

AN ENDOVASCULAR
TREATMENT FOR
AORTOILIAC ANEURYSMS
AND COMMON ILIAC
ARTERY ANEURYSMS

Patient information



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Introduction

This brochure is intended to provide basic information about **aortoiliac aneurysms and common iliac artery aneurysms**, 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 22. 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.

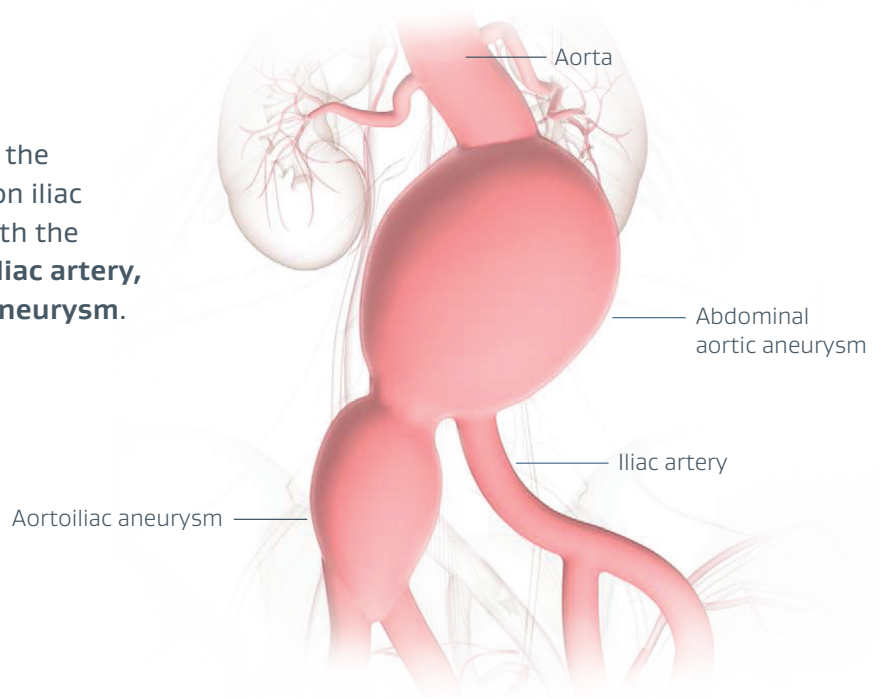
Aortoiliac aneurysm or common iliac artery aneurysm

The aorta is the largest blood vessel in the body. It carries blood away from the heart to the rest of the body. In the abdomen, the aorta splits (bifurcates) into the **iliac arteries**, which carry blood to the legs and other lower areas of the body.

An **aneurysm** is a ballooning (thinning and enlarging) of the artery caused by continuous blood pressure against a weakened area. Over time an aneurysm may grow, further weakening the wall of the artery, 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.

A **common iliac artery aneurysm** is the swelling or ballooning of the common iliac artery. When aneurysms occur in both the abdominal **aorta** and the **common iliac artery**, that is referred to as an **aortoiliac aneurysm**.



Causes

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

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

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

Abdominal aortic aneurysm (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 ever smoked and are over the age of 65. It's been reported that approximately 25 percent who have a AAA also have an aneurysm in their iliac arteries.

Symptoms

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

However, when symptoms do occur, pain is the most common and can be 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 aneurysms 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 aortoiliac aneurysm, or common iliac artery aneurysm, influences which treatment your doctor will recommend. Over time an aneurysm can cause the artery to grow to several times its normal size, which could result in a rupture. Ruptured aneurysms may be fatal, depending on location, 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 or side to repair the artery, replacing the diseased portion of the artery with a **fabric graft** that is sewn to the healthy portion of the artery. This requires stopping blood flow through the artery while the graft is sewn into place. A physician may also choose to combine an open surgical repair with an endovascular repair (see next page), which is referred to as a Hybrid repair.

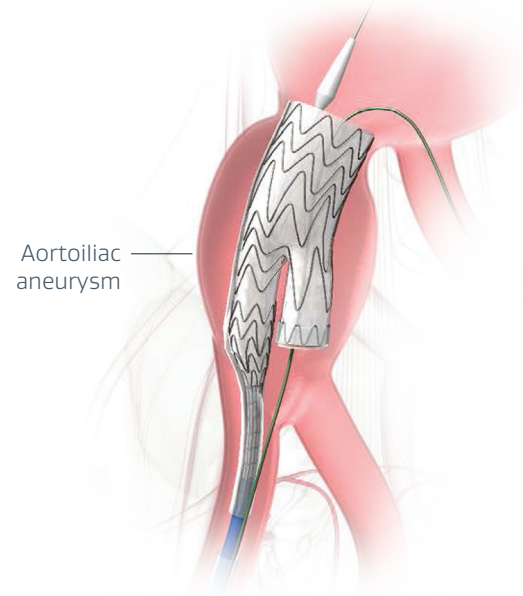
This procedure is typically performed under general anesthesia and takes about two to four hours to complete. Patients usually stay overnight in the intensive care unit, and about one week in the hospital. Recovery time from open surgical repair can take up to three months.

Endovascular repair

Endovascular repair involves sealing off the aneurysm by placing a **stent graft** inside of 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 artery 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 aortoiliac aneurysm, or common iliac artery aneurysm. Discuss the risks and benefits with your doctor to determine which option is best for you or your family member.



GORE® EXCLUDER® Iliac Branch Endoprosthesis

The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is intended to be used together with the GORE® EXCLUDER® AAA Endoprosthesis or GORE® EXCLUDER® Conformable AAA Endoprosthesis, which are grafts intended to repair an abdominal aortic aneurysm. These stent grafts consist of two pieces that line the aorta and extend from below the **renal** (kidneys) **arteries** into both iliac arteries.

