

*An Endovascular
Treatment for
Abdominal
Aortic Aneurysms*



Patient Information



EXCLUDER®

AAA ENDOPROSTHESIS

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This brochure has been provided as a courtesy from Gore & Associates. This brochure will help you learn more about risk factors and common symptoms as well as a less-invasive method of treating an abdominal aortic aneurysm (AAA). Whether you're trying to reduce your risk or supporting a loved one diagnosed with a AAA, we hope this information will be helpful to you and your family.

Each year approximately 200,000 new cases of **abdominal aortic aneurysms** are diagnosed.¹ Also known as a AAA, an abdominal aortic aneurysm is a bulge in the **aorta** which could **rupture** with life-threatening results. If you or a loved one has this disease, you may be seeking information on how it can be treated. This brochure describes abdominal aortic aneurysms and a relatively new way to treat them. One new treatment option is **endovascular repair** using an **endovascular graft**.

For your convenience, we have included a **Glossary of Medical Terms** on page 21 and space in this brochure on page 27 to jot down questions to discuss with your doctor. Words that are **bold** throughout the text can be found in the Glossary of Medical Terms.

This brochure is an informational and referral guide only, and is not intended to diagnose a medical condition. As with any surgery or medical procedure, the best resource for information and advice is your doctor.

1. Brewster DC. Presidential address: What would you do if it were your father? Reflections on endovascular abdominal aortic aneurysm repair. *Journal of Vascular Surgery* 2001; 33(6): 1139-47.

What is an *Abdominal Aortic Aneurysm (AAA)*?

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

The aorta is the main artery that carries oxygen-filled blood from the heart to all parts 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 (see Figure 1).

An **aneurysm** is a ballooning of the aorta which results from a weakened section in the artery that cannot support the force of blood flow (see Figure 2). Although an aneurysm can occur in any artery of the body, it is most common in the abdominal aorta and the iliac arteries. While the aorta's diameter normally ranges from $\frac{3}{4}$ -inch to 1-inch, an aneurysm can cause it to grow to several times its normal size. This condition, if not treated, could result in a **rupture** (bursting) of the aorta. The risk of rupture increases with aneurysm size and high blood pressure. Ruptured aneurysms are frequently fatal and are a leading cause of death in the US.

Figure 1

The aorta is the main artery that carries oxygen-filled blood from the heart. It is the largest artery in the body, extending from the chest to the abdomen where it then branches into the iliac arteries.

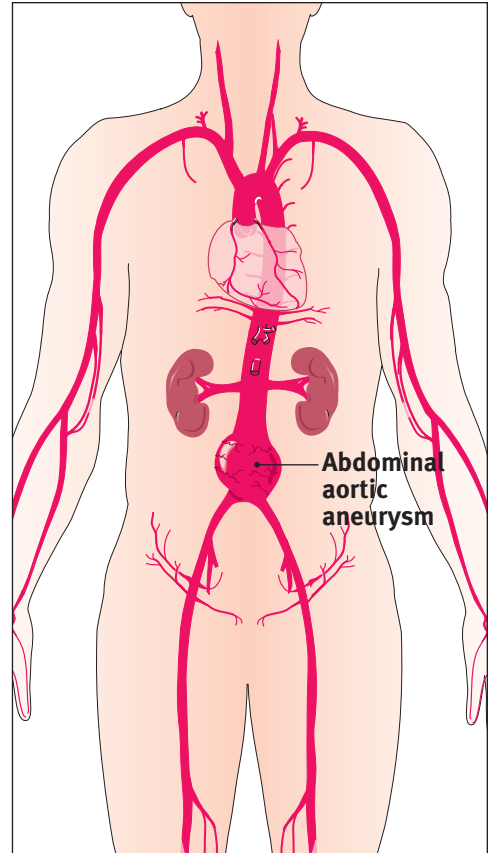
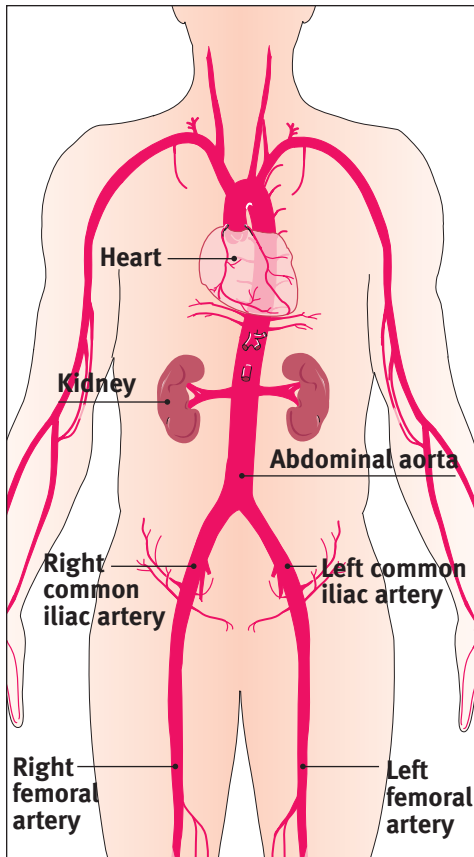


Figure 2

An aneurysm is the ballooning of the abdominal aorta. The weakened sections of the aortic wall are unable to support the force of blood flow over time.

