Alto™ Abdominal Stent Graft System

Instructions for Use

EN

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1. Device Description

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

The Alto™ Abdominal Stent Graft System includes:

- An Aortic Body Stent Graft and delivery catheter
- Ovation iX™ Iliac Limb Stent Grafts and delivery catheters
- Ovation iX™ Iliac Extension Stent Grafts and delivery catheters (as required)
- CustomSeal™ Polymer Fill Kit
- Autoinjector 2

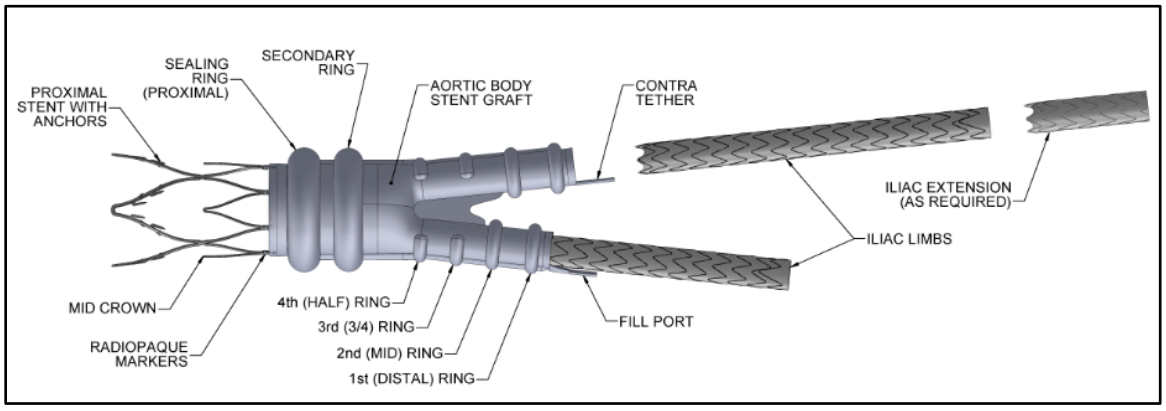


Figure 1: Schematic of Alto™ Abdominal Stent Graft System

The Alto™ Abdominal Stent Graft System incorporates the following primary modifications to the currently approved Ovation iX Abdominal Stent Graft System:

- Locating Sealing Ring 7mm below renal arteries,
- Incorporation of an integrated balloon, and
- Use of a lower pressure Autoinjector 2.

The modifications were based on feedback from Ovation iX users and maintain the fundamental design and technology characteristics of the polymer-based Ovation platform.

1.1 Alto™ Stent Graft Implant

Aortic Body

The aortic body is comprised of a proximal stent for suprarenal fixation and a low-permeability polytetrafluoroethylene (PTFE) graft connected using discrete attachments and attachment coils as shown in **Figure 2**. The bare proximal stent is designed with 8 anchors to help fixate the device 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.

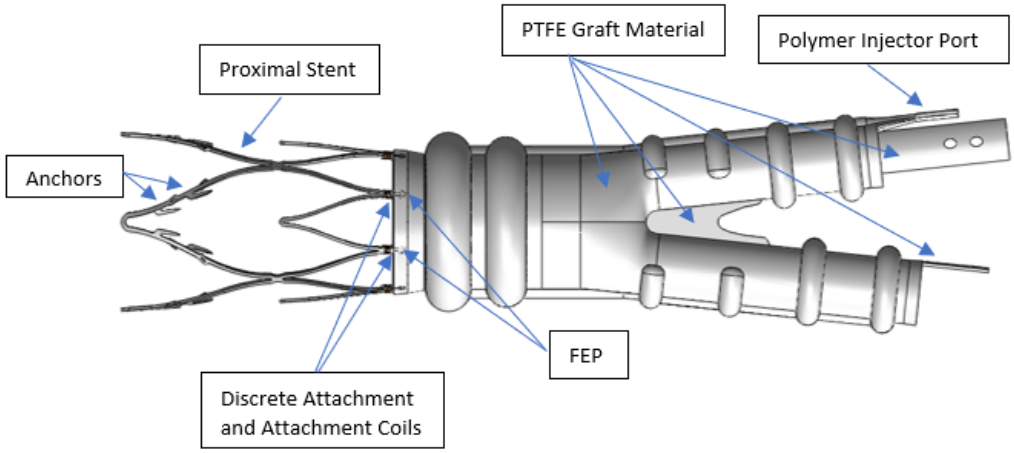


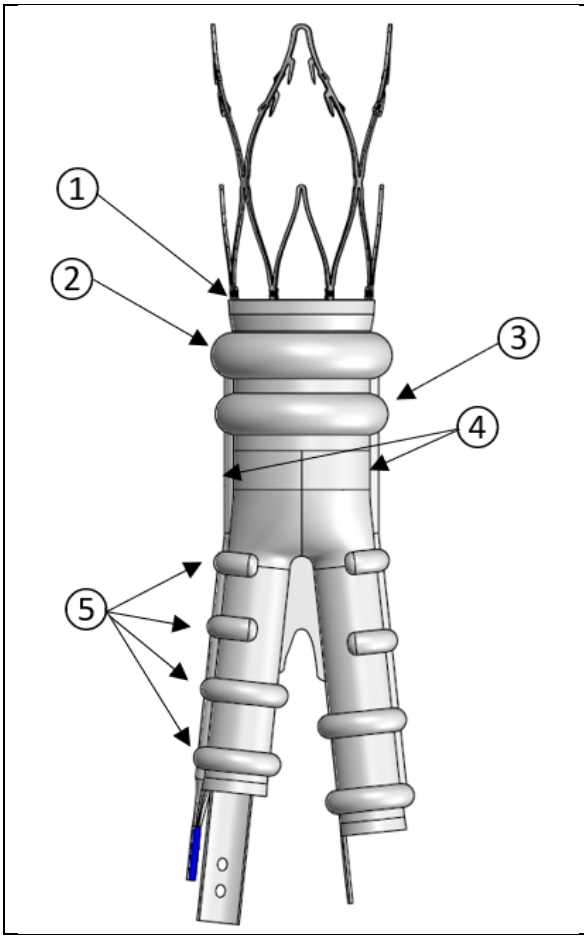
Figure 2: Image of Alto™ Aortic Body Stent Graft

Please reference the Alto™ Aortic Body Stent Graft Materials below in **Table 1**.

Table 1: Aortic Body Stent Graft Materials

Implant Component	Material
Graft	Polytetrafluoroethylene (PTFE)
Polymer Injector Port	Polytetrafluoroethylene (PTFE)
Proximal Stent	Nickel-Titanium (Nitinol) Alloy
Discrete Attachments	Nickel-Titanium (Nitinol) Alloy with Fluorinated Ethylene Propylene (FEP)
Radiopaque Markers (Attachment Coils)	Nickel-Titanium (Nitinol) Alloy

The nitinol proximal stent is radiopaque, and radiopaque markers (attachment coils) are located adjacent to the graft proximal edge. These radiopaque markers aid in the placement of the device in its intended location relative to the renal arteries. The fill polymer is radiopaque and provides visualization of the polymer fill channels once the graft is filled. **Figure 3** shows the location of the radiopaque markers in the Alto™ Aortic Body Stent Graft.



Item	Marker	Material
1	Stent to Graft Attachments at Collar	Nitinol wire and Nitinol Stent
2	Polymer Filled Primary Sealing Ring (Liquid and Cured) continuous marker	Radiopaque fill polymer chemistry
3	Polymer Filled Secondary Support Ring (Liquid and Cured) continuous marker	Radiopaque fill polymer chemistry
4	Polymer Filled Fill Channels (Liquid and Cured) continuous marker	Radiopaque fill polymer chemistry
5	Polymer Filled Leg Support Rings (Liquid and Cured) continuous marker	Radiopaque fill polymer chemistry

Figure 3: Location of the Radiopaque Markers in the Alto™ Aortic Body Stent Graft

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 channels and rings that are filled with a liquid radiopaque polymer (reference Figure 3 above) 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 4** below shows the device with its proximal sealing ring in the aorta. The aortic body is provided in five proximal seal ring sizes: 20, 23, 26, 29, and 34mm. While the diameter of the aortic body varies by product model, the trunk length (40mm), leg length (35mm on the ipsilateral side and 40mm on the contralateral side), as well as the distal inner diameters of the leg (11mm) are constant. Because of the sealing feature of the device, the sizing considerations are unique and described in further detail in Section 7.2 (Alto™ Abdominal Stent Graft Sizing).

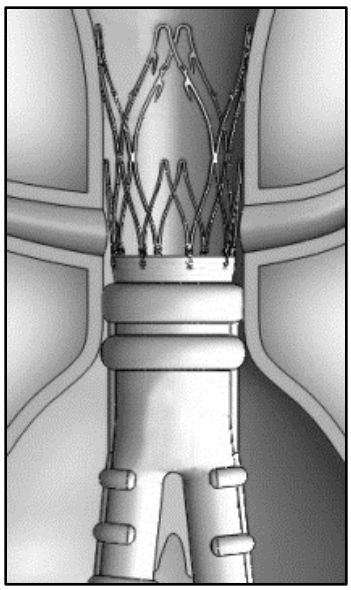


Figure 4: Alto™ Aortic Body Stent Graft in Aorta

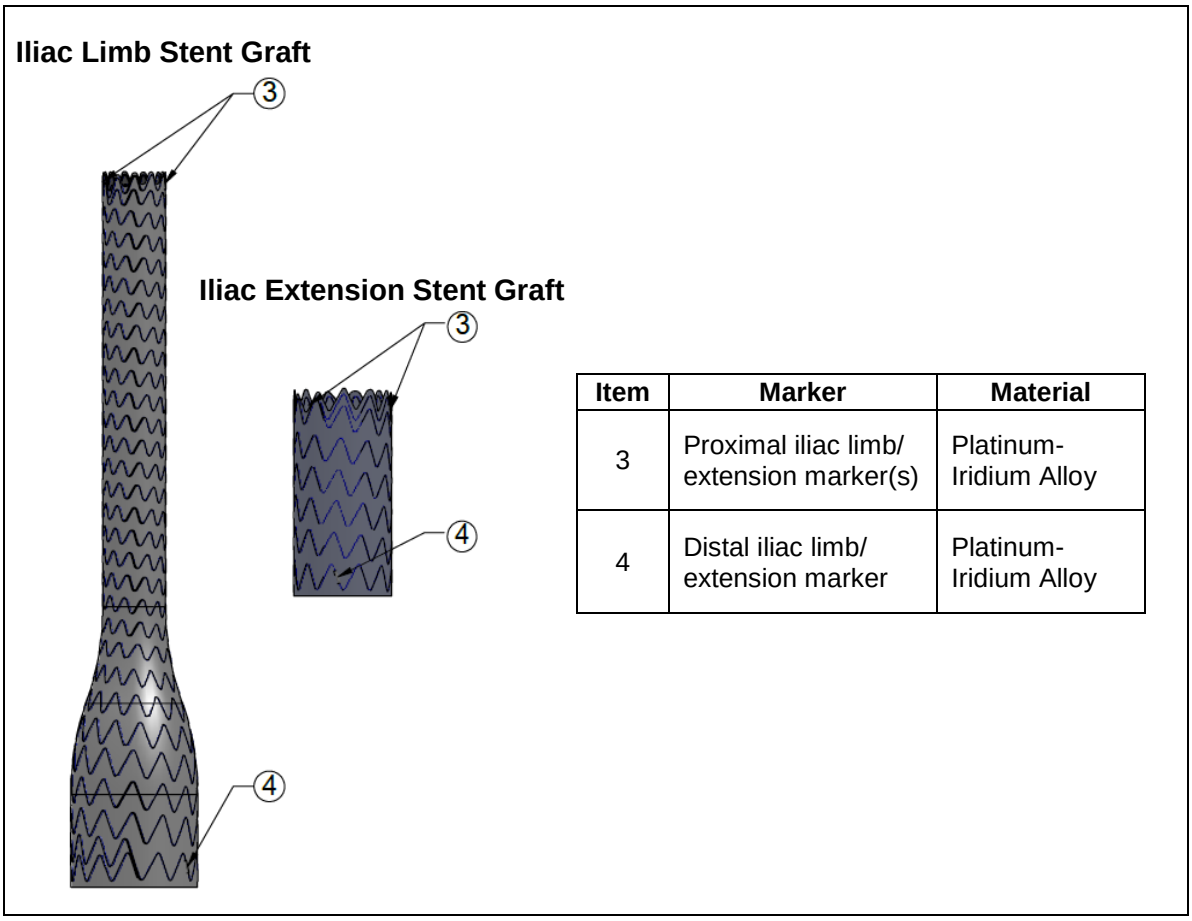
Iliac Limbs/Extensions

The iliac limbs and extensions are comprised of a nitinol stent encapsulated in low-permeability PTFE. The materials can be referenced in **Table 2** below. The iliac limbs are deployed into the leg sections of the aortic body. Radiopaque markers enable the physician to visualize the appropriate iliac limb - aortic body overlap or iliac extension – iliac limb overlap during a catheter-based deployment. The amount of overlap that is appropriate for each combination of devices can be referenced in Step 3 of Section 11.3.1.10, Iliac Extension Insertion and Deployment. The radiopaque markers are in the same location on the stent graft for both the Iliac Limbs and Extensions, as shown in **Figure 5**.