The IBE is connected to one side or both sides of the EXCLUDER® AAA Endoprosthesis with another stent graft.

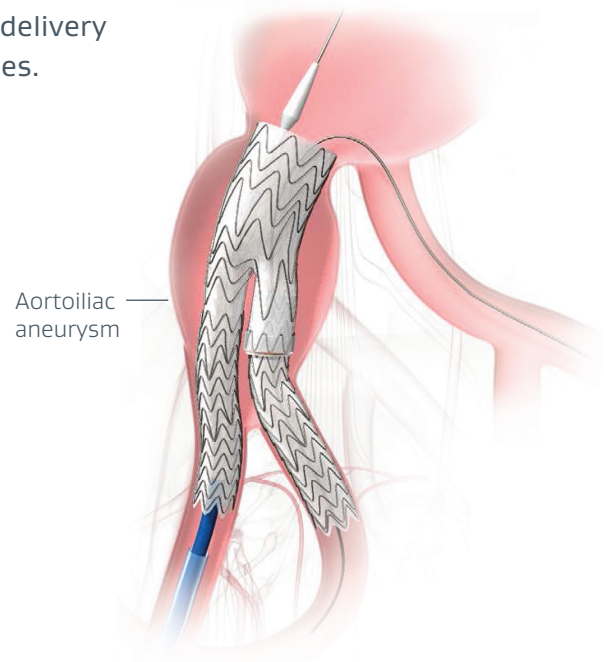
The stent grafts are made of ePTFE (expanded polytetrafluoroethylene) with an outer metallic support structure known as a stent.



GORE® EXCLUDER® Iliac Branch Endoprosthesis procedure

The procedure for implanting the IBE consists of the delivery of the stent grafts into the aorta and both iliac arteries.

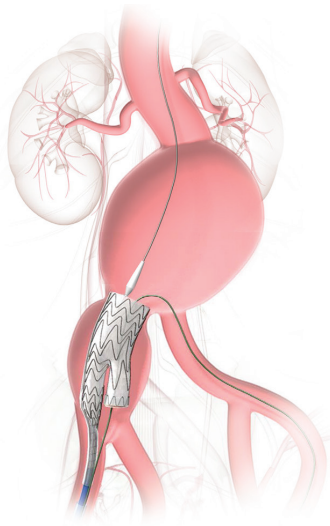
The stent grafts are implanted using **fluoroscopy**, real-time X-ray images, and is viewed on a monitor following these steps.



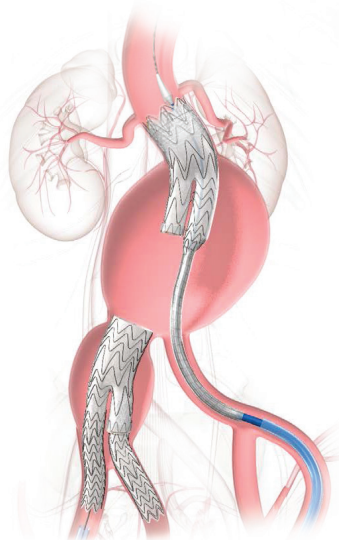
Procedure steps

1. The **delivery catheter**, which contains the stent graft, is inserted into the **femoral artery** and carefully guided up the iliac artery to the site of the aneurysm.
2. Once the stent graft is correctly positioned in the artery, it is released or deployed from the delivery catheter.
3. The device expands to the diameter of the artery. 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.

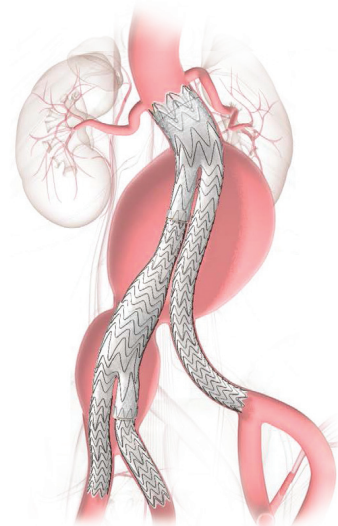
These steps are repeated for each subsequent stent graft in order to complete the procedure.



Iliac Branch Component deployment



Fully deployed IBE with initial deployment of AAA device



IBE and AAA devices fully deployed

Risks

Like open 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:

Endoleak — 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, 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.

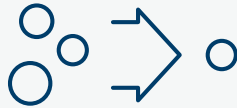
Death.

Benefits

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



The procedure is
**minimally
invasive**
compared to open
surgery and can be
performed under
local anesthesia



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® Iliac Branch 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 aortoiliac aneurysm, or common iliac artery aneurysm:

- 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

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 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.

Aortoiliac Aneurysm

An aneurysm of the aorta occurring in both the abdominal aorta and common iliac artery.

Common Iliac Artery

One of two large arteries that are the first division of the aorta, carrying blood away from the heart to the lower half of the body.

Common Iliac Artery Aneurysm

An aneurysm of the common iliac artery (can be one or both sides).

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.

Fabric graft

A synthetic graft sewn to the artery in an open surgical repair, to replace a diseased portion of the vessel.

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

Product Information on Aortoiliac and Common Iliac Artery Aneurysm

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

Together, improving life

 Consult Instructions
for Use
efu.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. R_x only

Products listed may not be available in all markets.

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W. L. Gore & Associates, Inc.
goremedical.com

Asia Pacific +65 67332882 **Australia/New Zealand** 1800 680 424 **Europe** 00800 6334 4673
United States Flagstaff, AZ 86004 800 437 8181 928 779 2771

