



# Abdominal Aortic Aneurysms: Understanding Your Treatment Options

## A Patient's Guide to Endovascular Stent Grafts



**Alto™**  
Abdominal Stent  
Graft System

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## Introduction

If you, or a loved one, have been diagnosed with an **abdominal aortic aneurysm** (a bulge that occurs in the part of the **aorta** that passes through the abdomen as a result of the weakening of the arterial wall), this guide will help answer some of the questions that you may have.

This guide contains information on how **abdominal aortic aneurysms** are treated with the Alto™ Abdominal Stent Graft System and what to expect after surgery.

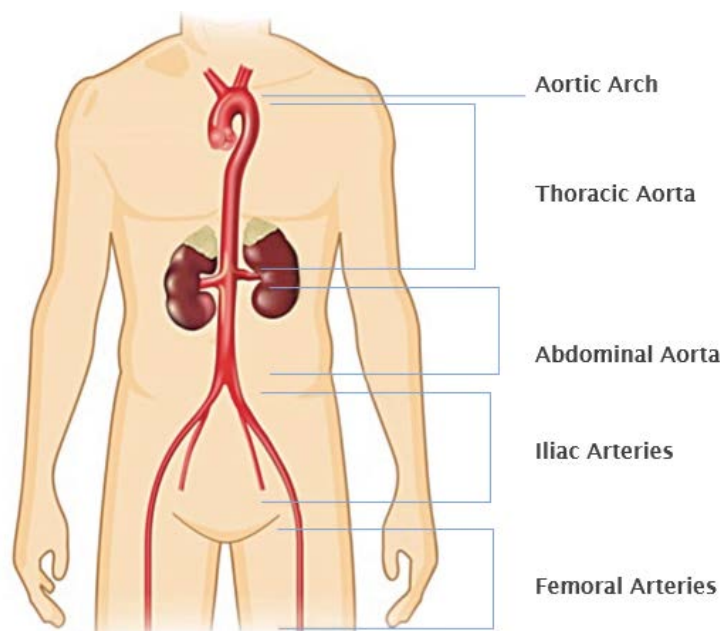
This information is being provided to you on behalf of Endologix, Inc. It is not intended to diagnose a medical condition. The treatment of **abdominal aortic aneurysms** may vary according to patient's needs and a doctor's assessment. Only a doctor can determine if you or your loved one is a good candidate for this treatment. As with any medical procedure, the best source for information and advice is your doctor.

This guide contains definitions of the medical terms used. All of the medical terms in **bold** letters are explained in the **Glossary** section. It may be helpful to write down any questions that you may have while you read this information packet so that you can discuss them with your doctor and healthcare team.

## Understanding Abdominal Aortic Aneurysm (AAA)

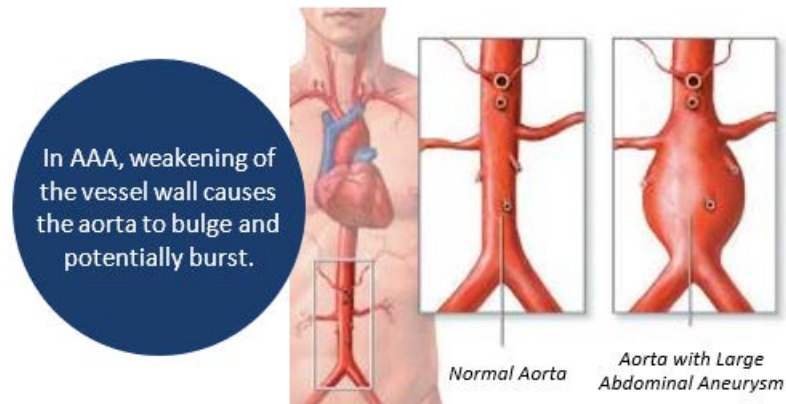
The **aorta** is the main and largest artery that carries blood from the heart to the rest of the body. The abdominal **aorta** is the part of the aorta just below the stomach, in the abdomen (see **Figure 1**). The abdominal aorta provides blood to organs that are in your abdomen, including the stomach, intestines, and kidneys.

The abdominal **aorta** branches into two large blood vessels called the **iliac arteries**, one on each side. The **iliac arteries** carry blood to the lower parts of the body and legs. The **iliac arteries** become the **femoral arteries** as the blood vessels extend into your thighs. (See **Figure 1**)



**Figure 1: Abdominal Aorta**

An **abdominal aortic aneurysm** (or AAA) is caused by weakening of the wall of the **aorta** due to age, disease or other conditions (see **Figure 2** below). As the bulge grows, the wall of the **aorta** becomes weaker. In many cases, patients with a growing aneurysm (bulge) may not have any symptoms or feel that their aneurysm is growing. This condition, if left untreated, could cause the **aorta** to rupture or burst. A rupture of the **aorta** leads to serious internal bleeding or death.



**Figure 2: Normal Aorta vs. Aorta with Large Abdominal Aneurysm**

## What Causes AAA?

The likelihood of having an **abdominal aortic aneurysm** is increased if you have a family history of **aneurysms**, smoking, high cholesterol, obesity, severe heart disease, and/or high blood pressure. **Abdominal aortic aneurysms** are more commonly found in men over 50 years of age, although younger people and women may also have them.