Stent radial force provides both fixation and sealing of the interface between the aortic body and each iliac limb, between the iliac limb and iliac extension, and between the iliac limb/extension and its landing zone in the iliac artery. The iliac limbs are available in 7 different distal diameters (10, 12, 14, 16, 18, 22, 28mm) and 5 different lengths (80, 100, 120, 140, 160mm). The proximal portion of the iliac limbs have a constant diameter of 14mm. The iliac extensions are available with a constant length of 45mm and the same 7 iliac limb distal diameters. The sizing considerations for the iliac limbs and extensions are described in further detail in Section 7.2 (Alto™ Abdominal Stent Graft Sizing).

Table 2: Iliac Limb/ Extension Stent Graft Materials

Implant Component	**Material**
Graft	Polytetrafluoroethylene (PTFE)
Stent and Attachments	Nickel-Titanium (Nitinol) Alloy
Radiopaque Markers	Platinum-Iridium Alloy



Item	Marker	Material
3	Proximal iliac limb/ extension marker(s)	Platinum-Iridium Alloy
4	Distal iliac limb/ extension marker	Platinum-Iridium Alloy

Figure 5: Location of Radiopaque Markers on the Iliac Limb/ Extension Stent Grafts

1.2 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 6 - 7**. The delivery catheters each have a lumen for use with a .035" (0.89 mm) guidewire to facilitate access and deployment. The outer sheaths are hydrophilic coated. There are two variations of the delivery system: one for the aortic body stent graft (Figure 6) and one for the iliac limbs/extensions (Figure 7). Both systems allow for the inner catheter to be withdrawn through the outer sheath, with the outer sheath and integrated hemostatic valve remaining in the vasculature to facilitate the introduction of ancillary devices.

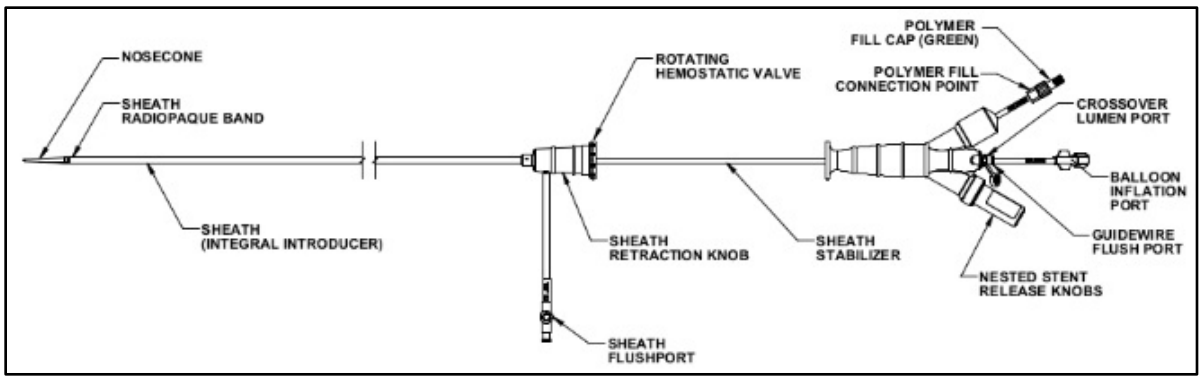


Figure 6: Schematic of Alto™ Abdominal Stent Graft System Aortic Body Delivery Catheter

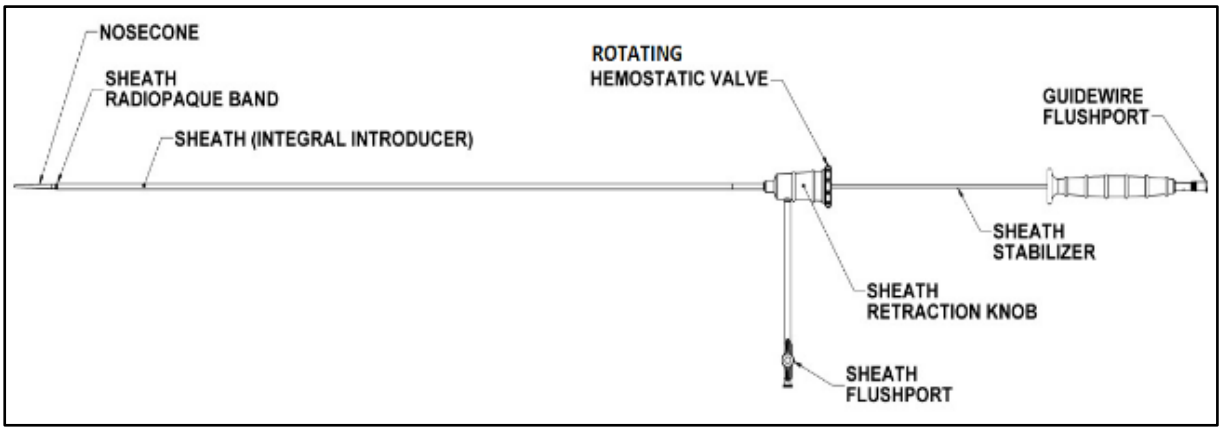


Figure 7: Schematic of Ovation iX Iliac Limb/ Iliac Extension Delivery Catheter

The aortic body is deployed via the aortic body delivery catheter (Figure 6), which has a working length of approximately 60cm and outer sheath diameter of 15Fr (inner diameter 13Fr). The catheter has a connection to the distal legs of the aortic body. During aortic body stent graft deployment, the device is first positioned, and the sheath is retracted. The proximal stent is deployed using stent release knobs on the handle, with an integral balloon used to facilitate graft opening. The fill polymer is then delivered through the fill connector port using the Autoinjector 2.

The contralateral and ipsilateral iliac limbs are each deployed via iliac limb delivery catheters (Figure 7). The iliac limb catheters have a working length of approximately 60cm and have 4 different outer diameters based on the iliac limb diameter: 10-14mm iliac limbs have a 12/10Fr outer/inner sheath diameter, 16-18mm iliac limbs have a 13/11Fr outer/inner sheath diameter, 22mm iliac limbs have a 14/12Fr outer/inner sheath diameter, and 28mm iliac limbs have a 15/13Fr outer/inner sheath diameter. After deployment of the aortic body, a guidewire is placed from the contralateral access site into the contralateral distal leg of the aortic body; the integrated crossover lumen on the aortic body delivery system can be utilized to facilitate the process. The contralateral iliac limb is advanced into

position and deployed into the aortic body leg by retracting the catheter sheath with the catheter in the appropriate position. The contralateral limb delivery catheter is then used as an integral sheath to facilitate the introduction of ancillary devices or withdrawn from the vasculature.

After the fill polymer cures within the primary sealing ring of the aortic body, the integral balloon of the aortic body delivery catheter can be used to improve sealing ring apposition. The catheter is detached from the fill port of the aortic body graft and can be 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 can then be 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.

The Alto™ 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 21** (Section 7.2) for patient sizing information and **Tables 22-24** (Section 9.1) for product sizes and configurations.

1.3 Polymer Fill Kit (CustomSeal™ Kit) and Autoinjector 2

The CustomSeal™ Kit is comprised of two fill syringes containing fill polymer, which is used to inflate a network of channels and rings in the aortic body (refer to Figure 3 above) and solidifies during the deployment procedure. The fill polymer is comprised of three components that are mixed within the fill syringes prior to injection into the aortic body stent graft. The components include a buffered solution containing a contrast agent which resides in one syringe and a reactive monomer that resides in the other syringe. The third component is a separate reactive monomer that resides within the connecting tube between syringes. The reaction between the two monomers results in the formation of a solid hydrogel within the primary sealing ring, secondary support ring, fill channels, and leg support rings in the graft material of the aortic body (refer to Figure 3) during the deployment procedure. The CustomSeal™ Kit (**Figure 8**) is labeled with a 14 minute detach time, meaning the aortic body delivery catheter should not be disconnected from the graft until the polymer has had 14-minutes to cure. The potential need to modify the polymer cure time based on the patient's body temperature is addressed in Section 4.4 below.

To prepare the fill polymer for injection into the aortic body stent graft, the two valves on the fill kit are opened and the components of the fill polymer are mixed by alternately depressing the two syringe plungers for a minimum of 20 full strokes (10 on each side). The appropriately filled syringe is removed from its carrier and then connected to the aortic body delivery catheter fill port. Figure 6 shows the location of the polymer fill port on the aortic body delivery catheter. The Autoinjector 2 is attached over the syringe plunger (see **Figure 9**) and given a quarter-turn to lock it in place. The Autoinjector 2 applies controlled force to the syringe plunger to inject the fill polymer into the graft until pressure equilibrium is reached and complete fill of the primary sealing ring, fill channels, and support rings in the graft material the of the aortic body is achieved.

Upon mixing and injection into the aortic body stent graft, the polymer components form a radiopaque cross-linked polymer that fills the primary sealing ring, fill channels, and support rings in the graft material of the trunk and legs of the aortic graft. The fill polymer radiopacity dissipates over time (1-2 months) so as not to create imaging artifacts that could interfere with endoleak detection in subsequent CT imaging follow-up.

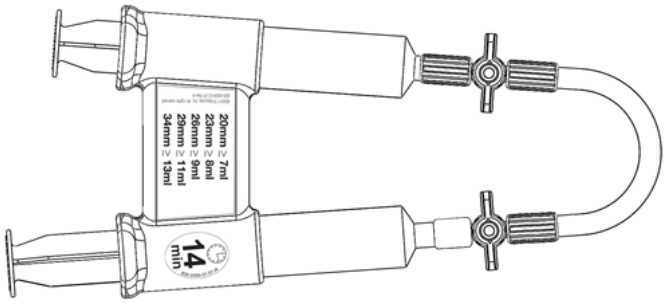


Figure 8: CustomSeal Kit with 14-minute Disconnection time

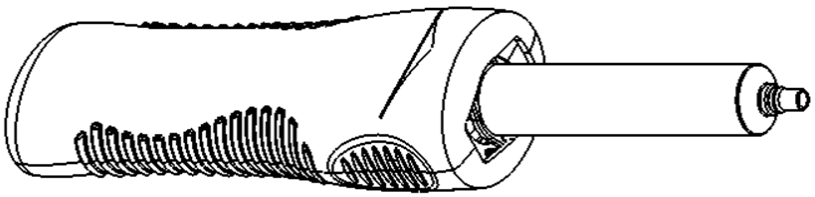


Figure 9: Autoinjector 2 Attached over Syringe Plunger

1.4 Alto™ Abdominal Stent Graft System Specific Anatomic Considerations

The specific design features of this endovascular graft impact how to assess a patient's suitability for treatment. The following diagrams indicate the specific anatomic

considerations that should be considered when evaluating suitability for treatment with the device as described in the Indications for Use statement.

