OVATION®

Abdominal Stent Graft System

Instructions for Use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

TRIVASCULAR®

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1. Device Description

The TriVascular Ovation® Abdominal Stent Graft System is an endovascular device delivered via a small diameter 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, and iliac extensions as required (**Figure 1**).

The TriVascular Ovation Abdominal Stent Graft System includes:

- An Aortic Body Stent Graft and delivery catheter
- Iliac Limb Stent Grafts and delivery catheters
- Iliac Extension Stent Grafts and delivery catheters, as required
- A Fill Polymer Kit
- An Autoinjector

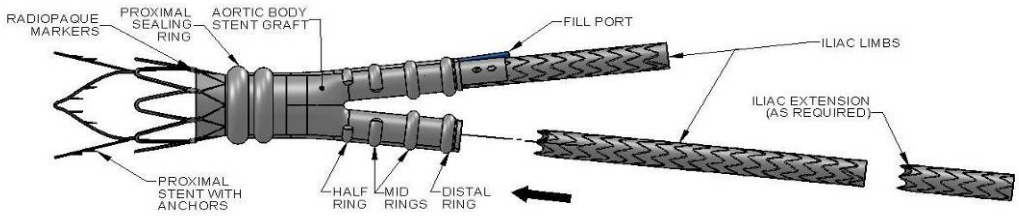


Figure 1. Schematic of Deployed TriVascular Ovation Abdominal Stent Graft System

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 so as to not obstruct the renal arteries. The graft has a fill port that connects the fill network of the graft to the delivery catheter. 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. **Figure 2** provides an image of the device with its sealing mechanism in the aorta. Because of this feature of the device, the sizing considerations are unique and described in Section 7. Patient Selection and Treatment.

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. The outward radial force of the stent provides both fixation and sealing of the interface between the aortic body and each iliac limb, between the iliac limb and iliac extension, and between the iliac limb/extension and its landing zone in the iliac artery.

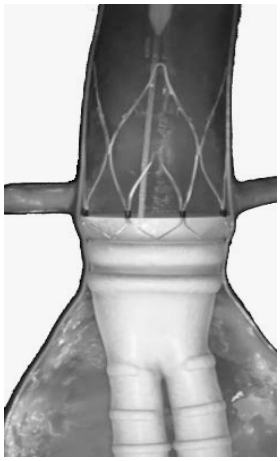


Figure 2. TriVascular Ovation Abdominal Stent Graft in aorta

1.1. Delivery System

To facilitate device introduction into the access vessel, the aortic body, the iliac limbs, and the iliac extensions are preloaded into delivery catheters (14F-15F OD, 13F–15F OD, and 13F–14F OD respectively), as illustrated in **Figure 3** and **Figure 4**. The aortic body is deployed via the aortic body delivery catheter. The aortic body delivery catheter has a lumen for use with a guidewire to facilitate access and deployment.

During stent graft deployment, the device is first positioned and the sheath is retracted. The proximal stent is then deployed using stent release knobs on the handle. 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 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 withdrawn from the vasculature. After the fill polymer cures within the sealing rings, the aortic body delivery catheter is disengaged from the fill port of the graft and withdrawn from the vasculature. The ipsilateral 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 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.

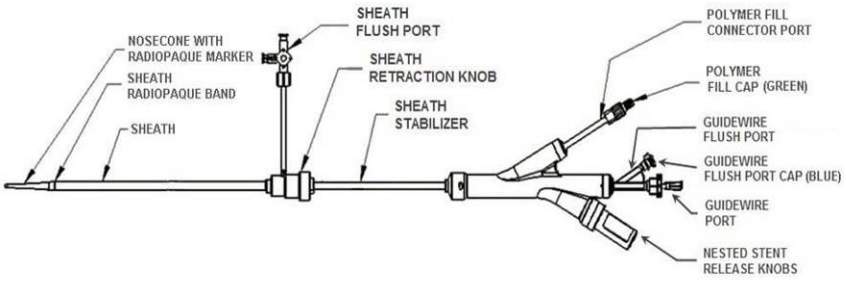


Figure 3. Schematic of TriVascular Ovation Abdominal Stent Graft System Aortic Body Delivery Catheter

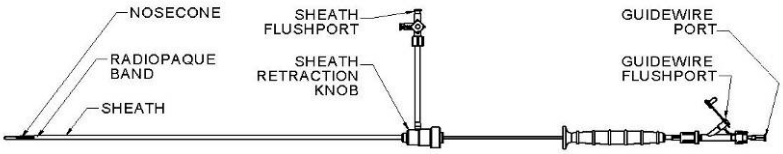


Figure 4. Schematic of TriVascular Ovation Abdominal Stent Graft System Iliac Limb/ Iliac Extension Delivery Catheter

The TriVascular Ovation Abdominal Stent Graft System is designed to accommodate various aortic anatomies, including a range of proximal and distal aortic neck diameters and aneurysm lengths. Refer to **Table 20** for patient sizing information and **Tables 21-23** for product sizes and configurations.

1.2. Fill Polymer and Autoinjector

The Fill Polymer Kit is shown in **Figure 5**. 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 of the channels in the wall of the aortic body graft. 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 polymer 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 catheter handle. The syringe plunger is then inserted into the Autoinjector (**Figure 6**) and the Autoinjector is given a quarter-turn to lock it in place. The Autoinjector applies controlled pressure to inject the fill polymer into the graft.

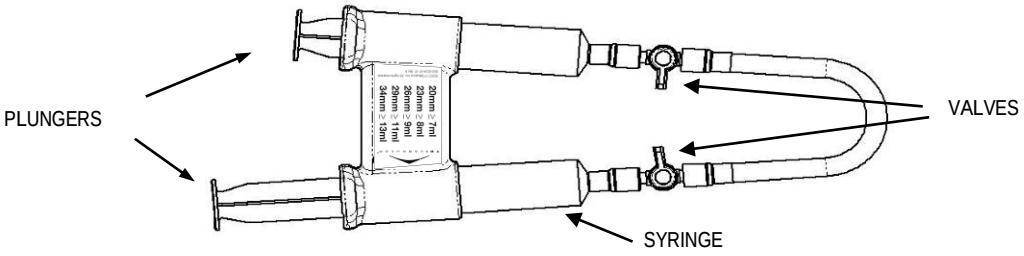


Figure 5. TriVascular Fill Polymer Kit

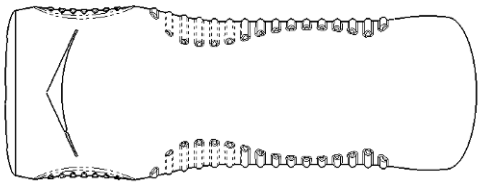


Figure 6. TriVascular Autoinjector

2. Indications for Use

The TriVascular Ovation 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 (femoral cutdown or percutaneous), devices, and/or accessories,
- Proximal aortic landing zone:
  - with an inner wall diameter of no less than 16 mm and no greater than 30 mm at 13 mm below the inferior renal artery, and

- with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm,

- Distal iliac landing zone:
  - with a length of at least 10 mm, and
  - with an inner wall diameter of no less than 8 mm and no greater than 20 mm.

3. Contraindications

- Patients who have a condition that threatens to infect the graft.
- Patients with known sensitivities or allergies to the device materials (including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, fluorinated ethylene propylene [FEP] or nitinol).

Also consider the information in Section 4. Warnings and Precautions.

4. Warnings and Precautions

CAUTION: Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.

4.1. General

- The Ovation Abdominal Stent Graft System is for single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Accurate fluoroscopic imaging is required during any endovascular procedure and for proper device deployment. Implantation of this device should occur in an operating room, endovascular suite, catheterization laboratory, or similar sterile environment, with appropriately trained personnel, and suitable equipment and imaging capabilities.
- Do not use this device if the patient is unable to be evaluated using the necessary preoperative and postoperative imaging.
- Always have a qualified surgery team available during implantation or re-intervention procedures in the event that conversion to open surgical repair is necessary.
- The TriVascular Ovation Abdominal Stent Graft System should only be used by physicians and teams experienced in endovascular techniques and who have been trained in its use.
- The long-term performance of this implant has not been established. All patients treated with this device must undergo periodic imaging to evaluate stent graft integrity and position, aneurysm size, and potential endoleaks and/or, occlusion of vessels in the treatment area. Significant aneurysm enlargement, a persistent endoleak, the appearance of a new endoleak, device migration, reduced blood flow through the graft, and/or decrease in renal function due to renal artery occlusion should prompt further investigation into the need for further patient treatment, including additional intervention or surgical conversion. Additional patient imaging follow up should be considered for patients with devices that have effectiveness issues.
- All patients should be carefully counseled on the need for long-term follow up. The device is not recommended in patients unable or unwilling to comply with the information in Follow-up Imaging Recommendations.

