

Patient Information

An Endovascular Treatment
for Aortoiliac Aneurysms
and Common Iliac Artery
Aneurysms



EXCLUDER®

ILIAC BRANCH
ENDOPROSTHESIS



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This brochure has been provided as a courtesy from W. L. 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 **aortoiliac aneurysm** or **common iliac artery aneurysm**. Whether you're trying to reduce your risk or supporting a loved one diagnosed with an **aortoiliac aneurysm** or **common iliac artery aneurysm**, 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. In approximately 15–40% of patients with AAA, the **aneurysm** extends into at least one of the common **iliac arteries**.² These are referred to as **aortoiliac aneurysms**. Additionally, the **aneurysm** may be isolated to the common iliac artery, which are referred to as **common iliac artery aneurysms**. If you or a loved one has this disease, you may be seeking information on how it can be treated. This brochure describes **aortoiliac aneurysms** and **common iliac artery aneurysms** and **endovascular repair** using an **endovascular graft**.

For your convenience, we have included a Glossary of Medical Terms on page 25 and space in this brochure on page 30 to jot down questions to discuss with your doctor.

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.

² Kirkwood ML, Saunders A, Jackson BM, Wang GJ, Fairman RM, Woo EY. Aneurysmal iliac arteries do not portend future iliac aneurysmal enlargement after endovascular aneurysm repair for abdominal aortic aneurysm. *Journal of Vascular Surgery* 2011;53(2):269-273.



What is an Aortoiliac Aneurysm or Common Iliac Artery Aneurysm?

An **aortoiliac aneurysm** or **common iliac artery aneurysm** is the swelling or ballooning of the abdominal **aorta** and **common iliac artery** or the **common iliac artery** alone.

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 dilation of the artery 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**. An **aneurysm** can cause these blood vessels to grow to several times their normal size. This condition, if not treated, could result in rupture (bursting) of the artery. The risk of rupture increases with **aneurysm** size and high blood pressure. Ruptured **aneurysms** are frequently fatal and are a leading cause of death.³

³ Kochanek KD, Xu J, Murphy SL, Miniño AM, Kung HC. Deaths: final data for 2009. *National Center for Health Statistics* 2011;60(3):1-116.

