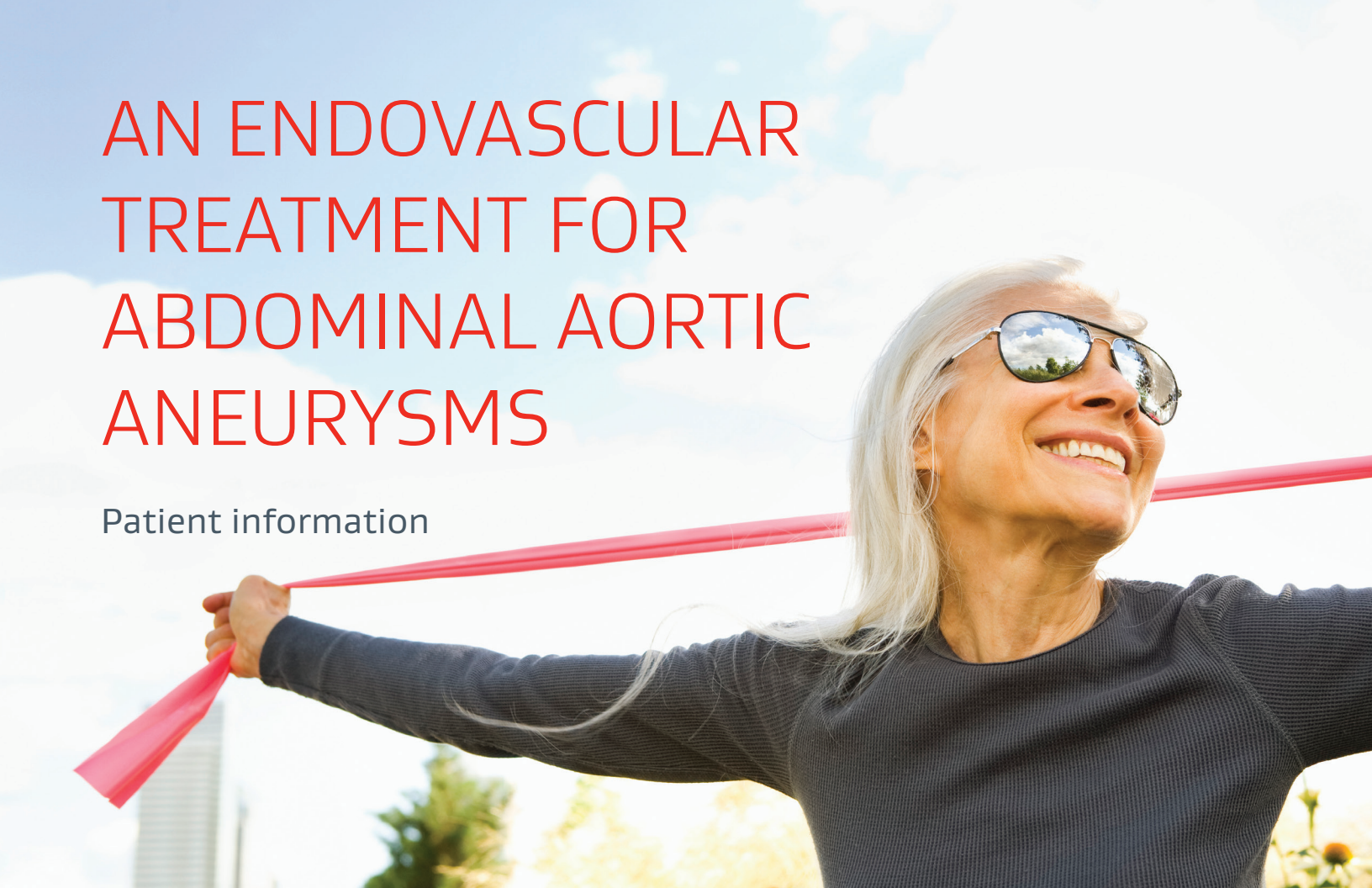
AN ENDOVASCULAR TREATMENT FOR ABDOMINAL AORTIC ANEURYSMS

Patient information



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Introduction

This brochure is intended to provide basic information about **abdominal aortic aneurysm (AAA)** and to assist you in making an informed decision about your treatment options. If you have any questions or concerns about the diagnosis or treatment of your medical condition, please talk to your doctor. A glossary of medical terms has also been included starting on page 18. Any words that are bold throughout the text can be found in the glossary.