4.2. Patient and Device Selection

- Access vessel diameter, vessel morphology and delivery system diameter should be compatible with vascular access techniques (femoral cutdown or percutaneous). Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude placement of the device.
- The Ovation Abdominal Stent Graft System has not been evaluated in patients who:
  - Are pregnant or nursing;
  - Are less than 18 years old;

- Have traumatic aortic injury, ruptured aneurysms, aneurysms pending rupture or require other emergent aorta/ aneurysm treatment;
- Have suprarenal, thoraco-abdominal, ilio-femoral, juxtarenal, pararenal, mycotic, inflammatory, dissecting or pseudo-aneurysms;
- Have hypercoagulability, bleeding diathesis or coagulopathy;
- Have mesenteric and/or celiac artery occlusive disease and a dominant patent inferior mesenteric artery;
- Have connective tissue disorder or congenital degenerative collagen disease, e.g., Marfan's or Ehler's-Danlos Syndrome;
- Require bilateral exclusion of hypogastric blood flow;
- Have baseline serum creatinine level of > 2.0 mg/dl;
- Have other medical, social or psychological conditions that preclude them from receiving the pre-treatment, required treatment, and post-treatment procedures and evaluations.

- Irregular calcification and/or plaque may compromise the fixation and/or sealing at the implantation sites.
- Key anatomic elements that may affect exclusion of the aneurysm include severe proximal neck angulation (> 60), distal iliac landing zone < 10 mm, and/or aortic neck/iliac inner wall diameter inappropriately sized to the stent graft.
- Inappropriate patient selection may result in poor device performance.
- This device is not recommended in patients who: have or are suspected of having an active systemic infection; cannot tolerate contrast agents necessary for intra-operative and post-operative follow up imaging; and/or have sensitivities or allergies to the stent graft system materials, antiplatelets or anticoagulants; have unstable angina and/or myocardial infarction (MI) or cerebral vascular accident (CVA) within 6 months prior to implantation; exceed weight and/or size limits necessary to meet imaging requirements.

4.3. Implant Procedure

- Refer to Section 11. Directions for Use for warnings and cautions specific to implant steps of the Ovation Abdominal Stent Graft System.
- Pre-operative planning for access and placement should be performed before opening the device packaging.
- Studies indicate that the danger of micro-embolization increases with increased procedure duration.
- Renal complications may occur from an excess use of contrast agents and/or as a result of an embolic or misplaced stent graft.
- Carefully inspect the device packaging and device for damage or defects prior to use. If signs of damage or defects exist or if premature breach of the sterile barrier is observed, do not use the device.
- Minimize handling of the stent graft constrained on the delivery catheter during preparation and insertion to decrease the risk of contamination and infection.
- Do not resterilize any components of the Ovation Abdominal Stent Graft System.
- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Do not excessively bend or kink the Ovation Abdominal Stent Graft System because it may damage the device and/or its components.
- Always use fluoroscopic guidance to advance the delivery system and to monitor the implant procedure, the device deployment and the fill polymer injection / cure.
- Exercise care in handling and delivery techniques to help prevent vessel rupture.
- Exercise particular care in difficult areas, such as areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels.
- If the iliac delivery system graft cover is accidentally withdrawn, the device will prematurely deploy and may be incorrectly positioned.
- Inaccurate placement or inadequate seal may result in increased risk of endoleak into the aneurysm.
- Do not continue advancing any portion of the delivery system if resistance is felt during advancement of procedure accessories or of stent graft system. Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels.
- Unless medically indicated, do not deploy the stent graft components in a location that will occlude arteries necessary to supply blood flow to organs or extremities or result in an endoleak.

- Stent graft components cannot be replaced or drawn back into the delivery system, even if the stent graft component is only partially deployed.
- Inadvertent partial deployment or migration of the stent graft may require surgical removal or repair.
- Do not push or pull the delivery system after complete deployment of the proximal stent to avoid inadvertent disconnection of the polymer fill connector from the implant.
- During device use, rotate entire delivery system as a unit. Do not independently rotate catheter sheath or handle.
- Inadequate seal zone may result in increased risk of endoleak into the aneurysm.
- Ensure an extra stiff wire is not inside the aortic body during injection of the fill polymer to allow conformance of the stent graft to the native anatomy when significant angulation is present.
- Use only the Autoinjector to fill the Aortic Body Stent Graft. Hand injection should not be used and may damage the implant.
- Confirm there is no tension on the aortic body stent graft prior to or during iliac limb or iliac extension placement to prevent possible stenosis or occlusion.
- Confirm cannulation of aortic body contralateral lumen to ensure accurate placement of the contralateral limb.
- It is important to accurately size and choose the balloons to be used during device deployment. Keep the balloon inside the graft during inflation and do not over-inflate within the stent graft. Although not observed during the Ovation clinical study, inflation of the balloon outside of the graft may lead to vessel damage or rupture. Carefully follow the balloon manufacturer's inflation parameters described in the product labeling.
- Any endoleak left untreated during the implantation procedure must be carefully monitored after implantation.
- Patients who experience hypersensitivity reactions during the procedure should be managed in accordance with standard recommendations for treatment of patients with radiocontrast agent allergies (e.g., antihistamines, corticosteroids, adrenaline).

4.4. MRI Information

- Non-clinical testing has demonstrated that the Ovation Abdominal Stent Graft System is MR Conditional. It can be scanned safely in both 1.5T and 3.0T MR systems using the specific testing parameters listed in Section 10.4, MRI Information.

5. Adverse Events

5.1. Potential Adverse Events

Adverse events that may occur and/or require intervention include but are not 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 (with transient or permanent ischemia or infarction) such as deep vein thrombosis, thromboembolism, microembolism, thrombophlebitis, phlebothrombosis, 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.

5.2. Incident Reporting

All incidents should be reported to TriVascular immediately. To report an event, contact your local representative and/or TriVascular at the contact number provided at the end of this document.

6. Summary of Clinical Information

The objective of the Ovation Abdominal Stent Graft System multicenter clinical study was to evaluate the safety and effectiveness of the Ovation Abdominal Stent Graft System in the treatment of subjects with AAA. The study was a prospective, consecutively enrolling, non-randomized multi-center clinical evaluation. A total of 161 subjects were enrolled in the pivotal study in the United States (111 subjects), Germany (30 subjects) and Chile (20 subjects).

The sample size of the study was calculated based upon the primary safety evaluation. It was estimated that 150 subjects with evaluable data at 30 days would provide 96% statistical power to test the primary safety

hypothesis (major adverse event [MAE] incidence of 11%) at the one-sided 0.05 level. A 15% attrition rate was anticipated through 12 months, which would yield approximately 128 subjects available to assess the primary effectiveness endpoint at 12 months. Should the rate for the primary effectiveness composite endpoint equal 88.2%, then 128 subjects would provide 80% power to test the primary effectiveness hypothesis at the one-sided 0.05 alpha level.

The sample size of the study provided adequate statistical power for the evaluation of safety and effectiveness. The analysis included endpoints that were consistent with current literature on endovascular stent grafts. The primary safety hypothesis was tested by comparing the 30-day major adverse event (MAE) incidence in subjects treated with the Ovation device to a target performance goal of 21%[1]. The primary effectiveness hypothesis was tested by comparing the 12-month composite treatment success rate in subjects treated with the Ovation device to a target performance goal of 80%. For effectiveness endpoint evaluation, an independent core lab reviewed CT scans and abdominal x-rays to assess aneurysm changes, device position and integrity, and endoleaks.

6.1. Subject Accountability and Follow-up

Of 161 subjects enrolled in the PMA study, 152 subjects were eligible for analysis at the 12-month follow up visit. Detailed subject accountability and follow-up are presented in Table 1. The numbers found in Table 1 as well as subsequent sections represent those subjects that had data available to assess the relevant parameters.

[1] Turnbull IC, Criado FJ, Sanchez L, et al. Five-year results for the Talent enhanced Low Profile System abdominal stent graft pivotal trial including early and long-term safety and efficacy. *J Vasc Surg.* Mar 2010;51(3):537-544

Table 1: Subject and Imaging Accountability Through 12-Month Follow-Up Visit – Ovation Treatment Group

Interval (Analysis Window)	Subject follow-up			Subjects with imaging performed (Core Lab)		Subjects with adequate imaging to assess the parameter (Core Lab)				Subject events occurring before next visit					
	Eligible	Clinical Follow-up	Imaging Follow-up	CT Imaging	KUB imaging	Aneurysm size increase	Endoleak	Migration	Stent Integrity	No implant	Conversion to surgery	Death	Withdrawal	Loss to follow-up	Not due for next visit yet
Originally Enrolled	161									0					
Events after implant but before a 1 Month visit												1			
1 Month (Day 1 - 90)	160	160 (100%)	161 (101%)[1]	160 (100%)	157 (98%)		153 (96%)		157 (98%)						
Events after 1 Month visit but before a 6 Month visit												1	1	1	
6 Month (Day 91 - 304)	157	156 (99%)	155 (99%)	154 (98%)	150 (96%)	154 (98%)	150 (96%)	154 (98%)	150 (96%)						
Events after 6 Month visit but before a 12 Month visit												2	3		
12 Month (Day 305 - 547)	152	152 (100%)	152 (100%)	150 (99%)	146 (96%)	150 (99%)	143 (94%)	150 (99%)	146 (96%)						

Data analysis sample size varies for each of the timepoints above and in the following tables. This variability is due to subject availability for follow-up as well as quantity and quality of images available from specific timepoints for evaluation. For example, the number and quality of images available for evaluation of endoleak at 6 months is different than the number and quality of images available at 12 months due to variation in the number of image exams performed, the number of images provided from the clinical site to the Core Lab, and or the number of images with acceptable evaluation quality.

[1] One subject expired before hospital discharge and is not eligible for 1 month visit, but has Imaging follow-up in 1-90 days time period post procedure.

