

**A Patient's Guide to Minimally Invasive
Abdominal Aortic Aneurysm Repair**

The Endologix Powerlink[®] System



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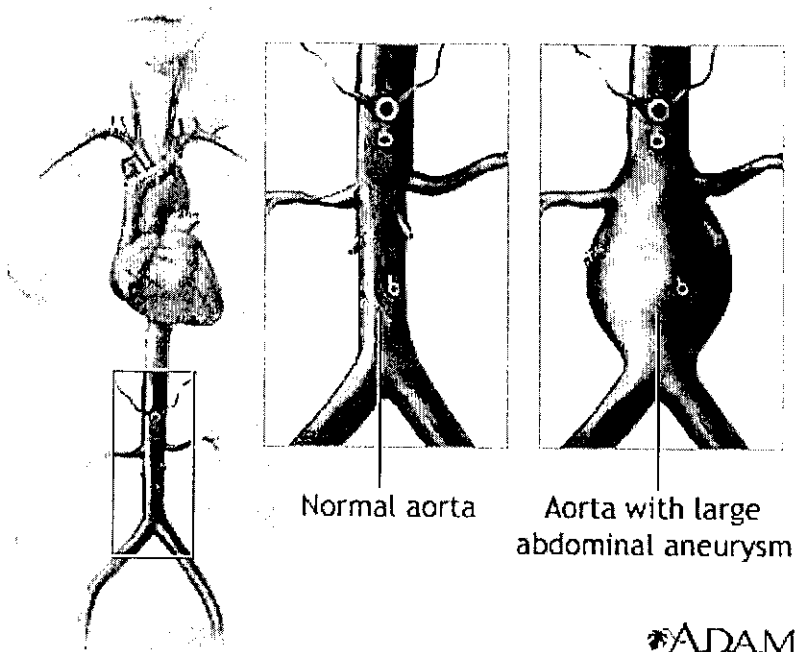
Introduction

This Patient's Guide has been provided to you on behalf of Endologix, Incorporated. The goal of this Guide is to help you learn more about your abdominal aortic aneurysm (AAA). You will learn about the symptoms of abdominal aortic aneurysms, how they are diagnosed, how they are treated with the Endologix Powerlink System, and what to expect after your surgery.

As with any surgery, the best source for information and advice is your doctor. After reading this Guide, you may have questions to ask your doctor. A section is provided in the back of this Guide for you to write questions you wish to ask your doctor. This Guide also contains definitions of the medical terms used throughout the Guide. All of the medical terms that are in **bold** are explained in the definition section at the back of the Guide.

What Is an Abdominal Aortic Aneurysm (AAA)?

The **aorta** is the largest blood vessel in your body. It carries blood from your heart to the rest of your body. The aorta extends from the chest to the abdomen, where it branches into the **iliac arteries**. The **iliac arteries** carry blood to the lower parts of the body and to the legs. An **abdominal aortic aneurysm (AAA)** occurs when the portion of the **aorta** passing through the abdomen bulges because of a weakening of the vessel wall. The walls become thin and lose their ability to stretch. The weakened sections of the wall may become unable to support the flow of blood through it and can **burst**. When an aneurysm bursts, it causes serious internal bleeding.



What causes a AAA?

The condition is fairly common in older adults and is more common in men than in women. Risk factors for developing it are age, smoking, family history of AAA, atherosclerotic disease, and high blood pressure.

What are the Symptoms of AAA?

Most patients diagnosed with AAA have no symptoms. However, for those patients that do have symptoms, the most common one is pain in the abdomen, back, or chest. The pain may range from mild to severe. In some patients, the pain in their abdomen spreads to their back. Others feel the aneurysm as a throbbing mass in their abdomen.

The AAA is often found during an examination for an unrelated health condition. During the examination, the patient may feel tenderness, back pain, abdomen pain, or pain in their legs. Your doctor may feel a bulge or throbbing in your abdomen.

If you have been diagnosed with a AAA and you develop back pain, abdomen pain, muscle pain, weakness in the legs, or dizziness, call your doctor immediately, or go to the closest emergency room.