What are Some of the Symptoms of an *Abdominal Aortic Aneurysm (AAA)*?

Many people do not experience any symptoms of a **AAA**. Because of this, it is very important to speak with your doctor about your risk of having or developing AAA disease. When symptoms do occur, pain is most commonly experienced. This can occur in the abdomen, back or chest area. Some patients describe the pain as anything from a mild pain to a severe pain or tenderness in the mid or upper abdomen or lower back. Other patients can feel the **aneurysm** as a pulsating or throbbing mass in their abdomen. Again, many people may not experience any of these symptoms, yet still be found to have a AAA.

Your doctor may discover a AAA during a routine physical exam. Your doctor may feel a bulge or pulsation (throbbing) in your abdomen. Most often, aneurysms are found during a medical test such as a **CT Scan** (also known as Computed Tomography or CAT Scan) or **ultrasound**.



Your doctor may also recommend an **angiogram** (see Figure 3), or additional testing such as **MRI** (Magnetic Resonance Imaging), or **IVUS** (Intravascular Ultrasound) to determine the precise location, size and shape of the aneurysm and your surrounding arteries.

Figure 3

An angiogram of an abdominal aortic aneurysm.

What Causes an *Abdominal Aortic Aneurysm (AAA)?*

Over time, the 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 **abdominal aortic aneurysm**.

Continuous blood pressure against this weakened area can result in the ballooning (enlarging and thinning) of the aortic artery.

Risk factors for developing an **aneurysm** include heredity (family history), smoking, heart disease, high blood pressure, and poor diet. Most doctors will advise simple preventative measures such as keeping your blood pressure under control, quitting smoking, and reducing cholesterol in your diet. These lifestyle changes could also aid in preventing further problems in the future.

If you are at risk for developing an aneurysm, your doctor may recommend periodic screening. This is commonly done with a simple physical exam and possibly **CT Scan** or **ultrasound**. Your doctor may also prescribe medication to lower your blood pressure.

How Do Doctors Treat an *Abdominal Aortic Aneurysm (AAA)*?

The size and location of the **abdominal aortic aneurysm**, and your general health, will determine how your **aneurysm** should be treated. When the aneurysm is small, your doctor may only recommend periodic check-ups to monitor the aneurysm. However, a larger, or rapidly growing (expanding) aneurysm poses more risk of bursting (**rupture**), and as such, may require treatment.

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



When Treatment Becomes Necessary, *What are My Treatment Options?*

▶ OPEN SURGICAL REPAIR

Open surgical repair has been the traditional choice to treat **abdominal aortic aneurysms**. During this type of operation, the doctor makes an incision (cut) in the abdomen or side of the patient and repairs the **aorta** by replacing the diseased section (**aneurysm**) with a **synthetic graft** (tube) that is sewn into place with suture. This procedure requires stopping the flow of blood through the aorta while the graft is being put into place. Open surgical repair is typically performed under general anesthesia and takes about 2 to 4 hours to complete. Patients usually stay overnight in the intensive care unit and another 5 to 7 days in the hospital. Depending on how quickly your body heals, hospitalization and recovery time may take about 3 months.

Although open repair is a proven medical procedure, not all patients can tolerate this major operation. Ask your doctor about the risks associated with an open procedure as they relate to your overall health condition.

▶ **ENDOVASCULAR REPAIR**

Endovascular repair is a relatively new procedure for the treatment of abdominal aortic aneurysms. Less invasive than open surgery, it involves excluding (sealing off) the aneurysm by placing an **endovascular graft** inside of the diseased aorta, making a new path for the blood to flow. The endovascular graft (GORE EXCLUDER® AAA Endoprosthesis) remains inside the aorta permanently through the use of metal prongs, or anchors, as well as a tight fit (radial force) against the wall of the aorta. Endovascular repair may be performed under general, regional or local anesthesia while the patient remains conscious (awake) but sedated, and typically takes 1 to 3 hours to complete. Patients may have a hospital stay of only a few days and can usually return to normal activity within 6 weeks after the procedure.

This procedure does require routine, periodic follow-up visits with your doctor. Tests are performed to evaluate the procedure and monitor the success of the treatment. Please see follow-up section on page 17 for further information.

Not every patient is a candidate for endovascular repair. With this in mind, please check with your doctor to see if you are a candidate. If you would like to learn more about abdominal aortic aneurysms, types of therapy, or more information about the GORE EXCLUDER® AAA Endoprosthesis, visit the websites listed on page 25.

What is the *GORE EXCLUDER® AAA Endoprosthesis?*

The GORE EXCLUDER® AAA Endoprosthesis is an implantable device positioned by a **delivery catheter**. The **endovascular graft** is intended to exclude (seal off) the **aneurysm** by placing the endovascular graft inside the diseased **aorta** to make a new path for the blood to flow.