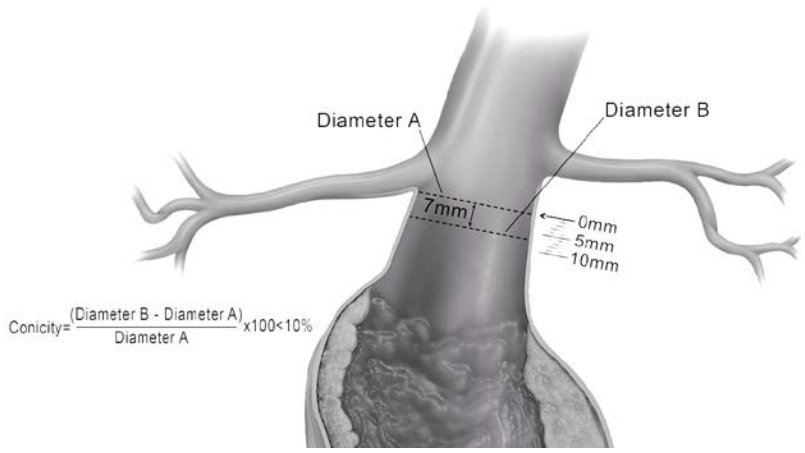


Figure A: Proximal Landing Zone and Conicity

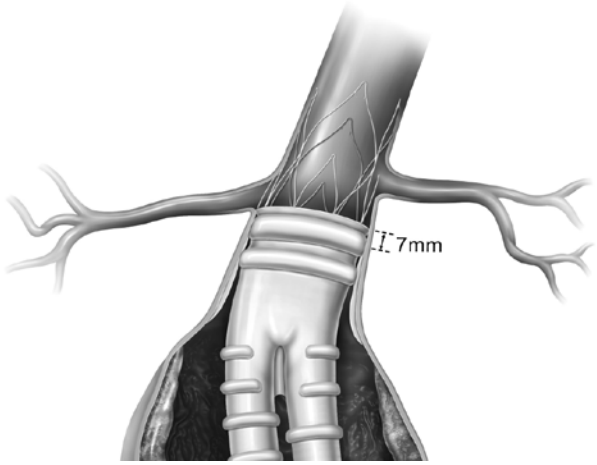


Figure B: Proximal Landing Zone

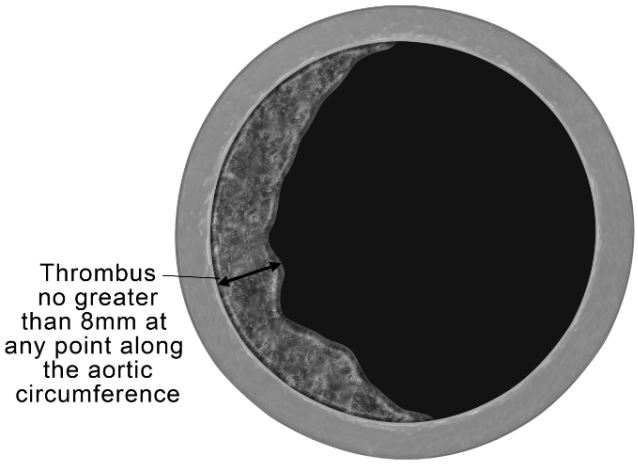


Figure C: Sealing Zone Thrombus

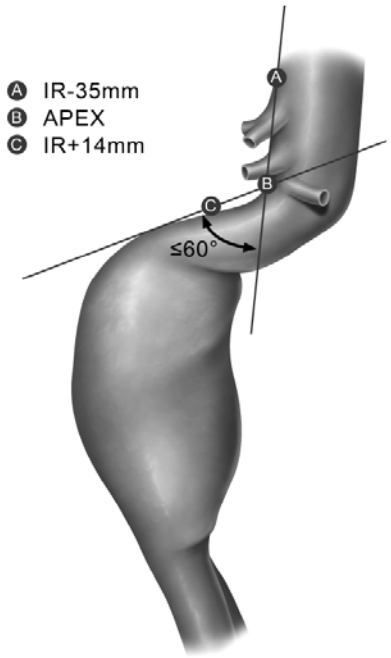


Figure D: Aortic Angle

2. Indications for Use

The Alto™ Abdominal Stent Graft System is indicated for treatment of patients with infrarenal abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair with the device, which includes the following:

- Adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories,
- A proximal aortic landing zone for the sealing ring 7mm below the inferior renal artery.
- An aortic sealing zone comprised of healthy aorta defined as:
    - Lack of significant thrombus > 8 mm in thickness; at any point along the aortic circumference at the level of 7mm below the inferior renal artery,
    - Lack of significant calcification at the level of 7mm below the inferior renal artery,
    - Conicity < 10% as measured from the inferior renal artery to the aorta 7mm below the inferior renal artery,
    - An inner wall diameter of no less than 16 mm and no greater than 30 mm at 7 mm below the inferior renal artery, and
    - An aortic angle of ≤ 60 degrees.

- A 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, contrast agents, fluorinated ethylene propylene (FEP), titanium, nickel, platinum, or iridium.

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

Warnings

- The Alto™ 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.
- Do not use this device if the patient is unwilling or unable to be evaluated using the necessary preoperative and postoperative imaging.

Precautions

- 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.
- 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 Alto™ 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

4.2 Patient and Device Selection

Warnings

- 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.

Precautions

- 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, stenotic, tortuous, aneurysmal, or thrombus-lined may preclude placement of the device.
- The Alto™ 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 or rupture, acutely ruptured aneurysms, aneurysms pending rupture, or those that require other emergent aorta/ aneurysm treatment;
  - Have suprarenal, thoracic, 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, plaque, and/or thrombus thickness > 8mm at any point along the aortic circumference of the seal zones may compromise the fixation and/or sealing at the implantation sites.
- Unhealthy aorta in the seal zones may result in increased risk of leakage into the aneurysm or migration of the prosthesis. Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (>60°), distal iliac landing zone <10 mm, aortic/iliac inner wall diameter inappropriately sized for the stent graft, and/or thrombus or calcium especially in the sealing zones.

- The aortic bifurcation should be able to accommodate the two 9mm iliac limbs of the Alto™ system. The diameter of the aortic bifurcation, in the physician's opinion, should not compromise flow through the iliac limbs.
- Pay close attention to the iliac graft landing zone morphology to assess for proper limb graft selection/suitability.
- Inappropriate patient selection may result in poor device performance or device performance not otherwise in accordance with the specifications.

4.3 Before and During the Implant Procedure

Warnings

- For single use only. Do not re-sterilize or re-use any components of the Alto™ Abdominal Stent Graft System. Re-use, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failures, which in turn may lead to injury, illness, or death of the patient.
- Note product "Use by" date and do not use if the date has been exceeded.
- 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 Alto™ 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.
- 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 would result in an endoleak.
- 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. Avoid excessive catheter manipulation to maintain delivery system connection.
- Use only the Autoinjector 2 to fill the Aortic Body Stent Graft. Hand injection should not be used and may damage the implant.
- Never use air of any gaseous medium to inflate the integral balloon.
- Hand injections of integral balloon solution with a maximum contrast concentration of 4:1 saline to contrast mixture using a syringe is recommended for integral balloon inflation. Do not use a pressure inflation device for integral balloon inflation.

- Do not inflate integral balloon beyond maximum inflation volume. Rupture of balloon may occur. Over-inflation may result in damage to vessel wall and/or vessel rupture, or damage to the stent graft.

Precautions

- 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. Return the defective package and/or device to Endologix.
- Minimize handling of the stent graft constrained on the delivery catheter during preparation and insertion to decrease the risk of contamination and infection.
- 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.
- 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 or migration of the device.
- 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.
- Confirm there is no tension on the aortic body stent graft prior to or during iliac limb or iliac extension placement to prevent possible stenosis or occlusion.
- Confirm cannulation of aortic body contralateral leg gate to ensure accurate placement of the contralateral limb.
- If resistance is encountered during catheter de-mate, confirm catheter was released from the aortic body using the third release knob. If catheter de-mate difficulty persists, verify catheter is not catching on the suprarenal stent. Once confirmed, the integral sheath can be used as a "buttress" to stabilize the aortic body. If nosecone retraction offers resistance, buttress 1st ring of the Ipsi Leg with the Aortic Body sheath. Prior to nosecone mating with sheath tip, retract sheath 2cm so the fill port is not pinched in the sheath/nosecone.
- It is not recommended to balloon prior to 14 minutes after completion of the final polymer mix. Ballooning prior to 14 minutes can create pressures high enough to damage the sealing ring and may result in a polymer leak.
- 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 Alto™ 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.

- Maximum contrast concentration of integral balloon solution is 4:1 saline and contrast mixture.
- Keep the integral balloon inside the graft. Inflation of the integral balloon outside of the graft may lead to vessel damage or rupture.
- Monitor balloon manipulations and inflation using fluoroscopy at all times.
- Fully deflate integral balloon and verify it is under syringe vacuum force prior to repositioning of catheter or removing from integral sheath.
- If balloon pressure is lost and/or balloon rupture occurs, deflate the balloon and proceed with catheter detach and withdrawal procedure.
- Exercise care with device selection and correct placement/positioning of the device in the presence of anatomically challenging situations such as areas of significant stenosis, intravascular thrombus, calcification, tortuosity, and/or angulation which can affect successful initial treatment of the aneurysm.
- After use, all components used and packaging materials may be a potential biohazard. Handle and dispose of in accordance with the accepted medical practice and with applicable local, state, and federal laws and regulations.

4.4 Polymer Information

Warnings

- Do not disconnect delivery system before specified detach time. Minimum delivery system to stent graft disconnection times are based on a minimum core body temperature of 35°C. 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. Disconnecting the delivery system before the minimum recommended time in the presence of low patient body temperature may result in a polymer leak.

Precautions

- 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 2 from the fill polymer syringe.
- 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.
- Patients who experience hypersensitivity reactions (including severe allergic reaction and/or anaphylactoid response) at any time during the procedure, particularly during polymer fill should be managed in accordance with standard

recommendations for treatment of patients with severe radiocontrast agent allergies (e.g., fluids, antihistamines, corticosteroids, epinephrine).

- 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 potential polymer leak. In the absence of other clear diagnoses causing hypotension during polymer fill, Endologix recommends that a hypersensitivity reaction (a severe allergic reaction or an anaphylactoid response) to intravascular polymer leak be considered a probable diagnosis. Patients with a polymer leak should undergo prompt treatment for a potential severe hypersensitivity response in accordance with institutional protocols (e.g., intravascular fluids, antihistamines, corticosteroids, epinephrine).
- External signs that may be indicative of a polymer leak include rapid emptying of the fill polymer syringe, an empty fill polymer syringe, incomplete filling of the polymer channels, and significant distal radiopaque marker movement. If observed, the patient should be closely monitored, and any suspected polymer leak treated as described above.
- Aneurysm treatment issues that may occur related to polymer leak (e.g. Type Ia endoleak due to incomplete graft polymer fill) should be treated with standard endovascular techniques at the physician's discretion, utilizing the ancillary equipment as listed in Section 10.3. The specific treatment will be dependent on the extent and location of incomplete filling of the polymer rings and the associated clinical findings.

4.5 Treatment and follow-up plan

Precautions

- The long-term performance of this implant has not yet been established
- All patients treated with this device must undergo lifelong 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 (> 5mm), 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. Supplemental patient-specific 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 (Section 12).
- Any endoleak left untreated during the implantation procedure must be carefully monitored after implantation.
- Following endovascular aneurysm repair, spinal cord ischemia may result in a rare complication of paraplegia or paraparesis. A cerebrospinal fluid drain is advised if spinal cord ischemia is suspected.

4.6 Magnetic Resonance Imaging (MRI) Safety Information

Nonclinical testing has demonstrated that the Alto™ device is MR conditional. The Alto™ device can be safely scanned in both 1.5T and 3.0T MR systems only, with the specified parameters as listed in Section 9.4.

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;
- Amputation;
- Anesthetic complications and subsequent attendant problems (aspiration);
- Aneurysm enlargement or rupture;
- Aortic damage (perforation, dissection, bleeding, rupture);
- Aortocaval fistulae;
- Aortoenteric fistulae;
- 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 ileus, obstruction, fistula;
- 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;
- Claudication;
- Contrast toxicity/anaphylaxis;
- 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;
- Edema;
- Embolic and thrombotic events (with transient or permanent ischemia or infarction) such as deep vein thrombosis, thromboembolism, micro-embolism, thrombophlebitis, phlebothrombosis, air embolism;
- Endoleaks (or peri-graft flow);
- Fever;
- Gastrointestinal complications;

- 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;
- Hematoma (surgical);
- Hepatic failure;
- Hypersensitivity (severe allergic reaction and/or anaphylactoid response) to x–ray contrast dye, anti-platelet therapy, device materials including polytetrafluoroethylene (PTFE), polyethylene glycol (PEG)-based polymers, contrast agents, fluorinated ethylene propylene (FEP), titanium, nickel, platinum or iridium;
- 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;
- Improper stent graft placement;
- Incomplete stent graft deployment;
- Insertion and removal difficulties;
- Lymphatic complications and subsequent attendant problems such as lymphocele, lymph fistula;
- Multi-system organ failure;
- Neoplasm;
- Open surgical conversion;
- 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;
- Polymer leak with hypersensitivity reaction;
- Possible infection–urinary tract, systemic or localized (access site), endograft;
- Prosthesis occlusion/stenosis;
- Pseudoaneurysm;
- 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;
- Renal failure/renal insufficiency
- Sepsis;
- Seroma;
- Shock;
- Spinal neurological deficit;
- Stenosis/occlusion of native vessel

- 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.
- Wound or access site complications

For the specific adverse events that occurred in the clinical study, please see Section 6.2.8 below.

5.2 Incident Reporting

All incidents, including any adverse events should be reported to Endologix immediately. To report an event, contact your local representative and/or Endologix at(707) 543-8800.