Is this a serious condition?

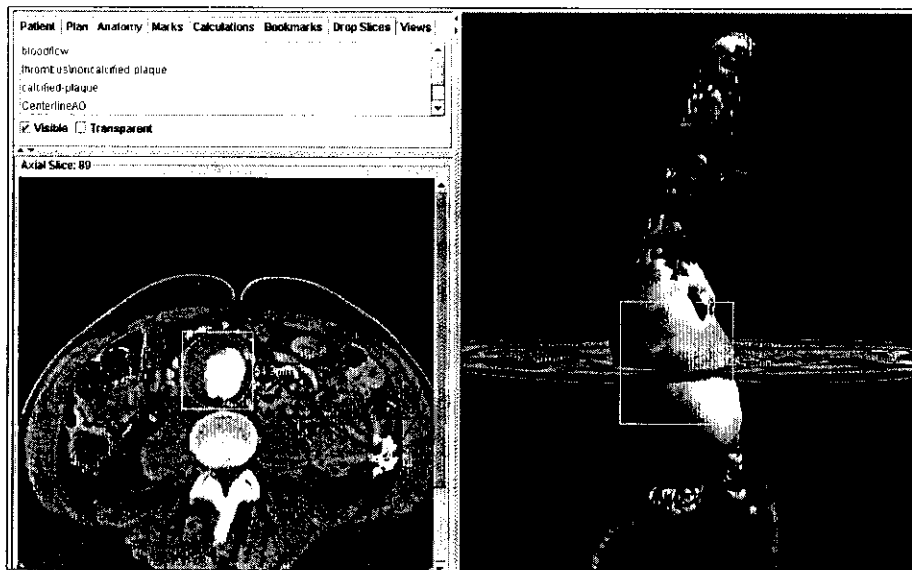
In the early stages, when the AAA is small in size, it may not be an immediate health risk to you. However, your doctor will want to check your condition on a regular basis to see if your AAA is growing.

In later stages, if the AAA continues to grow, it needs to be treated in order to prevent it from bursting and causing serious internal bleeding. The risk of an aneurysm bursting increases as the aneurysm grows in size, and with high blood pressure. Aneurysms that **burst** are very serious and may be fatal.

AAA Diagnosis and Screening

If you have been diagnosed in the early stages with a small aneurysm, your doctor will recommend periodic examinations. Your doctor may also recommend regular screening if you have risk factors for developing an aneurysm (family history of AAA, high blood pressure, smoking and heart disease).

This screening is commonly done with medical tests such as **CT scan**, **angiography**, and **ultrasound**. These tests can confirm the presence of the AAA and can determine its location, shape, size, and if it is in an early or late stage.



CT Scan

3D Reconstruction

Treatment of Abdominal Aortic Aneurysm (AAA)

The goal of all AAA treatment is to prevent the aneurysm from bursting. The size and location of the aneurysm within your body, as well as your general health, will determine how your doctor treats it.

Medical Management

If your aneurysm is small, your doctor may only recommend regular examinations to monitor the size of the aneurysm. A large aneurysm, or one that is rapidly growing, poses a risk of bursting and requires treatment.

There are two treatment options available to your doctor: **Open Surgical Repair** or **Endovascular Repair**.

Open Surgical Repair

In Open Surgical Repair, the doctor makes a cut in the abdomen or side of the patient and repairs the section of the aorta that has an aneurysm. The repair is done by replacing the aneurysm section with a fabric tube called a graft. The graft is sewn into place with sutures and acts as a replacement blood vessel. This procedure requires stopping of the flow of blood through the aorta while the graft is being sewn in place. The surgery is performed under general anesthesia and

takes about 2 to 4 hours to complete. Patients will usually stay overnight in the intensive care unit and another 5 to 7 days in the hospital. Depending on how your body heals, the overall recovery time may take up to 3 months or longer.

Open Surgical Repair is a well known surgical procedure that works. However, it involves major surgery and is not well tolerated by all patients, depending on their overall health conditions. Additionally, Open Surgical Repair has a long recovery period, and with a risk that you may not return to full function after the recovery period. As with any medical procedure, Open Surgical Repair has a risk for complications. Ask your doctor about the risks of Open Surgical Repair as they relate to your own health conditions.

