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endologix.com

May 6th, 2020

Urgent Field Safety Notice
Ovation iX Abdominal Stent Graft System

This FSN is specific to the following Ovation iX Abdominal Stent Graft Systems, and impacts all lot/serial numbers: TV-AB2080-I, TV-AB2380-I, TV-AB2680-I, TV-AB2980-I, TV-AB3480-I

Dear Physician,

As part of our commitment to patient safety, Endologix, Inc. is sending this communication to physician users of the Ovation iX Abdominal Stent Graft System to provide safety updates regarding polymer leaks during implantation.

Please review this information carefully and disseminate it to operating room staff and others within your organization to ensure awareness and immediate patient treatment in the event of a polymer leak during the procedure.

This letter provides information only; no product return is required.

Description of the Issue
On 6 August 2018, Endologix issued a safety update regarding polymer leaks with the Ovation iX aortic body stent graft. This letter reaffirms treatment recommendations for patients who experience a polymer leak during implantation and provides updated information on the current rate of polymer leaks, the rate of clinical harms and root cause. At the time of the 2018 safety update, the rate of polymer leak for the lifetime of distribution of Ovation iX was 0.65%. Currently the polymer leak rate is 0.86% over the lifetime of distribution of the device. These reports are based on voluntary complaint reporting and units sold, which may underestimate the true rate on a per patient basis.

A polymer leak can only occur during the polymer fill step of the index implantation procedure. After polymer cure (solidification) within the fill channel of the endograft (which may take up to 14 minutes intraoperatively using the CustomSeal fill polymer kit), there is no risk of ongoing liquid polymer leak. Polymer leaks into the circulation may be acutely associated with a hypersensitivity response to liquid polymer.

Clinical events related to polymer leaks may be systemic and/or aneurysm related (due to incomplete filling of the polymer rings).

Safety Update: Treatment of a Patient with Polymer Leak – Patient Reaction
During the polymer injection step of the procedure, systemic hypotension may indicate that a polymer leak is occurring. Blood pressure monitoring during polymer fill may assist in early identification of a potential polymer leak. In the absence of other obvious diagnoses causing sudden hypotension during polymer fill, Endologix recommends that a hypersensitivity reaction (an anaphylactoid response) to intravascular polymer leak be considered a probable diagnosis. Patients with a polymer leak should undergo immediate treatment for a potential severe hypersensitivity response in accordance with institutional protocols (e.g., intravascular fluids, antihistamines, corticosteroids, epinephrine).

In addition to systemic hypotension, device related findings that are indicative of a polymer leak include complete emptying of the fill polymer syringe, and incomplete filling of the polymer channels.

The table below outlines the number of patients reported to have systemic complications attributed to polymer leaks from Ovation iX commercial implants up to 29 February 2020, and for comparative purposes gives the rates quoted in the safety notification of 6 August 2018.

Systemic Response to Polymer Leak	Current lifetime rate (31 August 2015 to 29 February 2020)	Lifetime rate as per August 2018 FSN (31 August 2015 to 30 June 2018)
Death	0.03% (4/12393)	0.04% (3/7285)
Multi-organ failure[1], cardiac arrest, neurological complication[2]	0.06% (8/12393)	0.07% (5/7285)
Local tissue necrosis[3]	0.04% (5/12393)	0.15% (11/7285)*
Prolonged hemodynamic instability[4.]	0.04% (5/12393)	0.05% (4/7285)
Transient hemodynamic instability	0.65% (85/12393)	0.33% (24/7285)
Total patients with an event	0.86% (107/12393)	0.65% (47/7285)

[1]Includes dialysis, prolonged cardiac support, or liver failure;
[2]Includes stroke, paraplegia;
[3]Includes rash/skin necrosis (observed on the posterior lumbar area), muscle necrosis (para-spinal and in the lower limbs following an occurrence of compartment syndrome), renal, GI and lower limb ischemia.
[4]Includes >24 hour critical care support.
* Eight harms in this category have been corrected and reallocated from previous FSN. These patients are now classified to have transient hemodynamic instability
Figures in parentheses refer to the number of complaints received for each individual patient response as a percentage of total bifurcate units sold since product commercialization
Note: Each patient with a polymer leak complaint is only counted once, i.e. for its most severe harm.
These reports are based on voluntary complaint reporting and units sold, which may underestimate the true rate on a per patient basis