6. Summary of Clinical Information

6.1 Alto™ Abdominal Stent Graft System Clinical Study

The primary objective of the Alto™ Abdominal Stent Graft System U.S. pivotal study was to evaluate the safety and effectiveness of the Alto™ Abdominal Stent Graft System in the treatment of subjects with abdominal aortic aneurysm (AAA). The study was a prospective, consecutively enrolling, non-randomized multi-center clinical evaluation. A total of 75 subjects were enrolled at 13 sites in the United States.

6.1.1 Endpoint

The primary endpoint was defined as successful aneurysm treatment, a composite endpoint defined as the following:

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

Technical Success was a composite endpoint comprised of all of the following:

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

The primary endpoint was defined as treatment success at 1 year relative to a performance goal of 80%, which represents a classic one-year performance threshold for EVAR devices. The primary effectiveness hypotheses were defined as:

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

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

6.1.2 Sample Size

The sample size of the study was calculated based upon the primary endpoint of treatment success at 12 months. It was estimated that 60 subjects with evaluable data at 1 year would provide 80% statistical power to test the primary hypothesis (estimated treatment success of 92.8% at 12 months) at the one-sided 0.05 level. A 20% attrition rate was anticipated through 12 months, which led to a sample size of 75 subjects for the study. The primary endpoint at one year was calculated on 61 evaluable subjects.

6.1.3 Additional Assessments

Additional assessments included the following:

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

- AAA rupture
- Conversion to open repair
- Secondary interventions
- AAA-related mortality
- Adverse events, regardless of seriousness or cause, including:
    - Serious adverse events
    - Major adverse events
    - Procedure-related adverse events
    - Device-related adverse events

An External Independent Core Lab was utilized to evaluate CT and X-ray images from discharge (X-ray only) through the 1 year follow-up (CT and X-ray)They assessed the following events: aneurysm enlargement, endoleaks, stent fracture, stent graft migration, and other stent graft findings (stent graft kinking and stent graft compression), and angiograms upon request.

A Clinical Events Committee (CEC) was used to review and adjudicate all device related adverse events and all serious adverse events regardless of the relatedness to the device. The CEC also determined which adverse events would be considered Major Adverse Events (MAE) for evaluation of the primary (30 days) and secondary (1 year) safety endpoints. The committee consisted of three physicians representing multiple specialties familiar with abdominal aortic aneurysm repair. The CEC provided review to the Data Safety Monitoring Board (DSMB).

The DSMB committee was used to review the safety and progress of the clinical study and was responsible for reviewing the data associated with the device and the subjects. The DSMB provided independent recommendations to the sponsor based on its review of the data and input from the CEC.

6.1.4 Patient Screening and Enrollment

The patient screening process followed these steps:

1. The site consented the subject per their consent process.
2. The site submitted the subject's CT to Endologix.
3. Once received, subject CTs were reviewed by Endologix Imaging Services. Imaging Services evaluated the anatomical metrics of the subject against the inclusion/exclusion criteria and also the general suitability for EVAR. If the subject did not pass anatomical criteria, the subject was failed
4. If the subject passed Imaging Services, the CT was then reviewed by a Case Review Board (CRB). The CRB consisted of two vascular surgeons. At least one CRB member was required to review a case. Site investigators received standing invitations to each CRB call and summaries of CT reviews were disseminated to

the Site Investigators. The CRB reviewed the subjects' screening films for overall vascular suitability, such as excessive neck thrombus and a lack of proximal aortic neck.

5. If both the CRB and Imaging Services passed the subject, the site was given permission to enroll the subject.

A total of 140 subjects were screened for study inclusion with 75 subjects enrolled and 65 subjects rejected from study participation. The 65 excluded subjects were rejected by either: Imaging Services, CRB, or the Site Investigator. Twenty-five subjects were excluded by Imaging Services (on quantitative anatomic assessment of the CT). The most common reasons for study exclusion by Imaging Services were failure to meet juxtarenal aortic neck angulation $\leq 60^{o}$, patent iliac or femoral arteries that allow endovascular access with the Alto™ Abdominal stent graft system, and proximal aortic landing zone with an inner wall diameter of no less than 16mm and no greater than 30 mm at 7 mm below the inferior renal artery. Nineteen subjects were excluded by the CRB. The most common reasons for these patients being excluded were as follows: juxta-renal AAA, excess thrombus in the seal zone, narrow native bifurcation (<18mm), and aneurysm size being too small. Subjects could be excluded by the site investigator at any temporal point in the study. Twenty-one subjects were excluded by the Site Investigators. The most common reasons included: Site Investigator decision regarding subject anatomy, follow-up capabilities of subject and subject withdrawing consent. There were four subjects the site investigators determined were not appropriate candidates for the study due to anatomical reasons: one subject required hypogastric artery occlusion for a common iliac aneurysm and the subject refused internal iliac artery coil embolization; one subject required sac embolization due to large lumbar arteries noted on preoperative CT; the preop CT scan in one subject indicated that the upper RRA was dominant, however on angiogram the right kidney was supplied equally from the upper and lower RRAs therefore an alternative AAA device was considered; and the physician determined one subject to have poor follow-up capabilities.

6.1.4.1 Patients

Patients enrolled in this study had an infrarenal aortic aneurysm that met the following anatomical characteristics:

- patent iliac or femoral arteries that allowed endovascular access with the Alto™ Abdominal Stent Graft System
- proximal aortic landing zone with an inner wall diameter of no less than 16 mm and no greater than 30 mm at 7 mm below the inferior renal artery.
- adequate distal iliac landing zone with an inner wall diameter of no less than 8 mm and no greater than 25 mm.
- adequate distal iliac landing zone with a length of at least 10 mm. The resultant repair should have preserved patency in at least one hypogastric artery.

- distance from the most distal renal artery to most superior internal iliac artery measurement was at least 125 mm.
- juxtarenal aortic neck angulation $\leq 60^{o}$ if proximal neck was ≥ 7 mm and ≤ 45 degrees if proximal neck was < 7 mm.

Patients were excluded from the study if they met the following anatomic or physiologic characteristics:

- Significant thrombus > 8 mm in thickness; at any point along the aortic circumference at the level of 7mm below the inferior renal artery
- Diameter of aortic bifurcation that, in the physician's opinion, would compromise flow through the iliac limbs.
- dissecting aneurysm
- acutely ruptured aneurysm
- known thoracic aortic aneurysm or dissection
- history of connective tissue disease (e.g., Marfan's or Ehler's-Danlos syndrome)
- history of bleeding disorders or refuses blood transfusions
- Dialysis dependent renal failure or baseline serum creatinine level >2.0 mg/dl
- known hypersensitivity or contraindication to anticoagulation or contrast media that was not amenable to pre-treatment
- known allergy or intolerance to polytetrafluoroethylene (PTFE), PEG-based polymers, fluorinated ethylene propylene (FEP) or nitinol/ nickel
- limited life expectancy of less than 1 year
- other medical, social or psychological conditions that, in the opinion of the investigator, preclude them from receiving the pre-treatment, required treatment, and post-treatment procedures and evaluations

All patients enrolled in this study met these selection criteria based upon a clinical assessment of the investigator and by CT reviews of the anatomic criteria by Endologix Imaging Services, with additional input provided by the Case Review Board.

6.2 Study Results

6.2.1 Subject Accountability and Follow-up

One hundred percent (100%) of the eligible subjects completed the 1 month (75/75) and 6 month (72/72) follow-up. At 1 year, the visit compliance rate was 98.5% (67/68) for eligible subjects.

89.7% (61/75) to 94.1% (64/75) (depending on the metric being assessed) of subjects had adequate 1-year imaging as assessed by the external Core Laboratory. Two subjects withdrew before the 6 month follow up but after the 1 month follow-up, 1 subject withdrew before the 1 year follow-up but after the 6 month follow-up, 1 subject died before the 6 month follow up but after the 1 month follow-up, 2 subjects died

before the 1 year follow up but after the 6 month follow-up and 1 conversion was reported before the 1 year follow up visit but after the 6-month follow-up. There were no conversions that resulted in peri-operative death. One subject was lost to follow-up post 1 year follow-up visit window. Detailed subject accountability and follow-up are presented in **Table 3**. The numbers found in Table 3 as well as subsequent sections represent those subjects that had data available to assess the relevant parameters.

Table 3: Subject and Imaging Accountability Through 12 Month Follow-Up Visit (Alto™ Treatment Group)

							Imaging compliance											
							CT						X-ray					
									Adequate imaging to assess the parameter n (% of eligible) §					Adequate imaging to assess the parameter n (% of eligible)		Events occurring before next interval			
Visit	Eligible for follow-up*	Subjects with follow-up	Overdue (Past) †	Missed Visit‡	In window, follow-up pending¥	Not due for next visit€	Site Performed@	Corelab Reviewed#	Size Increase (Per Corelab)	Endoleak (Per Corelab)	Migration (Per Corelab)	Patency (Per Site)	Corelab Reviewed	Fracture	Other Stent Finding	LTF or WD	Died	Conversion	Conversion + Died
Operative	75	75	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	68 (90.7%)	68 (90.7%)	68 (90.7%)	0	0	0	0
1 Month	75	75 (100.0%)	0	0	0	0	74 (98.7%)	74 (100.0%)	74 (98.7%)	73 (97.3%)	74 (98.7%)	74 (98.7%)	70 (93.3%)	70 (93.3%)	70 (93.3%)	2	1	0	0
6 Month	72	72 (100.0%)	0	0	0	0	72 (100.0%)	72 (100.0%)	72 (100.0%)	70 (97.2%)	72 (100.0%)	72 (100.0%)	69 (95.8%)	69 (95.8%)	69 (95.8%)	1	2	1	0
1 Year	68	67 (98.5%)	1**	0	0	0	63 (92.6%)	65 (103.2%)$	64 (94.1%)	61 (89.7%)	64 (94.1%)	64 (94.1%)	61 (89.7%)	61(89.7%)	61 (89.7%)	0	0	0	0

**Eligible for follow-up = Subjects with follow-up + Overdue + Missed visit. Does not included those with follow-up pending, not yet due for the visit, previous deaths, conversions, and those lost to follow-up (LTF) or withdrawn (WD).*

†Subjects without a follow-up visit but not yet in next window

‡ Subjects without a follow-up visit and currently in next window

¥ Subjects currently in window, but data not yet available

€ Subjects not yet in the window

§These counts reflect the number of subjects with adequate imaging as determined by Core Lab.

*** This single subject was classified as overdue because the exit was on post-op day 455 and was therefore considered enrolled during the duration of the 1-year follow-up period. As there were no follow-up windows available beyond one year, the status is not classified as a missed visit.*

@Within each visit window, the "Site Performed" and 4 variables under "Adequate Imaging" all use the number of "Eligible" subjects as the denominator. On occasion the number of subjects with adequate imaging for a specific variable may be higher or lower than the "Site Performed" frequency, as the latter only counted images of the required type (Contrast CT or Non-Contrast CT + Duplex Ultrasound). As an example a site may not obtain a CT but still perform an ultrasound. This was not considered a compliant imaging visit for the site and thus it was not counted in the "Site Performed" column. Yet there still may be sufficient information for specific variables such as sac size, so the image was counted in those columns where evaluable information was gathered.

#The "Corelab reviewed" column represents the number of CTs/US reviewed by the corelab, and uses the number of adequate images within the "Site Performed" column as the denominator. On occasion more images were reviewed by the corelab than compliant images obtained by the site.

$One subject was recorded as only having an ultrasound and no CT at 1 year (the corelab reviewed the Ultrasound). Another subject did not have a contrast CT recorded by the site in the dataset, though the Corelab evaluated a non-contrast CT. The percentage was greater than 100% for the 1 year visit because two subjects did not have the required imaging type, but were captured under corelab reviewed

6.2.2 Study Demographics

Baseline data regarding subject demographics is summarized in **Table 4**. Most subjects enrolled in the study were male 93% (70/75), and elderly (mean age: 73 years). With respect to race/ethnicity, 77% (58/75) of the subjects were White / Not Hispanic or Latino, 15% (11/75) were Unknown/Not Hispanic or Latino, 1% (1/75) were White / Hispanic or Latino, and 1% (1/75) Black or African American / Not Hispanic or Latino.