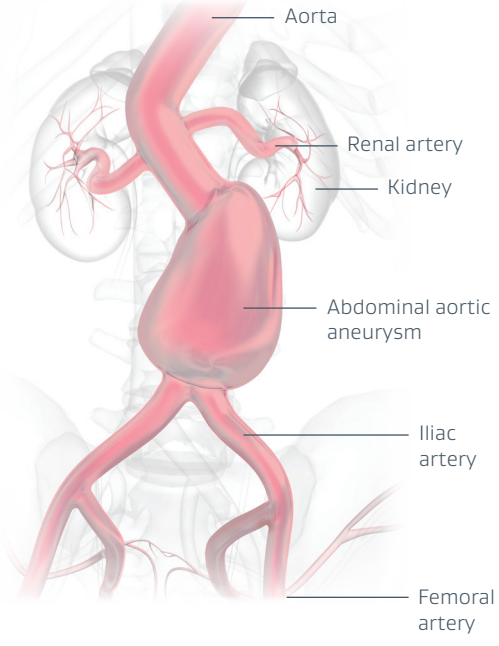
As with any surgery or medical procedure, the best resource for information and advice is your doctor. We hope this information will be helpful to you and your family.

Abdominal aortic aneurysm

The **aorta** is the largest blood vessel in the body. It carries blood away from the heart to the rest of the body. The abdominal aorta is the section of the vessel located within the abdomen.

An **aneurysm** is a ballooning (thinning and enlarging) of the aorta caused by continuous blood pressure against a weakened area. Over time an aneurysm may grow, further weakening the wall of the aorta, or it can burst completely causing **rupture**, which is bleeding inside the body.

An **abdominal aortic aneurysm (AAA)** is the swelling or ballooning of the abdominal aorta.



Causes

Over time, weakening of the aorta due to vascular disease, injury (trauma) or a genetic (hereditary) defect of the tissue within the arterial wall can cause an AAA.

Some of the key risk factors responsible for developing an AAA include:

- Smoking
- Family history of AAA
- Heart disease
- High blood pressure

AAA is known to occur more often in men than women, and the risk increases above the age of 50. Screening is especially recommended in men who have smoked and are over the age of 65.

Symptoms

In most cases, it is common not to experience any symptoms.

However, symptoms related to an AAA can vary. Pain is the most common, felt in the abdomen, back or chest area, and ranges from mild to severe. People also describe having tenderness in the mid or upper abdomen or lower back. Others have expressed the feeling of the aneurysm as a pulsating or throbbing mass in their abdomen.

Most AAAs are discovered during a routine physical exam or a medical test, such as a **CT scan** or **ultrasound**.

Treatment options

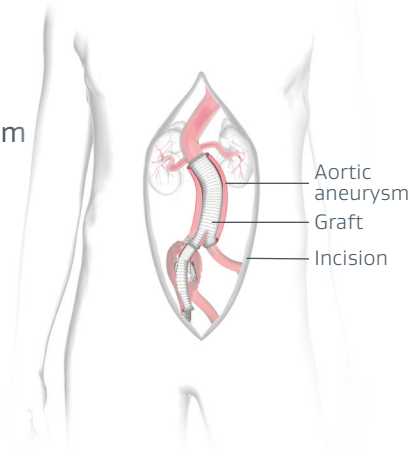
The size and location of an AAA influence which treatment your doctor recommends. Over time, an aneurysm can cause the aorta to grow to several times its normal size, which could result in a **rupture**. Ruptured aneurysms are frequently fatal and are a leading cause of death in the U.S.

Two primary treatment options are available if your doctor feels treatment is necessary: open surgical repair or **endovascular repair**.

Open surgical repair

Open surgical repair is a proven medical procedure that involves the doctor making an incision in the abdomen to repair the aorta by removing the aneurysm and replacing it with a fabric graft that is sewn to the aorta. This requires stopping blood flow through the aorta while the graft is being put into place.

This procedure is typically performed under general anesthesia and takes about 2–4 hours to complete. Patients usually stay overnight in the intensive care unit and about 1 week in the hospital. Recovery time from open surgical repair can take up to 3 months.