Safety Update: Treatment of a Patient with Polymer Leak – Aneurysm Management

Aneurysm related complications that may occur due to polymer leak (see table below) should be treated with standard endovascular techniques at the physician's discretion, utilizing the ancillary equipment listed in the Ovation iX Abdominal Stent Graft System Instructions for Use (IFU), or an open surgical approach. The specific treatment will be dependent on the extent and location of incomplete filling of the polymer rings and the associated clinical findings. In respect of intra-operative Type 1a endoleaks resulting from polymer leak (44 patients), there were two main treatment strategies, conservative management (in the cases of small endoleaks expected to resolve spontaneously) or the use of balloon expandable stents (in 29 cases). There were no patients who had an intra-operative Type 1a endoleak resulting from a polymer leak, that subsequently had a late Type 1a endoleak reported.

No patient with an iliac limb complication had a reported major or minor amputation.

The table below outlines the number of patients reported to have an aortic related complication attributed to a polymer leak from Ovation iX commercial implants up to 29 February 2020.

Intraoperative aneurysm related complications associated with polymer leak	Current lifetime rate (31 August 2015 to 29 February 2020)	Number (%) of complications resolved intra-operatively
Endoleak Type Ia	0.35% (44/12393)	28 (64%)
Endoleak Type Ib	0.008% (1/12393)	0
Endoleak Type IIIa	0.008% (1/12393)	0
Iliac limb complications* (lower limb ischaemia, iliac limb occlusion / thrombosis)	0.07% (9/12393)	7 (78%)

*includes lower limb ischemia, iliac limb occlusion, iliac limb thrombosis
Figures in parentheses refer to the number of complaints received for each individual patient response as a percentage of total bifurcate units sold since product commercialization
Note: Each patient with a polymer leak may generate more than one aneurysm related complication
These reports are based on voluntary complaint reporting and units sold, which may underestimate the true rate on a per patient basis

Root Cause of Polymer Leaks

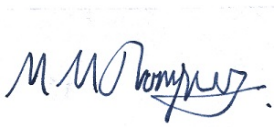
Continuing investigations since our safety update of 6 August 2018 have revealed that technical and procedural factors of the user (e.g. use of the cross over lumen before polymer fill, catheter manipulation) are not causative for the majority of polymer leaks, as was previously communicated. Adherence to the procedural steps within the Instructions for Use continues to be recommended and are not modified in this safety update.

The root cause for most polymer leaks is a material weakness adjacent to the polymer fill channel which may become compromised during pressurization with liquid polymer. Endologix is committed to eliminating these areas of material weakness with design and manufacturing changes.

Endologix Commitment

This communication is a continuing effort to provide product education and guidance to physicians and to reduce potential patient safety risks. We will continue to monitor the clinical experience with the Ovation platform, and we appreciate your willingness to work with us. We continue to work collaboratively with our Notified Body NSAI regarding updates to product labeling. Adverse reactions or quality problems experienced with the use of this product may be reported to your local Competent Authority either online, by regular mail or by fax. Please also notify Endologix of adverse events or quality problems by emailing Endologix at fieldassurance@endologix.com and/or contacting your Endologix representative. The product IFU can be accessed via website at www.trivascular.com/IFU or provided via hard copy upon request to Endologix EU Customer Service at +31 88 116 91 01. If you have any questions regarding the content of this notification, please contact Endologix EU Customer Service at +31 88 116 91 01.

Yours Sincerely



Matt Thompson FRCS MD
Chief Medical Officer Endologix Inc.