Table 4: Subject Demographics

Variable	Statistic	Alto™ Treatment Group
	N	75
Age (years)	Mean ± std	73 ± 7
Calculated body mass index (BMI), (kg/m^2)	Mean± std	30 ± 7
Gender		
Male	% (n/N)	93% (70/75)
Female	% (n/N)	7% (5/75)
Race/Ethnicity		
White / Not Hispanic or Latino	% (n/N)	77% (58/75)
White / Hispanic or Latino	% (n/N)	1% (1/75)
Black or African American / Not Hispanic or Latino	% (n/N)	1% (1/75)
Unknown / Not Hispanic or Latino	% (n/N)	15% (11/75)
Unknown / Hispanic or Latino	% (n/N)	1% (1/75)
Unknown / Unknown	% (n/N)	4% (3/75)

6.2.3 Baseline Medical History

Baseline medical history data is summarized in **Table 5**. Subjects presented with typical comorbidities observed in AAA patients, most commonly hypertension 83% (62/75), hyperlipidemia 76% (57/75), and smoking history 75% (56/75). Subjects were risk-classified using the American Society of Anesthesiology (ASA) criteria with most presenting as ASA class III and IV 93% (70/75).

Table 5: Subject Medical History

Variable	Alto™ Treatment Group % (n/N)
ASA Grade	
1/2	5 (7%)
3/4	70 (93%)
Cardiovascular History	72/75 (96%)
Coronary artery disease	35/75 (47%)
Valvular heart disease	11/75 (15%)
Angina pectoris or chest discomfort	5/75 (7%)
Cardiomyopathy	3/75 (4%)
Congestive heart failure	6/75 (8%)
Myocardial infarction	11/75 (15%)
Arrhythmia	17/75 (23%)
Hypertension	62/75 (83%)
Hypotension	0 (0%)
Hyperlipidemia	57/75 (76%)
Peripheral Vascular, Stroke, and Aneurysm History	75/75 (100%)
Peripheral vascular disease	13/75 (17%)
Carotid artery disease	6/75 (8%)
Transient Ischemic Attack (TIA)	4/75 (5%)
Stroke	0 (0%)
Family history of aneurysms	9/75 (12%)
Pulmonary History	71/75 (95%)
Tobacco use (Current)	15/75 (20%)
Tobacco use (Former)	56/75 (75%)
COPD	27/75 (36%)
Gastrointestinal, Genitourinary, Reproductive History	49/75 (65%)
Renal insufficiency	5/75 (7%)

Variable	Alto™ Treatment Group % (n/N)
Endocrine	31/75 (41%)
Diabetes (Type II)	22/75 (29%)
Hematological	9/75 (12%)
Anemia	5/75 (7%)
Psychosocial	11/75 (15%)
Depression	7/75 (9%)
Alcohol	3/75 (4%)
Other significant medical history	26/75 (35%)

6.2.4 Baseline Vascular Characteristics

Baseline data was reported by Imaging Services exclusively. **Table 6** provides the baseline vascular characteristics of the study population.

All subjects enrolled in this study met the inclusion criteria based on Imaging Services CT measurements. Mean AAA diameter was 51.7 mm, with a mean proximal neck length of 27.9 mm. External iliac diameters measured 8.2 ± 1.7mm on the left, and 8.1 ± 1.5mm on the right.

Table 6: Vascular Characteristics

Variable	Statistic	N	Alto™ Treatment Group*
Juxtarenal Angle (°)		75	23.1 ± 18.7
Aortic diameter Inferior Renal-35mm [1]	Min (mm)	75	25.0 ± 2.3
	Max (mm)	75	26.6 ± 2.4
	Average (mm)	75	25.9 ± 2.3
Aortic diameter Inferior Renal (or intended position)	Min (mm)	75	21.8 ± 2.5
	Max (mm)	75	23.2 ± 2.6
	Average (mm)	75	22.5 ± 2.5
Aortic diameter Inferior Renal + 7mm	Min (mm)	75	21.8 ± 2.3
	Max (mm)	75	23.0 ± 2.7
	Average (mm)	75	22.4 ± 2.4
Change from Inferior Renal to Inferior Renal+7 (%)		75	0.0 ± 7.2
Aortic diameter Inferior Renal + 10mm	Min (mm)	75	21.8 ± 2.5
	Max (mm)	75	23.4 ± 2.8
	Average (mm)	75	22.6 ± 2.5
Maximum Sac Diameter (mm)		75	51.7 ± 6.6
<40 mm[#]		4	5%
≥40, <50 mm		23	31%
≥50, <60 mm		40	53%
≥60 mm		8	11%
Native Bifurcation	Min (mm)	74	20.1 ± 5.1
	Max (mm)	74	26.2 ± 6.7
Transverse dimension of adjacent normal aortic segment (mm)		27	22.7 ± 4.1
Neck Length (mm)		75	27.9 ± 13.7
Distance from the most distal renal artery to most superior left internal iliac artery (mm)		75	182.5 ± 24.7
Distance from the most distal renal artery to most superior right internal iliac artery (mm)		75	181.2 ± 21.0
Inferior Renal to Aortic Bifurcation (mm)		75	110.9 ± 13.1
Right Distal Iliac Diameter	Min (mm)	75	15.8 ± 3.8
	Max (mm)	75	17.1 ± 4.0
	Average (mm)	75	16.5 ± 3.9
Right External Iliac Diameter	Min (mm)	75	7.6 ± 1.6
	Max (mm)	75	8.7 ± 1.6

Table 6: Vascular Characteristics

Variable		Statistic	N	Alto™ Treatment Group*
		Average (mm)	75	8.1 ± 1.5
Left Distal Iliac Diameter		Min (mm)	75	15.1 ± 3.0
		Max (mm)	75	16.4 ± 3.3
		Average (mm)	75	15.8 ± 3.1
Left External Iliac Diameter		Min (mm)	75	7.6 ± 1.9
		Max (mm)	75	8.7 ± 1.6
		Average (mm)	75	8.2 ± 1.7
Left Distal Iliac landing zone (mm)			75	49.1 ± 18.7
Right Distal Iliac landing zone (mm)			75	50.1 ± 20.7
SIR Calcification Grade[2]	Calcification 0% of circumference		14	19%
	Calcification <25% of circumference		49	65%
	Calcification 25-50% of circumference		11	15%
	Calcification >50% of circumference		1	1%
SIR Thrombus Grade[2]	Thrombus 0% of circumference		27	36%
	Thrombus <25% of circumference		16	21%
	Thrombus 25-50% of circumference		18	24%
	Thrombus >50% of circumference		14	19%

**Results are presented as mean ± SD (min, max) [med] or % of total responses.*

 # 4 patients were enrolled that had AAA diameters <40mm. All these four patients were enrolled under Rev A (under Rev A, this was not an inclusion exclusion violation). After this the protocol was amended under Revision B where subjects with AAA diameter <40mm could not be enrolled. No other subjects with AAA diameter <40mm were enrolled in the study after the corrective memo was distributed.

[1] Data provided by site imaging

[2] Proximal neck calcification and thrombus scoring: Amount of calcium and/or thrombus present in the cross-sectional area of the target location of the sealing ring (OR+4 to IR+10).

6.2.5 Devices Implanted/Used

A total of 75 aortic bodies,155 iliac limbs, and 7 iliac extensions were implanted in 75 subjects during the initial implant procedure. The design of this device requires implantation of at least one aortic body and two iliac limbs. Additional iliac limbs and iliac extensions could be used to extend the length of the device, where indicated. Four subjects had bilateral limb extensions. Four subjects had unilateral limb extensions (three on the left side and one on the right) Seven iliac extensions were used, and 5 iliac limbs were used as extensions. One subject had a Balloon Expandable Stent implanted at day 48 to treat a type Ia endoleak.

The summary of Alto™ components implanted is presented in Table 7. The total number of Alto™ devices implanted in each subject by diameter is presented in **Table 7**.

Table 7: Summary of Alto™ Components Implanted

Alto™ Components	Alto™ Treatment Group % (n/N)
Aortic Body	100% (75/75)
Ipsilateral limb	100% (75/75)
Contralateral limb	100% (75/75)
Iliac extension	9.3% (7/75)
Ipsi/contra limb used as extension	7.0% (5/75)

There were three subjects that received embolization coils during the index procedure: two subjects had coils placed in the left accessory renal arteries and one subject had coils placed in the internal iliac/hypogastric artery. There was one self-expanding stent placed in the external iliac due to stenosis and dissection.

Device use by size is presented in **Table 8** below. There were 75 aortic bodies, 155 iliac limbs, and 7 iliac extensions implanted.

Table 8: Distribution of Implanted Device Sizes

Device Type	Diameter (mm)	Alto™ Treatment Group % (n/N)
Aortic Body		75
	20	0.0% (0/75)
	23	18.7% (14/75)
	26	45.3% (34/75)
	29	29.3% (22/75)
	34	6.7% (5/75)
Iliac Limb		155*
	10	1.3% (2/155)
	12	9.7% (15/155)
	14	14.2% (22/155)
	16	26.5% (41/155)
	18	21.3% (33/155)
	22	18.7% (29/155)
	28	8.4% (13/155)
Iliac Extension		7
	10	0.0% (0/7)

Device Type	Diameter (mm)	Alto™ Treatment Group % (n/N)
	12	0.0% (0/7)
	14	0.0% (0/7)
	16	14.3% (1/7)
	18	57.1% (4/7)
	22	14.3% (1/7)
	28	14.3% (1/7)

[*]Five iliac limbs were used as extensions.

The Alto™ Abdominal Stent Graft System aortic body was 80 mm in length, the iliac limbs were available in 5 lengths (80 mm, 100 mm, 120 mm, 140 mm, and 160 mm), and the iliac extension was 45 mm in length as outlined in Section 9 (How Supplied).

6.2.6 Acute Procedural Information

The following secondary clinical utility endpoints were collected and are shown in **Table 9**. Bilateral percutaneous access was achieved in 90.7% (68/75) of subjects and 33.3% (25/75) of subjects did not require general anesthesia. The endovascular procedure was, on average, 90 minutes in duration with minimal blood loss (mean: 52.5 mL) and required a short hospital stay (mean: 1.3 day). 26.7% of subjects (20/75) were admitted to the ICU. Among subjects that went to the ICU, the mean was 0.9 days of stay in ICU. Mean fluoroscopy time was 20 minutes. Technical success (successful device delivery, deployment, and withdrawal) was achieved in 100% of cases.

Table 9 – Procedural Information

Variable	Statistic[*]	Alto™ Treatment Group
Total Procedure time (min)	N	75
	Median	90
	Min, Max	41, 241
< 90 min	% (n/N)	49.3% (37/75)
≥ 90 min, < 150 min	% (n/N)	44.0% (33/75)
≥ 150 min, < 210 min	% (n/N)	5.3% (4/75)
≥ 210 min	% (n/N)	1.3% (1/75)
Estimated Procedural Blood Loss (mL)	N	72
	Median	52.5
	Min, Max	10, 1000
Length of hospital stay (days)	N	75
	Median	1.3

Variable	Statistic*	Alto™ Treatment Group
	Min, Max	0.2, 20.2
Duration of ICU stay (among subjects admitted to ICU, in days)	N	20
	Median	0.9
	Min, Max	0.6, 1.3
Anesthesia Type	N	75
General	% (n/N)	66.7% (50/75)
Regional	% (n/N)	1.3% (1/75)
Local with Conscious Sedation	% (n/N)	32.0% (24/75)
Total Anesthesia time (min)	N	50
	Median	147
	Min, Max	86, 316
< 90 min	% (n/N)	2.0% (1/50)
≥ 90 min, < 150 min	% (n/N)	50.0% (25/50)
≥ 150 min, < 210 min	% (n/N)	28.0% (14/50)
≥ 210 min	% (n/N)	20.0% (10/50)
Fluoroscopy time (min)	N	75
	Median	20
	Min, Max	6,46
< 10 min	% (n/N)	6.7% (5/75)
≥ 10 min, < 20 min	% (n/N)	42.7% (32/75)
≥ 20 min, < 30 min	% (n/N)	28.0% (21/75)
≥ 30 min	% (n/N)	22.7% (17/75)
Aortic Body Access	N	75
Percutaneous	% (n/N)	94.7% (71/75)
Cut-down	% (n/N)	5.3% (4/75)
Technical Success@	% (n/N)	100% (75/75)

**Results are presented as Median (Min, Max), or as % of total responses.*

@ Technical Success is defined as:

Successful delivery, defined as ability to deliver the implant to the intended location without the need for unanticipated corrective intervention related to delivery, using an adjunctive device outside of the Alto™ Abdominal Stent Graft System;

Successful and accurate deployment, defined as:

- *deployment of the endovascular stent graft in the planned location*
- *patency of the endovascular stent graft, absence of device deformations (e.g. kinks, stent eversion, mal-deployment, misaligned deployment) requiring unplanned placement of an additional device within the endovascular stent graft*

Successful withdrawal of the delivery system without the need for unanticipated corrective intervention related to withdrawal

One subject had hospitalization time of 20.2 days. This subject was admitted to hospital one day before scheduled AAA repair due to a fall. Subject had some complications due to fall and was kept in the hospital. Subject had procedure on day 15 of being in the hospital. Subject was 73-year-old male who presented with HTN, HLD, tobacco use, morbid obesity, diabetes, peripheral vascular disease and ASA III who underwent successful implantation of the Alto™ stent graft system in a 65.6mm infrarenal aortic aneurysm. Intra-procedurally, the subject experienced blood loss of 1L due to access difficulties resulting in surgical cutdown and 2u PRBC transfused. Despite a difficult pre-operative course, there were no subsequent post-operative complications, and the subject was discharged on post-operative day 5 in good condition. The event was assessed as unrelated to the device by both the site and CEC. The subject successfully completed study follow-up and exited after completing the 1 year follow-up visit.

