

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 17. Any words that are bold throughout the text can be found in the glossary.

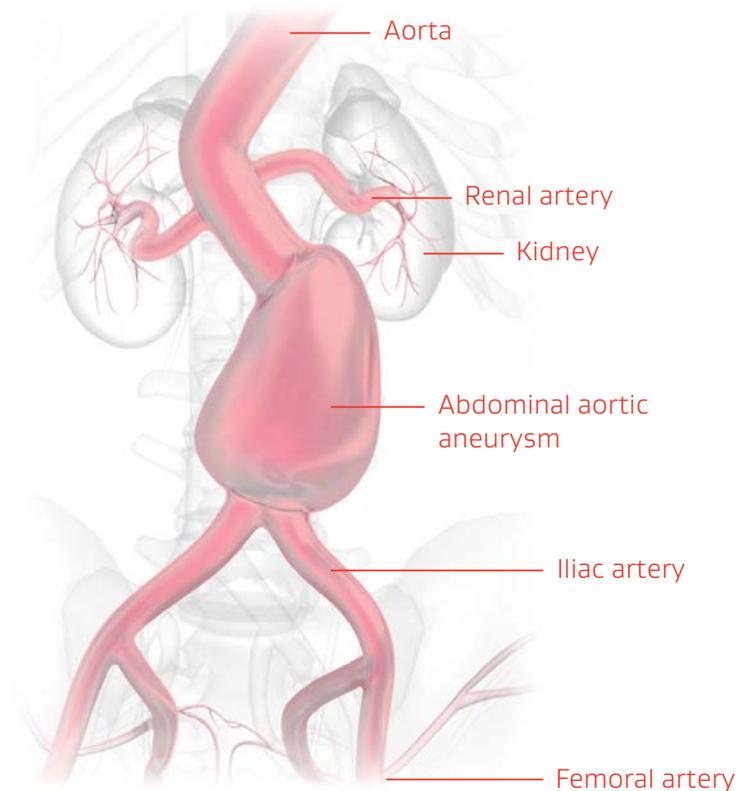
As with any surgery or medical procedure, the best resource for information and advice is your doctor. We hope this information will be helpful to you and your family.

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

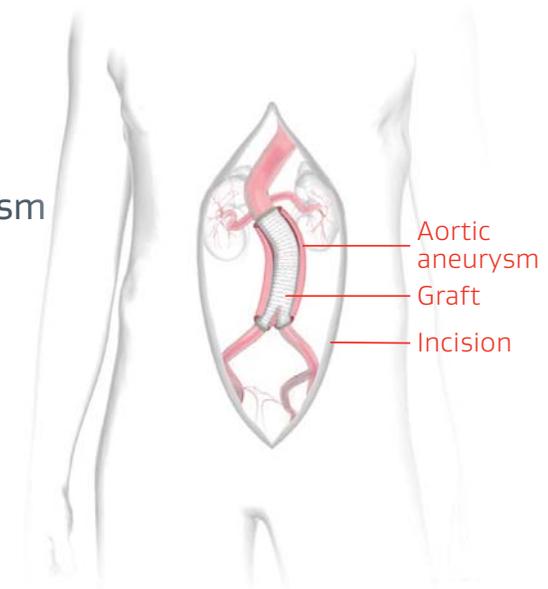
The size and location of an AAA influences which treatment your doctor recommends. Over time, an aneurysm can cause the aorta to grow to several times its normal size, which could result in a **rupture**. Ruptured aneurysms are frequently fatal and are a leading cause of death in the U.S.

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 two to four hours to complete. Patients usually stay overnight in the intensive care unit and about one week in the hospital. Recovery time from open surgical repair can take up to three 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 one to three hours to complete. Patients typically stay in the hospital for only one to two days and can usually return to normal activity within six 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.