The GORE EXCLUDER® AAA Endoprosthesis is a device that allows for **endovascular repair** of an **abdominal aortic aneurysm (AAA)**. The endovascular graft is a 2-piece, bifurcated graft that lines the aorta and extends 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.

The GORE EXCLUDER® AAA Endoprosthesis is delivered to the abdominal aorta in two sections; the trunk and the contralateral leg. The trunk receives its name from the large diameter at its top region, and is placed just below the renal arteries. It also includes 1 full leg which extends into 1 iliac artery. The other piece is called the contralateral leg component because it is placed in the other iliac artery to form a complete endovascular graft. Together, these 2 pieces form a bifurcated endovascular graft (see Figures 4, 5 and 6).

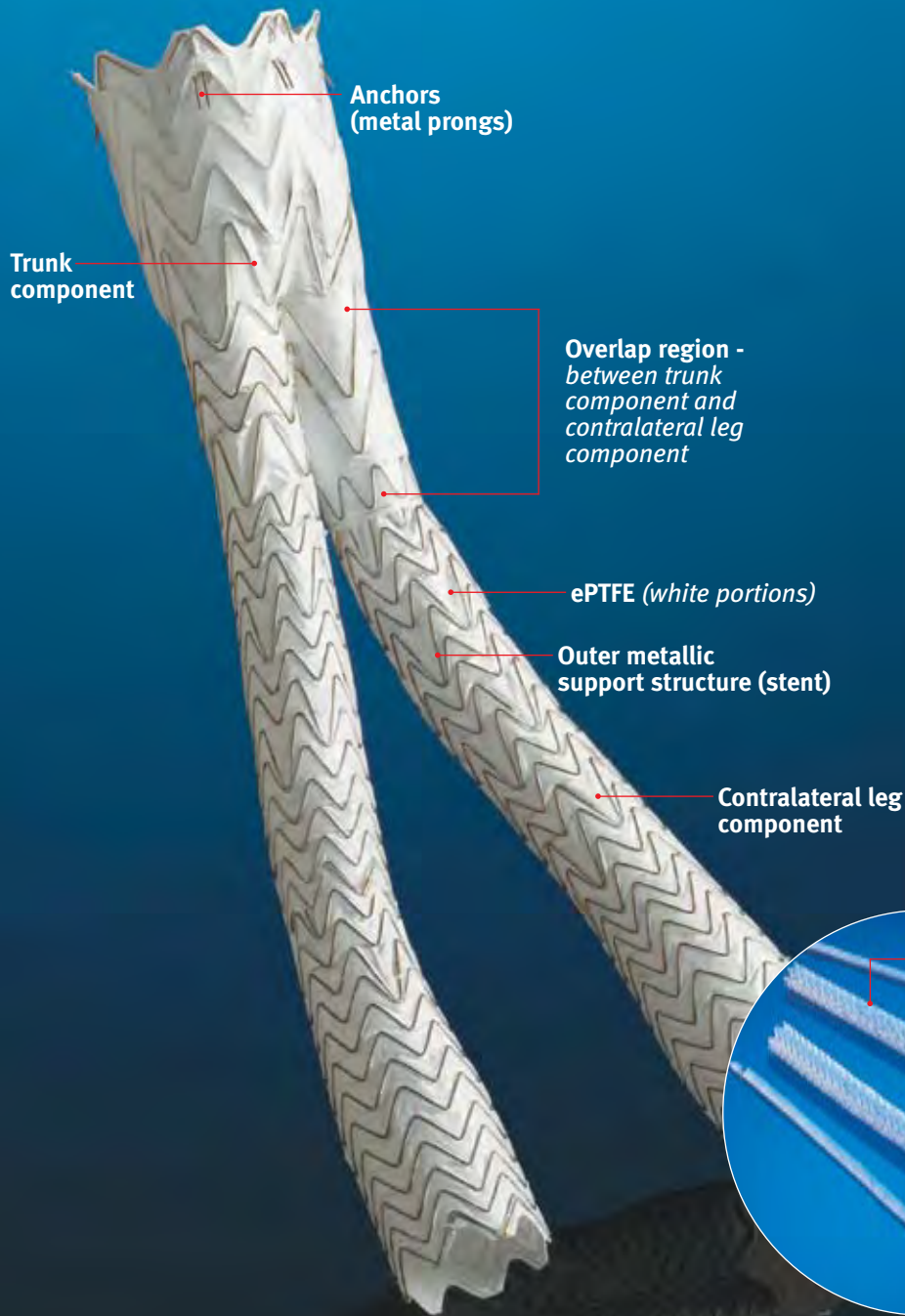


Figure 4

GORE EXCLUDER® AAA Endoprosthesis

Consists of two components:

➤ Trunk

➤ Contralateral Leg



Figure 5

Contralateral leg component - in its expanded size.
To the right is the contralateral leg component on a delivery catheter.

Trunk component - in its expanded size.
To the left is the trunk component on a delivery catheter.