6.2.7 Study Results: Safety Related

6.2.7.1 Major Adverse Events (MAEs) Through 365 Days

Secondary safety endpoints include major adverse events and the individual components through 1-year. The incidence of MAEs through 365 days (**Table 10**) in subjects treated with the Alto™ device was 10.7% (8/75). No subject had more than one event. Three subjects experienced bowel ischemia on post-operative days 1, 5, and 5 respectively. All three cases of bowel ischemia were adjudicated to be related to the procedure and not related to the device. Per the CEC, two of the subjects had anatomical factors that might have pre-disposed them to these events. One subject with bowel ischemia required no management to treat. One subject required a colonoscopy and a clear liquid diet. One subject had an SMA (superior mesenteric artery) angioplasty attempted but not completed due to difficulty with passage of catheters adjacent to suprarenal struts and findings of an 18mm pressure gradient. Subsequently, the subject's symptoms resolved. All three subjects that experienced bowel ischemia successfully completed the study at 1-year.

There was one subject that experienced procedural blood loss greater than 1,000 mL on post-operative day 0. The Clinical Events Committee (CEC) adjudicated this to be procedure related, and not related to the device. There were three deaths reported in the study. One subject died on post-operative day 97 due to unknown cause. One subject died on post-operative day 225 due to lung cancer, and another subject expired on post-operative day 248 due to complications of extremity trauma. All three deaths were adjudicated to not be procedure or device related. There was one subject that experienced a myocardial infarction (that did not lead to death) on post-operative day 225. This event was adjudicated to not be related to the device or procedure. Subject completed the study. There were no instances of paralysis, renal failure, respiratory failure, or stroke reported.

Table 10: MAE Rates Through 365 Days

Major Adverse Events	≤30 days	31 Days-1 Year	Total within Year 1
Subjects with ≥1 MAE	5.3% (4/75)	5.3% (4/75)	10.7% (8/75)
Death	0%	4.0% (3/75)	4.0% (3/75)
Bowel Ischemia	4.0% (3/75)	0%	4.0% (3/75)
Myocardial Infarction	0%	1.3% (1/75)	1.3% (1/75)
Paralysis (excludes paraparesis)	0%	0%	0%
Renal Failure (excludes renal insufficiency)	0%	0%	0%
Respiratory Failure	0%	0%	0%
Stroke (excludes TIA)	0%	0%	0%
Procedural blood loss ≥ 1000 cc	1.3% (1/75)	0%	1.3% (1/75)

6.2.7.2 All-cause Mortality Through 365 Days

Tables 11-12 provide the results of all-cause mortality. All-cause mortality through 365 days post-treatment was 4.0% (3/75). The three deaths all occurred after 30 days post-procedure, day 97, 225, and 248. The deaths were due to unknown cause (day 97), lung cancer (day 225), and complications of extremity trauma (day 248). All deaths were adjudicated by CEC as unrelated to the device and procedure. Freedom from all-cause mortality was estimated to be 100% at 30 days, 98.7% at 180 days, and 95.9% at 365 days. There were no AAA-related deaths in the study through 365 days.

Table 11: All-Cause Mortality Through 365 Days

Variable	≤30 Days	31-365 Days	0-365 Days
Death (All-cause)	0%	4.0% (3/75)	4.0% (3/75)

*

Table 12 - Freedom from All-Cause Mortality Through 365 Days: Kaplan-Meier Estimate

Variable	Treatment to 30 days	31 to 180 days	181 to 365 days
Number at risk[1]	75	75	73
Number of events[2]	0	1	2
Number censored[3]	0	1	33
Kaplan-Meier estimate[4]	100	98.7	95.9
Standard error	0	1.3	2.3

1 Number of subjects at risk at beginning of interval
2 All events within the time interval

3 Subjects are censored on the current post-op day as of the date of the data-cut, having completed the study, or upon exit or loss to follow-up
4. Estimate at the end of the time interval

6.2.8 Study Results: Effectiveness

6.2.8.1 Treatment Success

The primary endpoint met its pre-defined performance goal of 80%. The rate of successful aneurysm treatment to 1-year was 95.1% (58/61) (**Table 13**). A one-sided Clopper-Pearson 95% confidence interval was constructed for the treatment success rate seen in the study. The lower bound of this confidence interval was compared against the performance goal to evaluate the null hypothesis that the expected treatment success rate was less than or equal to 80%. The null hypothesis was rejected given the lower bound of 90%, thus the data supported the alternative hypothesis that treatment success was greater than 80%.

Table 13: Primary Endpoint: Treatment Success

Variable	Alto™ Treatment Group % (n/N)	Lower one-sided 95% Confidence Limit*	Target Performance Goal	Study Endpoint
Treatment success	95.1% (58/61)	87.8%	80%	MET

**Exact (Clopper-Pearson) confidence interval*

Given that 14 of 75 subjects were enrolled in the study but lacked the appropriate information to evaluate the primary endpoint, a post-hoc sensitivity analysis was conducted to calculate the Kaplan-Meier estimate of the primary endpoint. The Kaplan-Meier estimate of the primary endpoint shows 96.8% freedom from failure at 1-year, which is comparable to the prespecified primary analysis finding of 95.1%.

The primary endpoint is a composite of procedural technical success, and absence of rupture, conversion, secondary interventions for stenosis, occlusion, thromboembolic event, stent fracture or kink through 1 year, as well as absence of imaging findings at the 12 month imaging window (sac expansion >5 mm, stent migration> 10mm through 1 year, and type I or III endoleaks). There were three subjects that failed the endpoint defined below (**Table 14**). One subject had a conversion to open repair on day 273 post-implant, due to a device infection. One additional subject was noted to have aneurysm expansion (5.9mm) in the 1 year imaging window. This subject adjudicated by CEC as likely due to type II endoleak. An additional subject had a type IA endoleak present at the 30 day follow-up which was subsequently corrected by a balloon expandable stent on post-op day 48. The CEC adjudicated the event as related to the device. The subject successfully completed the study. The Kaplan-Meier estimate for type IA endoleaks is discussed separately.

Table 14: Treatment Success to 1 Year

Outcome	Result	Comparator
	(n=61)	
Total Subjects with Treatment Success	58 (95.1%)	80%
Total Subjects with Treatment Failure	3 (4.9%)	
Procedural technical failure	0 (0.0%)	
Aneurysm rupture	0 (0.0%)	
Conversion to open repair	1 (1.6%)	
Secondary interventions	0 (0.0%)	
Aneurysm sac expansion	1 (1.6%)	
Clinically significant migration	0 (0.0%)	
Type I endoleak*	1 (1.6%)	
Type III endoleak	0 (0.0%)	

***One subject had a Type Ia endoleak present at the 30-day follow-up and was treated and corrected with a Balloon Expandable Stent (secondary intervention) on post-op day 48.*

6.2.8.2 Technical Success

Technical success is shown in **Table 15**. Technical success was obtained in 100% (75/75) of patients, and there was no device malfunction (e.g. polymer leak) for any case during delivery that prevented Technical Success.

Table 15 - Effectiveness Endpoint: Technical Success Component

Technical Success	100% (75/75)
Successful Delivery*	100% (75/75)
Successful Deployment**	100% (75/75)
Successful Withdrawal#	100% (75/75)

** Successful delivery, defined as ability to deliver the implant to the intended location without the need for unanticipated corrective intervention related to delivery, using an adjunctive device outside of the Alto™ Abdominal Stent Graft System;*

***Successful and accurate deployment, defined as:*

- *deployment of the endovascular stent graft in the planned location*
- *patency of the endovascular stent graft, absence of device deformations (e.g. kinks, stent eversion, mal-deployment, misaligned deployment) requiring unplanned placement of an additional device within the endovascular stent graft*

 # Successful withdrawal of the delivery system without the need for unanticipated corrective intervention related to withdrawal

6.2.8.3 Device Integrity

The integrity of the stent graft was evaluated by the core lab using abdominal x-rays at regularly scheduled follow-up visits. Any fractured stents, and any other issues compromising the integrity of the stent graft were reported. The discharge or 1 month abdominal x-ray served as the baseline for all evaluations of stent graft integrity. Loss of stent graft integrity incidence was calculated as the number of subjects with loss of stent graft integrity divided by the number of subjects with adequate imaging to assess the endpoint. The core lab reported no device fractures or other issues compromising the integrity of the stent graft at any time point.

6.2.8.4 Migration

Migration was defined as evidence of proximal or distal movement of the stent graft >10mm relative to fixed anatomic landmarks. Spiral CT images will be used to determine migration at regularly scheduled follow-up visits. The 1 month image was used as the baseline assessment. There were no stent movements that met the protocol definition of migration. The largest movement reported was 7mm in one subject. This subject did not have any secondary intervention for migration during the study.

6.2.8.5 Endoleak

Endoleaks were evaluated by the Core Lab and are defined by the persistence of blood flow outside the lumen of the endovascular graft but within the aneurysm sac and can be classified as:

- Type I – Ineffective seal at either the proximal or distal sealing zones
    - Type IA – Ineffective seal at the proximal sealing zone
    - Type IB – Ineffective seal at the distal sealing zone
- Type II – Retrograde blood flow from lumbar arteries, the inferior mesenteric artery, or other collateral vessels into the aneurysm sac
- Type III – A leak caused by fabric tears or disruption, component disconnection, or graft disintegration
- Type IIIA - Junctional leak or component disconnection
- Type IIIB - Midgraft hole
- Type IV – Blood flow through an intact fabric.
- Unknown endoleak - Endoleak present but unable to assess type

The Kaplan-Meier methodology was used to estimate freedom-from-endoleak rates across the duration of the study. This accounts for subjects who were lost-to-follow-up or otherwise incapable of providing a contrast CT through 1 year. At 12 months, 61 patients had evaluable imaging for endoleaks. The freedom from type Ia endoleak rate at 6 months and 1 year was 98.7% (**Table 16**) as one subject reported

a type Ia endoleak. The type Ia endoleak was reported at the 1 month follow-up visit and treated post-operatively on day 48 with a balloon expandable stent (BES). The type Ia endoleak resolved, and aneurysm expansion was not reported for this subject. This event was adjudicated to be device related.

The freedom from type II endoleak rate at 6 months and 1 year was 53.3% and 51.7%, respectively. There was only one case of aneurysm sac expansion reported which the CEC adjudicated to be likely due to a type II endoleak. Subject exited the study without having a AAA secondary intervention.

Due to the high type II endoleak rate, an analysis was performed on the ELEVATE study to define factors responsible for Type II endoleaks. Baseline demographics, medical history, and anatomical measurements at baseline were evaluated using a logistic regression model. Among all baseline comorbidities, smoking status was a significant negative predictor (protective) for Type II endoleaks (Odds ratio: 0.12, 95% CI 0.026-.602).

The freedom from unknown endoleak rate at 6 months and 1 year was 96.0% and 94.3%, respectively. Unknown endoleaks were not adjudicated by the CEC.

There were no Type Ib, III or IV endoleaks observed in the study through 1-year.

Table 16: Kaplan Meier Estimates of Endoleaks (EL)

Kaplan Meier Estimates	6 Months	12 Months
Freedom from type IA EL	98.7%	98.7%
Freedom from type II EL	53.3%	51.7%
Freedom from unknown type EL	96.0%	94.3%

6.2.8.6 AAA Enlargement

Aneurysm enlargement was defined as a greater than 5 mm (diameter) increase in the aneurysm size. Spiral CT images were used to determine aneurysm enlargement at regularly scheduled follow-up visits. The 1 month image was used as the baseline assessment. One aneurysm diameter enlargement (**Table 17**), identified by the imaging core laboratory, was reported at 1 year post-treatment (1.6%, 1/61). The site noted this as an AE at the 6 month follow-up visit. The CEC adjudicated the aneurysm expansion as likely due to a type II endoleak. This event was also adjudicated to be serious, related to the procedure, and unrelated to the device. Subject exited the study successfully without any secondary interventions to treat aneurysm expansion.