Appendix 1: *Ovation Field Safety Notice (FS-0012) Customer Acknowledgement form*

Appendix 1: Ovation Field Safety Notice (FS-0012)
Customer Acknowledgement Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FS-0012
FSN Date	6 May 2020
Product/ Device name	Ovation iX Abdominal Stent Graft System
Product Code(s)	TV-AB2080-I, TV-AB2380-I, TV-AB2680-I, TV-AB2980-I, TV-AB3480-I
Batch/Serial Number (s)	All Lot and Serial Numbers

2. Return Acknowledgement to Endologix	
Email	FSCA-europe@endologix.com
Customer Helpline	+31 88 116 91 01
Postal Address	Endologix International Holdings B.V. Europalaan 30 5232 BC 's-Hertogenbosch, NL
Deadline for returning the Customer Form	Please return within **10** days of receipt of this notice
Acknowledgement Return Options • Take a picture of signed reply form with your smart phone and e-mail to the address above. • Scan the signed reply form and e-mail to the address above. • Mail the signed reply form to the postal address above. • Fax the signed reply form to +31 88 116 9199	

3. NO PRODUCT RETURN IS REQUIRED

4. Customer action undertaken on behalf of Physician or Healthcare Organization (Please check/mark all that apply.)	
☐	I confirm the receipt, the reading, and understanding of this Field Safety Notice
☐	The information and required actions have been brought to the attention of all relevant users and shall be executed.
☐	The affected devices are not being used in our Healthcare Organisation
Customer Print Name	
Name of Healthcare Organisation	
City / Country	
Customer Signature	
Date	

It is important your organization confirms it has received the FSN and acknowledges the actions detailed within the FSN. Your organization's reply is required objective evidence needed to monitor the progress and effectiveness of the corrective actions.

Ovation iX™ Abdominal Stent Graft System

Instructions for Use

EN

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0050

Endologix

810-0016-01-01 Rev C

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1. Device Description

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

The Ovation iX 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 Kit
- An Autoinjector

The Ovation iX Abdominal Stent Graft System refers to the use of the Ovation iX aortic body with either the Ovation iX or Ovation Prime iliac limb/iliac extension stent grafts.

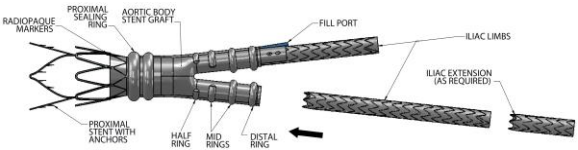


Figure 1. Schematic of Deployed Ovation iX Abdominal Stent Graft System

The aortic body 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 radiopaque markers are located adjacent to the graft proximal edge. These radiopaque markers aid placement of the device in its intended location relative to the renal arteries. To seal the proximal end of the graft and to provide support for the aortic body legs into which the iliac limbs are deployed, the graft body contains a network of inflatable rings that are filled with a liquid polymer that solidifies during the deployment procedure. The graft has a fill port that connects the fill network of the graft to the delivery catheter. Figure 2 provides an image of the device with its sealing ring in the aorta. Because of this feature of the device, the sizing considerations are unique and described in Section 6. 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. 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.

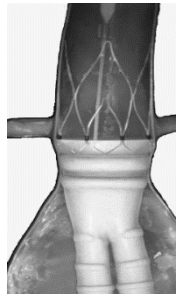


Figure 2. Aortic Body Stent Graft in aorta

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, as illustrated in Figures 3 - 5. The delivery catheters each have a lumen for use with a guidewire to facilitate access and deployment. The inner catheter of the Ovation iX stent graft delivery systems can be withdrawn through the outer sheath, with the outer sheath remaining in the vasculature to facilitate the introduction of ancillary devices. The aortic body delivery system includes an integrated crossover lumen as an option to facilitate guidewire access.

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

The contralateral and ipsilateral iliac limbs are each deployed via iliac limb delivery catheters. After deployment of the aortic body, a guidewire is placed from the contralateral access site into the contralateral distal leg of the aortic body; the integrated crossover lumen can be utilized to facilitate the process The contralateral iliac limb is advanced into position and deployed into the aortic body leg by retracting the catheter sheath with the catheter in the appropriate position. The contralateral limb delivery catheter is then used as an integral sheath (as described above) or withdrawn from the vasculature. After the fill polymer cures within the sealing rings, the aortic body delivery catheter is detached from the fill port of the graft and is used as an integral sheath (as described above) or withdrawn from the vasculature. The ipsilateral iliac limb delivery catheter is advanced over the ipsilateral guidewire and deployed using the method described above for the contralateral limb. The ipsilateral limb delivery catheter is then used as an integral sheath (as described above) or withdrawn from the vasculature.