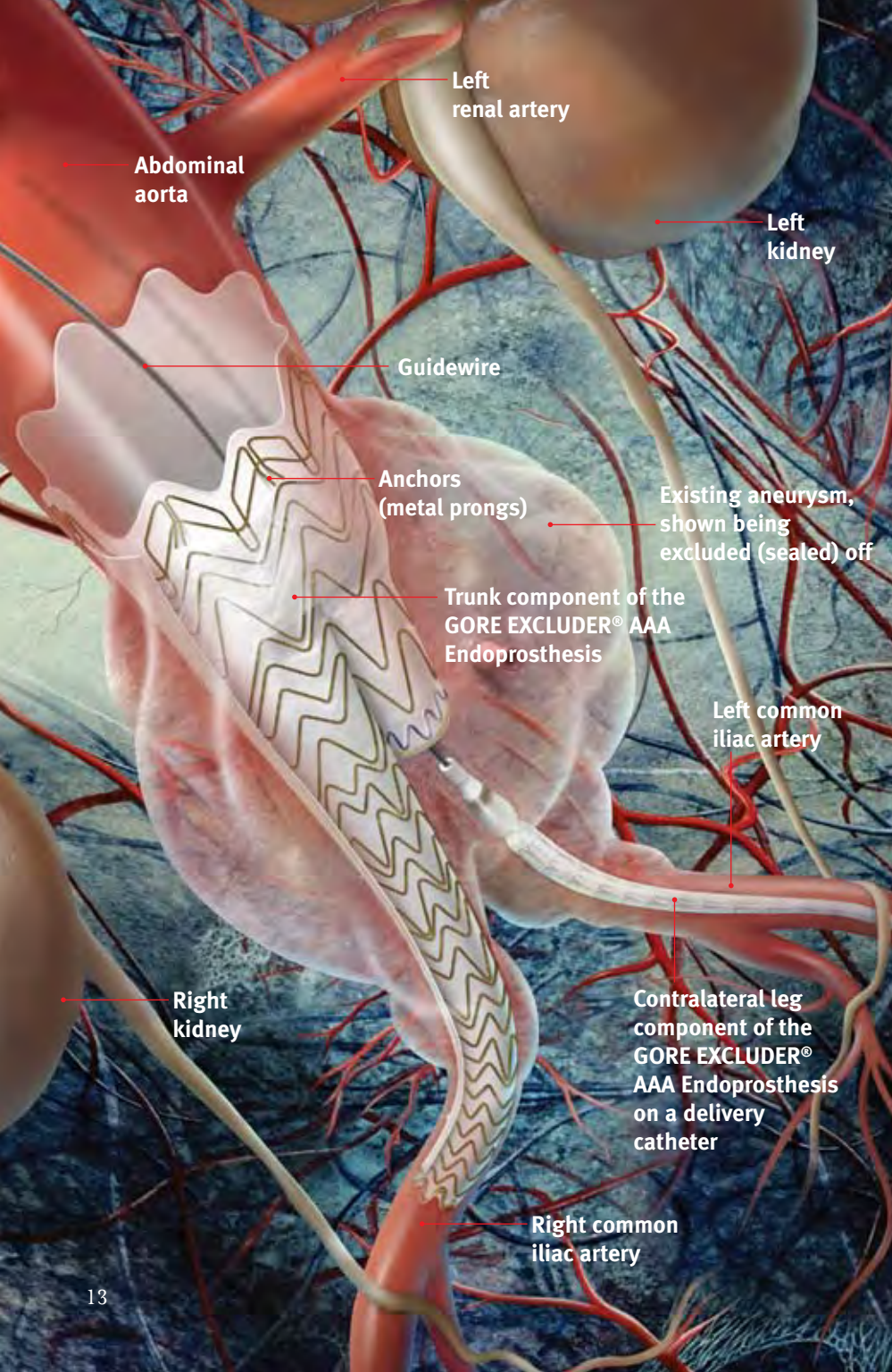


Figure 6

Artist's rendition of the delivery of a GORE EXCLUDER® AAA Endoprosthesis allowing for endovascular repair of an abdominal aortic aneurysm. The trunk component has been delivered and deployed and the contralateral leg component is being delivered from the left common artery on a delivery catheter.

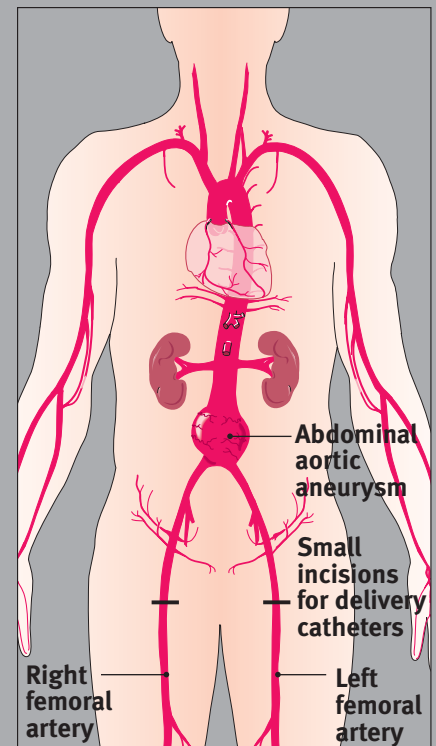
What is the *GORE EXCLUDER*[®] AAA Endoprosthesis?