Table 17: Core Lab Reported Sac Diameter Changes Through 12-Months

	Sac Diameter at Visit		Sac Diameter Change from 1 Month				
Timepoint	**N**	**Sac Diameter (mm)**	**N***	**Decreased (>5 mm)**	**Stable (±5 mm)**	**Increased (>5 mm)**	**No Growth**
Screening	75	51.7 ± 6.6	N/A	N/A	N/A	N/A	N/A
1 Month	74	51.1 ± 7.0	N/A	N/A	N/A	N/A	N/A
6 Months	72	49.6 ± 7.3	69	7 (10.1%)	62 (89.9%)	0 (0.0%)	69 (100.0%)
12 Months	64	49.0 ± 8.3	61	13 (21.3%)	47 (77.0%)	1 (1.6%)	60 (98.4%)

**This count represents the number of subjects with both a 1 month CT and later follow-up CT, so that a sac diameter change may be evaluated.*

6.2.8.7 Stent Graft Patency

Patency was defined as the absence of complete occlusion (100%) of the device or native vessel. Patency could be either within the device (device patency) or the native vessel outside the device (vessel patency). Thrombosis was defined as complete occlusion (100%) of the device or native vessel. Thrombosis could be either within the device (device thrombosis) or the native vessel outside the device treatment area (vessel thrombosis). Stenosis was defined as narrowing of the blood flow lumen that was less than 100% occlusion. Stenosis could be either within the device (device stenosis) or the native vessel outside the device treatment area (vessel stenosis). Patency, thrombosis, and stenosis may be evidenced by: CT, angiography, ultrasound or other imaging modality, or pathological analysis and was assessed by the sites for the study. The sites reported no adverse events for patency-related issues at any time point.

6.2.8.8 Thromboembolic Events

Thromboembolic events were defined as deep vein thrombosis, pulmonary embolism, embolic stroke, limb ischemia in the presence of occlusion or thrombosis with the stent graft. There were no thromboembolic events requiring a secondary intervention reported by the sites at any timepoint.

6.2.8.9 Conversion to Open Repair Through 12 Months

The conversion rate (**Tables 18-19)** through 365 days post-treatment was 1.3% (1/75). The freedom from conversion rate was 98.6% through 1 year. A subject was converted to open repair at 273 days post implant due to stent-graft infection. The conversion was successful, and the subject's infection resolved.

Table 18: Surgical Conversions Through 365 Days

Variable	≤30 Days	31-365 Days	0-365 Days
Conversion	0	1.3% (1/75)	1.3% (1/75)

Table 19: Freedom from Surgical Conversion through 365 Days: Kaplan-Meier Estimate

Variable	Treatment to 30 days	31 to 180 days	181 to 365 days
Number at risk[1]	75	75	73
Number of events[2]	0	0	1
Number censored[3]	0	2	34
Kaplan-Meier estimate[4]	100	100	98.6
Standard error	0	0	1.4

[1]Number of subjects at risk at beginning of interval
[2]All events within the time interval
[3]Subjects are censored on the current post-op day as of the date of the data-cut, having completed the study, or upon exit or loss to follow-up
[4]Estimate at the end of the time interval

6.2.8.10 **Secondary Interventions**

A total of 3 AAA-related secondary procedures were performed in 2 (2.7%) subjects; one subject had a type 1A endoleak and received ballooning and bare metal stent for intervention on post-operative day 48 which successfully treated the endoleak. This was adjudicated by the CEC to be device and procedure related. Another subject had a device infection and was converted to open repair on post-operative day 273. This was adjudicated by the CEC to be device related, but not procedure related. AAA-related secondary procedures can be seen in **Table 20**.

Table 20: AAA-Related Secondary Procedures Through 365 Days

Secondary Intervention	≤30 Days	31-365 Days	0-365 Days (Year 1)
	(N=75)	(N=75)	(N=75)
Total Subjects	0	2 (2.7%)	2 (2.7%)
Endoleak IA	0	1 (1.3%)	1 (1.3%)
Ballooning	0	1 (1.3%)	1 (1.3%)
Bare Metal Balloon Expandable Stent	0	1 (1.3%)	1 (1.3%)
Device Infection	0	1 (1.3%)	1 (1.3%)
Conversion to Open Repair	0	1 (1.3%)	1 (1.3%)

7. Patient Selection and Treatment

7.1 Individualization of Treatment

Physicians should work with each patient to decide whether or not the Alto™ Abdominal Stent Graft System would be an appropriate device to treat their aneurysm based on whether the patient meets the criteria specified in the Indications for Use, including:

- Adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories,
- A proximal aortic landing zone for the sealing ring 7mm below the inferior renal artery.
- An aortic sealing zone comprised of healthy aorta defined as:
    - Lack of significant thrombus > 8 mm in thickness; at any point along the aortic circumference at the level of 7mm below the inferior renal artery,
    - Lack of significant calcification at the level of 7mm below the inferior renal artery,
    - Conicity < 10% as measured from the inferior renal artery to the aorta 7mm below the inferior renal artery,
    - An inner wall diameter of no less than 16 mm and no greater than 30 mm at 7 mm below the inferior renal artery, and
    - An aortic angle of ≤ 60 degrees.
- A 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.

Please refer to Section 2 for further detail.

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
- Ability to tolerate general, regional, or local anesthesia

7.2 Alto™ Abdominal Stent Graft Sizing

The Alto™ 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 21**.

Table 21 - Patient Sizing Information

Aortic Body			Iliac Limb / Extension	
Stent Graft Diameter, mm	**Aortic ID, mm**	Maximum Aortic Vessel Diameter at Anchors, mm (35mm above the lowest renal)	**Stent Graft Diameter, mm**	**Iliac ID, mm**
20	16-17	⩽ 24	10	8-9
23	18-20	⩽ 26	12	10-11
26	21-23	⩽ 29	14	12-13
29	24-26	⩽ 32	16	14-15
34	27-30	⩽ 35	18	16-17
			22	18-20
			28	21-25

For the Aortic Body, confirm the aortic inner diameter at the location of the proximal sealing ring 7 mm below the inferior renal artery. Ensure adequate oversizing of the proximal stent at its anchoring location.

CAUTION: Proper sizing of the Alto™ 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. Confirm the length from the lowest renal artery to the native aortic bifurcation is >80mm to ensure the Alto™ graft can fit within the patient's anatomy. If pre-operative case planning measurements are not certain, ensure that all potential stent graft lengths and diameters are available to complete the procedure.

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 Alto™ Abdominal Stent Graft System.

8. Patient Counseling Information

Prior to treatment, the physician should review with the patient the risks and benefits of this endovascular device and 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 of aneurysm rupture as compared to the risk of endovascular repair with the Alto™ device as compared to other endovascular graft systems;
- Risks related to noninterventional treatment (medical management);
- The long-term safety and effectiveness of endovascular repair with the Alto™ device 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 Alto™ Abdominal Stent Graft System. Details regarding risks occurring during and after implantation of the device are provided in Section 5 (Adverse Events).

9. How Supplied

The Alto™ 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 CustomSeal Kit, and the Autoinjector 2.

9.1 Stent Graft Sizing and Configurations

The stent grafts are available in the following sizes and configurations (**Tables 22-24**).

Table 22: Alto™ Aortic Body Stent Graft Sizes

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

Table 23: Ovation iX Iliac Limb Sizes

Stent Graft Proximal Diameter, mm	Stent Graft Distal Diameter, mm	Catheter Working Length, cm	Delivery System Outer Profile, F	Integral Sheath 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	Integral Sheath 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 24: Ovation iX Iliac Extension Sizes

Stent Graft Proximal & Distal Diameters, mm	Catheter Working Length, cm	Delivery System Outer Profile, F	Integral Sheath 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	

9.2 Sterility Information

Stent Grafts/Delivery Systems are supplied STERILE and non-pyrogenic using an ethylene oxide (EO) process. The CustomSeal Kit and Autoinjector 2 are supplied STERILE using an E-beam sterilization process. The CustomSeal Kit is non-pyrogenic.

- Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damaged or if the sterilization barrier has been damaged or broken.
- Do not use after the expiration date printed on the label.
- Store in a cool, dry place.

- **For single patient use only.** Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of the product and packaging in accordance with hospital, administrative and/or local government policy.

10. Clinician Use Information

10.1 Physician Training

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

CAUTION: The Alto™ 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 Alto™ 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.

Further, the following are knowledge requirements for the use of this device:

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

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

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

10.2 Inspection Prior to Use

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

10.3 Materials Required

Please reference **Table 25** below for the equipment and ancillary items required for the Alto™ Abdominal Stent Graft System.

Table 25 - Equipment and Ancillary Items

Required Equipment	Ancillary Equipment
Alto™ Abdominal Stent Graft Aortic Body preloaded in Delivery System	Optional (to utilize integrated crossover lumen) • Guidewire, non-hydrophilic coated, maximum 0.018", exchange length required; tip must be compatible with a snare • Snare • Introducer sheath, 5F ID minimum
Ovation iX Iliac Limbs (2) preloaded in Delivery Systems	
	Ovation iX Iliac Extensions preloaded in Delivery Systems
CustomSeal Kit	Spare CustomSeal Kit, Timer or clock
Autoinjector 2	
Imaging Equipment with capability to record and recall all imaging • Imaging table, or operating room table designed for use with C-arm • Fluoroscopy capability • Digital Subtraction Angiography (DSA) capability • Appropriate personnel protection equipment for fluoroscopy	Video recorder Power injector with associated supplies
Angiography and exchange catheters Assortment of adequate sizes (0.035" [0.89mm] compatible) and assorted lengths	
Guidewires: Assorted sizes of physician's preference, 0.035" (0.89mm) compatible	
Contrast media	
Heparinized saline and syringes	
Vascular instruments and supplies	Endovascular supplies • 3-way stopcocks • Tuohy-Borst adaptors

Required Equipment	Ancillary Equipment
	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

10.4 MRI Safety Information

MR Conditional

MR Conditional

Non-clinical testing applicable to the Alto™ Abdominal Stent Graft System demonstrated that the device is MR Conditional. A patient with this device can be scanned safely under the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Alto™ Abdominal Stent Graft System is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the Alto™ Abdominal Stent Graft System when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

11. Directions for Use

11.1 Patient Preparation

- In general, utilize similar patient pre-operative steps as for standard AAA open repair: fasting, bowel preparation, and prophylactic antibiotic regimens. Prepare

and drape the patient for an open surgical AAA procedure, in the event that conversion to open repair is required.

- The patient anesthesia protocol utilized during the endovascular procedure is left to the discretion of the implanting physician and anesthesiologist. General anesthesia, regional anesthesia, or local anesthesia combined with conscious sedation are all successfully utilized during endovascular procedures.
- Appropriate procedural imaging is required to successfully position the Alto™ 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 Alto™ Abdominal Stent Graft System within the vasculature.

11.2 General Implant Procedure Precautions

- Do not kink the delivery catheters. Doing so may cause damage to the delivery catheters and the 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. Reference Aortic Body Catheter Detach and Withdrawal section for more information.
- Inadvertent partial deployment or migration of the stent graft may require surgical removal or repair.

11.3 Implant Procedure and Deployment Instructions

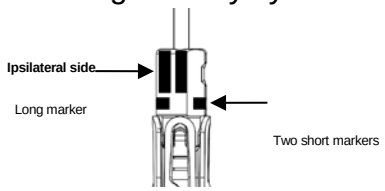
11.3.1.1 Vascular Access

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.

11.3.1.2 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.

11.3.1.3 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. Avoid excessive catheter manipulation to maintain delivery system connection.***
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.