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

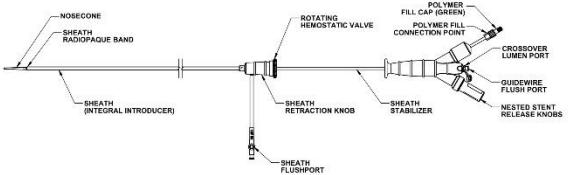


Figure 3. Schematic of Ovation iX Abdominal Stent Graft System Aortic Body Delivery Catheter

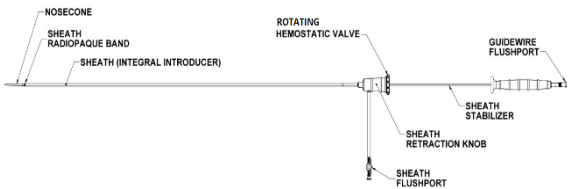


Figure 4. Schematic of Ovation iX Iliac Limb/ Iliac Extension Delivery Catheter

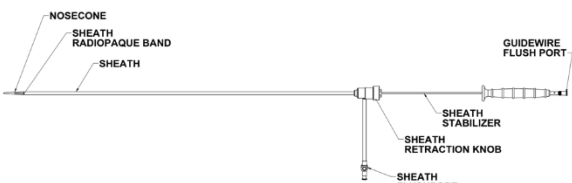


Figure 5. Schematic of Ovation Prime Iliac Limb/ Iliac Extension Delivery Catheter

The Ovation iX Abdominal Stent Graft System is designed to accommodate various aortic anatomies, including a range of proximal and distal aortic diameters, aneurysm lengths, and common iliac artery diameters. Refer to Table 1 for patient sizing information and Tables 2-6 for product sizes and configurations.

1.2. Fill Kit and Autoinjector

The Fill Kit options are shown in Figure 6 and Figure 7. Figure 6 is the Fill Polymer Kit ("one wing" or "two wing" valves) with 20 minute detach time and Figure 7 is the CustomSeal Kit with 14 minute detach time. The fill polymer is comprised of three components that are mixed prior to injection. Upon mixing and injection into the graft, the components form a radiopaque polymer that fills the proximal sealing rings in the wall of the aortic body graft and the ribs in the aortic body graft legs. The fill polymer radiopacity dissipates over time and may not be visible on fluoroscopy, X-ray or CT beyond 1-2 months post-implant.

Prior to use, the two valves on the fill kit are opened and the fill polymer is mixed by alternately depressing the two syringe plungers for a minimum of 20 full strokes. Thereafter, the fill syringe is disconnected from the connection tube, slipped out of the syringe support and connected to the fill polymer injection port on the aortic body delivery system. The syringe plunger is then inserted into the Autoinjector (Figure 8), and the Autoinjector is given a quarter-turn to lock it in place. The Autoinjector applies controlled force to the syringe plunger to inject the fill polymer into the graft.

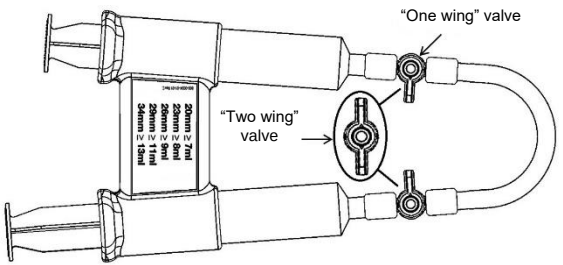


Figure 6. Fill Polymer Kit with 20 minute detach time

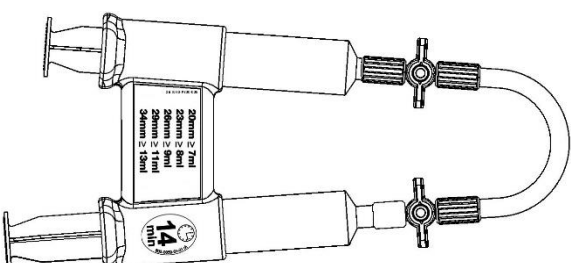


Figure 7. CustomSeal Kit with 14 minute detach time

Figure 8. Autoinjector

2. Indications for Use

The Ovation iX 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 25 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 iX 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.
- Polymer leaks are a unique potential risk of the Ovation device platform that have been reported post-market. The complications of polymer leakage into the vasculature have ranged from transient hypotension to severe life-threatening anaphylactoid reactions, tissue necrosis and death. When polymer leaks occur, underfilling of the Ovation iX sealing rings have led to intraoperative Type Ia endoleaks and iliac limb complications that have required additional therapy. The risk of polymer leak should be carefully considered along with the risks associated with alternative treatment options when making personalized treatment decisions for those individuals who fall within the indicated patient population as defined by the Indications for Use (Section 2).