## How Is AAA Diagnosed and What Are the Symptoms of AAA?

Often an **abdominal aortic aneurysm** is found during an examination being done for other unrelated health reasons, as it is likely that a person does not feel any symptoms of the **aneurysm** being present.

In other cases, symptoms may include mild to severe pain in the abdomen, chest, or back. Some patients might feel the **aneurysm** as a throbbing mass in their abdomen. Your doctor may feel a bulge or pulsation (throbbing) in your abdomen.

**Abdominal aortic aneurysms** can be detected through special tests including: **CTScan, MRI, Angiography, Ultrasound** and/or **x-ray**.

- **CT Scan:** A series of computerized **x-rays** that form a picture of your aneurysm.
- **MRI:** An imaging technique that uses magnetic fields and radio waves to form detailed images of structures within the body.
- **Angiography:** An **x-ray** method that uses a liquid dye called “**contrast**” (see Glossary) which is injected into the bloodstream to see blood flow through vessels.
- **Ultrasound:** An imaging technique used in follow-up of **Endovascular Repair** that creates an image through the use of high-frequency sound waves.
- **X-ray:** An imaging method which uses radiation to create a picture of the structures within the body.

## Is AAA a Serious Condition?

When a AAA is small in size, it may not be an immediate health risk to you. However, your doctor will want to check your condition on a regular basis to see if your AAA is growing.

If the AAA continues to grow it may require treatment to prevent it from bursting and causing serious internal bleeding. The risk of an aneurysm bursting increases as the aneurysm grows in size, as well as with high blood pressure. Aneurysms that burst are very serious and may be fatal.



## AAA Treatment Options

### Medical Management of AAA

Not all **abdominal aortic aneurysms** require surgery. The type of treatment you receive depends on several factors, such as your overall health, the size of the aneurysm, how quickly it's growing, and the size and shape of your arteries. Be sure to discuss treatment options with your physician.

#### **Small Aneurysms**

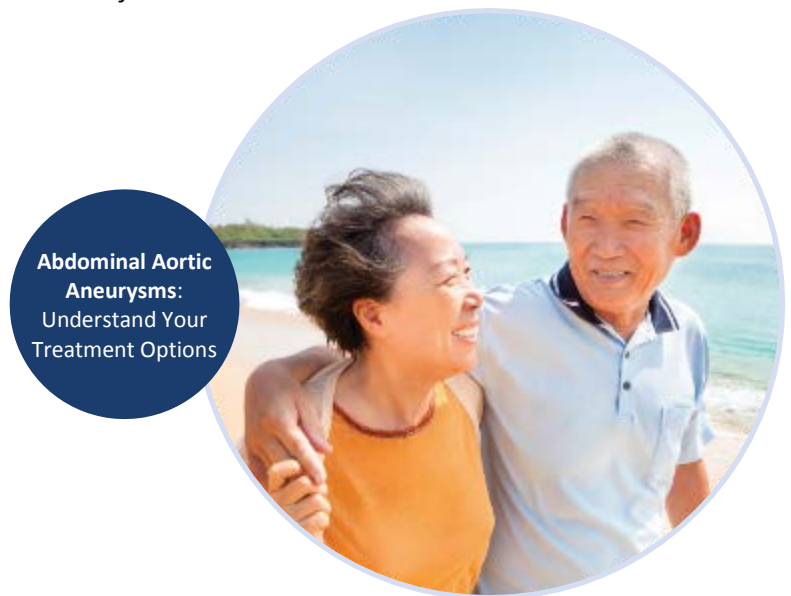
Small aneurysms will likely be kept under observation, but it may be necessary to have an ultrasound performed every 6-12 months to monitor any changes to its size or shape.

#### **Larger Aneurysms**

Aneurysms that are large, growing quickly, or of a certain shape suggest a higher risk. These larger aneurysms are more likely to need treatment, which involves surgery of some kind.

If your doctor recommends treatment of your **abdominal aortic aneurysm** because of the risk that your **aneurysms** will rupture (burst), he or she may discuss **Open Surgical Repair** and/or **Endovascular Repair** as potential treatment options.

*Risks and benefits are associated with both **endovascular repair** and **open surgical repair**. Patients should talk with their doctors about which option is best for them.*



## Open Surgical Repair

### *Open Surgical Repair Benefits*

- Standard method of treatment; well-proven surgical procedure
- Lasting results with decreased likelihood of having additional interventions over time
- Long-term follow-up exams with imaging studies generally not required
- Less risk from imaging requirements (less radiation and contrast dye exposure)

### *Open Surgical Repair Risks*

- General anesthesia required
- Major abdominal surgery/long abdominal cut
- Surgical complication rate is higher than minimally invasive EVAR
- Longer hospital stay and recovery time than EVAR
- Blood loss during procedure

**Open Surgical Repair** is performed in a hospital and requires general anesthesia. In an **Open Surgical Repair** (reference **Figure 3** below), the doctor makes a cut in your abdomen or side. The doctor removes the aneurysm and replaces it with a fabric or synthetic tube called a “graft”. The “graft” is sewn into place and acts as a replacement blood vessel. This surgery generally takes about 3 to 4 hours to complete. Patients typically stay overnight in intensive care and then remain in the hospital for an additional 5 to 7 days. It can take at least 3 months to fully heal from this surgery. **Open Surgical Repair** is commonly used and often works well.