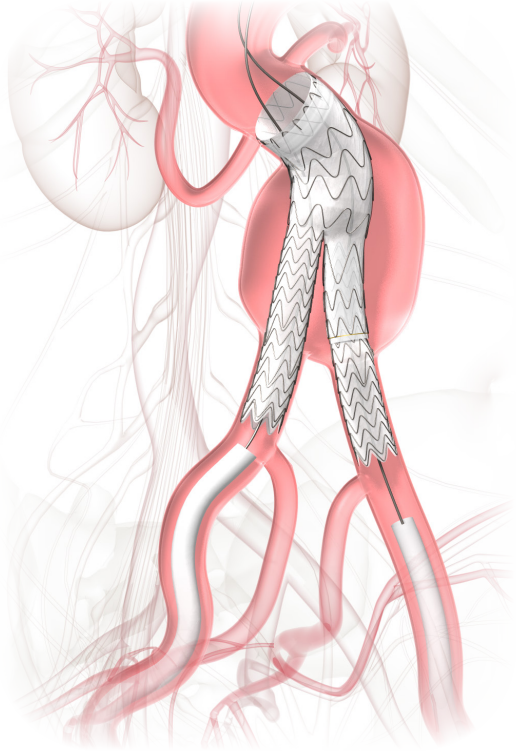


Endovascular repair

Endovascular repair involves sealing off the aneurysm by placing a stent graft inside the aneurysm, making a new path for the blood to flow. It is a less invasive procedure than open surgery and doesn't require an incision in the abdomen, since a stent graft is placed inside the aorta from a small incision made in each leg.

Endovascular repair may be performed under general, regional or local anesthesia and typically takes 1–3 hours to complete. Patients typically stay in the hospital for only 1–2 days and can usually return to normal activity within 6 weeks.

As with any surgery or medical procedure, there are potential complications with the treatment of an AAA. Discuss the risks and benefits with your doctor to determine which option is best for you or your family member.



GORE® EXCLUDER® Conformable AAA Endoprosthesis

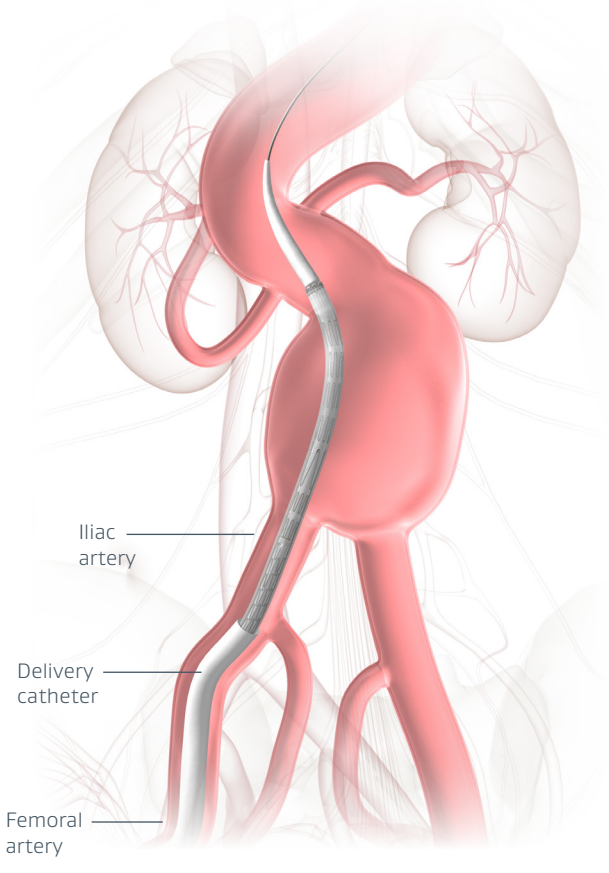
The GORE® EXCLUDER® Conformable AAA Endoprosthesis is an implantable **stent graft** designed for endovascular repair of an AAA.

The stent graft consists of 2 pieces that line the aorta and extend from below the **renal** (kidneys) **arteries** into both **iliac arteries**. It is made up of expanded polytetrafluoroethylene (ePTFE) with an outer metallic support structure known as a stent.

GORE® EXCLUDER® Conformable AAA Endoprosthesis procedure

The procedure for implanting the GORE® EXCLUDER® Conformable AAA Endoprosthesis consists of the delivery of the stent graft into the aorta and both iliac arteries.

The stent graft is implanted using **fluoroscopy**, real-time X-ray images and is viewed on a monitor following these steps.