6.2. Study Demographics and Baseline Medical History

Baseline data regarding subject demographics, medical history and baseline aortoiliac aneurysm characteristics are summarized in **Tables 2-4**.

Table 2: Subject Demographics

Variable	Statistics	Ovation Treatment Group
	N	161
Age (yr)	Mean ± std	73 ± 8
	Median	73
	Min, Max	54, 95
Gender		
- Male	% (n/N)	87.6% (141/161)
- Female	% (n/N)	12.4% (20/161)
Race		
- White	% (n/N)	92.5% (149/161)
- Black	% (n/N)	2.5% (4/161)
- Asian	% (n/N)	0.0% (0/161)
- American Indian or Alaska Native	% (n/N)	0.0% (0/161)
- Native Hawaiian or Other Pacific Islander	% (n/N)	0.0% (0/161)
- Unknown/Other	% (n/N)	5.0% (8/161)
Ethnicity		
- Hispanic or Latino	% (n/N)	9.3% (15/161)
- Not Hispanic or Latino	% (n/N)	89.4% (144/161)
- Unknown	% (n/N)	1.2% (2/161)

Table 3: Subject Medical History

Variable	Ovation Treatment Group % (n/N)
ASA Grade	
- I	5.6% (9/161)
- II	28.0% (45/161)
- III	59.6% (96/161)
- IV	6.8% (11/161)
Cardiovascular Disease	
- Coronary artery disease	44.7% (72/161)
- Valvular heart disease	11.8% (19/161)
- Angina	6.8% (11/161)
- Cardiomyopathy	6.8% (11/161)
- Congestive Heart Failure	7.5% (12/161)
- Myocardial infarction	20.5% (33/161)
- Arrhythmia	21.7% (35/161)
- Hypertension	84.5% (136/161)
- Hypotension	0.6% (1/161)
- Hyperlipidemia	70.2% (113/161)
Peripheral Vascular Disease, Stroke and Aneurysm History	
- Peripheral vascular disease	23.6% (38/161)
- Carotid artery disease	13.0% (21/161)
- Transient ischemic attack (TIA)	5.0% (8/161)

Variable	Ovation Treatment Group % (n/N)
- Stroke (CVA)	8.1% (13/161)
- Family History of aneurysms	6.2% (10/161)
Pulmonary History	
- Smoking	70.2% (113/161)
- Chronic obstructive pulmonary disease (COPD)	27.3% (44/161)
Gastrointestinal, Genitourinary, Reproductive History	
- Renal failure/insufficiency	13.7% (22/161)
- Diabetes	21.1% (34/161)
- Alcohol abuse	1.9% (3/161)
Hematological Problems (hemorrhage, coagulopathy disorder, anemia, platelet disorder)	7.5% (12/161)
Other Significant Medical Condition	75.8% (122/161)

The primary safety hypothesis of the clinical study was tested by comparing the 30-day major adverse event (MAE) incidence in subjects treated with the Ovation device to a target performance goal of 21%[2], which was established based upon a published 30 day MAE rate for a recently-approved FDA device. For comparison purposes, the baseline subject characteristics for Ovation and the device are provided in **Table 4** below.

Table 4. Comparison of Selected Baseline Subject Characteristics With Ovation Device and Talent Device

	Ovation device (n=161)	Talent Device* (n=166)
Demographics		
Age (yr, mean±SD)	73±8	74±7
White ethnicity (%)	92.5	92.8
Female gender (%)	12.4	8.4
Medical history (%)		
Angina	6.8	16.9
Arrhythmia	21.7	44.0
Cardiac revascularization	na	38.6
Congestive heart failure	7.5	28.3
Coronary heart disease	44.7	56.0
Hypertension	84.5	83.7
Myocardial infarction	20.5	38.6
Peripheral vascular disease	23.6	46.4
Diabetes	21.1	15.7
Chronic obstructive pulmonary disease	27.3	39.2
Smoking	70.2	84.9
Aortic morphology (mm, mean±SD)		
Maximum AAA diameter	53.6±9.0	55.0±9.3
Proximal neck length	23.0±12.5	22.9±12.5
Proximal neck diameter	22.5±2.7	25.3±3.6

*Data from reference[1].

6.3. Baseline Aortoiliac Characteristics

Table 5 provides the baseline aneurysm and anatomical measurements of the study population.

[2] Turnbull IC, Criado FJ, Sanchez L, et al. Five-year results for the Talent enhanced Low Profile System abdominal stent graft pivotal trial including early and long-term safety and efficacy. *J Vasc Surg.* Mar 2010;51(3):537-544

Table 5: Baseline Aortoiliac Characteristics

Variables	Statistics	Ovation Treatment Group
Proximal Aorta		
Aortic diameter 35 mm proximal to proximal renal artery (mm)[1]	N	160
	Mean ± SD	25.0 ± 2.7
	Median	25.0
	Min, Max	19.0, 32.2
Aortic diameter at distal renal artery (mm)[2]	N	161
	Mean ± SD	22.5 ± 2.7
	Median	22.5
	Min, Max	17.5, 31.0
Aortic diameter 7 mm distal to distal renal artery (mm)[1]	N	161
	Mean ± SD	22.1 ± 2.9
	Median	21.9
	Min, Max	16.0, 30.0
Aortic diameter 13 mm distal to distal renal artery (mm)[1]	N	161
	Mean ± SD	22.7 ± 3.1
	Median	22.0
	Min, Max	16.6, 32.3
Proximal neck length (mm)[2]	N	161
	Mean ± SD	23.0 ± 12.5
	Median	21.9
	Min, Max	1.0, 50.0
Juxtarenal angle (degrees)[1]	N	161
	Mean ± SD	19.1 ± 13.5
	Median	16.0
	Min, Max	0.0, 60.0
Aortic Aneurysm		
Maximum aortic aneurysm diameter (mm)[2]	N	161
	Mean ± SD	53.6 ± 9.0
	Median	52.5
	Min, Max	37.8, 90.0
Maximum aortic aneurysm diameter distribution (mm)		
	40.0-49.9	35.4% (57/161)
	50.0-59.9	50.3% (81/161)
	60.0-69.9	8.7% (14/161)
	70.0-79.9	3.1% (5/161)
	80.0-89.9	1.2% (2/161)
	90.0-99.9	1.2% (2/161)
Distal Aorta		
Aortic bifurcation diameter (mm)[2]	N	161
	Mean ± SD	20.3 ± 6.9
	Median	18.5

Variables	Statistics	Ovation Treatment Group
	Min, Max	11.5, 53.5
Left iliac diameter (mm)[2]	N	161
	Mean ± SD	13.7 ± 3.3
	Median	13.0
	Min, Max	8.7, 34.0
Left iliac minimum access diameter (mm)[2]	N	159
	Mean ± SD	7.0 ± 1.6
	Median	6.8
	Min, Max	3.2, 11.5
Right iliac diameter (mm)[2]	N	161
	Mean ± SD	13.9 ± 3.0
	Median	13.3
	Min, Max	8.3, 23.4
Right iliac minimum access diameter (mm)[2]	N	159
	Mean ± SD	7.0 ± 1.6
	Median	7.0
	Min, Max	3.5, 11.4

[1] Data provided by site imaging

[2] Data provided by imaging core lab

6.4. Devices Implanted

A total of 161 aortic bodies and 366 iliac limbs/iliac extensions were implanted in 161 subjects during the initial implant procedure. The design of this device requires implantation of at least one aortic body and two iliac limbs. Additional iliac limbs and iliac extensions could be used to extend the length of the device, where indicated. Aortic body and iliac limb (including iliac extensions) delivery and deployment were successful in all subjects. The total number of Ovation devices implanted in each subject is presented in **Table 6**, and device use by diameter is presented in **Table 7**. The entire spectrum of available aortic body and iliac limb diameters were used in this study.

Table 6: Number of Devices Implanted

Number of Ovation Devices Implanted	Ovation Treatment Group % (n/N)
3[1]	78.3% (126/161)
4	16.1% (26/161)
5	5.6% (9/161)

[1] Technical success was defined as implantation of one Ovation aortic body and a minimum of two Ovation iliac limbs (minimum of 3 Ovation devices). Additional Ovation Iliac limbs and/or iliac extensions may be implanted as extensions if additional vessel coverage is needed.

Additional accessory devices were implanted in the treatment area of 11 subjects during the index procedure as outlined in section 6.6.2 Technical success.

Table 7: Distribution of Implanted Device Sizes

Variables	Diameter (mm)	Ovation Treatment Group % (n/N)
Ovation aortic body	Overall	161
	20	2.5% (4/161)

Variables	Diameter (mm)	Ovation Treatment Group % (n/N)
	23	21.7% (35/161)
	26	36.0% (58/161)
	29	28.0% (45/161)
	34	11.8% (19/161)
Ovation iliac limbs /iliac extensions	Overall	366
	10	5.5% (20/366)
	12	21.9% (80/366)
	14	35.0% (128/366)
	16	16.9% (62/366)
	18	14.2% (52/366)
	22	6.6% (24/366)

The Ovation Abdominal Stent Graft System aortic body is 80 mm in length, The iliac limbs are available in 4 lengths (80 mm, 100 mm, 120 mm, and 140 mm), and the iliac extension is 45 mm in length as outlined in section 9. How Supplied. The iliac limbs can also be used as extensions when additional coverage is required in the iliac artery.