- **Length of procedure: 3 to 4 hours**
- **Hospital stay: 1 night in ICU, 5-7 days in hospital**
- **Recovery time: Up to 3 months or longer**



**Figure 3: Open Surgical Repair**

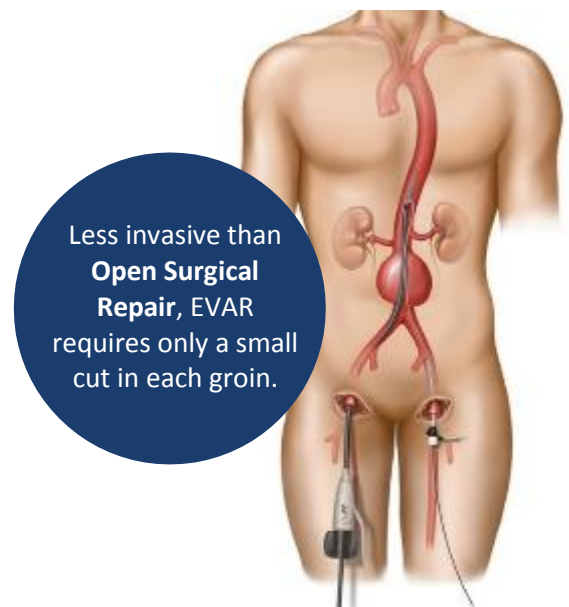
## Endovascular Repair

### *EVAR Benefits*

- Less invasive procedure and less blood loss than **Open Surgical Repair**
- Possibility that procedure can be performed under local anesthesia
- Small cut in 1 or both groins
- Lower surgical complication rate than **Open Surgical Repair**
- Shorter hospital stay and shorter recovery time than **Open Surgical Repair**

### *EVAR Risks*

- Higher potential for endoleak or late aneurysm bursting than after Open Surgical Repair
- Long-term follow-up imaging examinations required
- Possibility of additional endovascular or surgical procedure
- Typically performed with general anesthesia



**Figure 4: Endovascular Repair**

Prior to the procedure, **imaging** tests are performed. These tests allow the doctor to assess your **aneurysm** and whether **endovascular repair** (reference **Figure 4**) and **endovascular repair** with the Alto™ device is a treatment option for you.

**Endovascular repair** is **minimally invasive** compared to **Open Surgical Repair**. **Endovascular repair** usually has a shorter recovery period. The procedure usually lasts about 1 to 3 hours. Instead of making a large cut in the abdomen, the doctor makes a small cut or puncture where your lower abdomen and the top of your leg meet (groin area) to access the **femoral arteries**. The **delivery catheter** (a long, flexible tube) delivers the **stent graft** through the **femoral arteries** to put the **stent graft** in your **aorta** and **iliac arteries** to reinforce the weakened portion of your aorta. There are several manufacturers who market stent grafts in the United States to treat AAA. Your doctor can help you decide which stent graft is best suited for you. An endovascular procedure is performed under local, regional or general anesthesia.

The endovascular procedure is completed using the following steps:

- The **delivery catheter** is inserted and pushed up from the **femoral artery** into position in the **aorta**. The **stent graft** is positioned using **fluoroscopy**, an imaging technique that the physician uses to obtain real-time moving x-ray images of the stent graft during an endovascular repair procedure.
- When the **stent graft** is in the correct position, your doctor places the **main body** in the **aorta**. With the Alto™ abdominal stent graft system, channels in the **main body** are then filled with soft material (polymer) to create a seal against the **aorta** and provide support for the graft.
- Your doctor then inserts the **iliac limbs** into the **main body** through both **femoral arteries**. The **iliac limbs** are deployed in position. This completes the **stent graft** and creates a new path for the blood to flow.
- The **delivery catheters** are removed from the body.



- Your doctor will confirm the position of the **stent graft** and the flow of blood through the **stent graft** (and not into the **aneurysm**) using **angiography**.
- The cuts in your groin are closed with sutures and the procedure is complete.
- Patients may have a hospital stay of only a few days. Patients usually recover in 4 to 6 weeks.
- **Length of procedure: 1 to 3 hours**
- **Hospital stay: A few days**
- **Recovery time: 4 to 6 weeks**

- **Stent Graft:** A type of endovascular device with both metallic and graft components.
- **Main Body:** The largest part of the **stent graft** that is placed inside the **aorta**.
- **Iliac Limbs:** The two smaller parts of the **stent graft** that are placed inside the **iliac arteries** and connect to the **main body** of the **stent graft**.
- **Angiography:** An **x-ray** method that uses a liquid dye called “**contrast**” (see **Glossary**) which is injected into the bloodstream to see blood flow through vessels.
- **Contrast:** A liquid dye injected into the bloodstream to show blood vessels under **x-ray** or **CT scan**.