Each component of the **endovascular graft**, the trunk and the contralateral leg, is compressed into the end of a long, thin, tube-like device called a **delivery catheter** and inserted separately into your bloodstream. This is accomplished by making two small incisions, or punctures, in both **femoral arteries** in the groin area (see Figure 7). For example, the trunk delivery catheter is inserted through the right femoral artery, while the contralateral leg delivery catheter is inserted through the left femoral artery (see Figure 7).

Diagnostic measurements (CT, **angiography** and **IVUS**) of the **aorta** prior to the procedure allow your doctor to visualize the **aneurysm** and your arteries to select the proper size of **endovascular graft** to fit your anatomy.

Figure 7

Insertion sites of delivery catheters for placement of a GORE EXCLUDER[®] AAA Endoprosthesis.



What is the *GORE EXCLUDER®* AAA Endoprosthesis Procedure?

The GORE EXCLUDER® AAA Endoprosthesis procedure consists of the implantation of the GORE EXCLUDER® AAA Endoprosthesis to exclude an **abdominal aortic aneurysm (AAA)**. The **endovascular graft** is implanted using **fluoroscopy** (real-time X-ray images) viewed on a monitor in these simple steps:

1. A **delivery catheter** is inserted into the **femoral artery** and carefully guided up the leg artery to the site of the abdominal aortic aneurysm.
2. Once the endovascular graft is correctly positioned in the **aorta**, it is released or deployed from the delivery catheter.
3. The device self-expands inside the aorta to the diameter of your aorta and **iliac arteries**. The placement of the endovascular graft is designed to exclude (seal off) the **aneurysm** and reline the artery wall.
4. The delivery catheter is withdrawn from the body.

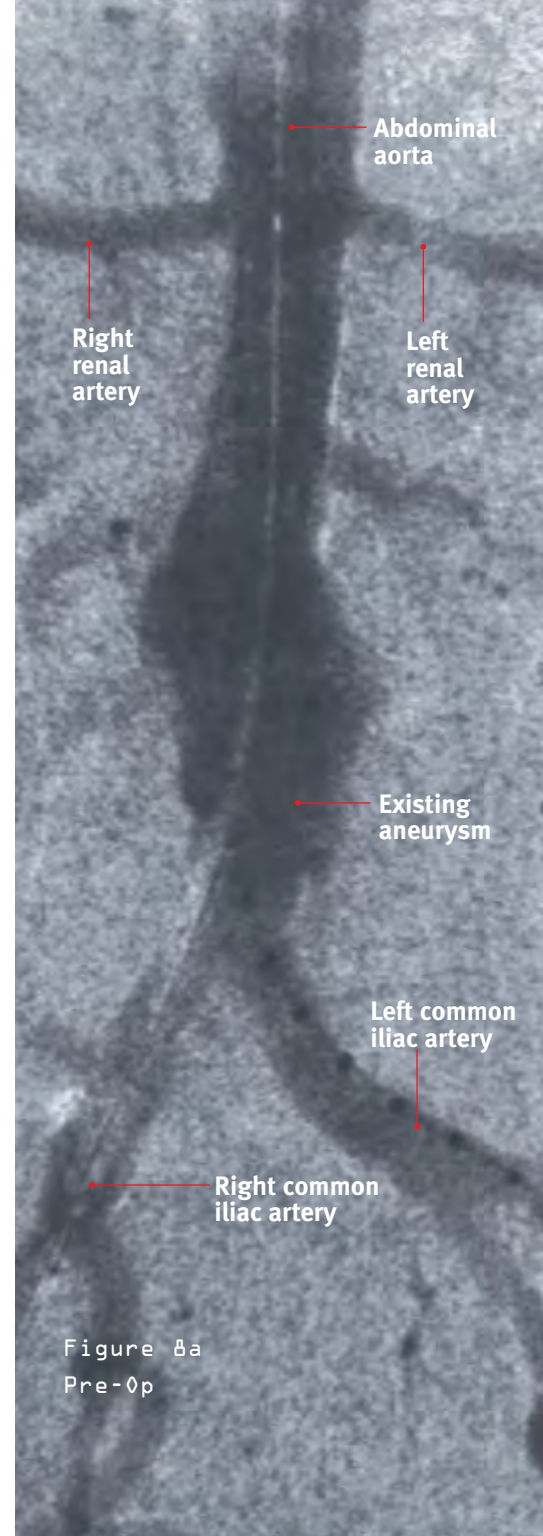


Figure 8a
Pre-op

These steps are the same for both the trunk component and contralateral leg component. At the end of the procedure, your doctor will confirm the position of the device and exclusion of blood flow to the aneurysm by using X-ray **angiography** (see Figures 8a and 8b). The doctor will then be able to determine whether the aneurysm has been successfully excluded before closing up the incision in each leg with a few sutures.