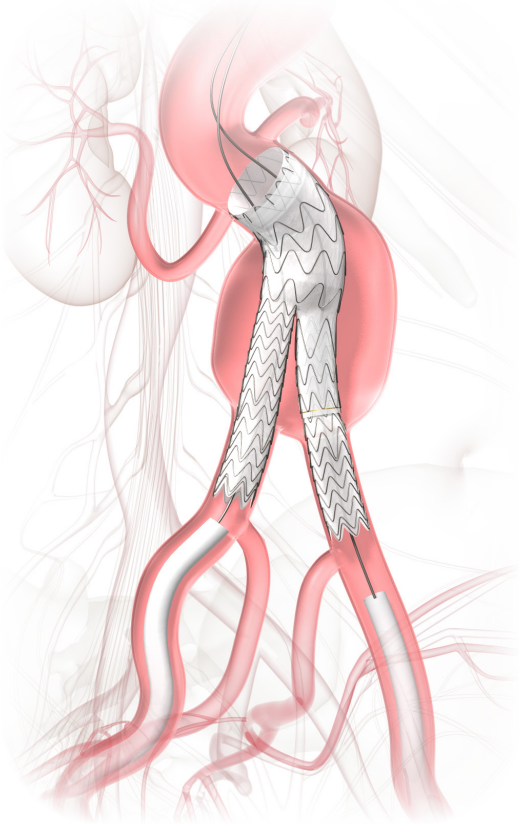
1. The **delivery catheter**, which contains the stent graft, is inserted into the **femoral artery** and carefully guided through the iliac artery to the site of the AAA.

2. Once the stent graft is correctly positioned in the aorta, it is released or deployed from the delivery catheter.

3. The device expands to the diameter of the aorta and iliac arteries. The placement of the stent graft is designed to exclude (seal off) the aneurysm and reline the artery wall.

4. Once the device is in place and has relined the artery wall, blood will flow through the stent graft.

5. The delivery catheter is withdrawn from the body.



GORE® EXCLUDER® Conformable AAA Endoprosthesis clinical data summary

A 175-patient study* was conducted in the United States to assess the safety and effectiveness of the GORE® EXCLUDER® Conformable AAA Endoprosthesis. Patients enrolled in this study are to be followed for 5-years post-procedure. Patients were enrolled based on their anatomy into 1 of 2 substudies: the 80-patient substudy with standard infrarenal aortic neck angulation (≤ 60º) and the ≥ 10 mm aortic neck length, or the 95-patient substudy with challenging infrarenal aortic neck angulation (> 60º, ≤ 90º).* The study included assessments of treatment safety at 30-days post-procedure and treatment success through 1-year post-procedure. Treatment success is defined as the ability to place the device as intended and confirmation that the device remained effective. The combined outcomes from both substudies show of the 171 patients evaluated for safety events at 30-days post-procedure, 168 were free of a safety event (98.2%). Of the 144 patients evaluated for treatment success through 1 year, 135 had successful aneurysm treatment (93.8%). For the remaining 31 patients, it was not possible to gather sufficient information to evaluate treatment success.

The following are notable safety and efficacy results through 1-year follow-up:

- 4 out of 142 patients (2.8%) experienced post-procedural Type 1a endoleaks (e.g., leakage of blood around the top of the stent graft into the aneurysm).
- 3 out of 150 patients (2.0%) had an increase in the size of their aneurysm.
- 9 out of 171 patients (5.3%) had surgical reinterventions. Most of the reinterventions (5 patients, 2.9%) involved minimally invasive procedures to block blood flow from small arteries filling the aneurysm while 1 patient (0.6%) had removal of the stent graft and surgical placement of a vascular graft.

* The study data reflects the combined outcomes from 80 subjects enrolled with infrarenal aortic neck angle ≤ 60° and aortic neck angle length ≥ 10 mm (short neck substudy) and 95 subjects enrolled with infrarenal aortic neck angle > 60° but ≤ 90° and aortic neck length ≥ 10 mm (high neck angulation substudy).

- 11 out of 173 subjects (6.4%) experienced major safety events including death (8), significant procedural blood loss (3), respiratory failure (3) and/or heart attack (1).
- There were no reports of rupture or bursting of the aneurysm, aneurysm-related death, unintended device movement and breakage of the device, and only 1 report of blockage or **occlusion** of blood flow through the device.

