



Instructions for Use



Table of Contents

1. Device Description	3
1.1. Delivery System	3
1.2. Fill Polymer	4
1.3. Ancillary Components	5
2. Indications for Use	5
3. Contraindications	5
4. Warnings and Precautions	6
4.1. General	6
4.2. Patient and Device Selection	6
4.3. Implant procedure	6
5. Adverse Events	7
5.1. Potential Adverse Events	7
5.2. Incident Reporting	8
6. Patient Selection and Treatment	9
6.1. Individualization of Treatment	9
6.2. Specific Patient Populations	9
7. Patient Counseling Information	9
8. How Supplied	10
8.1. Ovation Stent Graft & Delivery Systems	11
8.2. Fill Polymer Kit & Autoinjector	11
9. Clinician Use Information	12
9.1. Physician Training	12
9.2. Inspection Prior to Use	12
9.3. Materials Required	12
9.4. MRI Information	14
10. Directions for Use	15
10.1. Patient Preparation	15
10.2. Implant Procedure	15
10.3. Deployment Instructions	15
11. Follow-up Imaging Recommendations	21
12. Symbols	23

1. Device Description

The TriVascular Ovation™ 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 alternate endovascular blood conduit for isolating the aneurysm from the high pressure flow of blood, thereby reducing or eliminating the risk of rupture. The stent graft is a modular configuration comprised of an aortic body section, two 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
- Two Iliac Limb Stent Grafts and delivery catheter
- Iliac Extension Stent Grafts and delivery catheter, as required
- A Fill Polymer Kit
- An Autoinjector

The aortic section is comprised of a proximal stent for suprarenal fixation and a low-permeability 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 the implant contains radiopaque markers adjacent to the proximal graft edge. These radiopaque markers serve as positioning aids during placement of the device and allow the implant to be located so that it can be positioned to not obstruct the renal arteries. To seal the proximal end of the graft and to provide support into which the iliac limbs are deployed, the graft body contains a network of inflatable rings that are filled with a liquid polymer that solidifies during the deployment procedure. The graft has a fill port that connects the fill network of the graft to the delivery catheter.

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

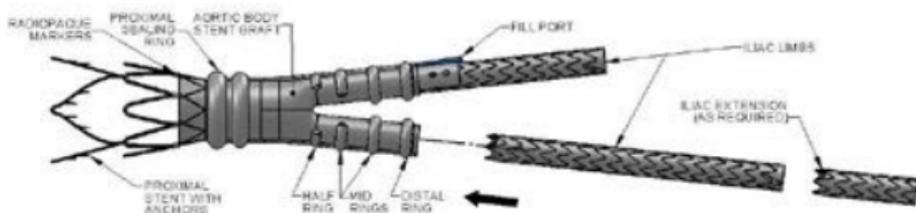


Figure 1. Schematic of Deployed TriVascular Ovation Abdominal Stent Graft

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 low-profile delivery catheters (14F–15F OD, 13F–15F OD, and 13F – 14F OD respectively, Figure 2 and Figure 3). The aortic body is deployed via the aortic body delivery catheter. The aortic body delivery catheter has a lumen that allows for the use of a guidewire to help deliver the stent graft to the deployment site.

During stent graft deployment, the device is 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 (supplied).

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 then advanced into position and deployed into the aortic body by retracting the catheter sheath with the catheter in the appropriate position. 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 then advanced over the ipsilateral guidewire and deployed using the method described above for the contralateral limb.

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.

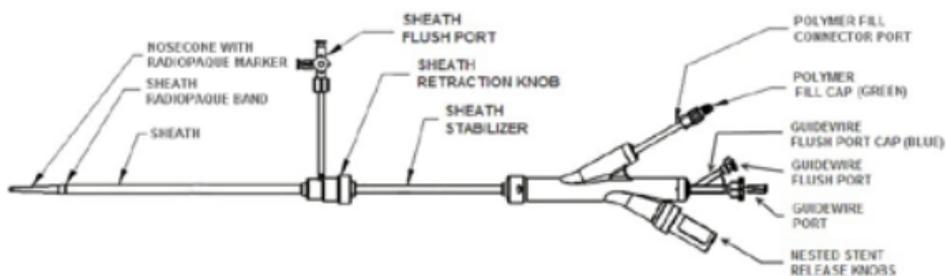


Figure 2. Schematic of TriVascular Ovation Abdominal Stent Graft System aortic body delivery catheter

