stent fracture, loss of stent graft system component integrity, graft twisting and/or kinking, graft

material wear, dilation, erosion, puncture, endograft occlusion, migration, dislodgement, endoleak;

- Embolic and thrombotic events transient or permanent ischemia or infarction such as deep vein thrombosis, thromboembolism, microembolism, thrombophlebitis, phlebothrombosis and/or air embolism;
- General discomfort related to the procedure;
- Generalized inflammatory response that may be associated with elevated levels of systemic mediators of inflammation, elevated temperature;
- Genitourinary complications and subsequent attendant problems such as ischemia, erosion, fistula, incontinence, hematuria, infection;
- Hepatic failure;
- Insertion and other vascular access site complications such as infection, dissection, transient fever, bleeding, pain, delayed healing, abscess formation, hematoma, dehiscence, seroma, cellulitis, nerve injury/damage, neuropathy, neuralgia, vasovagal response, pseudoaneurysm, anastomotic false aneurysm, arteriovenous fistula;
- Impotence/ sexual dysfunction;
- Lymphatic complications and subsequent attendant problems such as lymphocele, lymph fistula;
- Multi-system organ failure;
- Neoplasm;
- Operative and post–operative bleeding and hemorrhage, coagulopathy;
- Paralysis (temporary or permanent) such as paraplegia, monoplegia, paresis, spinal cord ischemia, hemiplegia, bowel or bladder incontinence;
- Pericarditis;
- Pneumothorax;
- Possible infection–urinary tract, systemic or localized, endograft;
- Pulmonary/respiratory events and subsequent attendant problems such as pulmonary insufficiency, pneumonia, respiratory depression or failure, pulmonary edema, pulmonary embolism, atelectasis, pleural effusion;
- Radiation injury, late malignancy;
- Sepsis;
- Seroma;
- Shock;
- Spinal neurological deficit;
- Surgical conversion to open repair; and/or
- Vascular spasm or vascular injury/trauma including damage to blood vessels and surrounding tissues, atherosclerotic ulcer, vessel dissection, perforation, plaque dissection, stenosis, pseudoaneurysm, vessel occlusion, embolization, ischemia, tissue loss, limb loss, gangrenous disease, worsened or new onset claudication, edema, fistula, bleeding, rupture, death.

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

- 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;
- Low risk of injury to the access vessels due to the low profile and flexible delivery system.

10.0 STUDY RESPONSIBILITIES

10.1 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/EC review and approval are obtained, and ensuring that reviewing IRBs/ECs are promptly informed of significant new information about the study.

10.2 IRB/EC Approval

A Sponsor shall not begin an investigation until an IRB/EC has approved the study.

10.3 Selection of Investigators

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

10.4 Selection of Monitors

A Sponsor shall select monitors qualified by training and experience to monitor the study in accordance with applicable Good Clinical Practice (GCP) and ICH Harmonized Tripartite Guidelines.

10.5 Accountability and Control of Device

Sponsor shall ship devices only to qualified investigators participating in the study. The investigator shall maintain adequate records of the receipt and disposition of all 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.

10.6 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.

10.7 Informing Investigators

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

10.8 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 (GCP) 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 the study Sponsor 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/or 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/EC, or other applicable regulatory agencies.

10.9 Responsibilities of Investigators

An investigator is responsible for ensuring that the study is conducted in accordance with the signed agreement, the protocol, IRB/EC and other applicable 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. Investigator shall return unused devices to the Sponsor, or dispose of device as directed by Sponsor.

A study Sponsor representative 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/EC withdrawal, unanticipated adverse device effects, deviations from the protocol, use of a device without obtaining subject consent, as well as progress reports to IRB/EC (annually at minimum) are also the responsibility of the investigator.

10.10 Source Documentation

Investigators are responsible for maintaining information in the study subjects' medical records that corroborate data entered into the eCRF. 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, device/procedure time, AEs, 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.

10.11 Maintaining Records

The study Sponsor will maintain hard or electronic copies of correspondence, data, shipment of devices, adverse device effects, and other records related to the clinical trial. 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:

- Source Documents – 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 Sponsor-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/EC Correspondence – includes approval letter(s), and any adverse event reporting or other correspondence with the IRB/EC.
- 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 Accountability 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 that the study is closed.

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.

10.12 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 the study Sponsor clinical trial 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 trial 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/EC policies.

Investigators should 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	Study Sponsor and IRB/EC	Within 5 days of event
Changes in or Deviations from the protocol	Prior approval from: Study Sponsor and IRB/EC	Prior to use
Non-urgent protocol deviation	Study Sponsor and IRB/EC (if required)	Upon eCRF completion.

10.13 Termination of Study

The Sponsor 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.

11.0 STUDY COMMITTEES

11.1 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.

11.2 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.

12.0 TRAINING

The study Sponsor 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 Alto Abdominal Stent Graft System and its deployment, as well as the essential ancillary equipment necessary to perform the implant procedure with the device.