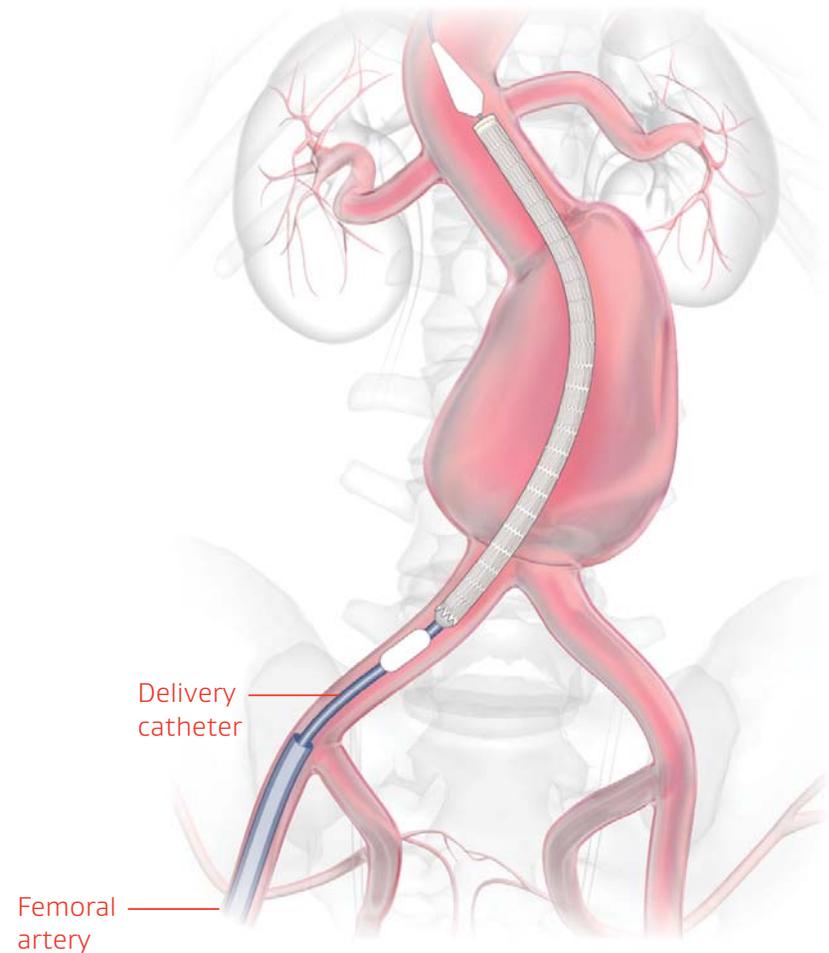
The stent graft consists of two pieces that line the aorta and extend from below the **renal** (kidneys) **arteries** into both **iliac arteries**. It is made up of ePTFE (expanded polytetrafluoroethylene) with an outer metallic support structure known as a stent.



GORE[®] EXCLUDER[®] Conformable AAA Endoprosthesis Procedure

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

The stent graft is implanted using **fluoroscopy**, real-time X-ray images, and 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. The delivery catheter is withdrawn from the body.



GORE® EXCLUDER® Conformable AAA Endoprosthesis Clinical Data Summary

The GORE® EXCLUDER® Conformable AAA Endoprosthesis clinical study was an 80-patient study conducted in the United States to assess the safety and effectiveness of the EXCLUDER® Conformable Abdominal Stent Graft. Patients enrolled in this study were followed for one year. The study met the predefined endpoints of treatment success at one year. Treatment success was defined as the ability to place the device as intended and not experience device related safety events through 30 days post procedure and effectiveness events through one year. All 79 patients evaluated for safety events at 30 days post procedure were free of a safety event (100%). Of the 66 patients evaluated for treatment success at one year, 65 had successful aneurysm treatment (98.5%). 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 GORE® EXCLUDER® Conformable AAA Endoprosthesis compares to the other EVAR devices.

One-year patient follow-up has detected the following:

- 0 out of 72 patients (0%) experienced leakage of blood around the stent graft into the aneurysm that was related to the device,
- 1 out of 73 patients (1.4%) had increases in the size of their aneurysm
- 0 out of 79 patients (0%) had removal of the stent graft and surgical placement of a vascular graft,
- 3 out of 79 subjects (3.8%) experienced major safety events including death (3)

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. No patients in the study experience occlusion/blockage of their 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 GORE® EXCLUDER® Conformable AAA Endoprosthesis may apply to you.

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 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.

The use of this device requires fluoroscopy and use of dyes for imaging. 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 and especially the calves.

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

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.

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

Impotence.

Kidney problems.

Liver problems.

Death.

Benefits

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

Some of these are:

The procedure is minimally invasive.

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.



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. These visits commonly occur at one month, six months and annually thereafter.

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

Other considerations

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

- Consult your doctor about your ability to perform strenuous physical activities.
- The stent graft is not expected to trigger any passenger screening devices, such as airport security scanners; however, consult with your doctor before traveling.
- 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 healthcare 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 healthcare 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, expanded 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

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

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