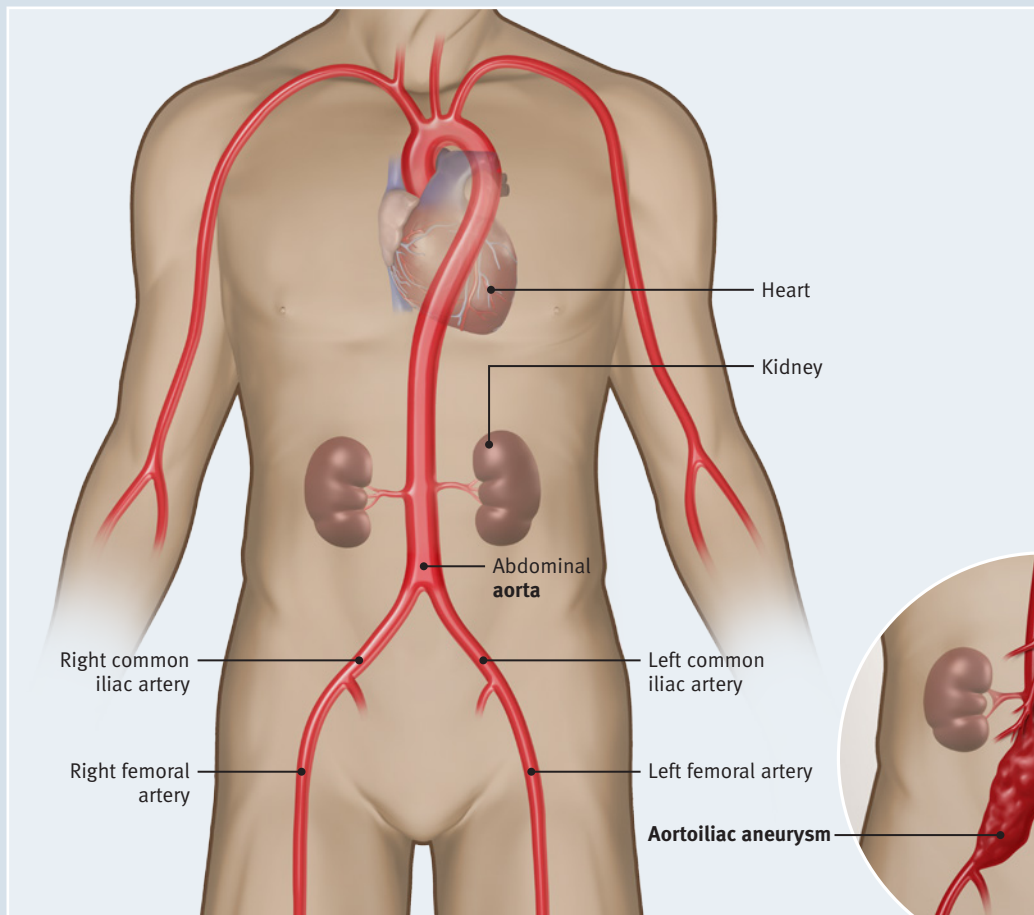


Figure 1

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**.

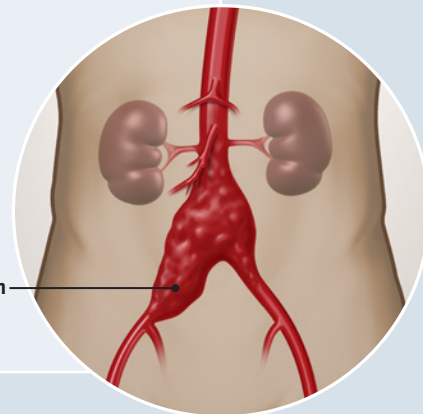


Figure 2

An **aneurysm** is the ballooning of an artery, such as the **aorta** or common iliac artery. The weakened sections of the artery wall are unable to support the force of blood flow over time and may rupture (burst).

What are Some of the Symptoms of an Aortoiliac Aneurysm or Common Iliac Artery Aneurysm?

Many people do not experience any symptoms of an **aortoiliac aneurysm** or **common iliac artery aneurysm**. Because of this, it is very important to speak with your doctor about your risk of having or developing an **aortoiliac aneurysm** or **common iliac artery aneurysm**. 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.

Your doctor may discover an **aortoiliac aneurysm** or **common iliac artery aneurysm** during a routine physical exam. Your doctor may feel a bulge or pulsation (throbbing) in your abdomen. **Aneurysms** may be 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**, 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.





What Causes an Aortoiliac Aneurysm or Common Iliac Artery Aneurysm?

Over time, the 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**. 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. Doctors may 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 done with a simple physical exam and possible **CT Scan** or **ultrasound**.

How Do Doctors Treat an Aortoiliac Aneurysm or Common Iliac Artery Aneurysm?

The size and location of the **aortoiliac aneurysm**, or **common iliac artery 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.⁴

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

⁴ Brown PM, Zelt DT, Sobolev B. The risk of rupture in untreated aneurysms: the impact of size, gender, and expansion rate. *Journal of Vascular Surgery* 2003;37(2):280-284.





When Treatment Becomes Necessary,

What are My Treatment Options?

OPEN SURGICAL REPAIR

During this type of operation, the doctor makes an incision (cut) in the abdomen or side of the patient and repairs the **blood vessel** 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 **blood vessel** while the graft is being put into place. Open surgical repair 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 another five to seven days in the hospital. Depending on how quickly your body heals, your recovery time may take about three 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 procedure for the treatment of **aortoiliac aneurysm** and **common iliac artery aneurysm**. 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® Iliac Branch Endoprosthesis and 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 one to three hours to complete. Patients may have a hospital stay of only a few days and can usually return to normal activity within six 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 20 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 **aortoiliac aneurysm, common iliac artery aneurysm**, types of therapy, or more information about the GORE® EXCLUDER® Iliac Branch Endoprosthesis and GORE® EXCLUDER® AAA Endoprosthesis, visit the websites listed on page 29.



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 two-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 one full leg which extends into one 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 two pieces form a bifurcated **endovascular graft** (see *Figures 4 and 6*).

What is the GORE® EXCLUDER® Iliac Branch Endoprosthesis?

Similar to the GORE® EXCLUDER® AAA Endoprosthesis, the GORE® EXCLUDER® Iliac Branch Endoprosthesis is an implantable device that is intended to exclude the **aneurysm**.

The GORE® EXCLUDER® Iliac Branch Endoprosthesis is a device that allows for **endovascular repair** of **aortoiliac aneurysms** and **common iliac artery aneurysms**. The **endovascular graft** is a two-piece, bifurcated graft that lines the common iliac artery that extends into both the external and internal **iliac arteries**. The GORE® EXCLUDER® Iliac Branch Endoprosthesis is connected to one side or both sides of the GORE® EXCLUDER® AAA Endoprosthesis through the use of a bridge device.