Endovascular Repair

Endovascular Repair is less invasive than Open Surgical Repair in that it requires a smaller cut. Instead of making a large cut in the abdomen, the doctor makes a small cut in one groin and a small puncture in the other groin to get to the **femoral arteries** (blood vessels).

An **endovascular stent graft** is inserted through the small cut in the leg and placed inside the aneurysm in the aorta. Blood then flows through the endovascular stent graft rather than the weakened aneurysm part of the aorta. The endovascular stent graft (The Powerlink stent graft) remains inside the aorta permanently. The Endovascular Repair procedure may be done under local anesthesia and takes about 1 to 3 hours to complete. Patients will usually have a hospital stay of only a few days. Depending on how your body heals, the overall recovery time is usually 4 to 6 weeks.

Not every patient is a candidate for Endovascular Repair. As with any surgical procedure, Endovascular Repair has a risk of complications. Open Surgical Repair and Endovascular Repair both have advantages and disadvantages based upon each patient's health condition and needs. Ask your doctor about the possible risks of Endovascular Repair as they relate to your own health conditions.

What are the Advantages and Disadvantages of the Different Treatment Options?

Open Surgical Repair

ADVANTAGES

Standard method of treatment

Well-proven surgical procedure

Lasting results

Long term follow-up examinations of patient generally not required

DISADVANTAGES

General anesthesia required

Major abdominal surgery / long abdominal cut

Surgical complication rate is higher than Endovascular Repair

Longer hospital stay and recovery time than Endovascular Repair

Endovascular Repair

ADVANTAGES

Minimally invasive procedure

Local anesthesia may be used

Small cut in one groin, small puncture in the other groin

Lower surgical complication rate than Open Surgical Repair

Shorter hospital stay and shorter recovery than Open Surgical Repair

DISADVANTAGES

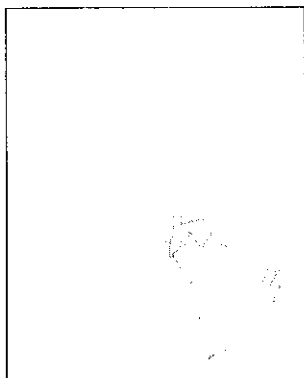
Long-term results are unknown

Higher potential for **endoleak** or aneurysm bursting than with Open Surgical Repair

Long term follow-up examinations are required

Possibility of additional endovascular or surgical procedures.