6.5. Study Results: Safety Endpoints

6.5.1. Major Adverse Events (MAEs) Through 30 Days

The incidence of MAEs through 30 days in subjects treated with the Ovation device was 2.5%.

Table 8. Primary Safety Endpoint: Major Adverse Events Through 30 Days

Variable	Ovation Treatment Group % (n/N)	Upper One-Sided 95% Confidence Limit	Target Performance Goal	Study Endpoint
Major adverse events[1]	2.5% (4/161)	5.4%	21%	MET

[1] A major adverse event was defined as any of the following: death, myocardial infarction, stroke, renal failure, respiratory failure, paralysis, bowel ischemia, or procedural blood loss ≥ 1,000 cc

Table 9. MAE Components Through 30 Days

Variable	Ovation Treatment Group % (n/N)
Number of subjects with one or more major adverse events[1,2]	2.5% (4/161)
- All-cause death	0.6% (1/161)
- Myocardial infarction	1.2% (2/161)
- Renal failure	1.2% (2/161)
- Respiratory failure	0.6% (1/161)
- Paralysis	0.0% (0/161)
- Stroke	0.0% (0/161)
- Bowel ischemia	0.6% (1/161)
- Procedural blood loss ≥1000 cc	1.2% (2/161)

[1] A major adverse event (MAE) was defined as any of the following: death, myocardial infarction, stroke, renal failure, respiratory failure, paralysis, bowel ischemia, or procedural blood loss ≥ 1,000 cc

[2] A subject may report multiple MAEs; hence, number of subjects with any MAE may not be the sum of those in each MAE category

6.5.2. All-cause Mortality Through 365 Days

The following tables and figures provide the results of all-cause mortality. All-cause mortality through 365 days post-treatment was 2.5%

Table 10. All-cause Mortality Through 365 Days

Variable	Treatment to 365 days % (n/N)	Treatment to 30 days % (n/N)	31 to 365 days % (n/N)
All-cause mortality	2.5% (4/161)	0.6% (1/161)	1.9% (3/159)

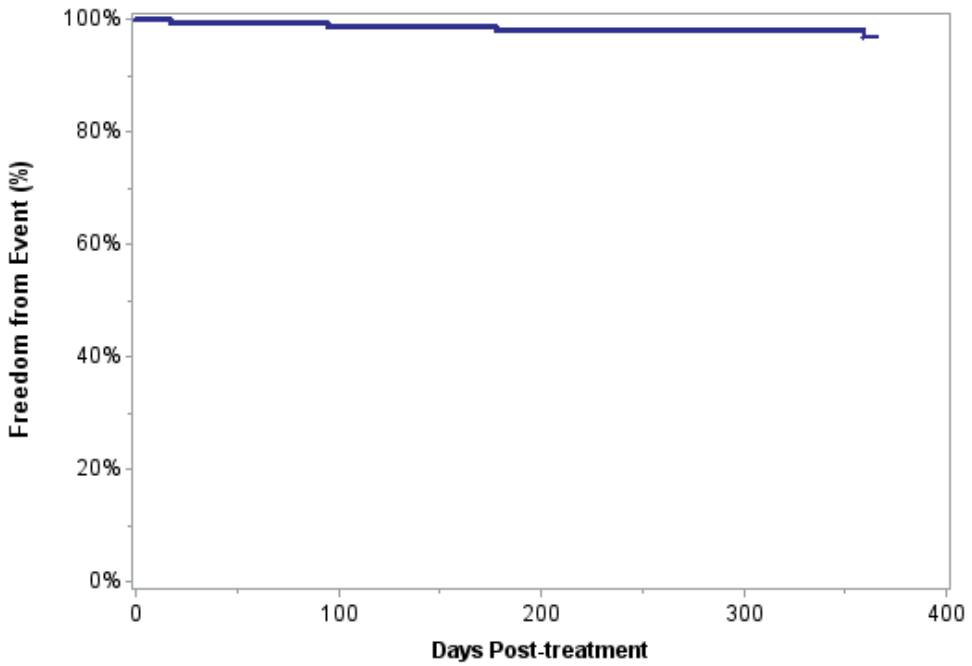


Figure 7. Freedom From All-cause Mortality Through 365 Days: Kaplan-Meier Estimate

Table 11. Freedom from All-cause Mortality Through 365 Days: Kaplan-Meier Estimate

Variable	Treatment to 30 days	31 to 182 days	183 to 365 days
Number at risk[1]	161	159	157
Number of events	1	2	1
Number censored[2]	0	0	156
Kaplan-Meier estimate[3]	0.994	0.981	0.972
Standard error[3]	0.006	0.011	0.014

[1] Number of subjects at risk at beginning of interval
[2] Subjects are censored because their last follow-up has not reached the end of the time interval or because they are lost to follow-up. In addition, all subjects followed beyond 365 days are censored at 365 days.
[3] Estimate made at end of time interval

6.5.3. AAA-related Mortality at 30 days and 12 Months

AAA-related mortality through 365 days post-treatment was 0.6% (1 of 161): 1 AAA-related death occurred on day 16 (within 30 days) after the index procedure due to abdominal sepsis and disseminated intravascular coagulation. During the index procedure, the site reported a polymer leak from the Aortic Body and the subject experienced a hypersensitivity reaction. A proper root-cause analysis was performed and the cause of the disconnection was identified. The device component responsible for the disconnection between the Aortic Body and the Fill Polymer Kit was modified after the event occurred to prevent recurrence. No additional disconnections have been reported in the pivotal study.

Table 12. AAA-related Mortality Through 365 Days

Variable	Treatment to 365 days % (n/N)	Treatment to 30 days % (n/N)	31 to 365 days % (n/N)
AAA-related mortality[1]	0.6% (1/161)	0.6% (1/161)	0.0% (0/159)

[1] AAA-related mortality defined as death from rupture of the abdominal aortic aneurysm or from any procedure intended to treat the AAA. If a death occurred within 30 days of any procedure intended to treat the AAA, then it is presumed to be aneurysm-related.

The Kaplan-Meier estimate of freedom from AAA-related death through 365 days was 99.4%.

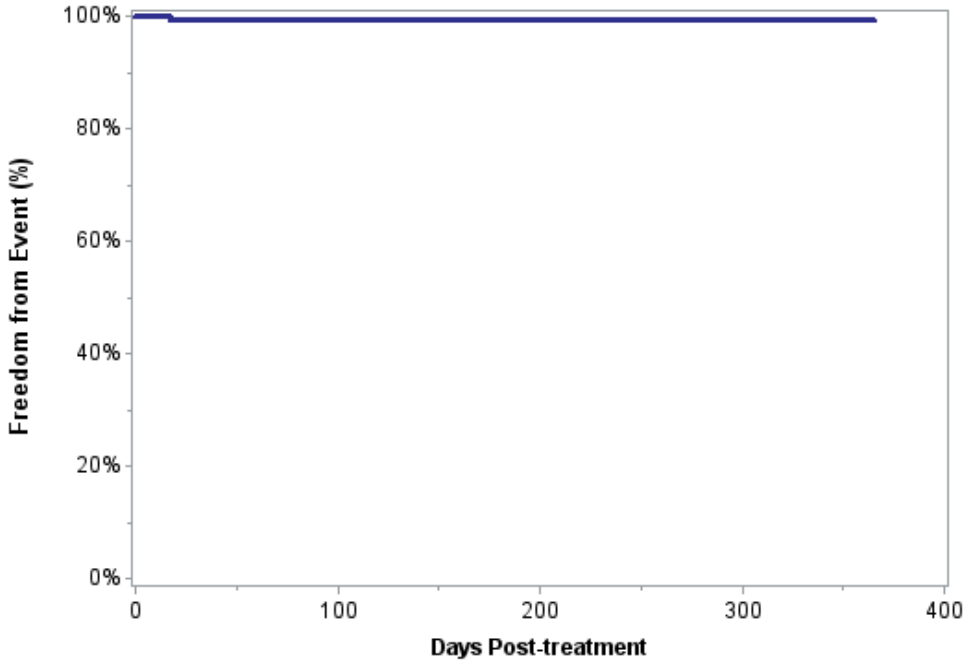


Figure 8. Freedom from AAA-related Mortality Through 365 Days: Kaplan-Meier Estimate

Table 13. Freedom from AAA-related Mortality[4] Through 365 Days: Kaplan-Meier Estimate

Variable	Treatment to 30 days	31 to 182 days	183 to 365 days
Number at risk[1]	161	159	157
Number of events	1	0	0
Number censored[2]	0	2	157
Kaplan-Meier estimate[3]	0.994	0.994	0.994
Standard error[3]	0.006	0.006	0.006

[1] Number of subjects at risk at beginning of interval

[2] Subjects are censored because their last follow-up has not reached the end of the time interval or because they are lost to follow-up. In addition, all subjects followed beyond 365 days are censored at 365 days.

[3] Estimate made at end of time interval

[4] AAA-related mortality defined as death from rupture of the abdominal aortic aneurysm or from any procedure intended to treat the AAA. If a death occurred within 30 days of any procedure intended to treat the AAA or within the hospital stay if the subject was not discharged within 30 days, then it is presumed to be aneurysm-related.

6.5.4. AAA Rupture through 12 Months

No AAA rupture was reported through 365 days post-treatment.

6.5.5. Conversion to Open Repair through 12 months

No surgical conversion was reported through 365 days post-treatment.