The GORE® EXCLUDER® Iliac Branch Endoprosthesis is delivered into the common iliac artery in two sections: the Iliac Branch Component and the Internal Iliac Component. The Iliac Branch Component is placed within the common iliac artery and extends into the external iliac artery. The Internal Iliac Component is placed within the internal iliac artery.

The GORE® EXCLUDER® Iliac Branch Endoprosthesis is used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis. When being treated with the Iliac Branch Endoprosthesis, a total of four pieces form a double bifurcated **endovascular graft** (*Figures 4, 5, and 7*).

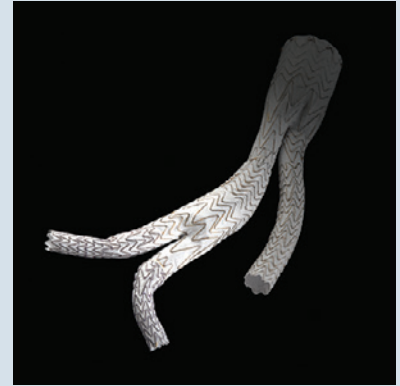
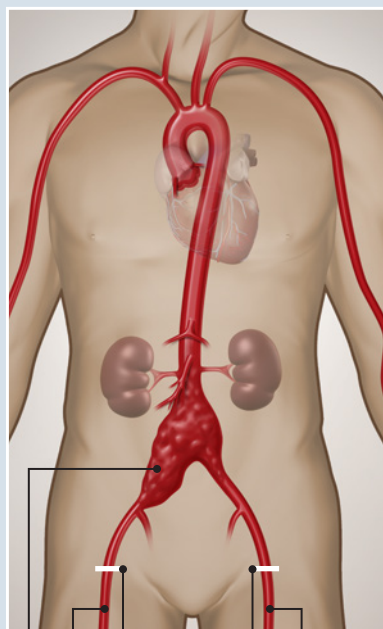


Figure 3

Insertion sites of **delivery catheters** for placement of a GORE® EXCLUDER® Iliac Branch Endoprosthesis



Aortoiliac aneurysm

What is the GORE® EXCLUDER® Iliac Branch Endoprosthesis? *(continued)*

Each component of the **endovascular graft**, the trunk, the contralateral leg (bridge), the iliac branch component, and the internal iliac component, 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 3*).

For example, if the trunk **delivery catheter** is inserted through the right femoral artery, then the contralateral leg **delivery catheter** would be inserted through the left femoral artery (see *Figure 3*).

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.