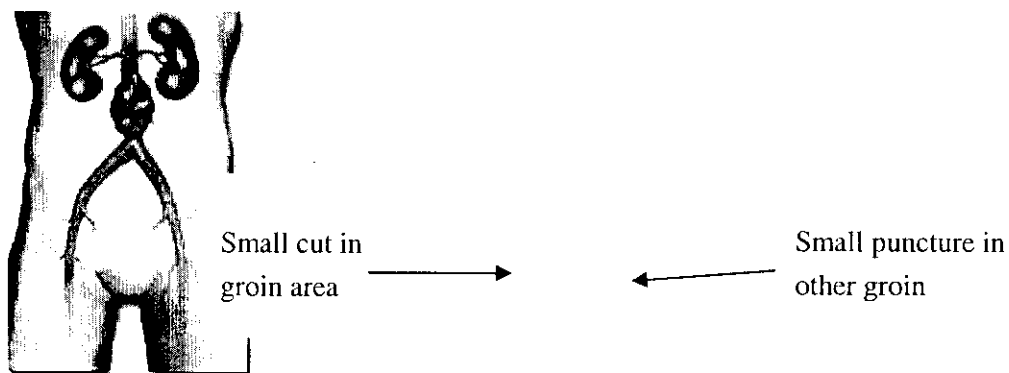
The Powerlink System



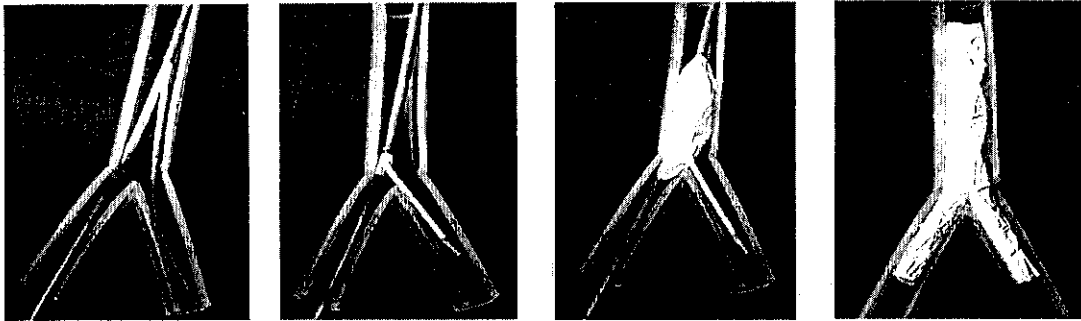
Your doctor has chosen the Endologix Powerlink System to perform your Endovascular Repair procedure. The Powerlink System is a **stent graft** made in one-piece, with a **main body** and two **limbs**. The Powerlink Stent Graft is also made of a fabric tube (called the graft) which is made of ePTFE, a Teflon type of material. But it is called a stent graft because it has a metallic structure which is made of a cobalt chromium alloy that is attached inside the graft for full support.

How is the Powerlink System Implanted?

The entire Powerlink stent graft is compressed into a long, thin plastic tube called a **delivery catheter**. Your doctor will insert thin wires into your **femoral arteries** through a small cut in one groin and a small puncture in the other groin.



The delivery catheter is inserted and advanced over the wire into position in your **aorta** (see Figure A). The stent graft is placed into position within your body so that the **main body** of the stent graft is positioned in the aneurysm of the **aorta**, with the two **limbs** of the stent graft extending from the **aorta** into the **iliac arteries** (see Figures B & C). When the main body and limbs of the stent graft are in proper position, the **stent** portion of the stent graft is allowed to expand (see Figure D). This expansion of the stent graft holds it in place within your aorta. The wire and delivery catheter are then withdrawn from the body.



A

B

C

D

The doctor uses a visualization method during this process known as **fluoroscopy** (real time X-ray images) viewed on a monitor in order to place the stent graft in the proper position within your body.

Before the Endovascular Repair procedure, your doctor will use diagnostic measurements (**CT scan, angiography, and/or ultrasound**) of your **aorta** to visualize the aneurysm and to select the proper size of stent graft to fit your body. At the end of the procedure, your doctor will confirm the correct position of the stent graft and the prevention of blood flow to the aneurysm using X-ray angiography before closing the cut in your leg with a few sutures.

As always, X-ray types of imaging, **CT scans, and angiograms** carry potential risks of either radiation exposure, or allergic reactions related to the **contrast dye** used during the tests. The occurrence of an allergic reaction to the contrast dye is a rare condition. The benefits of these tests in viewing your abdominal aortic aneurysm far outweigh the risk posed by the test. Speak with your doctor about any concerns you may have about the follow-up tests.

What Should I Expect After the Endovascular Procedure?

Because there are smaller cuts, Endovascular Repair may result in less discomfort, shorter hospital stays and faster recovery. Your hospital stay may be only a few days. You may be able to return to your normal activities within 4 to 6 weeks after the procedure.

However, Endovascular Repair requires regular follow-up examinations by your doctor.

Why is Follow-up Important?

There are some problems associated with Endovascular Repair which cannot be felt. The most serious of these would be continued aneurysm growth. This is why your regular follow-up examinations are so important. Below is a list of problems that could lead to continued aneurysm growth.

Endoleak - occurs when blood from the aorta continues to leak into the abdominal aneurysm. Most endoleaks cannot be felt and do not require treatment. However, an endoleak may lead to aneurysm growth and should be carefully followed over time. A small number of endoleaks require further treatment.

Graft movement – this is when the position of the stent graft after placement in your body shifts over time. You cannot feel when the graft moves, however it can be seen with a **CT scan**.