13.0 INFORMED CONSENT

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

APPENDIX I: References

1. Hallin, A., Bergqvist, Holmber, L. Literature Review of Surgical Management of Abdominal Aortic Aneurysm. Eur J Vasc Surgery 2001; 22:197-204.

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3. Brewster, David C., Cronenwett, Jack L., Hallett, John W. Jr., Johnston, K.Wayne, Krupski, William C., Matsumura, Jon S.. Guidelines for the Treatment of Abdominal Aortic Aneurysms. J Vascular Surgery 2003; 37:1106-1116

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

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8. Lavori PW, 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 AF, Robinson PA, Boland JP, Lucente FC, Stuart SP, Neuman SS, Hall MD, Hoak BA. 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 DC, Geller SC, Kaufman JA, Cambria RP, Gertler JP, LaMuraglia GM, Atamian S, Abbott WM. Initial experience with endovascular aneurysm repair: Comparison of early results with outcome of conventional open repair. J Vasc Surg 1998; 27 (6): 992-1005.
4. Buth J, Laheij RJF. Early complications and endoleaks after endovascular abdominal aortic aneurysm repair: Report of a multicenter study. J Vasc Surg 2000; 31 (1), Part I: 134-146.
5. Chuter TA, Risberg B, Hopkinson BR, Wendt G, Scott AP, Walker PJ, 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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7. May J, White GH, Yu W, Ly CN, Waugh R, Stephen MS, Arulchelvam M, Harris JP. Concurrent comparison of endoluminal versus open repair in the treatment of abdominal aortic aneurysms: Analysis of 303 patients by life table method. J Vasc Surg 1998; 27 (2): 213-221.
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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 subject's risk of undergoing anesthesia. The scale represents the significance of the subject'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. Subject not at extremes of age. *(Note: Age is sometimes ignored as affecting operative risk; however, subjects 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 Months Follow-Up	1 Year Follow-Up
Medical/Surgical History	X[2]					
Physical Exam	X[2]		X	X	X	X
ABI	X					
Spiral Contrast Enhanced CT[5]	X[3]			X	X	X
Laboratory Assessments (BUN, Creatinine and Serum Pregnancy)[1]	X[1]			X[1]	X[1]	X[1]
Adverse Event Assessment		X	X	X	X	X
Device/aneurysm assessment based on imaging (endoleak, migration, integrity, patency)		X	X[4]	X	X	X

[1] BUN, creatinine and serum pregnancy HCG required no more than 30 days prior to the implant/surgical for baseline. At every follow up time point beginning with 1 month follow up, only serum creatinine will be collected. *Note: the serum pregnancy is required for females of child-bearing potential only and only at baseline. BUN is only required at baseline.*

[2] Baseline medical/surgical history and physical exam performed no more than 30 days prior to the implant/surgical procedure.

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

[4] Only the device will be assessed via X-Ray at discharge as no CT is performed at that visit.

[5] 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.

APPENDIX V: CT Scanning Techniques

Reminders:

- The Sponsor 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 must be sent to the Sponsor.

	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 VI: Explant Procedures

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 the Sponsor to obtain shipping instructions.
7. Please alert the Sponsor within 24-hours of the explant and the shipment of the device.
8. Explant information must be completed in the Adverse Event/ Secondary Intervention eCRF in EDC 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 the Sponsor 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.

APPENDIX VII: Informed Consent Templates

DRAFT INFORMED CONSENT

Study Title:	**E**xpanding Patient Applicability with Po**L**ymer S**E**aling O**VAT**ion Alto St**E**nt Graft IDE Study (**ELEVATE** IDE Study)
Trial Number:	771-0013
Researcher:	Investigator Name Site Name Site Address Site Address Investigator Telephone:
Sponsor:	TriVascular, Inc. (a wholly owned subsidiary of Endologix, Inc.) 3910 Brickway Blvd. Santa Rosa, CA 95403 Telephone: +1 707.543.8807

Patient Name: _____

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 trial designed to evaluate the Ovation Alto Abdominal Stent Graft System, a device used in the treatment of patients with abdominal aortic aneurysms (AAA). The clinical trial will enroll up to 75 patients at up to 15 U.S. clinical sites.

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 Alto 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 Alto 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.

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, and you may have blood tests that will require approximately 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 at one (1) year after the procedure. Additional study follow-up may occur through five (5) years. Treatment with the study device will require lifelong medical follow-up, either after the study is completed or subject withdrawal.

At each of the follow-up visits, you will have a physical exam, CT scan, X-ray (Kidney Ureter, Bladder (KUB)), and may have blood tests that will require approximately 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

There are other endovascular AAA repair devices that are approved for use. You have the choice of having your treatment with the Ovation Alto Abdominal Stent Graft System, with standard surgery, with another commercially available endovascular device or no treatment for your aneurysm. 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.