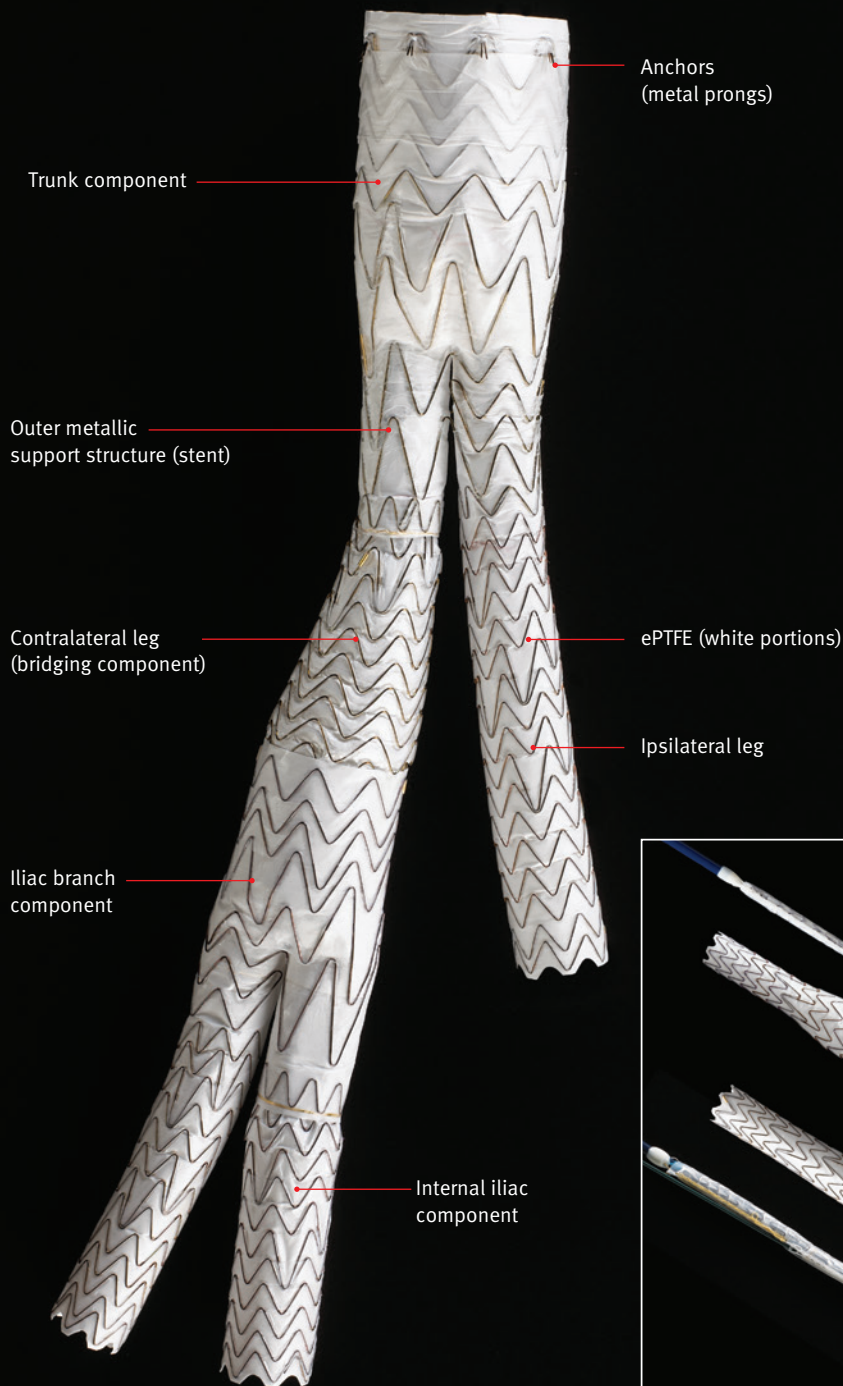


Figure 4

GORE® EXCLUDER® AAA Endoprosthesis

Consists of two components:

- Trunk
- Contralateral Leg
(bridging component)

GORE® EXCLUDER® Iliac Branch Endoprosthesis

Consists of two components:

- Iliac Branch Component
- Internal Iliac Component



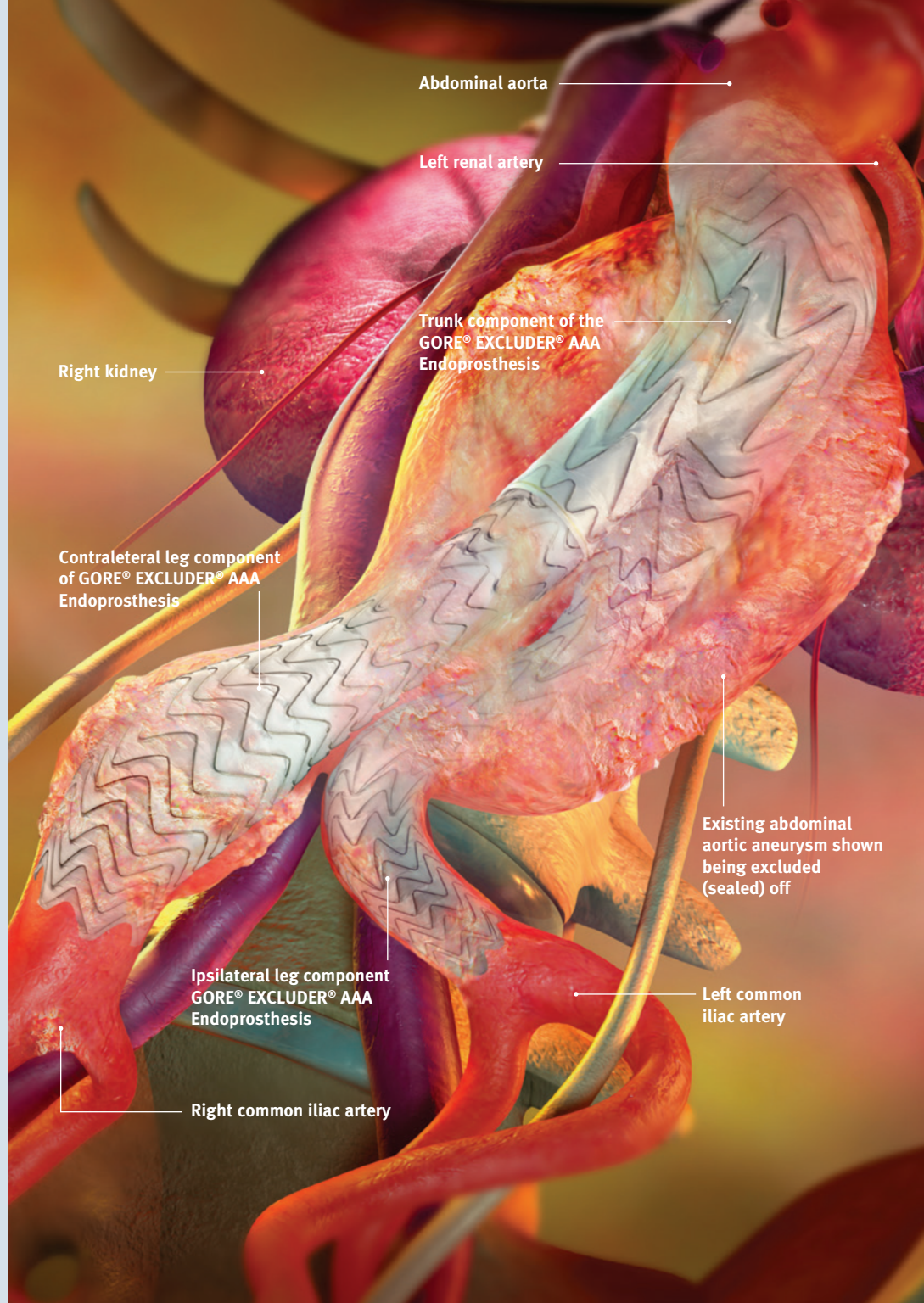
Figure 5

Internal Iliac Component — in its expanded size. Top right is the internal iliac component on a **delivery catheter**.

Iliac Branch Component — in its expanded size. Bottom left is the iliac branch component on a **delivery catheter**.

Figure 6

Artist's rendition of
a deployed GORE®
EXCLUDER® AAA
Endoprosthesis allowing
for endovascular
repair and exclusion
of an **abdominal aortic
aneurysm**.