6.6. Study Results: Effectiveness Endpoints

6.6.1. Treatment success

Treatment success, defined as technical success (successful delivery and deployment of one Ovation aortic body and a minimum of two Ovation iliac limbs) and freedom from AAA enlargement, migration, type I or III endoleak, AAA rupture, or surgical conversion through 12 months, was 99.3%.

Table 14. Primary Effectiveness Endpoint: Treatment Success Through 12-Month Follow-up Visit

Variable	Ovation Treatment Group % (n/N)	95% Lower Confidence Limit	Target Performance Goal	Study Endpoint
Treatment Success [1,2]	99.3% (137/138)	96.8%	80.0%	met

[1] Treatment success was defined as the proportion of subjects that met all of the following criteria: technical success (defined as successful delivery and deployment of one aortic body and two iliac limbs), freedom from type I and III endoleak at 12 months (core lab assessed), freedom from stent graft migration at 12 months (core lab assessed), freedom from AAA enlargement at 12 months (core lab assessed), freedom from AAA rupture through 12 months (site assessed), and freedom from conversion through 12 months

[2] The 12-month analysis window ranges from 305 to 547 days

6.6.2. Technical success

Technical success, defined as successful delivery and deployment of one Ovation aortic body and a minimum of two Ovation iliac limbs, was 100%.

Additional accessory devices were implanted in the treatment area of 11 subjects during the index procedure as outlined in **Table 15** below.

Table 15: Accessory devices implanted in treatment area, location, and reason for implantation

Accessory device	Number of Subjects	Implant location	Reason for implantation
Balloon expandable stent	3	Proximal aortic neck	Type IA endoleak
	1	Right iliac	Dissection in right iliac

Accessory device	Number of Subjects	Implant location	Reason for implantation
Self-expanding stents	1	Left iliac	Extend the left iliac limb
Stent graft	2	Proximal aortic neck	Type IA endoleak
	1	Iliac limb	Dissection
Embolization coil	1	Aorta	Type IA endoleak
	1	Right internal iliac	Type IB endoleak
Multiple balloon-expandable and self-expanding stents	1	Aortic neck and iliac limbs	Type IA endoleak/stenosis in left proximal iliac limb

6.6.3. AAA Enlargement

Aneurysm diameter enlargement, identified by the imaging core laboratory at the 12 months post-treatment (compared to the 1-month imaging), was reported in 1 subject. One subject with enlargement at 6 months had an increase slightly greater than 5 mm. At the 12 month visit, the subject's aneurysm diameter decreased to an overall diameter change of < 5 mm during the 12 month period. A second subject had AAA diameter increase reported by the imaging core laboratory at the 12 month assessment, but the site reported a 3 mm decrease in AAA diameter at the 12 month assessment. This subject has a type II site-reported endoleak but no required intervention.

Table 16. AAA Diameter Change Through 12-Month Follow-up Visit

Variable	6 months % (n/N)[2]	12 months % (n/N)[2]
AAA diameter increase > 5 mm[1]	0.6% (1/154)	0.7% (1/150)
AAA diameter change ≤ 5 mm[1]	83.1% (128/154)	67.3% (101/150)
AAA diameter decrease > 5 mm[1]	16.2% (25/154)	32.0% (48/150)

Data provided by imaging core lab

Analysis windows are: 6 months (91 to 304 days), and 12 months (305 to 547 days)

[1] 1-month imaging serves as the baseline measure. If 1-month imaging was missing the first available postoperative image served as the baseline measure

[2] Denominator at each time point is the number of subjects with at least one readable scan in the time interval

6.6.4. Migration

The proportion of subjects with a device migration (evidence of proximal or distal movement of the stent graft > 10 mm relative to fixed anatomic landmarks) identified by the imaging core laboratory through 12 months post-treatment was 0% (0 of 161).

6.6.5. Endoleak

No type I, III, or IV endoleaks were identified by the imaging core laboratory through 12 months post-treatment. Concordance of imaging results at the 12-month follow-up visit between the core laboratory and the site-reported data was 89.5%. Type II endoleak incidence at the 1-year follow-up visit was 34.3%. As the typical type II endoleak identified in this study was small (median volume: 1.1 cc), the endoleak detection rate in this study was likely due, in part, to high-quality imaging.

Three (3) subjects (3/158, 1.9%) were treated with secondary interventions for type II endoleak between 31 to 365 days. Sites reported 1 subject (1/158, 0.6%) that was treated for type IA endoleak and 1 subject (1/158, 0.6%) that was treated for type IA and type IB endoleaks, all between 31-365 days. These type I endoleaks were not detected during review by the imaging core laboratory.

Table 17. Imaging Core Lab-reported Endoleaks Through 12-month Follow-up Visit

Variable	Treatment to 12 months % (n/N)[1,2]	1 month % (n/N)[1,2]	6 months % (n/N)[1,2]	12 months % (n/N)[1,2]
Endoleaks	47.1% (74/157)	44.4% (68/153)	42.0% (63/150)	38.5% (55/143)
- Type I	0.0% (0/157)	0.0% (0/153)	0.0% (0/150)	0.0% (0/143)
- Type II[3]	42.0% (66/157)	40.5% (62/153)	38.0% (57/150)	34.3% (49/143)
- Type III	0.0% (0/157)	0.0% (0/153)	0.0% (0/150)	0.0% (0/143)
- Type IV	0.0% (0/157)	0.0% (0/153)	0.0% (0/150)	0.0% (0/143)
- Indeterminate origin	8.9% (14/157)	3.9% (6/153)	4.0% (6/150)	4.2% (6/143)

Data provided by imaging core lab

Analysis windows are: 1 month (1 to 90 days), 6 months (91 to 304 days), and 12 months (305 to 547 days)

[1] Denominator at each time point is the number of subjects with at least one readable scan in the time interval

[2] Numerator may not equal the sum of type endoleaks if more than one type was identified in the same subject

[3]The protocol-specified CT methodology may have influenced endoleak detection rates, thereby increasing the reported rates. Slice thicknesses of 0.6 to 2.0 mm were recommended in the protocol, which were ultimately reconstructed by the imaging core laboratory to 2.0 mm for analysis. In contrast, 3-5 mm slices are commonly utilized in the follow-up of patients treated with endovascular stent grafts, which are not as effective in detecting small leaks

6.6.6. Loss of Stent Graft Integrity

Loss of stent graft integrity was identified by the imaging core laboratory through 12 months post-treatment in 2.5% (4 of 159) of subjects. The time to initial event identification was 30 days (n=1), 6 months (n=1), and 12 months (n=2). Each event was identified as stent fracture in the mid-strut area of the proximal stent and none were associated with clinical sequelae. Furthermore, evaluation of the stent fractures confirmed they did not correlate to specific anatomic patient criteria, such as severe angulation or short neck lengths.

Table 18. Loss of Stent Graft Integrity Through 12-Month Follow-up Visit

Variable	Treatment to 12 months % (n/N)[1,2]	1 month % (n/N)[1,2]	6 months % (n/N)[1,2]	12 months % (n/N)[1,2]
- Stent fracture	2.5% (4/159)	0.6% (1/157)	1.3% (2/150)	2.7% (4/146)

Data provided by imaging X-ray core lab

Analysis windows are: 1 month (1 to 90 days), 6 months (91 to 304 days), and 12 months (305 to 547 days)

[1] Denominator at each time point is the number of subjects with at least one readable scan in the time interval. Missing or unreadable 1 Month measures were imputed with available discharge X-ray measures

[2] Numerator is number of subjects with a stent fracture reported in the time interval. Once a stent fracture is reported it will also be reported at each subsequent time interval.

6.6.7. Clinical Utility Data

The secondary Clinical Utility endpoints were evaluated:

- Blood loss
- Duration of procedure
- Length of hospital stay
- Type of anesthesia
- Type of vascular access

Table 19. Clinical Utility

Variable	Statistics	Ovation Treatment Group
Procedure time (min)	N	161
	Mean ± SD	110 ± 41

Variable	Statistics	Ovation Treatment Group
	Median	105
	Min, Max	46, 264
Procedural blood loss (cc)	N	158
	Mean ± SD	231 ± 264
	Median	150
	Min, Max	15, 2500
Hospital stay (days)[2]	N	161
	Mean ± SD	2 ± 3
	Median	1
	Min, Max	0, 33
Anesthesia type[1]		
- General	% (n/N)	65.8% (106/161)
- Regional	% (n/N)	16.8% (27/161)
- Local	% (n/N)	23.6% (38/161)
- Conscious sedation	% (n/N)	11.2% (18/161)
Vascular access type		
- Cutdown	% (n/N)	52.2% (84/161)
- Percutaneous	% (n/N)	42.9% (69/161)
- Cutdown and percutaneous	% (n/N)	5.0% (8/161)

[1] Numerator may not equal the sum of types if more than one type occurred in the same subject

[2] Date of death was used as discharge date for subjects who expired prior to discharge

6.6.8 Subject Accountability and Follow-up Beyond 12 Months

Eighty-five (85) subjects have been followed beyond 12 months, including 55 with completed follow-up visit and imaging assessed by the site; 41 with CTs assessed by the Core Lab; and 26 with X-rays assessed by the Core Lab. Study follow-up is ongoing. No aneurysm ruptures, conversions to surgical repair, MAEs, device-related adverse events (AE), type I or III endoleaks or migrations were reported beyond 12 months. One subject with stent fracture and two subjects with AAA enlargements were reported at the 2 year follow up. There were no clinical sequelae in the subject with the reported stent fracture, and type II endoleaks were reported in the subjects with the AAA enlargements. No interventions have been required for these subjects. One subject death was determined to be AAA-related because it was a supra-renal aneurysm rupture superior to the stent graft but in the target vessel segment. The additional 5 deaths beyond 12 months were not AAA-related.