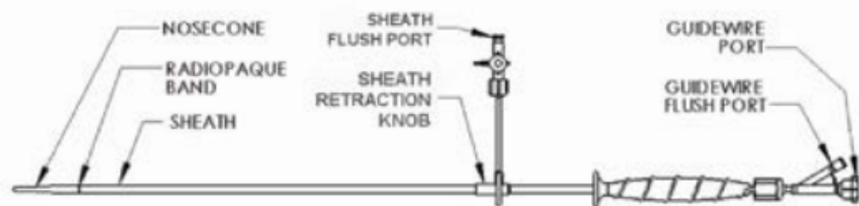


Figure 3. Schematic of TriVascular Ovation Abdominal Stent Graft System iliac limb/ iliac extension delivery catheter

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 1 for patient sizing information and Tables 2-4 for product sizes and configurations.

1.2. Fill Polymer

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

Just prior to use, the two valves on the kit are opened and the fill polymer is mixed by alternately depressing the two syringe plungers for a 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 5), and the syringe given a quarter-turn to lock it in place. The autoinjector applies controlled pressure to inject the fill polymer into the graft without requiring continuous attention from the operator.

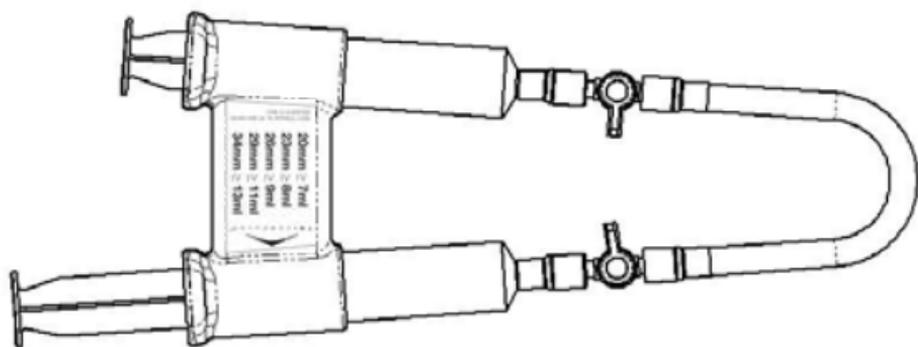


Figure 4. TriVascular Fill Polymer Kit

1.3. Ancillary Components



Figure 5. TriVascular Autoinjector

2. Indications for Use

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

- Adequate iliac/femoral access compatible with vascular access techniques, devices, and/or accessories,
- Non-aneurysmal proximal aortic neck:
 - with a length of at least 7 mm proximal to the aneurysm,
 - with an inner wall diameter of no less than 16 mm and no greater than 30 mm, and
 - with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm,
- Non-aneurysmal distal iliac landing zone:
 - with a length of at least 10 mm,
 - with an inner wall diameter of no less than 8 mm and no greater than 20 mm.

3. Contraindications

- Patients who have a condition that threatens to infect the graft.
- Patients with sensitivities or allergies to the device materials.

4. Warnings and Precautions

4.1. General

- 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.
- Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.
- 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. This experience should include:
 - Vascular access techniques
 - Guidewire and catheter techniques
 - Fluoroscopic and angiographic image interpretation
 - Embolization
 - Angioplasty
 - Endovascular stent placement
 - Appropriate use of contrast agents
 - Techniques to minimize radiation exposure
 - Expertise in patient follow-up modalities
- The long-term performance of this implant has not been established. All patients treated with this device must undergo periodic imaging to evaluate the stent graft, aneurysm size, aneurysm pulsatility, device migration, leaks, device integrity and occlusion of vessels in the treatment area. Significant aneurysm enlargement, evidence of perigraft flow, the appearance of a new endoleak, change in aneurysm pulsatility, device migration and/or reduced blood flow through the graft should prompt further investigation into the need for further patient treatment.
- 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. Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude placement of the device.
- Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites.
- 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.

4.3. Implant procedure

- 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.

- 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 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 and the device deployment.
- Inaccurate placement or inadequate seal may result in increased risk of leakage 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.
- 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).

5. Adverse Events

5.1. Potential Adverse Events

Adverse events that may occur include but are not limited to:

- Acute and chronic renal failure, renal microembolism, renal insufficiency, renal artery occlusion, contrast toxicity;
- Allergic reaction to x-ray 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, 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, loss of stent graft system component integrity, endograft occlusion, migration, or dislodgement, endoleak;
- Embolic and thrombotic events 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, bleeding, pain, delayed healing, abscess formation, hematoma, dehiscence, seroma, 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;
- Possible infection–urinary tract, systemic or localized, endograft;
- Pneumothorax;
- 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, collateral 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 the Authorized Representative at the contact number provided at the end of this document.