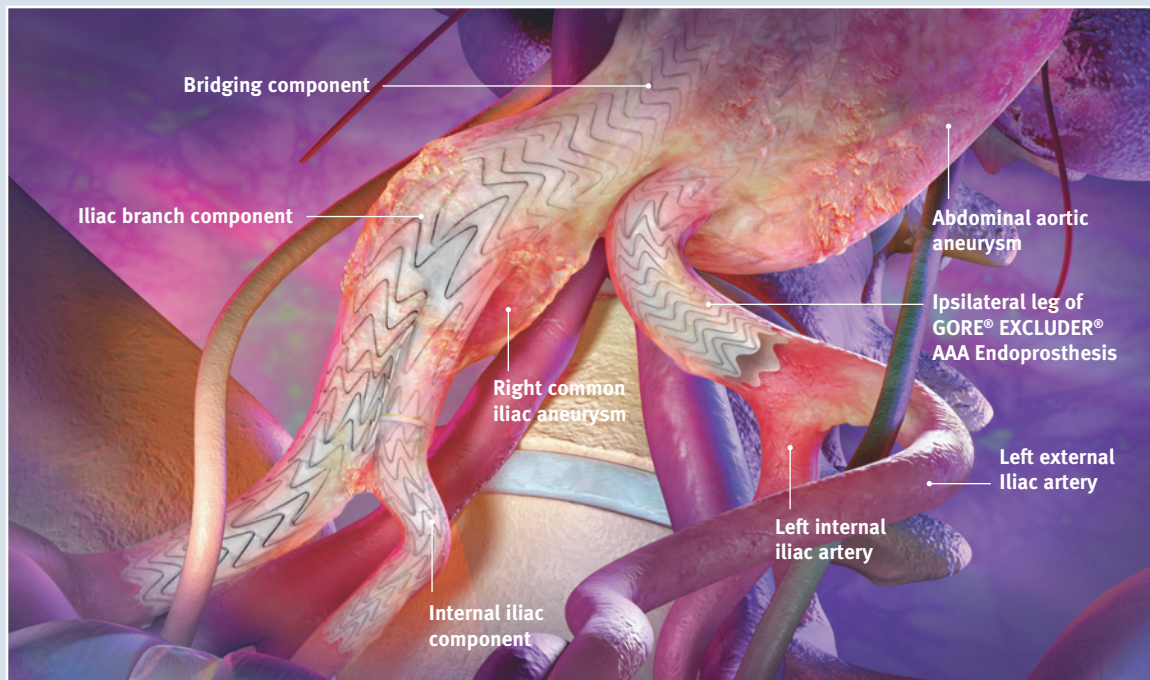
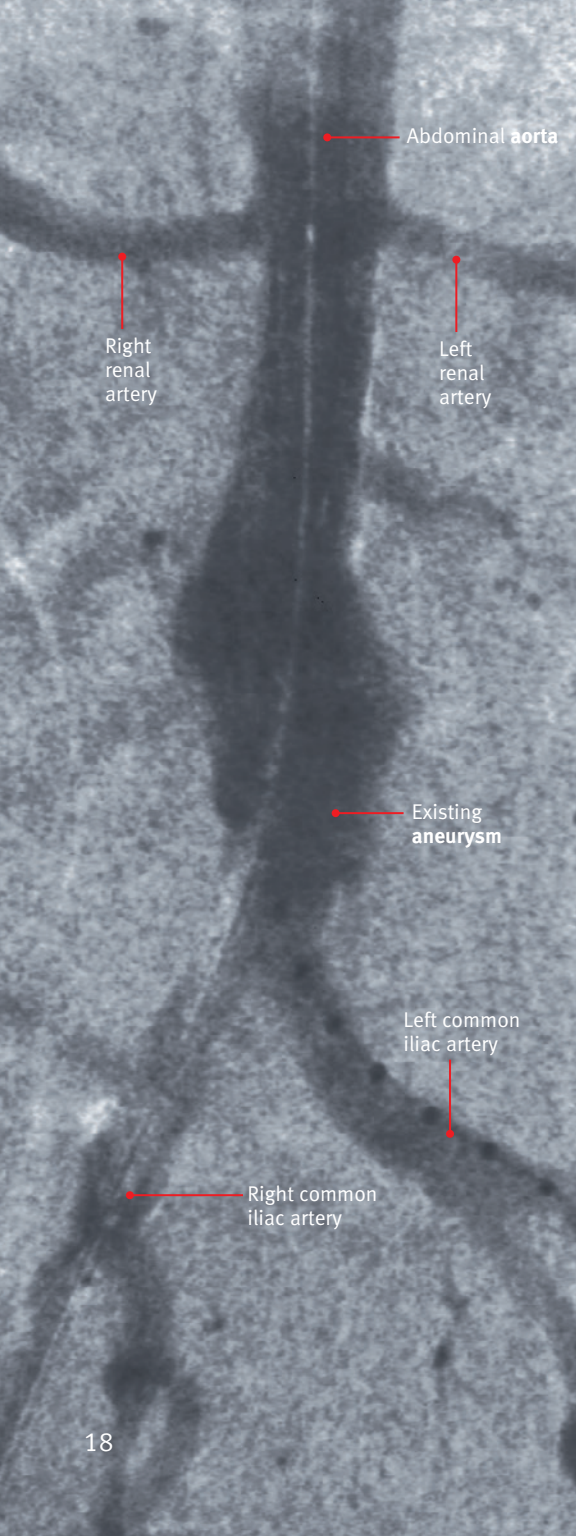


Figure 7

Artist's rendition of a deployed GORE® EXCLUDER® Iliac Branch Endoprosthesis and GORE® EXCLUDER® AAA Endoprosthesis allowing for **endovascular repair** and exclusion of an **aortoiliac aneurysm**. Both components (Iliac Branch Component and Internal Iliac Component) of the GORE® EXCLUDER® Iliac Branch Endoprosthesis have been deployed in the right **common iliac artery**. The GORE® EXCLUDER® AAA Endoprosthesis has been deployed in the abdominal **aorta** and left **common iliac artery**, with the bridging component connecting the GORE® EXCLUDER® AAA Endoprosthesis to the GORE® EXCLUDER® Iliac Branch Endoprosthesis.



What is the GORE® EXCLUDER® Iliac Branch Endoprosthesis Procedure?