The biggest benefit of having your **abdominal aortic aneurysm** treated is a decreased chance of rupture. If left untreated, your aneurysm may continue to grow, which can lead to rupture. If your **abdominal aortic aneurysm** grows to 5.5 cm in diameter, annual rupture risk may be 3 to 15%<sup>1</sup> (3 to 15 out of 100 people).

## Product Description: Endovascular Stent Graft for Abdominal Aortic Aneurysms

An **endovascular stent graft system** is intended for permanent implant. Each **stent graft** is enclosed in a small catheter (a long, flexible tube) that is inserted using each of your **femoral arteries** (blood vessels that supply the blood to your legs) for placement of the **stent graft** in your **aorta** and **iliac arteries**.

The **stent graft** is made of metal stents and fabric. The metal portion of the stent is made from nitinol, a metal commonly used in many implantable medical devices. The fabric used in the Alto™ device is also a material (**PTFE**) that is commonly used in many implantable medical devices.

There is a channel in the aortic part of the Alto™ **stent graft** which is injected with a soft material (**polyethylene glycol– or PEG- based polymer**). The soft material starts out as a liquid and cures to a solid state during the procedure. The soft material is a special material designed to ensure the **stent graft** is tight against the wall of the **aorta**. Once the Alto™ stent graft **main body** (the **main body** is the largest part of the **stent graft** that is placed inside the **aorta**) is placed in your **aorta**, it is 20 mm (less than 1 inch) to 34 mm (less than 1 1/2 inches) in diameter, depending on the size of your **aorta**.

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<sup>1</sup> Brewster DC, Cronenwett JL, Hallett JW, Jr., Johnston KW, Krupski WC, Matsumura JS. Guidelines for the treatment of abdominal aortic aneurysms Report of a subcommittee of the Joint Council of the American Association for Vascular Surgery and Society for Vascular Surgery. J Vasc Surg. May 2003;37(5):1106-1117.

The **iliac limbs** are the two smaller parts of the **stent graft** that are placed inside the **iliac arteries** and connect to the **main body** of the **stent graft**. These components are used to allow blood to pass through the device, removing pressure from the weakened **aorta**. (see Figure 5)



**Figure 5: Implanted Stent Graft**

## What to Expect After Treatment

Immediately after recovery from the **stent graft** procedure you may be required to lie flat for 4 to 6 hours. This allows for the healing to begin in your groin. Some patients experience mild discomfort (such as swelling of the groin area or fever), but this usually resolves in 2 days. Other side effects may include numbness of the legs, nausea, vomiting, leg pain or throbbing, lack of appetite, **endoleak** (blood flow into the **abdominal aortic aneurysm** after placement of a **stent graft**), and/or absence of bowel movement for 1 to 3 days. Your doctor will provide you with specific care and follow-up instructions.

Please also refer to the Risks section of this patient information booklet.

## When to Call Your Doctor After Endovascular Repair

In between follow up visits to check the **endovascular stent graft**, call your doctor immediately or visit the nearest emergency room if you experience any of the following symptoms:

- Pain, numbness, or weakness in the legs, back, chest, or abdomen
- Discoloration or coldness in the leg
- Dizziness
- Fainting
- Rapid heartbeat
- Sudden weakness

If you don't seek medical attention for these symptoms, they could seriously harm you or cause your death.

## Patients Who Are Not Candidates for Endovascular Repair

Not all patients are candidates for **endovascular repair**. The **stent graft** is not right for you if:

- You have a condition that could create an infection to the **stent graft**, and/or
- You have sensitivities or are allergic to the device materials (including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, contrast agents, fluorinated ethylene propylene [FEP], titanium, nickel, platinum, or iridium).
- You are unwilling or unable to commit to having the lifetime annual imaging follow-up required after stent graft placement

Allergies and potential infection can cause problems during the follow up imaging exams or long-term implant of the device, possibly requiring removal by an **open surgical procedure**. It is important to tell your doctor about any condition that could create an infection to the **stent graft** or if you have any sensitivities or allergies.

The information will help your doctor decide if the **stent graft** is not right for you.

The Alto™ **abdominal stent graft** has not been evaluated in the following patients:

- Are pregnant or nursing;
- Are less than 18 years old;
- Have traumatic aortic injury or **aneurysm rupture** or require other emergent **aorta/aneurysm** treatment;
- Have aneurysms in places other than the **abdominal aorta** and **iliac arteries**;
- Have a bleeding problem;
- Have connective tissue problems;
- Have other artery disease that would interfere with the **stent graft** treatment.

The Alto™ **abdominal stent graft** is not recommended if you have any of the following conditions:

- Body infection;
- Allergy to the device materials;
- Allergy to the dyes that are used in follow up **imaging** exams;
- Allergy to the medicines used during the operation (antiplatelets or anticoagulants);
- Stroke within 3 months before the operation.

Your physician will need to help you decide whether it is appropriate for you to get an **endovascular stent graft** if any of these situations apply to you.

If you have poor kidney function, you should ask your doctor about the dyes used in some of these **imaging** studies as they may further decrease kidney function.

If you have **endovascular repair** of your **abdominal aortic aneurysm**, it is very important that you attend regularly scheduled follow-up appointments with your doctor.