7. Patient Selection and Treatment

7.1. Individualization of Treatment

The TriVascular Ovation Abdominal Stent Graft System must be selected in a size appropriate to the patient's anatomy. Proper sizing of the device is the responsibility of the physician. The sizing options for the device are detailed in **Table 20** Patient Sizing Information.

Table 20. Patient Sizing Information

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

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

* At the intended proximal sealing ring location (13mm below the inferior renal artery). Ensure adequate oversizing of the proximal stent at its anchoring location.

CAUTION: Proper sizing of the Ovation Abdominal Stent Graft is the responsibility of the physician. This stent graft sizing incorporates the recommended device oversizing for anatomical dimensions and was based on *in-vitro* test data.

The recommended overall length of the deployed, implanted system should extend from just distal to the lowest renal artery to just above the internal iliac bifurcation. Ensure that all potential stent graft lengths and diameters are available to complete the procedure, especially if pre-operative case planning measurements are not certain.

Considerations for patient selection include but are not limited to:

- Patient's age and life expectancy
- Co-morbidities (e.g., cardiac, pulmonary or renal insufficiency prior to surgery, morbid obesity)
- Patient morphologic suitability for endovascular repair
- Patient's suitability for open surgical repair

During the case planning process, TriVascular may consult with physicians in their efforts to determine appropriate stent graft sizing based on the physician's assessment of the patient's anatomical measurements. The benefits and risks previously described must be considered for each patient before use of the Ovation Abdominal Stent Graft System.

7.2. Specific Patient Populations

The Ovation Abdominal Stent Graft System has not been evaluated in patients who:

- Are pregnant or nursing;
- Are less than 18 years old;
- Have traumatic aortic injury, ruptured aneurysms, aneurysms pending rupture or require other emergent aorta/ aneurysm treatment;
- Have suprarenal, thoraco-abdominal, ilio-femoral, juxtarenal, pararenal, mycotic, inflammatory, dissecting or pseudo-aneurysms;
- Have hypercoagulability, bleeding diathesis or coagulopathy;
- Have mesenteric and/or celiac artery occlusive disease and a dominant patent inferior mesenteric artery;
- Have connective tissue disorder or congenital degenerative collagen disease, e.g., Marfan's or Ehler-Danlos Syndrome;
- Require bilateral exclusion of hypogastric blood flow;
- Have baseline serum creatinine level of > 2.0 mg/dl;
- Have other medical, social or psychological conditions that preclude them from receiving the pre-treatment, required treatment, and post-treatment procedures and evaluations.

8. Patient Counseling Information

Prior to treatment, the physician should review with the patient the risks and benefits of this endovascular procedure, including:

- Risks and benefits of aneurysm repair given the patient's age and life expectancy;
- Risks, benefits and differences of open surgical repair;
- Risks, benefits and differences of endovascular repair;
- Risks related to noninterventional treatment (medical management);
- Risks of aneurysm rupture as compared to the risk of endovascular repair;
- The long-term safety and effectiveness of endovascular repair has not been established;
- The importance of life-long, regular follow up to assess patient's health status and the stent graft performance;
- Subsequent endovascular or open surgical repair of the aneurysm may be required;
- Patients with specific clinical findings (e.g. endoleaks, enlarging aneurysms) should be monitored closely;
- Signs to seek prompt medical attention (including limb occlusion, aneurysm enlargement, or rupture).

TriVascular recommends that the physician disclose to the patient, in written form, all risks associated with treatment using the Ovation Abdominal Stent Graft System. Details regarding risks occurring during and after implantation of the device are provided in Section 5, Adverse Events. Additional counseling information can be found in the Patient Information Booklet.

9. How Supplied

The Ovation Abdominal Stent Graft System is comprised of the aortic body stent graft/ delivery system, the iliac limbs and iliac extensions stent graft/delivery systems, the fill polymer kit, and the autoinjector.

The stent grafts are available in the following sizes and configurations.

Table 21. Aortic Body Stent Graft Sizes

Stent Graft Proximal Diameter	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
20 mm	57 cm	14 F	80 mm
23 mm			
26 mm			
29 mm			
34 mm		15 F	

Table 22. Iliac Limb Sizes

Stent Graft Proximal Diameter	Stent Graft Distal Diameter	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
14 mm	10 mm	53 cm	13 F	80 mm
	10 mm			100 mm
	10 mm			120 mm
	10 mm			140 mm
	12 mm			80 mm
	12 mm			100 mm
	12 mm			120 mm
	12 mm			140 mm
	14 mm			80 mm

Stent Graft Proximal Diameter	Stent Graft Distal Diameter	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
	14 mm			100 mm
	14 mm			120 mm
	14 mm			140 mm
	16 mm		14 F	80 mm
	16 mm			100 mm
	16 mm			120 mm
	16 mm			140 mm
	18 mm			80 mm
	18 mm			100 mm
	18 mm			120 mm
	18 mm			140 mm
	22 mm		15 F	80 mm
	22 mm			100 mm
	22 mm			120 mm
	22 mm			140 mm

Table 23. Iliac Extension Sizes

Stent Graft Proximal and Distal Diameters	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
10 mm	53 cm	13 F	45 mm
12 mm			
14 mm			
16 mm			
18 mm		14 F	
22 mm			

9.1. Sterility Information

The Stent Grafts/Delivery Systems are supplied STERILE and non-pyrogenic using an ethylene oxide (EtO) process. The Fill Polymer Kit and Autoinjector are supplied STERILE using an E-beam sterilization process. The Fill Polymer Kit is non-pyrogenic.

- Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damaged or if the sterilization barrier has been damaged or broken.
- Do not use after the expiration date printed on the label.
- Store in a cool, dry place.
- **For single patient use only.** Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of the product and packaging in accordance with hospital, administrative and/or local government policy.

10. Clinician Use Information

10.1. Physician Training

CAUTION: Always have a vascular surgery team available during implantation or re-intervention procedures in the event that conversion to open surgical repair is necessary.

CAUTION: The Ovation Abdominal Stent Graft System should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device.

The recommended skill/ knowledge requirements for physicians using the Ovation Abdominal Stent Graft System are outlined below. If you have questions about the product or sizing, contact TriVascular via the information in the back of this manual.

Patient Selection:

- Knowledge of the natural history of abdominal aortic aneurysm (AAA), co-morbidities, and complications associated with AAA repair.
- Knowledge of radiographic image interpretation, device selection and sizing.

A multi-disciplinary team that has combined procedural experience with:

- Femoral cutdown, arterial bypass, arteriotomy, and repair
- Percutaneous access and closure techniques
- Non-selective and selective guidewire and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

10.2. Inspection Prior to Use

Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product and contact your TriVascular representative for return information.

10.3. Materials Required

Additional accessory devices may also be required because approximately 7% of clinical study subjects were treated during the index procedure with a non-TriVascular device component at the physician's discretion. These accessory devices may include balloon-expandable and self-expanding stents (for proximal aorta or iliac placement, respectively), stent grafts, and/or embolization coils.

Table 24. Equipment and Ancillary Items

Required Equipment	Ancillary Equipment
TriVascular Ovation Abdominal Stent Graft Aortic Body preloaded in Delivery System	
TriVascular Ovation Abdominal Stent Graft Iliac Limbs (2) preloaded in Delivery Systems	
	TriVascular Ovation Abdominal Stent Graft Iliac Extensions preloaded in Delivery Systems
	Additional TriVascular Fill Polymer Kit
TriVascular Fill Polymer Kit	Timer or clock
TriVascular Autoinjector	

Required Equipment	Ancillary Equipment
Imaging Equipment with capability to record and recall all imaging • Imaging table, or operating room table designed for use with C-arm • Fluoroscopy capability • Digital Subtraction Angiography (DSA) capability • Appropriate personnel protection equipment for fluoroscopy	Video recorder Power injector with associated supplies
Angiography and exchange catheters Assortment of adequate sizes (0.035" compatible) and assorted lengths	
Guidewires: Assorted sizes of physician's preference, 0.035" compatible, 180 cm compatible	
Contrast media	
Heparinized saline and flushing syringes	
Vascular instruments and supplies	Endovascular supplies • 3-way stopcocks • Tuohy-Borst adaptors Optional: • Introducer sheaths < 35 cm length • Range of appropriately sized (balloon diameter and length and shaft length) angioplasty balloons: - 12 mm diameter non-compliant balloon(s) for possible ballooning of iliac limb to aortic body junction; - Non-compliant balloons for treatment of and equivalent size to the distal iliac diameter; - Compliant and non-compliant balloons for treatment of and equivalent size to the aortic diameter. • Range of sizes of stents (self-expanding and balloon-expandable) and stent grafts • Embolization devices such as coils

10.4. MRI Information

MR Conditional

10.4.1. MR Conditional

The Ovation Abdominal Stent Graft System was determined to be MR Conditional.