The GORE® EXCLUDER® Iliac Branch Endoprosthesis procedure consists of the implantation of the GORE® EXCLUDER® Iliac Branch Endoprosthesis and the GORE® EXCLUDER® AAA Endoprosthesis to exclude an **aortoiliac aneurysm** or **common iliac artery aneurysm**. 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 **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 7a (Pre-Op)

These steps are the same for the trunk component, the contralateral leg component (bridge), the iliac branch component, and the internal iliac 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 7a and 7b*). 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 7b (Post-Op)

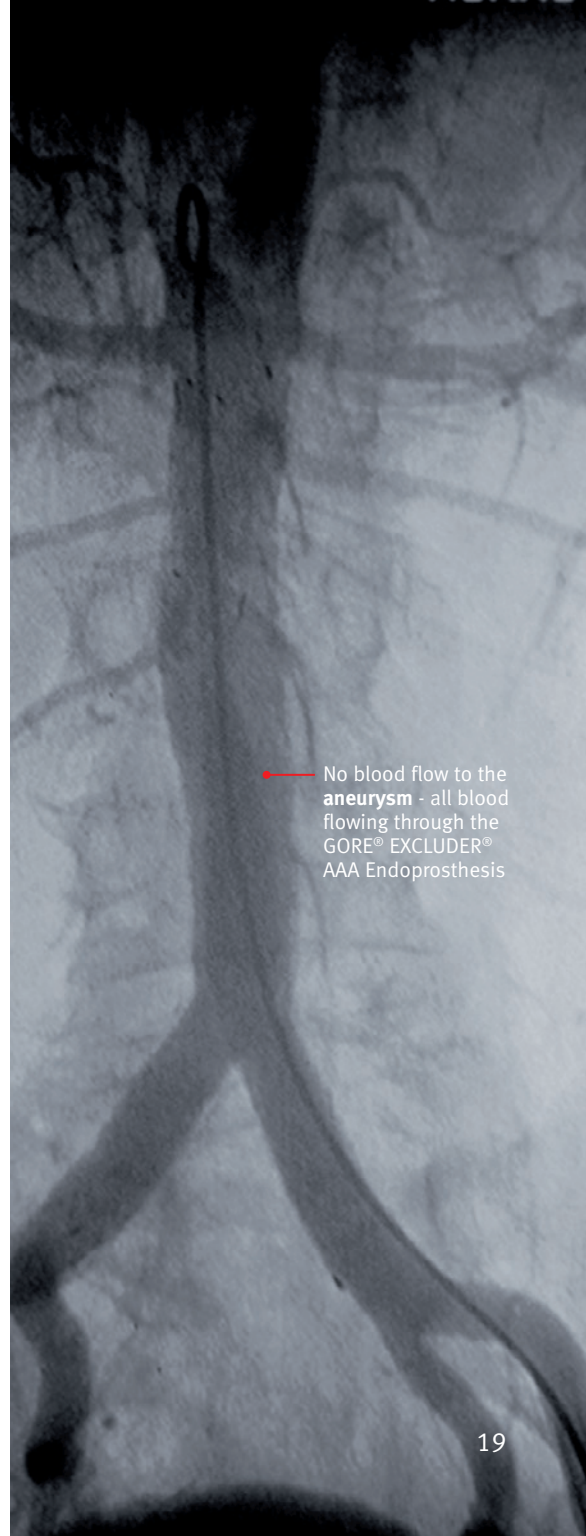
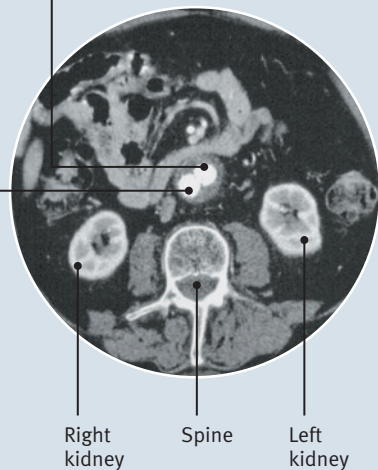


Figure 8

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**



What Follow-Up Evaluations Will I Have?

Currently, follow-up is advised to include check-ups at one month, six 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 8 and 9*) 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.^{5, 6}

There is some risk of allergic reactions related to the contrast dye used in these **CT Scans**.⁷ Please ask your doctor if you have any concerns regarding these tests and exams.

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 9) and / or growth of the **aneurysm**.

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

⁵ Prinssen M, Wixon CL, Buskens E, Blankensteijn JD. Surveillance after endovascular aneurysm repair: diagnostics, complications, and associated costs. *Annals of Vascular Surgery* 2004;18(4):421-427.

⁶ Walsh SR, Tang TY, Boyle JR. Renal consequences of endovascular abdominal aortic aneurysm repair. *Journal of Endovascular Therapy* 2008;15(1):73-82.

⁷ Pasternak JJ, Williamson EE. Clinical pharmacology, uses, and adverse reactions of iodinated contrast agents: a primer for the non-radiologist. *Mayo Clinic Proceedings* 2012;87(4):390-402.