Your doctor needs to find out if your **stent graft** is working right. If you don't go, your doctor won't know if:

- Your blood is leaking from your **stent graft**
- Your **stent graft** has moved (migrated)
- Your **stent graft** has other issues

Treatment with the Alto™ **abdominal stentgraft** may not be recommended if you cannot have regular follow-up **imaging** and/or have bleeding disorders, have kidney disease, cannot use blood thinners or cannot tolerate **imaging dyes**. EVAR is not recommended in patients who are not willing or not able to get the needed pre-operative and post-operative imaging. This includes patients who cannot tolerate contrast needed for **imaging** studies or potentially those whose size/weight does not allow them to get the needed **imaging** studies. EVAR is also not recommended for patients who do not have the appropriate vessel anatomy.

As described in the **Magnetic Resonance Imaging (MRI)** section, you will receive a patient implant card that will provide guidance to healthcare providers regarding these conditions. After implant with the **endovascular stent graft**, it is still safe to have **MRI** procedures under certain conditions but show the implant card prior to having **MRI** exams so that your healthcare providers are aware of these conditions.

## Alto™ (ELEVATE) Clinical Study Summary

The ELEVATE Study was a 75-patient study conducted in the United States to assess the safety and effectiveness of the Alto™ Abdominal Stent Graft System. Patients enrolled in this study were followed for one year. The study met the predefined endpoint of treatment success at one year. Treatment success was defined as the ability to place the device as intended and not experience device related events through one year. Of the 61 patients evaluated at one year, 58 had successful aneurysm treatment (95.1%). The remaining 14 patients lacked appropriate information to evaluate the primary endpoint.



Although the types of risks are similar to other EVAR procedures and AAA stent grafts, please talk to your doctor to better understand how the Alto™ Abdominal Stent Graft System compares to the other EVAR devices. One year patient follow-up has detected the following:

- *1 out of 61 patients (1.6%) experienced leakage of blood around the stent graft into the aneurysm that was related to the device,*
- *1 out of 61 patients (1.6%) had increases in the size of their aneurysm,*
- *1 out of 75 patients (1.3%) had removal of the stent graft and surgical placement of a vascular graft,*
- *2 out of 75 patients (2.7%) had additional procedures to treat the aneurysm or related to the stent graft, and*
- *8 out of 75 patients (10.7%) experienced major safety events including death (3), lack of blood flow to gastrointestinal tract (bowel ischemia; 3), heart attack (1) and blood loss (1)*

No patients in the study have had a rupture/burst of the aneurysm or aneurysm-related death. No patients in the study experienced unintended device movement or breaks in the device.

Your risk of having these events may be higher or lower. You should discuss the likely risk of these events throughout your life with your doctor and discuss how the risks and benefits of the Alto™ Abdominal Stent Graft System may apply to you.

## Risks with Endovascular Repair

As with any medical procedure, **endovascular repair** involves risks of experiencing **complications** and side effects related to the Alto™ device and/ or the procedure. There may be risks associated with

treatment due to your particular vascular anatomy that could lead to complications (bleeding, device movement, loss of seal) during and after the procedure. While most people who are implanted with the Alto™ Abdominal Stent Graft do not experience major side effects, it is important to familiarize yourself with the potential risks associated with the procedure.

Only your doctor can tell you if any of the side effects or problems you are experiencing could seriously harm you or cause your death. You should talk to your doctor about how your situation may be different or similar.

The major risks associated with AAA stent grafts include, but are not limited to the following:

- Complications from anesthesia
- Rupture or enlargement of the aneurysm or aorta
- Deployment or device malfunction
- Stent fracture
- General discomfort
- Leakage of blood around the stent graft into the aneurysm (endoleak)
- Movement or migration of the stent graft over time
- Obstruction of a blood vessel by a blood clot that becomes dislodged from another site (thromboembolism)
- Hypersensitivity to x-ray contrast or device materials
- Increased exposure to radiation due pre-operative and post-operative CT imaging
- Polymer leak with hypersensitivity/ allergic reaction
- Bowel events such as abnormal blood flow to the intestines or bowel
- Blood or bleeding events such as anemia
- Death
- Cardiac events such as congestive heart failure, heart attack, or stroke
- Paraplegia or paralysis
- Renal failure or complications related to the contrast used during the procedure
- Nervous system complications
- Respiratory failure
- Surgical conversion to open repair
- Procedural blood loss
- Contrast toxicity
- Hypertension
- Infection or severe tissue damage
- Impotence/ sexual dysfunction
- Inflammation
- Fever

After your **endovascular repair**, there is a chance than an **endoleak** may cause your **abdominal aortic aneurysm** to begin to grow again. If this happens, your doctor may recommend a second **endovascular repair** procedure to fix it. If the aneurysm continues to grow and is not repaired, it could **rupture**.