Non-clinical testing demonstrated that the Ovation Abdominal Stent Graft System is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

10.4.2. Static Magnetic Field

- Static magnetic field of 1.5 or 3.0-Tesla
- Maximum spatial gradient magnetic field of 3000-Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 4 W/kg in the first level controlled mode for a maximum scan time of 15 minutes

10.4.3. MRI-Related Heating

In non-clinical testing, the Ovation Abdominal Stent Graft System produced the following temperature rises during MRI performed for 15-min of scanning (i.e., per pulse sequence) in 1.5-Tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems:

	1.5-Tesla	*3-Tesla*
MR system reported, whole body averaged SAR	4.0-W/kg	4.0-W/kg
Calorimetry measured values, whole body averaged SAR	2.9-W/kg	3.7-W/kg
Highest temperature change	+2.6˚C	+3.0˚C

These temperature changes will not pose a hazard to a patient under the conditions indicated above.

10.4.4. Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Ovation Abdominal Stent Graft System. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	8,875-mm^2	353-mm^2	12,026-mm^2	628-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

The artifacts extend approximately 4- to 6-mm from the metallic portion of the device, both inside and outside the device lumen.

11. Directions for Use

11.1. Patient Preparation

- In general, utilize similar patient pre-operative steps as for standard AAA open repair: fasting, bowel preparation, and prophylactic antibiotic regimens. Prepare and drape the patient for an open surgical AAA procedure, in the event that conversion to open repair is required.
- The patient anesthesia protocol utilized during the endovascular procedure is left to the discretion of the implanting physician and anesthesiologist. General anesthesia, regional anesthesia, or local anesthesia combined with conscious sedation are all utilized during endovascular procedures.
- Appropriate procedural imaging is required to successfully position the TriVascular Ovation Abdominal Stent Graft System in the vasculature and to assure appropriate arterial wall apposition. Always use fluoroscopy for guidance, delivery, fill polymer injection/cure, and observation of the TriVascular Ovation Abdominal Stent Graft System within the vasculature.

11.2. General Implant Procedure Precautions

- Do not kink the delivery catheters. Doing so may cause damage to the delivery catheters and the TriVascular Ovation Abdominal Stent Graft System.
- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocols. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the stent graft constrained on the delivery catheter during preparation and insertion to decrease the risk of contamination and infection.
- Do not continue advancement of the guidewire or delivery catheter if resistance is felt, as vessel or delivery catheter damage may occur. Stop and assess the cause of the resistance.
- Inadvertent partial deployment or migration of the stent graft may require surgical removal or repair.

11.3. Implant Procedure and Deployment Instructions

Vascular Access

1	Establish bilateral access using standard interventional technique.
2	Place an angiographic catheter suprarenal from contralateral side and perform angiographic assessment of patient's vasculature.
3	Identify reference positions for renal arteries.
4	Insert a 0.035" guidewire on ipsilateral side and position appropriately.

Delivery System(s) Preparation

1	Inspect all packaging for damage or loss of sterile barrier. If damage is observed, replace with another device.
2	Using sterile technique, remove delivery system from its sterile package and place it onto sterile field.
3	Inspect delivery system for damage; if present, replace device.
4	For the aortic body only, carefully retract delivery system outer sheath approximately 1 cm to facilitate retraction within the vasculature. Advance catheter sheath to its original position. If sheath retraction is difficult, replace device.
5	Flush delivery sheath with heparinized saline using the sheath flush port. ***CAUTION: For the Aortic Body, ensure the polymer fill tube contains no liquid after flushing the sheath. If liquid is identified, replace the Aortic Body Stent Graft Catheter.***
6	Flush guidewire lumen (blue cap) with heparinized saline using guidewire flush port on handle while placing a finger over the open end of the guidewire port. Close blue cap.

Aortic Body Insertion and Deployment

1	Remove introducer sheath from ipsilateral access site (if applicable).
2	Load aortic body delivery system over guidewire.
3	Activate hydrophilic coating on delivery sheath exterior by gently wiping surface with heparinized saline.
4	Position delivery system with the sheath flush port and nested knobs towards patient's ipsilateral side.
5	Using continuous fluoroscopic guidance, insert delivery system into vasculature and advance it until the implant radiopaque markers are about 1 cm proximal to the intended landing site.
6	Orient aortic body laterally within aneurysm sac until nosecone radiopaque marker or fill tube radiopaque marker is toward patient's ipsilateral side. ***CAUTION: Rotate entire delivery system as a unit. (Do not independently rotate catheter sheath or handle.)***
7	Under fluoroscopic guidance, retract delivery system outer sheath until the sheath retraction knob meets handle.
8	Verify implant radiopaque markers are just proximal to the landing site. If necessary, carefully reposition delivery system.
9	Deploy first segment of proximal stent: turn first stent release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.
10	Orient C-Arm to align implant radiopaque markers to achieve orthogonality of view.
11	Precisely position implant radiopaque markers at final proximal landing site. Using contrast injections, as needed, confirm implant position relative to renal arteries.
12	Retract angiographic catheter away from proximal stent.
13	Deploy remainder of proximal stent: turn second stent release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.
WARNING: DO NOT push or pull the delivery system after complete deployment of the proximal stent to avoid inadvertent disconnection of the polymer fill connector from the implant.	
WARNING: To allow conformance of the stent graft to the native anatomy when significant angulation is present, ensure that an extra stiff wire is not inside the aortic body during injection of the fill polymer.	

Fill Polymer Preparation

1	Using sterile technique, place fill polymer kit and Autoinjector onto sterile field.
2	Open both fill kit syringe valves, and transfer contents between syringes for a minimum of 20, uninterrupted, full strokes. Transfer contents into syringe with green band (fill syringe) and close both stopcocks. Remove tear tab and disconnect fill syringe. Note: If voiding air or any fill polymer from the fill syringe prior to closing the stopcocks, the following minimum volume of fill polymer must remain in the fill syringe to ensure complete fill of the stent graft.

Aortic Body Stent Graft Diameter	*Fill Syringe Volume*
20 mm	≥ 7 ml
23 mm	≥ 8 ml
26 mm	≥ 9 ml
29 mm	≥ 11 ml
34 mm	≥ 13 ml

3	Note the time, or start a timer, when mixing is complete.

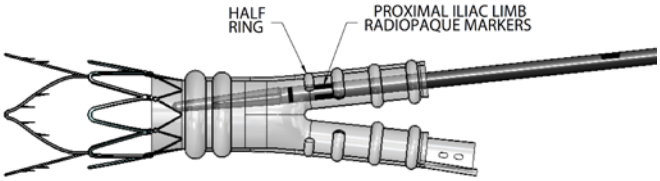
WARNING: Should an error occur in the timing, mixing, or transfer, discard the fill polymer. Injection of the fill polymer should occur immediately after mixing. If injection of the fill polymer has been delayed 3 or more minutes after mixing, discard the fill polymer. Start mixing with a new fill polymer kit.

Fill Polymer Injection

WARNING: DO NOT push or pull the delivery system after complete deployment of the proximal stent to avoid inadvertent disconnection of the polymer fill connector from the implant.	
WARNING: To allow conformance of the stent graft to the native anatomy when significant angulation is present, ensure that an extra stiff wire is not inside the aortic body during injection of the fill polymer.	
WARNING: Use only the Autoinjector to fill the Aortic Body Stent Graft. Hand injection should not be used and may damage the implant.	
1	Remove green fill cap from polymer injection port on handle.
2	Attach fill syringe to polymer injection port on handle.
3	Firmly hold filled syringe stationary and push Autoinjector over plunger, ensuring that the Autoinjector is placed over the syringe body “shoulders”. Rotate Autoinjector 90 degrees to lock (confirmed with an audible “click”). Fill polymer will begin filling aortic body.
4	Using fluoroscopy, intermittently observe filling of graft with radiopaque fill polymer.
WARNING: During fill polymer injection and cure, observe the delivery system and/or syringe for inadvertent disconnection or fill polymer release. Radiopaque marker movement and/or rapid emptying of the fill polymer syringe may be indications that the fill polymer is not filling the stent graft. If observed, immediately disconnect the Autoinjector from the fill polymer syringe.	
WARNING: Patients who experience hypersensitivity reactions during the procedure should be managed in accordance with standard recommendations for treatment of patients with radiocontrast agent allergies (e.g., antihistamines, corticosteroids, adrenaline).	

Contralateral Limb Insertion and Deployment

1	Refer to Delivery System(s) Preparation for delivery system preparation steps.
2	Cannulate the contralateral lumen with a guidewire.
	CAUTION: Confirm cannulation of graft true contralateral lumen to ensure correct placement of the contralateral limb.
3	Use imaging techniques to locate the contralateral internal iliac artery.
4	Confirm appropriate size (diameter and length) of iliac limb selected for contralateral side
5	Maintaining guidewire position, remove angiographic catheter and introducer sheath from contralateral access site (if applicable).
6	Load iliac limb delivery system over guidewire.

	CAUTION: Confirm there is no tension on the aortic body stent graft prior to or during iliac limb placement to prevent possible stenosis or occlusion.
7	Using continuous fluoroscopic guidance, insert iliac limb delivery system into vasculature until proximal iliac limb radiopaque markers align with the most proximal ½ ring of the aortic body. 
8	Confirm proximal and distal iliac limb radiopaque markers are at the appropriate locations and that the iliac limb is in the contralateral lumen of the Aortic Body Stent Graft leg.
9	Retract sheath to deploy iliac limb while maintaining catheter handle position.
10	Maintain position of sheath and retract catheter handle to reseat nosecone in end of delivery system outer sheath.
11	Remove iliac limb delivery system from vasculature while maintaining guidewire position. Re-insert angiographic catheter and advance to suprarenal aorta.