- 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 Ovation iX 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:
  - Knowledge of the natural history of AAA, common comorbidities, and complications associated with AAA repair
  - Vascular access techniques
  - Nonselective and selective guidewire and catheter techniques
  - Radiographic, 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 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 stent graft integrity and position, aneurysm size, aneurysm pulsatility, and potential endoleaks and/or occlusion of vessels in the treatment area. Significant aneurysm enlargement, a persistent endoleak, the appearance of a new endoleak, change in aneurysm pulsatility, 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 iX 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 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 Syndrome;
- Have ectatic iliac arteries requiring bilateral exclusion of hypogastric blood flow.

- 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/iliac inner wall diameter inappropriately sized for the stent graft.
- Inappropriate patient selection may result in poor device performance or device performance not otherwise in accordance with the specifications.
- 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 creatinine level of >2.0mg/dl; have unstable angina and/or myocardial infarction (MI) or cerebral vascular accident (CVA) within 3 months prior to implantation; and/or exceed weight and/or size limits necessary to meet imaging requirements.

4.3. Implant Procedure

- Refer to section 10. Directions for Use for warnings and cautions specific to implant steps of the Ovation iX 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 iX 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 components of the Ovation iX Abdominal Stent Graft System because it may damage the device and/or its components.
- Do not use the aortic body device if the polymer fill tube on the delivery system contains liquid after flushing.
- 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 or retracting the guidewire or 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 firmly pull the aortic body 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.
- Discard the fill polymer should an error occur in the timing, mixing or transfer. During fill polymer injection and cure, observe catheter radiopaque marker for movement and if observed, immediately disconnect the Autoinjector from the fill polymer syringe.
- Use only the Autoinjector to fill the Aortic Body Stent Graft. Hand injection should not be used and may damage the implant.
- During fill polymer injection or use of the integrated crossover lumen, confirm there is no tension on the aortic body stent graft to allow conformance of the stent graft to the native anatomy.
- Confirm cannulation of aortic body contralateral lumen to ensure accurate placement of the contralateral limb.
- Do not disconnect delivery system before specified detach time. 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.
- If resistance is encountered during catheter withdrawal, identify cause of resistance and resolve prior to continuing withdrawal.
- It is important to accurately size and choose the balloons to be used during device deployment and to follow the balloon deployment instructions. 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.
- Non-clinical testing has demonstrated that the device 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 9.4, MRI Information.

- 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 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 Endologix immediately. To report an event, contact your local representative and/or Endologix at the contact number provided at the end of this document.

6. Patient Selection and Treatment

6.1. Individualization of Treatment

The Ovation iX Abdominal Stent Graft System must be selected in sizes 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 1 Patient Sizing Information.

Table 1. Patient Sizing Information

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

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

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

CAUTION: Proper sizing of the Ovation iX 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 common 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, Endologix 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 iX Abdominal Stent Graft System.

6.2. Specific Patient Populations

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

- Are pregnant or nursing;
- Are less than 18 years old;
- Have traumatic aortic injury or rupture or require other emergent aorta/aneurysm treatment;
- Have suprarenal, thoraco-abdominal, mycotic or pseudo-aneurysms;
- Have acutely ruptured aneurysms or aneurysms pending rupture;
- Have hypercoagulability, bleeding diathesis or coagulopathy;
- Have ilio-femoral, thoracic or inflammatory aneurysms;
- Have juxtrarenal AAA;
- Have pararenal AAA;
- 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 Syndrome.

7. 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).

Endologix recommends that the physician disclose to the patient, in written form, all risks associated with treatment using the Ovation iX Abdominal Stent Graft System. Details regarding risks occurring during and after implantation of the device are provided in Section 5, Adverse Events.