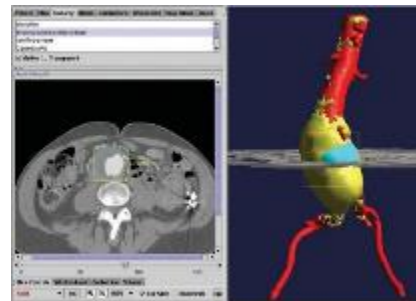
It is important to schedule regular follow-up visits with your doctor. Long-term results of this **stent graft** have not yet been established. Most problems with **endovascular repair** do not have symptoms. Follow-up visits with your physician are important to determine whether your **stent graft** is performing properly.

Follow-up visits will help the doctor to check your **aneurysm** and **stent graft** on a regular basis. Some problems that might occur are listed above in the Risks section of this booklet. Your doctor will schedule follow-up visits depending on your condition. You may need to be seen more frequently if there are concerns noted by your doctor.

Regular, life-long follow-up examinations are required after the implantation of the Alto™ Abdominal Stent Graft System. The reason for the regular exams is to check the position of the device, gauge flow of blood through device, and look for changes in the size of your aneurysm (growing, shrinking).

Most often these will occur at one month, six months, one year, and annually thereafter. At each visit, **CT scans (Figure 6)** will be performed to look at your **stent graft**. If you have poor kidney function, you should ask your doctor about the dyes used in some of these imaging studies as they may be harmful. The reason for the regular exams is to check the position of the device, gauge flow of blood through the device, and look for changes in the size of your **aneurysm** (if it is shrinking or growing). Frequency will be determined by your doctor and may include the following tests:

- Physical examination
- Abdominal **x-rays**
- **Ultrasound**
- **CT scan**



**Figure 6 Image of CT Scan**

## Implant Device Identification Card

Prior to leaving the hospital, you will be provided a patient implant card. Keep this card in your wallet at all times and show the card to your health care providers so that they know you have been treated for this disease with this device. The implant card includes your doctor's name and phone number; the hospital, city, and country where your procedure was performed; type and name of device; and date of implant. If asked, the card will show that it is safe to have an **MRI** after implant of the Alto™ stent graft only when completed under certain conditions.



## Magnetic Resonance Imaging (MRI)

After implant with the endovascular stent graft, it is still safe to have **MRI** procedures under certain conditions. Your patient implant card will provide guidance to healthcare providers regarding these conditions. Show this card to your healthcare providers.



## Device Tracking

US Federal Law, Title 21 Code of Federal Regulations Part 821, requires the tracking of all AAA stent grafts at all stages of distribution. As required by federal regulation, once you are implanted with the Alto™ abdominal stent graft, the hospital staff will forward device tracking information to Endologix, Inc., that will include, only with your consent, your personal contact information.

## Lifestyle Changes and Travel

The **endovascular stent graft** is not expected to interfere with or trigger a response in passenger screening devices such as airport security scanners.

- You will need to go for regular follow up visits to check your **stent graft**.
- Please consult your doctor about your ability to perform strenuous physical activities.

Please consult your doctor if your follow-up visit needs to be rescheduled as a result of travel.

## Glossary

### **Abdominal Aortic Aneurysm**

Sometimes referred to as “AAA.” This is a bulge that occurs in the part of the aorta that passes through the abdomen. The bulge occurs due to weakening of the arterial wall.

### **Anemia**

A condition in which someone lacks enough red blood cells to carry enough oxygen to the body’s tissues.

### **Aneurysm Rupture**

A burst or tear in the vessel wall near or at the location of the bulging or “ballooning” of the weakened area of the blood vessel (i.e., abdominal aortic aneurysm).

### **Angiography**

An x-ray method that uses a liquid dye called “contrast” (see definition below) which is injected into the bloodstream to see blood flow through vessels.

### **Aorta**

The main artery that carries blood from the heart to the rest of the body.

### **Congestive Heart Failure**

Chronic progressive condition where fluid builds up around the heart and causes it to pump inefficiently.

### **Contrast**

A liquid dye injected into the bloodstream to show blood vessels under x-ray or CT scan.

### **CT (Computed Tomography) Scan**

A series of computerized x-rays that form a picture of your aneurysm.

### **Complication**

An occasional problem that occurs as a result of a medical treatment.

### **Delivery Catheter**

A long, thin tube-like device that the doctor uses in delivering and positioning the stent graft during the endovascular repair procedure.

### **Endoleak**

Blood flow into the abdominal aortic aneurysm after placement of a stent graft.

### **Endovascular Stent Graft**

A stent graft placed within a diseased vessel to seal off the aneurysm without the use of Open Surgical Repair.

### **Endovascular Repair**

Involves the placement of an endovascular stent graft to seal off an aneurysm and create a new blood flow path within the weakened artery.



**Femoral Arteries**

Two blood vessels (one in each leg) that carry blood to the thigh region. Doctors can use the femoral arteries as a path to reach the iliac arteries and the aorta during endovascular repair.

**Fluoroscopy**

A real time x-ray image that is viewed on a monitor. The doctor generally uses fluoroscopy to visualize the placement of the endovascular stent graft during an endovascular repair procedure.

**Hypersensitivity**

Undesirable reactions produced by normal immune system, including allergies and autoimmune reactions.

**Hypertension**

Abnormally high blood pressure.

**Iliac Arteries**

Two large blood vessels (one on each side) that connect the lower end of the aorta to the upper end of the femoral arteries.