Aortic Body Catheter Detach and Withdrawal

1	A minimum of 20 minutes after completion of fill polymer mixing, disconnect Autoinjector from aortic body delivery system, holding the Autoinjector tightly to control its force once it is unlocked from the syringe shoulders. ***WARNING: Do not disconnect the delivery system before 20 minutes to prevent potential release of fill polymer.*** ***CAUTION: Patients with a core body temperature lower than 35˚C may require at least an additional minute per degree below 35˚C prior to disconnection.***
2	Release catheter from aortic body: turn third release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.
3	Using fluoroscopy, carefully withdraw inner catheter until fill lumen disengages from stent graft. The radiopaque marker on the polymer fill port should move away from stent graft. ***WARNING: If resistance is encountered during catheter withdrawal, STOP. Identify cause of resistance and resolve prior to continuing withdrawal. Catheter rotation may be sufficient to overcome resistance.***
4	While maintaining guidewire position, stabilize sheath and retract catheter handle to reseat nosecone in end of delivery system outer sheath.
5	Remove the aortic body delivery system.

Ipsilateral Limb Insertion and Deployment

1	Refer to Delivery System(s) Preparation for delivery system preparation steps.
2	Follow the appropriate procedural steps for ipsilateral limb deployment as previously described in Contralateral Limb Insertion and Deployment.

Deployment Completion

1	Verify aneurysm exclusion. Perform angiography from proximal to distal landing sites.
2	Although not required as part of the implant procedure, angioplasty balloons of appropriate sizes (diameter equivalent to the vessel size) may be used to improve aneurysm exclusion or to improve the stent graft lumen. ***WARNING: It is important to accurately size the balloons and not over-inflate within the stent graft. It is also important not to balloon outside of stent graft. Carefully follow the balloon manufacturer's inflation parameters described in the product labeling.*** • Prepare balloon catheters and other adjunctive devices to be used according to the manufacturer's Instructions For Use. • Iliac limb/ aortic body junction: The junction may be ballooned using a 12 mm non-compliant balloon, inflated to no more than 5 atm. The "kissing balloon" technique may be utilized at this location. • Distal iliac: The area may be ballooned using a non-compliant balloon the same diameter as the distal

	iliac diameter. ***WARNING: Do not balloon the iliac limb/ aortic body junction or the distal iliac with a compliant balloon.*** • After removal of the angiographic catheter (if present), the proximal aortic body may be ballooned before delivery system removal with a compliant balloon of the same diameter as the proximal aortic diameter. A non-compliant balloon may be used in the aortic body only after the delivery system is removed. ***CAUTION: It is not recommended to balloon prior to 20 minutes after completion of the final polymer mix. Ballooning prior to 20 minutes could damage the sealing rings.***
3	If no other interventions are required and aneurysm exclusion has been verified, remove the angiographic catheter and maintain guidewire position(s). If extension of the iliac is required, proceed with the Iliac Extension Insertion and Deployment steps below.
4	Remove guidewires and introducer sheaths. Close vascular access.

Iliac Extension Insertion and Deployment

1	Using the radiopaque markers on the distal end of the iliac limb as a target and using standard endovascular techniques, cannulate the iliac limb lumen with a guidewire (if necessary).
2	Determine the amount of extension required. If 20 mm or less, use of a straight distal extension is recommended. Refer to the table below for the distal straight extension diameters (Iliac Extension Sizes, 45 mm length) recommended for use with each iliac limb distal diameter.

		Iliac Extension Size (Straight, 45 mm length)					
		10	12	14	16	18	22
Iliac Limb Distal Diameter	10	X	X	X			
	12		X	X	X		
	14			X	X	X	
	16				X	X	X
	18					X	X
	22						X
		20 mm Maximum allowable extension					

3	To use an iliac limb as an extension, refer to the table below. Based on the iliac limb distal diameter and the amount of extension required, select the appropriate extension component length.

Iliac Limb Distal Diameter (mm)	**Amount of Extension Required (mm)**	**Extension Component Length (mm)**
10 12	Up to 50	80
	51 - 70	100
	71 - 90	120
	91 - 110	140
14 16 18 22	Up to 10 *	80 *
	11 - 20	100
	21 - 40	120
	41 - 60	140
* Diameter of extension must be ≥ distal diameter of iliac limb		

3	Prepare the iliac extension delivery system as described in Delivery System(s) Preparation.
4	Maintaining guidewire position, remove angiographic catheter and introducer sheath from access site (if applicable).
5	Load the iliac extension delivery system over the guidewire.
	CAUTION: Confirm there is no tension on the aortic body stent graft prior to or during iliac extension placement to prevent possible stenosis or occlusion.

6	Insert the delivery system into the vasculature until the distal radiopaque marker of the extension is aligned at the distal target. Use continuous fluoroscopic guidance to ensure proper positioning of the stent graft.
7	Verify the appropriate position of the extension relative to the iliac limb and vasculature. 
8	Retract sheath to deploy stent graft while maintaining catheter handle position.
9	While maintaining guidewire position, stabilize sheath and retract catheter handle to reseat nosecone in end of delivery system outer sheath.
10	Remove delivery system from vasculature while maintaining guidewire position.
11	Advance and inflate an appropriate size non-compliant balloon in the overlap region. Follow the manufacturer's recommended method for size selection, preparation, and use of balloons.
12	Re-insert angiographic catheter and advance to the suprarenal aorta. Perform deployment completion angiography as described above.

12. Follow-up Imaging Recommendations

TriVascular recommends the following imaging schedule for patients treated with the Ovation Abdominal Stent Graft System. The appropriate follow up imaging and imaging modalities for a particular patient are the responsibility of the clinician.

Table 25. Recommended Patient Imaging Schedule

	Contrast Enhanced Spiral CT*	Abdominal X-rays**
Pre-procedure (baseline)	**X**	
Pre-discharge		
1 month	**X**	**X**
6 month	**X**	**X**
12 month (annually thereafter)	**X**	**X**

* Abdominal/ Pelvic. Used to assess graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration, stent graft patency, AAA size, occlusion of branch vessels, and endoleak (including source and type if present).

** AP, lateral, left oblique and right oblique views. Used to assess the presence of stent fracture. Ensure the entire device is captured on images for device assessment.

Patients should be counseled on the importance of adhering to the recommended follow-up schedule during the first year and annually thereafter. More frequent follow-up may be required for some patients based on clinical evaluation.

12.1. Non-Contrast CT

For patients with impaired renal function or those who are allergic to contrast medium, a spiral CT without contrast may be considered to assess stent graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration and size of the AAA with diameter and volume measurements.

12.2. Duplex Ultrasound

For patients with impaired renal function or those who are allergic to contrast medium, a color-duplex ultrasound may be considered to assess size of AAA with diameter, endoleaks, and stent graft occlusion and stenosis.

12.3. MRI or MRA

Patients with impaired renal function, i.e., renal insufficiency, may also be considered for magnetic resonance imaging or angiography (MRI, MRA) in facilities that have expertise in this area. Artifact may occur related to the stent, and care should be used to insure adequate imaging of the outer aneurysm wall to assess AAA size. Volume measurement may be helpful if the aneurysm is not clearly shrinking. If there are concerns regarding imaging of calcified areas, fixation sites, or the outer wall of the aneurysm sac, adjunctive CT without contrast may be needed. Specific information on MRI can be found in Section 10.4 MRI Information.

TriVascular recommends contrast enhanced Spiral CT data for reconstruction. The requirements are outlined in **Table 26**.

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.

Table 26. Spiral CT Requirements

	Minimum Protocol	High Resolution Protocol (Recommended)
Scan Mode	Helical	Helical
Scan Parameters	110-140 kVp, Auto mAs or 170-400 mA scan time of 0.5 sec	110-140 kVp, Auto mAs or 170-400 mA scan time of 0.5 sec
Slice Thickness	3 mm	0.625 – 2 mm
Slice Interval	3 mm	0.625 – 2 mm
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 2 cm distal to the lowest hypogastric artery origin	Pre-op: Lesser trochanter of femurs to include femoral bifurcations Post-op: At least 2 cm distal to the lowest hypogastric artery origin
Contrast	Standard per Radiology Department	Standard per Radiology Department
Volume	80 ml contrast with 40 ml saline flush or Standard Contrast Volume with Saline Flush per Radiology Department	80 ml contrast with 40 ml 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

13. Device Registration

The following supplementary documentation is included with the Ovation Abdominal Stent Graft System:

- Device Implant Card: This card contains physician, stent graft and hospital information. Physicians should complete this card and instruct the patient to keep it in their possession at all times. The patients should refer to this card anytime they visit additional health practitioners, particularly for additional diagnostic procedures (e.g. MRI).
- Device Tracking Documents: The documentation is to be completed by the hospital staff and forwarded to TriVascular for the purposes of tracking all patients who received an Ovation Abdominal Stent Graft System (as required by Federal Regulation).

14. Symbols

	Batch Code
	Use by
	Contents
	Non-pyrogenic
	Consult Instructions for use
	MR Conditional
	Do not reuse
	Do not resterilize
	Keep dry
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Manufacturer

Manufacturer:

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For patent coverage, see www.TriVascular.com/patents