8. How Supplied

The Ovation iX 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 kit, and the Autoinjector.

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

Table 2. Ovation iX Aortic Body Stent Graft sizes

Stent Graft Proximal Diameter, mm	Catheter Working Length, cm	Delivery System Outer Profile, F	Delivery System Inner Diameter, F	Covered Stent Graft Length, mm
20	60	14	12	80
23				
26				
29				
34		15	13	

Table 3. Ovation Prime Iliac Limb sizes

Stent Graft Proximal Diameter, mm	Stent Graft Distal Diameter, mm	Catheter Working Length, cm	Delivery System Outer Profile, F	Covered Stent Graft Length, mm
14	10	53	13	80
	10			100
	10			120
	10			140
	12			80
	12			100
	12			120
	12			140
	14			80
	14			100
	14			120
	14			140
	16		14	80

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

Table 4. Ovation iX Iliac Limb sizes

Stent Graft Proximal Diameter, mm	Stent Graft Distal Diameter, mm	Catheter Working Length, cm	Delivery System Outer Profile, F	Delivery System Inner Diameter, F	Covered Stent Graft Length, mm
14	10	60	12	10	80
	10				100
	10				120
	10				140
	10				160
	12				80
	12				100
	12				120
	12				140
	12				160
	14				80
	14				100
	14				120
	14				140
	14				160
	16		13	11	80
	16				100
	16				120
	16				140
	16				160

Stent Graft Proximal Diameter, mm	Stent Graft Distal Diameter, mm	Catheter Working Length, cm	Delivery System Outer Profile, F	Delivery System Inner Diameter, F	Covered Stent Graft Length, mm
	18				80
	18				100
	18				120
	18				140
	18				160
	22		14	12	80
	22				100
	22				120
	22				140
	22				160
	28		15	13	80
	28				100
	28				120
	28				140
	28				160

Table 5. Ovation Prime Iliac Extension sizes

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

Table 6. Ovation iX Iliac Extension sizes

Stent Graft Proximal & Distal Diameters, mm	Catheter Working Length, cm	Delivery System Outer Profile, F	Delivery System Inner Diameter, F	Covered Stent Graft Length, mm
10	60	12	10	45
12				
14				
16		13	11	
18				
22		14	12	
28		15	13	

8.1. Sterility Information

Stent Grafts/Delivery Systems are supplied STERILE and non-pyrogenic using an ethylene oxide (EO) process. The Fill Kit and Autoinjector are supplied STERILE using an E-beam sterilization process. The Fill 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 iX 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 iX Abdominal Stent Graft System is outlined below. If you have questions about the product or sizing, contact Endologix 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

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 Endologix representative for return information.

9.3. Materials Required

Table 7. Equipment and Ancillary Items

Required Equipment	Ancillary Equipment
Ovation iX Abdominal Stent Graft Aortic Body preloaded in Delivery System	Optional (to utilize integrated crossover lumen) • Guidewire, 0.018" maximum, exchange length required • Snare • Introducer sheath, 5F ID minimum
Ovation iX or Ovation Prime Iliac Limbs (2) preloaded in Delivery Systems	
	Ovation iX or Ovation Prime Iliac Extensions preloaded in Delivery Systems
Fill Polymer Kit or CustomSeal Kit	Timer or clock
Autoinjector	
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

Required Equipment	Ancillary Equipment
Angiography and exchange catheters Assortment of adequate sizes (0.035" [0.89mm] compatible) and assorted lengths	
Guidewires: Assorted sizes of physician's preference, 0.035" (0.89mm) 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. - *Note: Non-compliant balloons with long tapers/large "shoulders" may not be suitable for use with this device.* • Range of sizes of commercial stents • Embolization devices such as coils

9.4. MRI Information

MR Conditional

MR Conditional

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

Non-clinical testing applicable to the Ovation iX Abdominal Stent Graft System demonstrated that the device 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 1.5 or 3.0-Tesla, only
- Maximum spatial gradient magnetic field of 12,000-Gauss/cm (extrapolated) or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence)

- Normal Operating Mode of operation for the MR system

MRI-Related Heating

In non-clinical testing applicable to the Ovation iX Abdominal Stent Graft System, the test article 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	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	+2.0 ˚C	+2.4 ˚C
Temperature scaled to whole body averaged SAR of 2-W/kg	1.4 ˚C	1.7 ˚C

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 iX Abdominal Stent Graft System. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5 mm relative to the size and shape of this implant. The artifacts extend approximately 4- to 6-mm from the metallic portion of the device, both inside and outside the device lumen.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	9,305-mm^2	1,011-mm^2	13,082-mm^2	1,514-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

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 Ovation iX 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 Ovation iX Abdominal Stent Graft System within the vasculature.