**Imaging**

The use of Angiography, CT Scans, Fluoroscopy, MRI, Ultrasound, x-rays and/or other techniques to obtain pictures of the inside of the body.

**(Iliac) Limb**

The two smaller parts of the stent graft that are placed inside the iliac arteries and connect to the main body of the stent graft.

**Main Body**

The largest part of the stent graft that is placed inside the aorta.

**MRI (Magnetic Resonance Imaging)**

An imaging technique that uses magnetic fields and radio waves to form detailed images of structures within the body.

**Migration**

The movement of the graft away from the desired location.

**Minimally Invasive**

A surgical technique involving a puncture or cut of the skin without exposing the internal organs.

**Open Surgical Repair**

A type of surgery performed to repair an aneurysm. To reach the aneurysm, a doctor makes a large cut through the abdomen of the patient. The doctor repairs the aorta by replacing the aneurysm section with a fabric tube called a "graft." The "graft" is sewn into place and acts as a replacement blood vessel.

**Paralysis**

Loss of muscle function in the body.

**Paraplegia**

Paralysis of the legs and lower body.

**Polyethylene Glycol (PEG)**

The base material used in the “soft material” injected into the Alto™ endovascular stent graft during implantation.

**Polymer**

Material made of long, repeating chains of molecules with unique properties that can make it soft and flexible or rigid.

**PTFE**

A polymer of tetrafluoroethylene (commonly known as Teflon). The fabric used in the Alto™ endovascular stent graft. PTFE is used widely in medical applications.

**Radiation**

The process of giving off energy in the form of waves or rays that cannot be seen.

**Renal Failure**

When the kidneys become unable to filter waste products from the blood.

**Respiratory Failure**

A condition in which the blood doesn't have enough oxygen or has too much carbon dioxide.

**Stent**

Metal part of the stent graft that provides anchoring of the graft to the aorta.

**Stent Fracture**

Separation of the stent structure as seen on angiogram. (See definition of **angiography**).

**Stent Graft**

A type of endovascular device with both metallic and graft components.

**Thromboembolism**

Obstruction of a blood vessel by a blood clot that becomes dislodged from another site.

**Ultrasound**

An imaging technique used in follow-up of Endovascular Repair that creates an image through the use of high- frequency sound waves.

**X-ray**

An imaging method used to create a picture of the structures within the body.

## Where to Find Out More Information

### Background Information on **Abdominal Aortic Aneurysms:**

VascularWeb Patient Information

Website: [www.vascularweb.org](http://www.vascularweb.org)

VascularWeb is a World Wide Web (WWW) based global resource of information and service for individuals interested in improving vascular health worldwide.

VascularWeb is sponsored and owned by the American Association for Vascular Surgery (AAVS) and the Society for Vascular Surgery (SVS), both non-profit organizations.



### **Society of Interventional Radiology**

Website: [www.sirweb.org](http://www.sirweb.org)

The Society of Interventional Radiology (SIR) is a professional society for doctors who specialize in interventional or minimally invasive procedures.

SIR is a non-profit, national organization deeply committed to its mission to improve health and the quality of life through the practice of cardiovascular and interventional radiology.

### **Medicare**

Website: <http://www.medicare.gov/coverage/ab-aortic-aneurysm-screening.html>

[www.medicare.gov/coverage/ab-aortic-aneurysm-screening.html](http://www.medicare.gov/coverage/ab-aortic-aneurysm-screening.html)

Medicare Part B (Medical Insurance) covers an abdominal aortic screening ultrasound once if you're at risk. You're considered at risk if you have a family history of abdominal aortic aneurysms, or you're a man age 65-75 and have smoked at least 100 cigarettes in your lifetime. The Medicare website provides information on the need for aneurysm screening for patients at increased risk for aneurysms.

### **Society for Vascular Surgery**

Website: <https://vascular.org/>

The Society for Vascular Surgery® (SVS) seeks to advance excellence and innovation in vascular health through education, advocacy, research and public awareness. The organization was founded in 1947 and currently has a membership of more than 5,600. SVS membership is recognized in the vascular community as a mark of professional achievement.

### **U.S. National Library of Medicine**

Website: [www.medlineplus.gov](http://www.medlineplus.gov) The National Library of Medicine (NLM), on the campus of the National Institutes of Health in Bethesda, Maryland, is the world's largest medical library. The library collects

materials in all areas of biomedicine and health care, as well as works on biomedical aspects of technology, the humanities, and the physical, life and social sciences.

### Product Information

U.S. Department of Health and Human Services, Food and Drug Administration

Website: [www.fda.gov](http://www.fda.gov)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/>

<http://DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm> (reference Alto™ Abdominal Stent Graft System P120006)

A U.S. government agency intended to promote and protect the public health by helping safe and effective products reach the market in a timely way and monitoring products for continued safety after they are in use.

## Questions You May Want to Discuss with Your Doctor

What are the treatment options for my AAA?

What are my potential benefits and risks associated with **open surgical repair**?

What are my potential benefits and risks associated with **endovascular repair**?

What are my potential benefits and risks associated with the use of the Alto™ Abdominal Stent Graft System for treatment of *my* AAA (as compared to other marketed devices)?