RISKS

Inherent risks with the device exist, as with many medical procedures. 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;
- liver failure;
- neoplasm;
- mild or severe blockage of blood flow to your legs or arms due to blood clots or damage to the blood vessels;
- amputation;
- nerve injury; paraplegia, paraparesis, paralysis
- stroke;
- urinary complications such as incontinence, blood in your urine or infection;

- 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, the study Sponsor requests that the removed study device be returned to them for examination.

RADIATION

The risks specific to participating in this study may also include complications associated with radiation exposure from the x-rays. However, care will be taken to minimize your exposure to the x-rays and the special dye. The follow-up testing has been chosen to decrease the amount of unnecessary exposure to x-rays but at the same time ensure that complete information about how you are progressing is collected. One of the risks associated with radiation exposure is cancer. The natural incidence of fatal cancer is about 1 chance in 5. Everyday radiation exposure from natural occurring background radiation (sun, radon exposure in the home) is approximately 3 mSv per year. CT scans and the stent graft delivery use x-rays as part of the standard-of-care. In this study, you will receive a small amount of extra radiation and angiography that might increase your risk of cancer by a small amount.

MEDICATION

Due to your condition, you may already be on blood thinning medication. Patients on blood thinning medications have been known to have a higher incidence of bleeding complications, such as ulcers, or strokes, both of which can be fatal. Blood thinning medications also increase the risk of bleeding at the site (groin area) where instruments are inserted into the arteries. After your AAA procedure, your doctor may change your medicines. Your doctor will discuss with you all the necessary medications with you before you are released from the hospital. If you experience any problems or symptoms, call your doctor immediately.

POTENTIAL BENEFITS

You should know that the success rates of treating patients with AAAs with a system such as the Ovation Alto Abdominal Stent Graft System are compelling and this type of treatment is fast becoming the method of choice for repairing aneurysms since it is minimally invasive. Furthermore, it does not always require general anesthesia or admission into the Intensive Care Unit postoperatively.

While there may be no direct benefit to you from your participation in this study, 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 government health agencies. You also grant permission for this medical information to be made available to the following people:

- The study Sponsor — the manufacturer of the Ovation Alto 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 who may be contracted by the Sponsor to supervise/validate the clinical information obtained in the Study.
- The local Institutional Review Board (IRB) or Ethics Committee (EC).

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 will not receive any payments for participating in this study. The sponsor of this study, Trivascular, Inc. (a wholly owned subsidiary of Endologix, Inc.), will reimburse the hospital for the cost of procedures and/or activities performed in connection with this study that are in addition to what would usually be covered by your health care system. This

includes activities/procedures related to follow up visits that would not normally be required if you were having standard surgical aneurysm repair or endovascular aneurysm repair with another commercially available device. Additionally, you will not be billed for these procedures and research-related activities. The costs of all medical care associated with injuries related to your participation in this study are your responsibility. There will be no compensation for lost wages or other non-medical costs and no compensation for medical expenses associated with your participation in this study.

Your doctor will provide you medical care immediately when you need it, and he will also treat you for any complication that may occur during the study because of your participation in the study.

You are not expected to have any health problem as a result of taking part in this study. However, as with any treatment, unexpected events may occur. If you develop any device-related health problems, you will be given adequate medical care.

This consent form is not intended for you to waive your legal rights or that anyone involved in this procedure or study is exempt from responsibility for negligence. This includes the legal right to seek compensation for damages.

By signing this document, you or your legal representative give your consent to take part in the study.

If you experience an illness or injury during the course of the study, call your doctor immediately. If you have an emergency, go to the nearest emergency room to get treatment.

PUBLIC INTERNET DATABASE REGISTRATION

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

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/Ethics Committee 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 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 the Sponsor, agents of the Sponsor, governmental health agencies, and Institutional Review Board/Ethics Committee.

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)

Revision History

Rev	DCO #	Description of Change	Initiator
B	17-0074	Addition of BES device description; clarification of definition of: patency, thrombosis, stenosis and embolic and thrombotic events. Update from Wilson Score method to exact binomial. updated number of sites from 15 to 16; Electronic Data Capture (EDC) Host name updated per current. Clarification of site reported Study primary objectives. Clarification of Inclusion Criteria 5 (b) and (c), Exclusion Criteria 9. Clarification of treatment period assessments recording in eCRF's. KUB Xray assessment added to Pre Discharge section. CRF where discharge assessments to be collected clarified. Clarification of Unscheduled follow up visit data collection eCRF. Clarification of open surgical conversion reporting to sponsor, Xray views under imaging assessment, SAE's, technical failures, explants. Clarification of Primary endpoint and additional evaluations. Clarification of data collection for CRF's. Clarification of Appendix IV: Schedule of activities. Clarification of Appendix VI: Explant procedures.	S. Moltchanoff