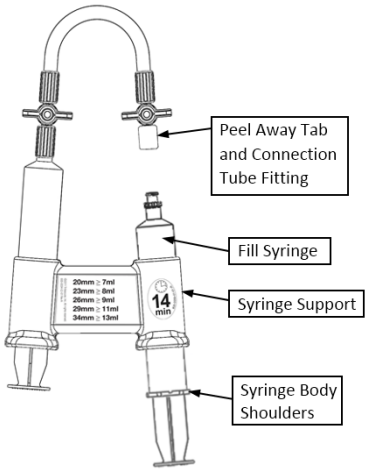
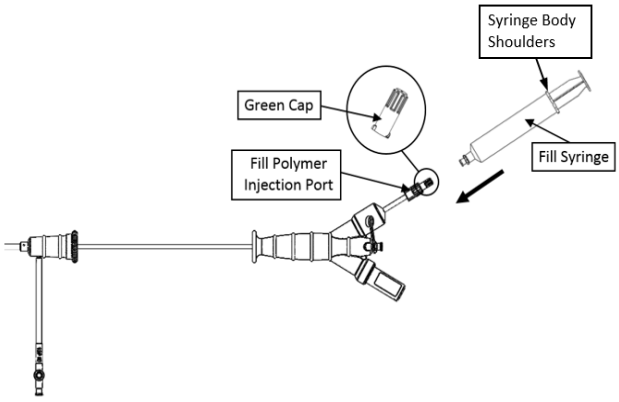
<table>
<tr><td>10</td><td>Deploy first segment of proximal stent (mid crown): turn first stent release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.</td></tr>
<tr><td>11</td><td>Remove white cap from balloon injection port on handle. Inflate balloon with standard 4: 1 saline and contrast mixture. Adhere to recommended inflation volumes in chart below.
Completely deflate the integral balloon by pulling vacuum on the inflation syringe.
<table>
<tr><th>Aortic Body Stent Graft Diameter</th><th>Recommended Integral Balloon Inflation Volume</th><th>Maximum Integral Balloon Inflation Volume</th></tr>
<tr><td>20 mm</td><td rowspan="3">5 ml</td><td>7 ml</td></tr>
<tr><td>23 mm</td><td>8 ml</td></tr>
<tr><td>26 mm</td><td>12 ml</td></tr>
<tr><td>29 mm</td><td rowspan="2">10 ml</td><td>15 ml</td></tr>
<tr><td>34 mm</td><td>19 ml</td></tr>
</table>
WARNING: Maximum contrast concentration of integral balloon solution is 4: 1 saline and contrast mixture.
WARNING: Never use air or any gaseous medium to inflate the integral balloon.
WARNING: Hand injections using a syringe are recommended for integral balloon. Do not use a pressure inflation device for integral balloon inflation.
WARNING: Don’t inflate integral balloon beyond maximum inflation volume. Rupture of balloon may occur. Over-inflation may result in damage to vessel wall and/or vessel rupture, or damage to the stent graft.
WARNING: Fully deflate integral balloon and verify it is under syringe vacuum force prior to positioning of catheter.</td></tr>
<tr><td>12</td><td>Orient C-Arm to align implant radiopaque markers to achieve orthogonality of view.</td></tr>
<tr><td>13</td><td>Precisely position implant radiopaque markers at final proximal landing site. Using contrast injections, as needed, confirm implant position relative to renal arteries.</td></tr>
<tr><td>14</td><td>Retract angiographic catheter away from proximal stent.</td></tr>
<tr><td>15</td><td>Deploy remainder of proximal stent (proximal crown): turn second stent release knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td colspan="2">WARNING: DO NOT utilize the crossover lumen at this point in the procedure. Utilizing the crossover lumen before polymer fill may result in polymer leak.</td></tr>
</table>

11.3.1.4 Fill Polymer Preparation

1	Using sterile technique, place CustomSeal Kit and Autoinjector 2 onto sterile field.
2	Open both fill kit syringe valves, and transfer contents between syringes for a minimum of 20 full uninterrupted strokes. Note: Confirm each syringe has bottomed out prior to beginning the 20 uninterrupted full strokes. Transfer contents into syringe with green band (fill syringe) to the minimum Fill Syringe Volume listed below 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 be 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 The CustomSeal Kit contains a label that indicates the minimum polymer volume required in the syringe to adequately fill each stent graft size. These minimum volumes should be followed to manage the total amount of fill polymer injection and to reduce the amount of fill polymer in the event of a polymer leak.
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 has been delayed 2 or more minutes using the CustomSeal Kit, discard the fill polymer. Start mixing with a new fill kit.	

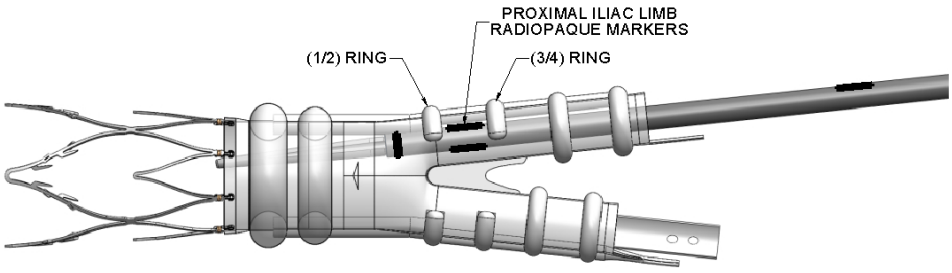
11.3.1.5 Fill Polymer Injection

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. Premature detachment may result in polymer leak.
WARNING: Use only the Autoinjector 2 to fill the Aortic Body Stent Graft. Hand injection should not be used and may damage the implant.

1	Remove peel away tab and disconnect the fill syringe from the connection tube fitting. Remove the syringe from the syringe support. Detach the green fill cap from the fill polymer injection port on the catheter handle.   **CustomSeal Kit** **Distal End of Aortic Body Delivery Catheter**
2	Attach fill syringe to polymer injection port on handle.
3	Firmly hold filled syringe stationery and push Autoinjector 2 over plunger, ensuring that the Autoinjector 2 is placed over the syringe body “shoulders.” Rotate Autoinjector 2 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: 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: During fill polymer injection and cure, observe the delivery system and/or syringe for inadvertent disconnection or fill polymer release/leak into the patient. Hypotension, significant distal 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 and is leaking into the patient. If observed, immediately disconnect the Autoinjector 2 from the fill polymer syringe.	
WARNING: Patients who experience hypersensitivity reactions (including severe allergic reaction and/or anaphylactoid response) during polymer fill should be managed in accordance with standard recommendations for treatment of patients with severe radiocontrast agent allergies (e.g., fluids, antihistamines, corticosteroids, epinephrine).	

11.3.1.6 Contralateral Limb Insertion and Deployment

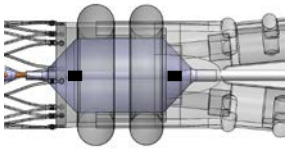
1	Refer to Delivery System(s) Preparation for delivery system preparation steps.
2	Cannulate the contralateral gate with a guidewire. The integrated crossover lumen in the aortic body delivery system may be used to facilitate the process using a maximum 0.018" guidewire. ***WARNING: Utilize the crossover lumen only after fill polymer injection. Utilizing the crossover lumen before polymer fill (i.e., in the wrong sequence) increases the chance of polymer leak.*** ***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 the aortic body contralateral leg gate 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 (3/4) ring and the 4th (1/2) 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. Independent of length, a docking zone (overlap) of 35 mm should be utilized between the iliac limb and the Aortic Body Stent Graft. The desired length can be calculated using Table 23 (Ovation iX Iliac Limb Sizes) in Section 9.1 (Stent Graft Sizing and Configuration). The measured distance from the lowest renal ostium to the hypogastric artery is the total treatable length. Using the Aortic Body covered length plus the selected iliac limb covered length and subtracting the overlap (35mm) provides the total device covered length. The total device covered length should not be greater than the total treatable length.
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 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.

11.3.1.7 Aortic Body Catheter Detach and Withdrawal

1	A minimum of 14 minutes after completion of fill polymer mixing, disconnect Autoinjector 2 from syringe, holding the Autoinjector 2 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 (14 minutes) to prevent potential release of fill polymer*** ***CAUTION: Patients with a core body temperature lower than 35°C may require at least an additional minute per degree below 35°C prior to disconnection.*** ***NOTE: Disconnecting before the minimum recommended time in the presence of low patient body temperature may result in a polymer leak.***

<table>
<tr><td>2</td><td>Re-advance aortic body guidewire.</td></tr>
<tr><td>3</td><td>The integral balloon may be used to improve seal ring apposition with the vessel wall as follows:

Using fluoroscopy, position the integral balloon radiopaque markers proximal to the aortic body primary sealing ring and distal to the secondary ring.
 
Inflate integral balloon with standard 4: 1 saline and contrast mixture. Adhere to recommended inflation volumes in chart below. Completely deflate the integral balloon by pulling vacuum on the inflation syringe.

<table>
<tr><th><u>Aortic Body Stent Graft Diameter</u></th><th><u>Maximum Integral Balloon Inflation Volume</u></th></tr>
<tr><td>20 mm</td><td>7 ml</td></tr>
<tr><td>23 mm</td><td>8 ml</td></tr>
<tr><td>26 mm</td><td>12 ml</td></tr>
<tr><td>29 mm</td><td>15 ml</td></tr>
<tr><td>34 mm</td><td>19 ml</td></tr>
</table>

WARNING: Maximum contrast concentration of integral balloon solution is 4: 1 saline and contrast mixture.
WARNING: Never use air or any gaseous medium to inflate the integral balloon.
WARNING: Hand injections using a syringe are recommended for integral balloon. Do not use a pressure inflation device for integral balloon inflation.
WARNING: Don’t inflate integral balloon beyond maximum inflation volume. Rupture of balloon may occur. Over-inflation may result in damage to vessel wall and/or vessel rupture, or damage to the stent graft.
WARNING: Fully deflate integral balloon and verify it is under syringe vacuum force prior to positioning of catheter
WARNING: Keep the integral balloon inside the graft. Inflation of the integral balloon outside of the graft may lead to vessel damage or rupture
CAUTION: Monitor balloon manipulations and inflation using fluoroscopy at all times.
CAUTION: If balloon pressure is lost and/or balloon rupture occurs, deflate the balloon and proceed with catheter detach and withdrawal procedure.
CAUTION:
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 ring.</td></tr>
<tr><td>4</td><td>Release catheter from aortic body: turn graft release (third) knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.</td></tr>
</table>

5	Using fluoroscopy, carefully withdraw inner catheter. The radiopaque marker on the guidewire lumen should move away from stent graft. ***WARNING: If resistance is encountered during catheter demate, STOP. Confirm catheter was released from the aortic body using graft release knob (third release knob). If catheter demate difficulty persists, verify catheter is not catching on the suprarenal stent. Once confirmed, the integral sheath can be used as a "buttress" to stabilize the aortic body.*** ***If nosecone retraction offers resistance, buttress 1st ring of the Ipsilateral Leg with Aortic Body sheath. Prior to nosecone mating with sheath tip, retract sheath 2cm so the fill port is not pinched in the sheath/nosecone.***
6	While maintaining guidewire position, slightly retract sheath and then retract catheter handle to reseat nosecone in end of delivery system outer sheath. Catheter rotation may be sufficient to overcome resistance.
7	To use the 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.

11.3.1.8 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.

11.3.1.9 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: It is not recommended to balloon prior to 14 minutes after completion of the final polymer mix. Ballooning prior to 14 minutes can create pressures high enough to damage the sealing ring and may result in a polymer leak.***
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.

11.3.1.10 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		

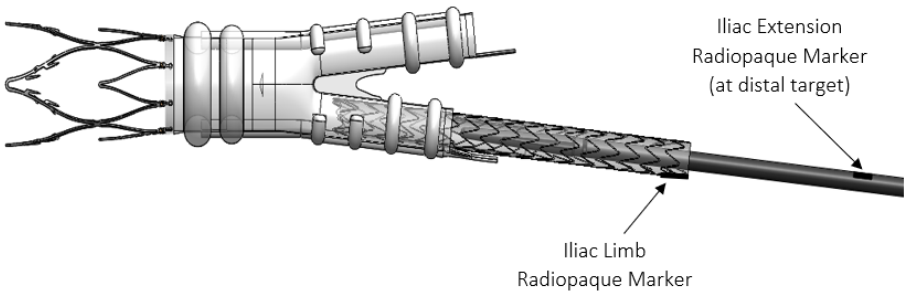
4 Prepare the iliac extension delivery system as described in Delivery System(s) Preparation.

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 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.

12. Follow-up Imaging Recommendations

Endologix recommends the following imaging schedule (**Table 26**) for patients treated with the Alto™ Abdominal Stent Graft System. The appropriate follow up imaging and imaging modalities for a particular patient are the responsibility of the clinician.

Table 26: 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.

12.1 Non-Contrast CT

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

12.2 Duplex Ultrasound

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

12.3 MRI or MRA

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

Endologix recommends contrast enhanced Spiral CT data for reconstruction. The requirements are outlined in **Table 27**.

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 27: Spiral CT Requirements

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

	Minimum Protocol	High Resolution Protocol (Recommended)
Scan Delay	ROI – threshold 90-100 HU in aorta	ROI – threshold 90-100 HU in aorta
Field of View	Large Body	Large Body
Reconstruction Algorithm	Standard	Standard

13. **Device Registration**

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

14. **Symbols**

LOT	Batch Code
	Use by
	Contents
	Non-pyrogenic
e-IFU	Consult Instructions for use, https://www.trivascular.com/IFU
Rx only	Prescription only
MR	MR Conditional
	Do not reuse
STERILIZE	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
	Manufacturer
EP PAT	For patent coverage, see www.endologix.com/patents
ID	Delivery system inner diameter
POLYMER	Polymer
BALLOON	Balloon
MIV	Maximum Inflation Volume

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