6. Patient Selection and Treatment

6.1. Individualization of Treatment

The TriVascular Ovation Abdominal Stent Graft System must be selected in a size appropriate to the patient's anatomy. The sizing options for the device are detailed in Table 1 Patient Sizing Information.

Table 1. 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. Ensure adequate oversizing of the proximal stent at its anchoring location.

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

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.

6.2. Specific Patient Populations

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

- Are pregnant or nursing;
- Have traumatic aortic injury;
- Have suprarenal or thoraco-abdominal aneurysms;
- Have acutely ruptured aneurysms or aneurysms pending rupture;
- Have hypercoagulability;
- Have ilio-femoral, thoracic or inflammatory aneurysms;
- Have juxtarenal AAA;
- Have pararenal AAA;
- Have mesenteric artery occlusive disease;
- Have connective tissue disorder.

7. Patient Counseling Information

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

- Risks, benefits and differences of open surgical repair;
- Risks, benefits and differences 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;
- Signs to seek prompt medical attention (including limb occlusion, aneurysm enlargement, or rupture).

8. How Supplied

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

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

Table 2. Ovation 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 3. Ovation 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	
	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		

Stent Graft Proximal Diameter	Stent Graft Distal Diameter	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
	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 4. Ovation Iliac Extension sizes

Stent Graft Proximal and Distal Diameter	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			
22 mm			
		14 F	

8.1. Ovation Stent Graft & Delivery Systems

Contents are supplied STERILE and non-pyrogenic using an ethylene oxide (EO) process.

- 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.

8.2. Fill Polymer Kit & Autoinjector

Contents 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.

9. Clinician Use Information

9.1. 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.

Patient Selection:

- Knowledge of the natural history of abdominal aortic aneurysm (AAA) and co-morbidities 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

9.2. 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.

9.3. Materials Required

Table 5. 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
TriVascular Fill Polymer Kit	Timer or clock
TriVascular Autoinjector	
Imaging Equipment with capability to record and recall all imaging <ul style="list-style-type: none"> • 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, 150 cm compatible	
Contrast media	
Heparinized saline and flushing syringes	
	Radiopaque ruler with centimeter increments, or equivalent
Vascular instruments and supplies	Endovascular supplies <ul style="list-style-type: none"> • 3-way stopcocks • Tuohy-Borst adaptors Optional: <ul style="list-style-type: none"> • Introducer sheaths < 35 cm length • Range of appropriately sized (balloon diameter and length and shaft length) angioplasty balloons: <ul style="list-style-type: none"> - 12 mm diameter non-compliant

Required Equipment	Ancillary Equipment
	balloon(s) for possible ballooning of iliac limb to aortic body junction; <ul style="list-style-type: none"> - 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. <ul style="list-style-type: none"> • Range of sizes of commercial stents • Embolization devices such as coils

9.4. MRI Information



MR Conditional

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:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

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:

	<u>1.5-Tesla</u>	<u>3-Tesla</u>
MR system reported, whole body averaged SAR	2.9-W/kg	2.9-W/kg
Calorimetry measured values, whole body averaged SAR	2.1-W/kg	2.7-W/kg
Highest temperature change	+1.9 °C	+2.3 °C

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

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	353	12,026	628
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.

10. Directions for Use

10.1. 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 successfully 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, and observation of the TriVascular Ovation Abdominal Stent Graft System within the vasculature.

10.2. Implant Procedure

- 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.

10.3. 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	Remove delivery system from its sterile package.

3	Using sterile technique, place delivery system onto sterile field.
4	Inspect delivery system for damage; if present, replace device.
5	For the aortic body <u>only</u> , 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.
6	Flush delivery sheath with heparinized saline using the sheath flush port.
7	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	Using continuous fluoroscopic guidance, insert delivery system into vasculature and advance it until the implant marker coils are about 1 cm proximal to the intended landing site.
5	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.)
6	Under fluoroscopic guidance, retract delivery system outer sheath until the sheath retraction knob meets handle.
7	Verify implant marker coil positioning is just proximal to the landing site. If necessary, carefully reposition delivery system.
8	Deploy first segment of proximal stent: turn first stent release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.
9	Orient C-Arm to align implant marker coils to achieve orthogonality of view.
10	Precisely position implant marker coils at proximal landing site. Using contrast injections, as needed, confirm position of the implant relative to renal arteries.
11	Retract angiographic catheter away from proximal stent, if necessary.
12	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 an extra stiff wire is not inside the aortic body during injection of the fill polymer.