Figure 9

Follow-up **angiogram** showing an **endoleak**.





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 **aneurysm**. While most **endoleaks** do not cause any medical problems, 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.

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 **aortoiliac aneurysm** or **common iliac artery aneurysm**. 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 **aortoiliac aneurysm** or **common iliac artery 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.

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.





Glossary

Aorta

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

Aortoiliac Aneurysm

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

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.

Common Iliac Arteries

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 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 vessel 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

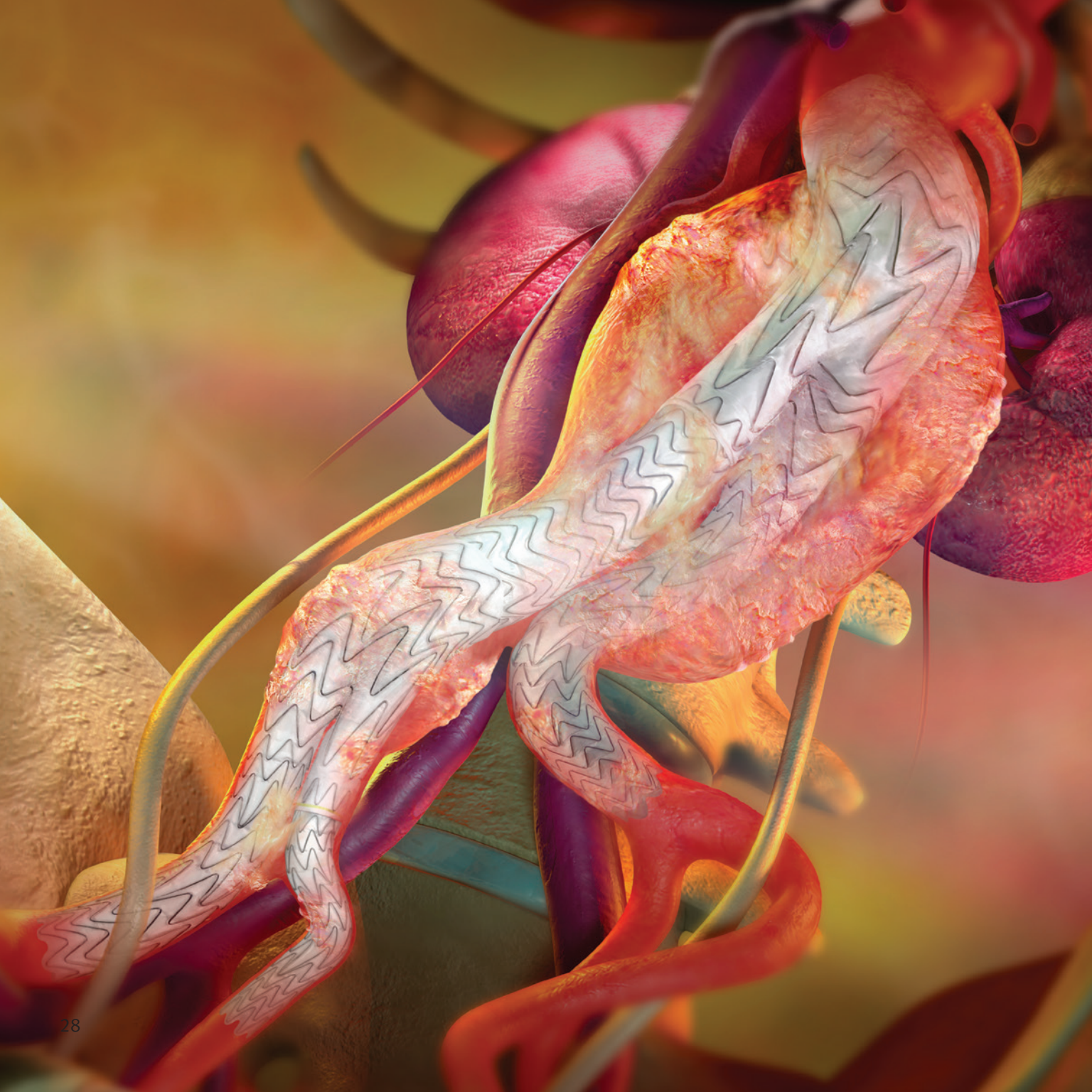
A tear in the vessel wall near or at the location of the ballooning (enlarging and thinning) of the weakened area of the blood vessel allowing blood to spill into the peritoneal cavity (hemorrhage).

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.

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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.

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