The GORE® EXCLUDER® Conformable AAA Endoprosthesis met the safety and effectiveness performance goals in both substudies. There were more patients in the challenging infrarenal aortic neck angulation substudy that reported post-procedure Type 1a endoleaks (4 of 75, 5.3%), surgical reinterventions (7 of 92, 7.6%) and major safety events (8 of 94, 8.5%) through 1-year follow-up than patients in the standard infrarenal aortic neck angulation substudy. However, any comparisons between substudy outcomes may have limitations because the challenging infrarenal aortic neck angulation substudy enrolled more patients. Other limitations to available clinical data include lack of longer-term follow-up information and limited usage of the large-diameter devices (due to limited anatomical applicability within the patients that participated in the study).

Your experiences may vary, and you may have higher or lower risks regarding these types of events. You should discuss your particular anatomy, the likely risk of these events throughout your life and the risks and benefits of the GORE® EXCLUDER® Conformable AAA Endoprosthesis with your doctor.

Risks

Like surgery, endovascular repair with a stent graft comes with risks. It is important to discuss the risks and benefits of treatment with your doctor.

Some of the potential risks associated with stent grafts include:

Endoleaks — when blood from the aorta continues to leak into the abdominal aneurysm. Most endoleaks do not require treatment.

Stent graft movement — movement of the stent graft from its original position over time.

Stent graft failure-related issues — these issues may be detected using imaging techniques such as X-rays.

Aneurysm growth.

Aneurysm rupture — symptoms include dizziness, fainting, rapid heartbeat or sudden weakness.

Limb occlusion — symptoms include pain in the hip(s) or leg(s) during walking, or discoloration.

Implant procedure and recommended follow-up visits require fluoroscopy and use of dyes for imaging. Patients may experience radiation-related complications and those patients with kidney problems may be at risk of kidney failure due to the use of dyes.

Swelling of the groin area.

Nausea and vomiting.

A hole or a tear of the blood vessels are risks associated with any catheter-based procedure.

Formation of an abnormal passage between your arteries and veins.

Bowel complications including death of a portion of your bowel tissue requiring surgical removal.

Cramping pain and weakness in the legs, especially the calves.

Formation of blood clots that block the flow of blood to your organs.

Risks (continued)

Fever and inflammation.

Infection of the aneurysm and device access site, pain or bleeding.

Complications of the nervous system including total or partial paralysis of the lower half of the body with involvement of both legs, confusion, stroke and transient ischemic attack.

Blockage of the device or blood vessel.

Surgical conversion to open surgical repair.

Reoperation or intervention.

Problems affecting your urinary and reproductive organs including infection and tissue death.

Impotence.

Kidney problems.

Liver problems.

Death.

Benefits

There are a number of potential benefits to having an endovascular repair with a stent graft.

Some of these are:

The procedure is minimally invasive compared to open surgery.

The procedure can be performed under local anesthesia.

There is a lower surgical complication rate.

Less loss of blood during the procedure than open surgical repair, reducing the risk of needing a blood transfusion.

Less time spent in the intensive care unit after the procedure and the potential for a shorter hospital stay.

The short-term benefits of the device should be carefully weighed with the need to return on an annual basis for imaging studies and routine follow up, as well as the potential need for additional minimally invasive interventions in the longer term. Also, the uncertainty with regard to longer term outcomes (e.g., sustained aneurysm exclusion from blood flow and/or change in aneurysm size) should be carefully considered.

Follow-up

After endovascular repair with the GORE® EXCLUDER® Conformable AAA Endoprosthesis, follow-up exams will typically consist of a physical examination and imaging, such as a CT scan, to check the aneurysm and evaluate the stent graft performance.

Follow-up will be scheduled with your doctor on a regular basis. Regular follow-ups will be required even in the absence of obvious symptoms (e.g., pain, numbness, weakness). Endoleaks can repressurize the aneurysm and may lead to aneurysm expansion or rupture. Follow-up exams are very important after device placement. These visits commonly occur at 1 month, 6 months and annually thereafter. Keeping up with follow-up monitoring is particularly important for those patients with challenging anatomy (e.g., severe infrarenal aortic neck angulation) who may be at higher risk of post-procedural events. If you are unwilling or unable to commit to annual imaging, then endovascular repair may not be a good option to consider for you.

When should I call my doctor?

Contact your doctor immediately if you experience any of the following symptoms after repair of your AAA:

- Pain, numbness, coldness or weakness in the legs or buttocks
- Any back, chest, abdominal or groin pain
- Dizziness, fainting, rapid heartbeat or sudden weakness
- Any other unusual symptoms

Other patient considerations

Certain patients should not receive the GORE® EXCLUDER® Conformable AAA Endoprosthesis. This includes patients with known sensitivity or allergy to device materials (ePTFE, FEP, nickel titanium alloy and gold), patients who have a condition that threatens to infect the graft.