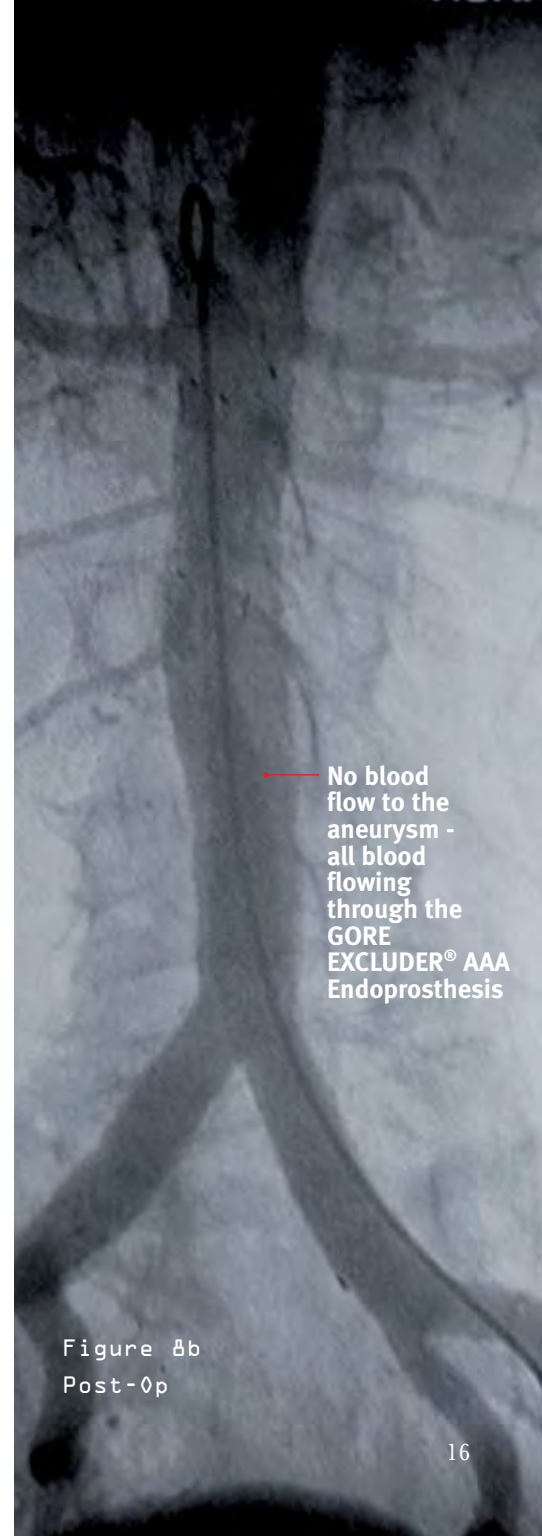


Figure 8b
Post-Op

What Follow-Up Evaluations Will I Have?

Currently, follow-up is advised to include check-ups at 1 month, 6 months and annually thereafter. It is very important that you go to all follow-up visits recommended by your doctor.

The follow-up exams will consist of routine X-rays, **CT Scans** (Figures 9 and 10) and a physical exam. The exams may also include blood tests, and **ultrasound** or **MRI Scans** if other imaging methods are necessary.

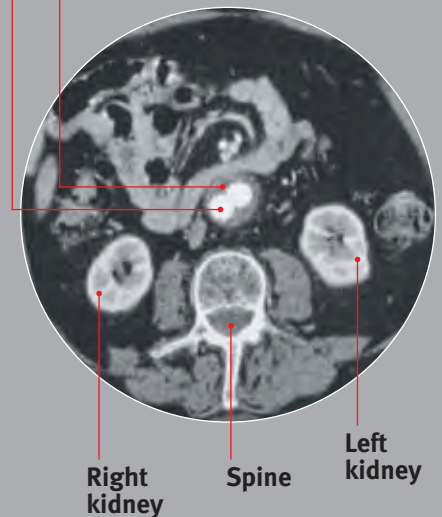
These follow-up exams carry some minimal risk. However, the benefits of these tests clearly outweigh any potential risks. There is a rare risk of allergic reactions related to the **contrast dye** used in these CT Scans. Please ask your doctor if you have any concerns regarding these tests and exams.

Figure 9

A CT Scan of an abdominal aortic aneurysm with a GORE EXCLUDER® AAA Endoprosthesis.