10.2. General Implant Procedure Precautions

- Do not kink the delivery catheters. Doing so may cause damage to the delivery catheters and the stent grafts.
- 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. Implant Procedure and Deployment Instructions

Vascular Access

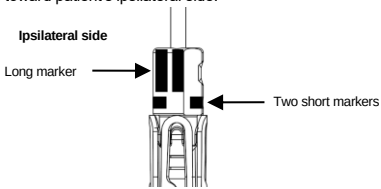
1	Establish bilateral access using standard interventional technique.
2	Place an angiographic catheter suprarenal from contralateral side and perform angiographic assessment of patient's vasculature, if needed.
3	Identify reference positions for renal arteries.
4	Insert a 0.035" (0.89mm) guidewire on 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 delivery system onto sterile field.
3	Inspect delivery system for damage; if present, replace device.
4	Flush delivery system sheath with heparinized saline using the sheath flush port. The rotating hemostatic valve may be turned to tighten valve seal. ***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.***

5	Flush guidewire lumen with heparinized saline using guidewire flush port on handle.
6	Place blue cap over crossover lumen port.

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 aortic body radiopaque markers are about 1 cm proximal to the intended landing site.
6	To orient aortic body laterally, rotate entire aortic body delivery system until the two short delivery system radiopaque markers are visible on each side of the guidewire AND the long delivery system 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 aortic body radiopaque markers are just proximal to the landing site. If necessary, carefully reposition delivery system.
9	Verify long delivery system radiopaque marker is still oriented towards patient's ipsilateral side. Rotate entire aortic body delivery system, if needed.
10	Deploy first segment of proximal stent: turn first stent release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.
11	Orient C-Arm to align implant radiopaque markers to achieve orthogonality of view.
12	Precisely position implant radiopaque markers at final proximal landing site. Using contrast injections, as needed, confirm implant position relative to renal arteries.
13	Retract angiographic catheter away from proximal stent.
14	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 firmly 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, 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 kit and Autoinjector onto sterile field.
2	Open both fill kit syringe valves, and transfer contents between syringes for a minimum of 20 full uninterrupted 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 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 if using the Fill Polymer Kit or injection has been delayed 2 or more minutes using the CustomSeal Kit, discard the fill polymer. Start mixing with a new fill kit.

Fill Polymer Injection

WARNING: DO NOT firmly 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, ensure that an extra stiff wire is not inside the aortic body during injection of the fill polymer.

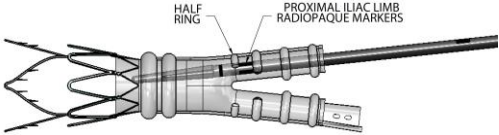
WARNING: Use only the Autoinjector to fill the Aortic Body Stent Graft. Hand injection should not be used and may damage the implant.

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	Retract aortic body guidewire tip to radiopaque marker distal to aortic body.
5	Using fluoroscopy, intermittently observe filling of graft with radiopaque fill polymer.
CAUTION: Confirm there is no tension on the aortic body stent graft to allow conformance of the stent graft to the native anatomy.	
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. The integrated crossover lumen in the aortic body delivery system may be used to facilitate the process using a maximum 0.018" guidewire. ***CAUTION: Confirm there is no tension on the aortic body stent graft prior to or during use of the integrated crossover lumen to allow conformance of the stent graft to the native anatomy.*** ***CAUTION: If resistance is felt when retracting a crossover guidewire from the ipsilateral side, do not apply excessive tension. The crossover guidewire will be removed when the aortic body catheter is detached and withdrawn.***
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. Confirm there is no tension on the aortic body stent graft prior to or during iliac limb placement within the aortic body.