Fill Polymer Preparation

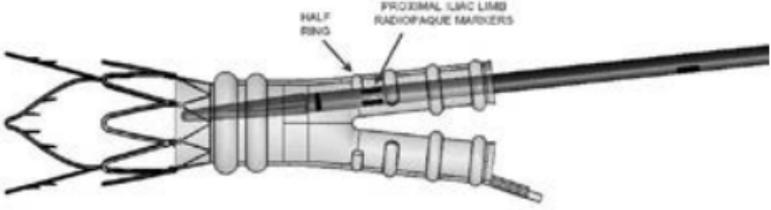
1	Using sterile technique, place fill polymer kit and autoinjector onto sterile field.												
2	<p>Open both fill kit syringe valves, and transfer contents between syringes for a minimum of 20 full strokes. Completely transfer contents into syringe with green band (fill syringe) and close both stopcocks. Remove tear tab and disconnect fill syringe.</p> <p>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 completely fill the stent graft.</p> <table border="0" data-bbox="277 434 878 668"> <thead> <tr> <th style="text-align: center;"><i>Aortic Body Stent Graft Diameter</i></th> <th style="text-align: center;"><i>Fill Syringe Volume</i></th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">20 mm</td> <td style="text-align: center;">≥ 7 ml</td> </tr> <tr> <td style="text-align: center;">23 mm</td> <td style="text-align: center;">≥ 8 ml</td> </tr> <tr> <td style="text-align: center;">26 mm</td> <td style="text-align: center;">≥ 9 ml</td> </tr> <tr> <td style="text-align: center;">29 mm</td> <td style="text-align: center;">≥ 11 ml</td> </tr> <tr> <td style="text-align: center;">34 mm</td> <td style="text-align: center;">≥ 13 ml</td> </tr> </tbody> </table>	<i>Aortic Body Stent Graft Diameter</i>	<i>Fill Syringe Volume</i>	20 mm	≥ 7 ml	23 mm	≥ 8 ml	26 mm	≥ 9 ml	29 mm	≥ 11 ml	34 mm	≥ 13 ml
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3	Note the time, or start a timer, when mixing is complete.												
<p>WARNING: Should an error occur in the timing, mixing, or transfer, discard the fill polymer. Start mixing with a new fill polymer kit.</p>													
<p>WARNING: 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.</p>													

Fill Polymer Injection

<p>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.</p>	
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 “shoulders” of the syringe body. 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.
<p>WARNING: During fill polymer injection and cure, observe the delivery system and/or syringe for inadvertent disconnection or fill polymer spill. 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 this is observed, immediately disconnect the Autoinjector from the fill polymer syringe.</p>	
<p>WARNING: Patients who experience hypersensitivity reactions during the procedure should be managed in accordance with standard recommendations for treatment of patients with radiocontrast agent</p>	

allergies (e.g., antihistamines, corticosteroids, adrenaline).

Contralateral Limb Insertion and Deployment

1	Cannulate the contralateral lumen with a guidewire.
CAUTION: Confirm cannulation of graft true lumen to ensure accurate placement of the contralateral limb.	
2	Use imaging techniques to locate the contralateral internal iliac artery.
3	Confirm appropriate size (diameter and length) of iliac limb selected for contralateral side, and prepare iliac limb delivery system (per above instructions).
4	Maintaining guidewire position, remove angiographic catheter and introducer sheath from contralateral access site (if applicable).
5	Load iliac limb delivery system over guidewire. Confirm there is no tension on the aortic body stent graft prior to or during placement of the iliac limb within the aortic body.
6	Using continuous fluoroscopic guidance, insert iliac limb delivery system into vasculature until proximal iliac limb radiopaque markers align with the ½ ring of the aortic body (most proximal ring).
 <p>The diagram shows a cross-section of the iliac limb delivery system. A central guidewire is visible. Labels point to a 'HALF RING' and 'PROXIMAL ILIAC LIMB RADIOPAQUE MARKERS'. The system is shown in a curved position, likely within a vessel or sheath.</p>	
7	Confirm distal iliac limb radiopaque markers are at the appropriate location and that the iliac limb is in the contralateral lumen.
8	Retract sheath to deploy iliac limb while maintaining catheter handle position.
9	Maintain position of sheath and use catheter handle to retract nosecone to sheath.
10	Remove iliac limb delivery system from vasculature while maintaining guidewire position. Re-insert angiographic catheter and advance to suprarenal aorta.