Blood (white) flows through the endoprosthesis

Cross-sectional view of the endoprosthesis legs excluding (sealing off) blood flow to the shrinking aneurysm



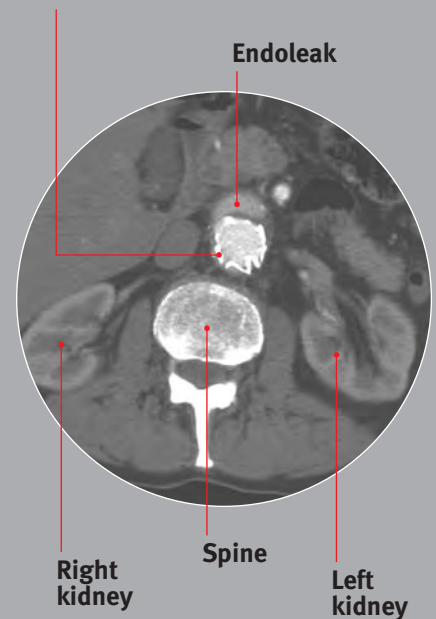
These tests and exams are performed because they are necessary in evaluating the outcome of your treatment and any changes over time. Your doctor may also request additional evaluations based on findings at the follow-up visits. These may include finding a return of blood flow in the **aneurysm** (Figure 10) and/or growth of the aneurysm.

This type and frequency of follow-up visits is generally not required after open surgical repair.

Figure 10

Follow-up angiogram showing an endoleak.

Cross-sectional view of the trunk component with blood flow



When Should I *Call My Doctor?*

The long-term safety and effectiveness of **endovascular repair** has not been established.

Some patients may require additional treatment for conditions such as:

Endoleak – An endoleak occurs when blood from the **aorta** continues to leak into the abdominal **aneurysm**. While most endoleaks do not cause any medical problem, a small number require additional treatment.

Aneurysm growth or rupture – Symptoms of aneurysm growth are not always present, but when they are, the most common symptom is pain, also numbness, weakness in the legs, back, chest, or abdomen. 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 or coolness of the leg.



Patient Counseling Information

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

- Risks and differences between endovascular repair and open surgical repair.
- 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.

In such cases, your doctor may recommend outpatient procedures and/or surgery.

As with any surgery or medical procedure, there are potential complications with the treatment of an **abdominal aortic aneurysm (AAA)**. Discuss the risks and benefits with your doctor, and refer to this brochure for basic information.

Contact your doctor immediately if you should experience any symptom potentially associated with your abdominal aortic aneurysm. Remember, symptoms are not always present, but when they are, the most common symptom is pain, occurring in the abdomen, back or chest area, or tenderness in the mid or upper abdomen, lower back or side.



Glossary of Medical Terms



Aorta

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

Abdominal Aortic Aneurysm (AAA)

A ballooning (enlarging and thinning) of the aorta due to a weakening in the arterial wall that occurs in the abdomen area. This term is often abbreviated as "AAA".

Aneurysm

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

Angiography/Angiogram

A method whereby dye is injected into the bloodstream to view blood flow through the blood vessels under X-ray. Utilizes contrast (dye) and small **radiation** exposure. The resulting image is an angiogram.

Contrast (dye)

A drug injected into the vascular system to show blood flow through the blood vessels on the X-ray image.

CT Scan (Computed Tomography Scan)

An imaging technique that creates very precise, thin, cross-sectional views of your abdomen and aorta. This technique often utilizes contrast (dye) and small radiation exposure. Also known as a CAT scan.

Delivery Catheter

A long, thin, tube-like tool that assists in the positioning and delivering of an endovascular graft through the vascular system.

Endoleak

Blood flow into the abdominal aortic aneurysm after placement of an endovascular graft.

Endovascular Graft

A synthetic graft implanted within a diseased vessel intended to relieve weakened vessel walls without the use of open surgery techniques.

Endovascular grafts are delivered to the diseased aorta at a small size and then are deployed or expanded to the size of the vessels in which it is placed.

Endovascular Repair

Considered to be less invasive than open surgery, it involves the use of an endovascular graft to exclude (seal off) an aneurysm inside a diseased aorta, making a new path for blood to flow.

Endovascular Treatment

The use of real time X-rays and guidewires to treat unhealthy arteries with small incisions in the femoral arteries.

Femoral Arteries

Two arteries located in each leg which carry blood to the femur or thigh region of each leg. Doctors gain access to the iliac arteries and the aorta through the use of the femoral arteries (see Figure 1).

Fluoroscopy

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

Guidewire

Long, flexible wire that is placed in an artery to track a delivery catheter and other endovascular accessories to implant an endovascular graft.

Iliac Arteries

Two arteries that deliver blood to the legs and connect the aorta to the femoral arteries in each leg. The iliac arteries begin from the bifurcation (separation) of the aorta which occurs in your abdomen.

IVUS (Intravascular Ultrasound)

An ultrasound probe on a delivery catheter placed inside your arteries to see the vessel walls and measure diameters and lengths of your arteries.

MRI (Magnetic Resonance Imaging)

A procedure using magnetic fields and radio waves to form an image of structures inside the body.

Occlusion

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

Radiation

A form of energy that allows your doctor to see blood vessel structures and other anatomy inside your body.

Renal Arteries

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

Rupture

A tear in the vessel wall near or at the location of the ballooning (enlarging and thinning) of the weakened area of the blood vessel allowing blood to spill into the peritoneal cavity (hemorrhage).