7	Using continuous fluoroscopic guidance, insert iliac limb delivery system into vasculature until proximal iliac limb radiopaque markers are between the 3rd ring and the 4th (half-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.
9	Retract sheath to deploy iliac limb while maintaining catheter handle position.
10	Maintain position of sheath and retract catheter handle to position nosecone in end of delivery system outer sheath.
11	To use the Ovation iX integral sheath: While maintaining guidewire position, move entire delivery system to desired position. Retract handle to remove catheter from outer sheath. If needed, rotate hemostatic valve to maintain hemostasis. Alternatively, remove entire delivery system from vasculature.

Aortic Body Catheter Detach and Withdrawal

1	For the Fill Polymer Kit, a minimum of 20 minutes after completion of fill polymer mixing, disconnect Autoinjector from syringe, holding the Autoinjector tightly to control its force once it is unlocked from the syringe shoulders. For the CustomSeal Kit, a minimum of 14 minutes after completion of fill polymer mixing, disconnect Autoinjector from syringe, holding the Autoinjector tightly to control its force as it is unlocked from the syringe shoulders. ***WARNING: Do not disconnect the delivery system before the specified detach time to prevent potential release of fill polymer (20 minutes for the Fill Polymer Kit or 14 minutes for the CustomSeal Kit).*** ***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	Re-advance aortic body guidewire.
3	Release catheter from aortic body: turn third release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.
4	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.***

5	While maintaining guidewire position, stabilize sheath and retract catheter handle to reseat nosecone in end of delivery system outer sheath.
6	To use the Ovation iX integral sheath: While maintaining guidewire position, move entire delivery system to desired position. Retract handle to remove catheter from outer sheath. If needed, rotate hemostatic valve to maintain hemostasis. Alternatively, remove entire delivery system from vasculature.

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. 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. The aortic body may be remodeled using a balloon up to 40 minutes after the completion of the CustomSeal Kit polymer mix. ***CAUTION: For the Fill Polymer Kit, 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. For the CustomSeal Kit, it is not recommended to balloon prior to 14 minutes after completion of the final polymer mix. Ballooning prior to 14 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	28
Iliac Limb Distal Diameter	10	X	X	X				
	12		X	X	X			
	14			X	X	X		
	16				X	X	X	
	18					X	X	X
	22						X	X
	28							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
	111 – 130	160
14 16 18 22 28	Up to 10 *	80 *
	11 - 20	100
	21 - 40	120
	41 - 60	140
	61-80	160
* Diameter of extension must be ≥ distal diameter of iliac limb		

4	Prepare the iliac extension delivery system as described in Delivery System(s) Preparation.

5	Maintaining guidewire position, remove angiographic catheter and introducer sheath from access site (if applicable).
6	Load the iliac extension delivery system over the guidewire. Confirm there is no tension on the Aortic Body Stent Graft prior to or during iliac extension placement.
7	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.
8	Verify the appropriate position of the extension relative to the iliac limb and vasculature. 
9	Retract sheath to deploy stent graft while maintaining catheter handle position.
10	While maintaining guidewire position, stabilize sheath and retract catheter handle to reseat nosecone in end of delivery system outer sheath.
11	To use the Ovation iX integral sheath: While maintaining guidewire position, move entire delivery system to desired position. Retract handle to remove catheter from outer sheath. If needed, rotate hemostatic valve to maintain hemostasis. Alternatively, remove entire delivery system from vasculature.
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

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

Table 8. 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. 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.

11.1. 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.

11.2. 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.

11.3. 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 9.4 MRI Information.

Endologix recommends contrast enhanced Spiral CT data for reconstruction. The requirements are outlined in Table 9.

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 9. 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

	Minimum Protocol	High Resolution Protocol (Recommended)
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

12. Symbols

LOT	Batch Code
	Use by
	Contents
	Non-pyrogenic
e-IFU	Consult Instructions for use, www.e-labeling.eu
MR	MR Conditional
	Do not reuse
	Do not resterilize
	Keep dry
	Do not use if package is damaged
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
14 min	14 minutes minimum post fill polymer mix prior to aortic body catheter detach
EC REP	Authorized Representative in the European Community
	Manufacturer
EP PAT	For patent coverage, see **www.endologix.com/patents**
ID	Delivery system inner diameter
	Request printed copy.

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