Aortic Body Catheter De-Mate 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 shoulders of the syringe. WARNING: Do not disconnect the delivery system before 20 minutes to prevent potential release of fill polymer.
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 band 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, use catheter handle to retract nosecone to tip of delivery system outer sheath.
5	Remove the aortic body delivery system.

Ipsilateral Limb Insertion and Deployment

1	Follow the appropriate procedural steps for ipsilateral limb deployment as previously described in Contralateral Limb Insertion and Deployment.
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Deployment Completion

1	Verify aneurysm exclusion. Perform angiography from proximal landing site to distal landing sites.
2	<p>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.</p> <p>WARNING: It is important to accurately size the balloons and not over-inflate within the stent graft. Carefully follow the balloon manufacturer's inflation parameters described in the product labeling.</p> <ul style="list-style-type: none"> • 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. <p>WARNING: Do not balloon the iliac limb/ aortic body junction or the distal iliac with a compliant balloon.</p> <ul style="list-style-type: none"> • 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 noncompliant balloon may be used in the aortic body only after the delivery system is removed. <p>CAUTION: It is not recommended to balloon prior to 15 minutes after completion of the final polymer mix. Ballooning prior to 15 minutes could damage the sealing rings.</p>
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	<p>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.</p> <table border="1" data-bbox="166 359 966 771"> <thead> <tr> <th colspan="2" rowspan="2"></th> <th colspan="6">Iliac Extension Size (Straight, 45 mm length)</th> </tr> <tr> <th>10</th> <th>12</th> <th>14</th> <th>16</th> <th>18</th> <th>22</th> </tr> </thead> <tbody> <tr> <th rowspan="6">Iliac Limb Distal Diameter</th> <th>10</th> <td>X</td> <td>X</td> <td>X</td> <td></td> <td></td> <td></td> </tr> <tr> <th>12</th> <td></td> <td>X</td> <td>X</td> <td>X</td> <td></td> <td></td> </tr> <tr> <th>14</th> <td></td> <td></td> <td>X</td> <td>X</td> <td>X</td> <td></td> </tr> <tr> <th>16</th> <td></td> <td></td> <td></td> <td>X</td> <td>X</td> <td>X</td> </tr> <tr> <th>18</th> <td></td> <td></td> <td></td> <td></td> <td>X</td> <td>X</td> </tr> <tr> <th>22</th> <td></td> <td></td> <td></td> <td></td> <td></td> <td>X</td> </tr> <tr> <td colspan="2"></td> <td colspan="6" style="text-align: center;">20 mm Maximum allowable extension</td> </tr> </tbody> </table>			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					
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8	<p>Verify the appropriate position of the extension relative to the iliac limb and vasculature.</p> 
9	Retract sheath to deploy stent graft while maintaining catheter handle position.
10	Maintain position of sheath and use catheter handle to retract nosecone to sheath.
11	Remove delivery system from vasculature while maintaining guidewire position.
12	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.
13	Re-insert angiographic catheter and advance to the suprarenal aorta. Perform deployment completion angiography as described above.

11. Follow-up Imaging Recommendations

TriVascular recommends the following imaging schedule for patients treated with the Ovation Abdominal Stent Graft System.

Table 6. Recommended patient imaging schedule

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

* Abdominal/ Pelvic

** AP, lateral, left oblique and right oblique views

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.

TriVascular recommends contrast enhanced Spiral CT data for reconstruction. The requirements are outlined in Table 7.

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 7. 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	<u>Pre-op:</u> Lesser trochanter of femurs to include femoral bifurcations <u>Post-op:</u> At least 2 cm distal to the lowest hypogastric artery origin	<u>Pre-op:</u> Lesser trochanter of femurs to include femoral bifurcations <u>Post-op:</u> 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

12. Symbols



Batch Code



Use by



Contents



Non-pyrogenic



www.trivascular.com/IFU

Consult Instructions for use
www.trivascular.com/IFU



MR Conditional



Upper limit of temperature for excursions
during transit only



Do not reuse



Do not re-sterilize



Keep dry



Do not use if package is damaged



Sterilized using ethylene oxide



Sterilized using irradiation



Authorized Representative in the European
Community



Manufacturer



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