Synthetic Graft

A man-made material in tube form intended to replace diseased human vessels.

Ultrasound

An image created through the use of high-frequency sound waves.

Where Can I Get More Information?

Aneurysms

Background Information on Abdominal Aortic Aneurysms

American Heart Association

www.americanheart.org

Founded in 1924, today the American Heart Association is the largest voluntary health organization fighting cardiovascular diseases and stroke.

Mayo Clinic

www.mayoclinic.com

MayoClinic.com is the latest chapter in a long and successful consumer health publishing history of the Mayo Clinic. This presence on the Web is a natural extension of Mayo's long-standing commitment to provide health education to patients and the general public.

Interventional Therapy

Society of Interventional Radiology

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 scientific organization deeply committed to its mission to improve health and the quality of life through the practice of cardiovascular and interventional radiology.

US National Library of Medicine

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

W. L. Gore & Associates, Inc.

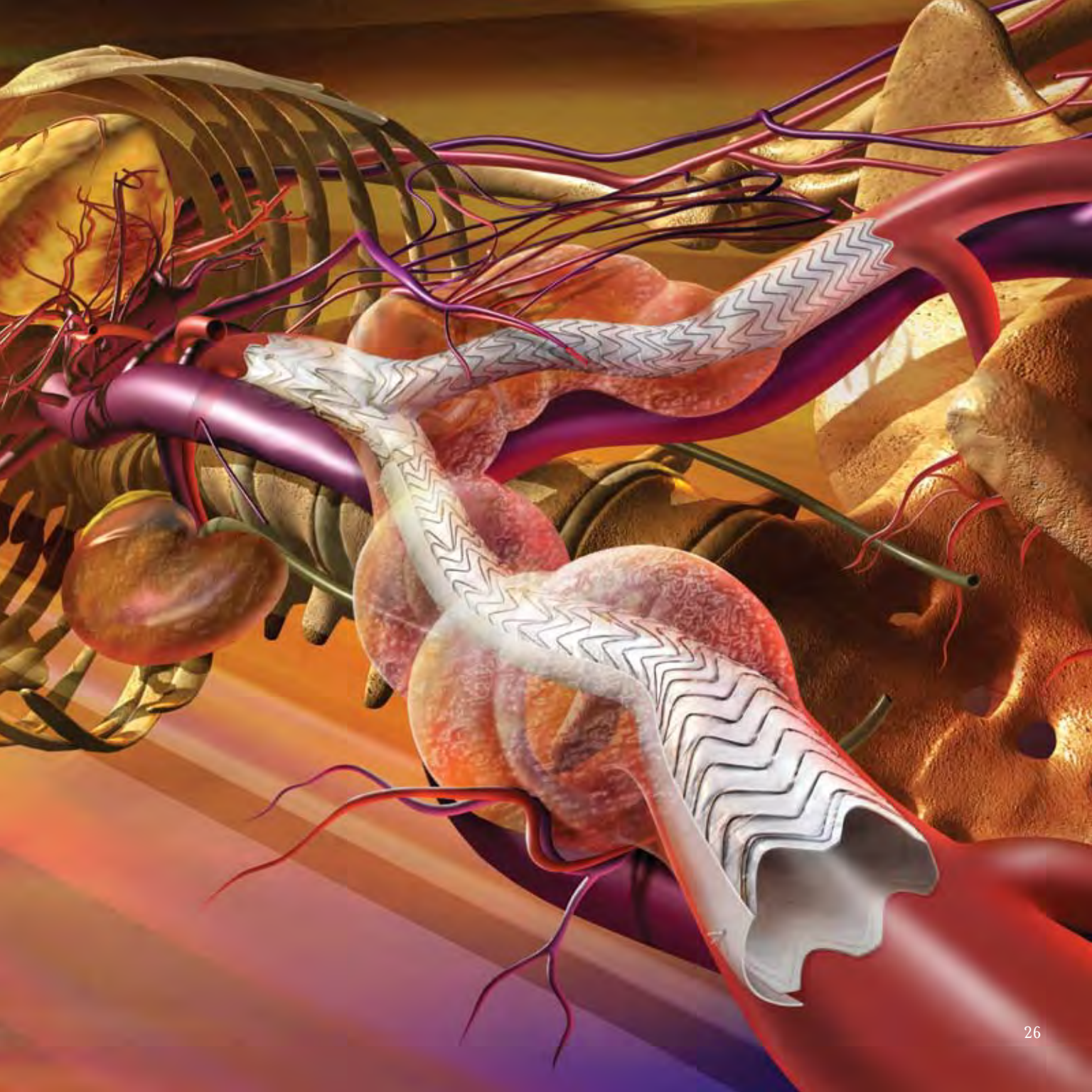
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US Department of Health and Human Services Food and Drug Administration

www.fda.gov

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Questions
for My Doctor —

Questions
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W. L. GORE & ASSOCIATES, INC.

Medical Products Division
Flagstaff, Arizona 86004

800.528.8763 (US)
00800.6334.4673 (EU)

goremedical.com

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