After undergoing an endovascular repair procedure, there are some lifestyle changes that you should be aware of:

- Consult your doctor about your ability to safely perform strenuous physical activities.
- An implanted stent graft typically will not trigger screening or metal detectors, like those at airports or secure building entrances, but consult your doctor about your specific device.
- You should carry your permanent implanted device identification (ID) card in your wallet.

Implanted device identification card

After the procedure, your doctor will give you a temporary implanted device ID card. The temporary implanted device ID card will tell you the size and number of your abdominal aortic stent graft implants.

A permanent ID card will be provided later and will list the following information:

- Type of device implanted
- Date of implant
- Your doctor's information
- Magnetic resonance imaging (MRI) information

Be sure to tell all of your health care providers that you have the stent graft and show them your implanted device ID card. You should keep your patient ID card available at all times.

Magnetic resonance imaging

It is still safe to have **MRI** procedures, under certain conditions. MRI information is provided on your implanted device ID card. Before having an MRI, always show your implanted device ID card to your health care providers.

Glossary of medical terms

Aorta
The main artery (blood vessel) that carries blood from the heart to the rest of the body.

Abdominal aortic aneurysm (AAA)
A ballooning (thinning and enlarging) of a weakening area of the aorta wall in the abdomen.

Aneurysm
A ballooning (thinning and enlarging) of a weakened area of a blood vessel.

CT (computed tomography) scan
An imaging technique that uses multiple scans to create a very precise view of your abdomen and aorta. Also known as a CAT scan.

Delivery catheter
A long, thin, tube-like tool that assists in the delivery and positioning of a stent graft.

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

Endovascular repair

A procedure in which a stent graft is placed inside a diseased vessel without surgically opening the tissue surrounding the weakened vessel to exclude (seal off) an aneurysm inside the aorta, making a new path for blood to flow.

Endovascular treatment

The use of a stent graft, guidewires and real-time X-rays to treat unhealthy arteries via small incisions in the femoral arteries to gain access to the iliac arteries and the aorta.

Femoral arteries

Two arteries located in each leg, which carry blood to the femur or thigh region of each leg.

Fluoroscopy

A real-time X-ray image that is viewed on a monitor used during endovascular repair.

Guidewire

Long, flexible wire that is placed in an artery to help guide the delivery catheter and other accessories to implant the stent graft.

Iliac arteries

The iliac arteries begin from the bifurcation (separation) of the aorta in your abdomen. These arteries connect the aorta to the femoral arteries delivering blood to the legs.

Magnetic resonance imaging (MRI)
A technique that uses magnetic fields to form images of structures within the body.

Occlusion
The blocking of an artery, causing the stop of normal blood flow.

Renal arteries
Two arteries attached to the aorta that carry blood to the left and right kidney.

Rupture
A tear in the vessel wall near or at the location of the weakened area of the aneurysm allowing blood to flow into the abdomen.

Stent graft
A synthetic graft implanted within a weakened blood vessel to exclude (seal off) from the inside. Compressed stent grafts are delivered via catheter to the weakened area, and once positioned, expand to fit the size of the vessels in which it is placed.

Synthetic graft
A man-made material in tube form intended to replace damaged blood vessels.

Ultrasound
An imaging technique that creates a picture of an area inside the body using high-frequency sound waves.

Where can I get more information?

Background Information on AAA

American Heart Association	heart.org
Society for Vascular Surgery	vascular.org/patients

Interventional therapy

Society of Interventional Radiology	sirweb.org
U.S. National Library of Medicine	medlineplus.gov

Product Information on AAA

W. L. Gore & Associates, Inc.	goremedical.com/conditions
U.S. Department of Health and Human Services Food and Drug Administration	fda.gov

Questions for my doctor

You and your doctor should review the risks and benefits when discussing this stent graft and procedure including:

- Risks and differences between endovascular repair and open surgical repair of an AAA.
- Potential advantages of traditional open surgical repair.
- Potential advantages of endovascular repair.
- The possibility that additional endovascular treatment or surgery may be required after initial endovascular repair.

In addition to the potential risks and benefits of an endovascular repair, your doctor should consider your commitment to and compliance with post-operative follow-up as necessary to ensure continuing safe and effective results.

Notes

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Together, improving life

Consult Instructions for Use
eifu.goremedical.com

Refer to *Instructions for Use* at goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

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