Your doctor will order regular follow-up examinations with medical tests such as a physical exam, **CT scan**, **angiography**, and/or **ultrasound** to view the results of your treatment and any changes that may occur over time. It is important that you go to all of the follow-up examinations recommended by your doctor. These examinations are generally required at one month, six months, one year, and yearly thereafter following your AAA procedure. Your doctor may require additional follow-up tests based on the findings at the regular follow-up visits.

When Should I Call My Doctor?

Although most of the problems associated with Endovascular Repair cannot be felt, call your doctor immediately if you experience any of the following symptoms, or go to the closest emergency room. The following symptoms are the most common potential problems as a result of your Endovascular Repair:

Aneurysm growth – symptoms are:

Pain in the legs, back, chest or abdomen

Numbness in the legs, back, chest, or abdomen

Weakness in the legs, back, chest, or abdomen

Aneurysm bursting (rupture) – a very serious condition that results in internal bleeding.

Symptoms are:

Dizziness

Fainting

Rapid heartbeat

Sudden weakness

Stent Graft Blockage - symptoms are:

Pain in the legs or hip during walking

Discoloration or coolness in the leg

What Do I Do with my Patient Implant Card?

If you receive an Endologix Powerlink Stent Graft, you will receive an Endologix Powerlink Patient Implant Card. Keep this card handy at all times. The card provides valuable information on:

The type of device implanted

The date of your implantation

Your doctor's name and phone number

MRI information

Recommended follow-up

Tell all of your health care providers that you have a stent graft and show them your Endologix Powerlink Patient Implant Card.

What if I need Magnetic Resonance Imaging (MRI)?

Following implantation with the stent graft, it is still safe for you to have most **MRI** procedures. **MRI** safety information is provided on your Endologix Powerlink Patient Implant Card. Be sure to tell all of your health care providers that you have a stent graft and show them your Endologix Powerlink Patient Implant Card.

Definition of Medical Terms

Abdominal Aortic Aneurysm (AAA) – a ballooning (enlarging or thinning) that occurs in the part of the aorta that passes through the abdomen (stomach area). The ballooning is due to a weakening in the arterial wall.

Aneurysm – a ballooning (enlargement of the vessel diameter and/or thinning of the vessel wall) of a weakened area of a blood vessel.

Angiography/Angiogram – angiography is an X-ray method that uses contrast (dye) injected into the bloodstream to see blood flow through blood vessels. The resulting image is an **angiogram**.

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

Burst – a tear in the vessel wall that allows blood to spill into the abdominal cavity resulting in serious internal bleeding. This type of tear may occur in the location of the ballooning of an aneurysm.

Contrast dye – a drug that is injected into the blood system to show blood flow through the blood vessels under X-ray types of imaging or CT scan.

CT Scan (Computed Tomography Scan) – an imaging technique that creates a series of computerized x-rays that form a picture of your aneurysm. Also known as a “CAT scan”

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 repair an 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. It is considered to be a less invasive approach than Open Surgical Repair.

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.

Iliac Arteries – two large blood vessels (called femoral arteries), in each leg which connect to the lower end of the aorta .

Limb – the two smaller parts of the stent graft that are placed inside the iliac arteries.

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.

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.

Stent – metal part of the stent graft that provides internal support and holds the stent graft in place.

Stent graft – a type of endovascular graft with a metallic stent inside the internal structure of the graft fabric cover.

Stent Graft Blockage – when the limbs of the stent graft become blocked and limit the amount of blood that can flow through the stent graft. This is an undesirable condition that may be felt as pain, weakness, or numbness in the legs.

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

Where Can I Get More Information?

Aneurysms

Background Information on Abdominal Aortic Aneurysms

VascularWeb Patient Information Website: 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.

Interventional Therapy

Society of Interventional Radiology Website: 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.

U.S. National Library of Medicine Website: 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

US Department of Health and Human Services

Food and Drug Administration Website: www.fda.gov

A US 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.

Contact Information

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Endologix Inc., located in Irvine, California, is engaged in the development of minimally invasive therapies for the treatment of aortic aneurysms.