Which **stent grafts** are approved for treating AAA?

What is my potential risk of rupture with any **stent graft**, including the Alto™ Abdominal Stent Graft System?

What if my AAA continues to grow after **endovascular treatment**?

Would I have to limit activities after either kind of treatment? If so, for how long?

How long could my **stent graft** remain implanted in my body?



Will health insurance pay part or all of the cost associated with this procedure?

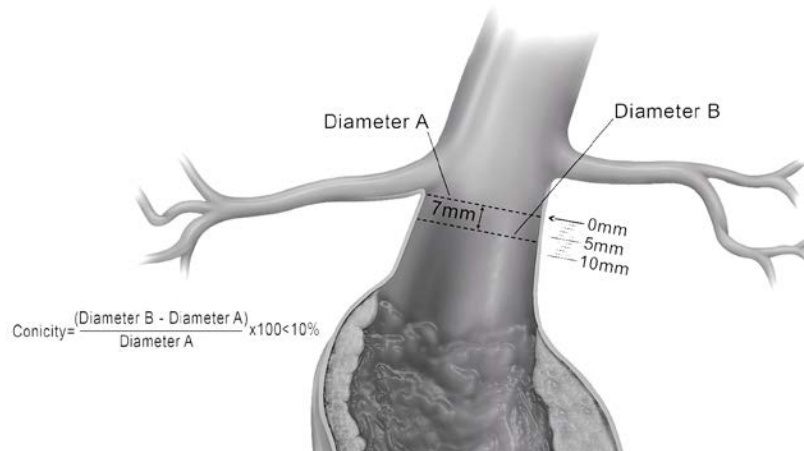
After the procedure, how often will you require to see me for follow-up?

Which tests will be performed for follow-up?

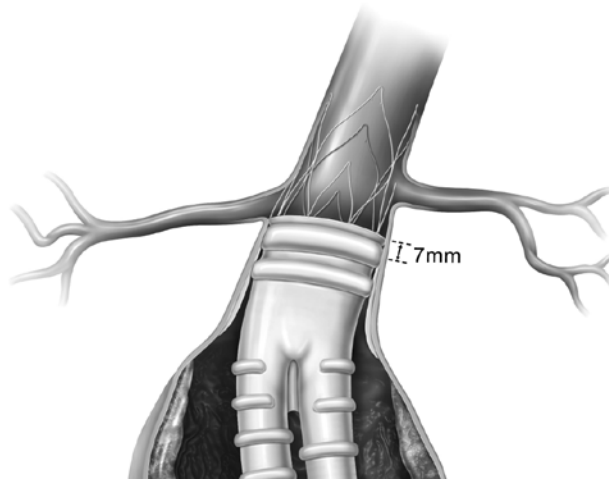
How many **stent graft** procedures has my doctor performed?



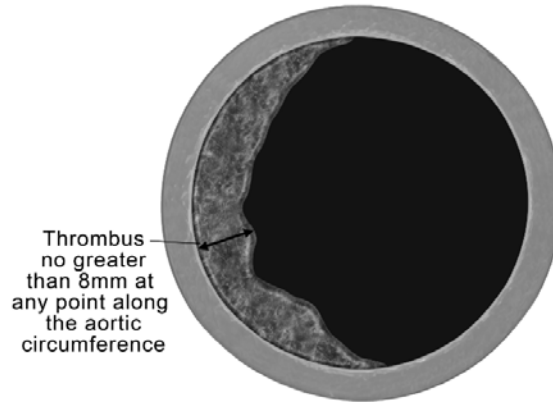
**Alto™ Abdominal Stent Graft System Specific Anatomic Considerations:** The specific design features of this endovascular graft impact how to assess a patient’s suitability for treatment. The following diagrams indicate the specific anatomic considerations that should be considered when evaluating suitability for treatment with the device as described in the Indications for Use statement.



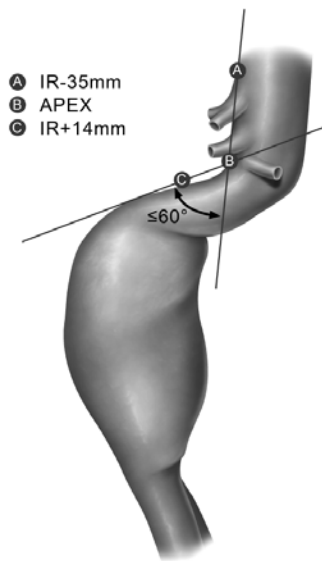
**Figure A: Proximal Landing Zone and Conicity**



**Figure B: Proximal Landing Zone**



**Figure C: Sealing Zone Thrombus**



**Figure D: Aortic Angle**

**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  $\leq 60$  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.

**CONTRAINDICATIONS:** The system is contraindicated for use in patients who have a condition that threatens to infect the graft and in 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. Also consider the information in Section 4 Warnings and Precautions of the systems' Instructions for Use.

Refer to Instructions for Use for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

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

NOTE: Not all product components are available in every country. Please consult with your Endologix representative to confirm product availability.

Please refer to current product Instructions for Use.

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