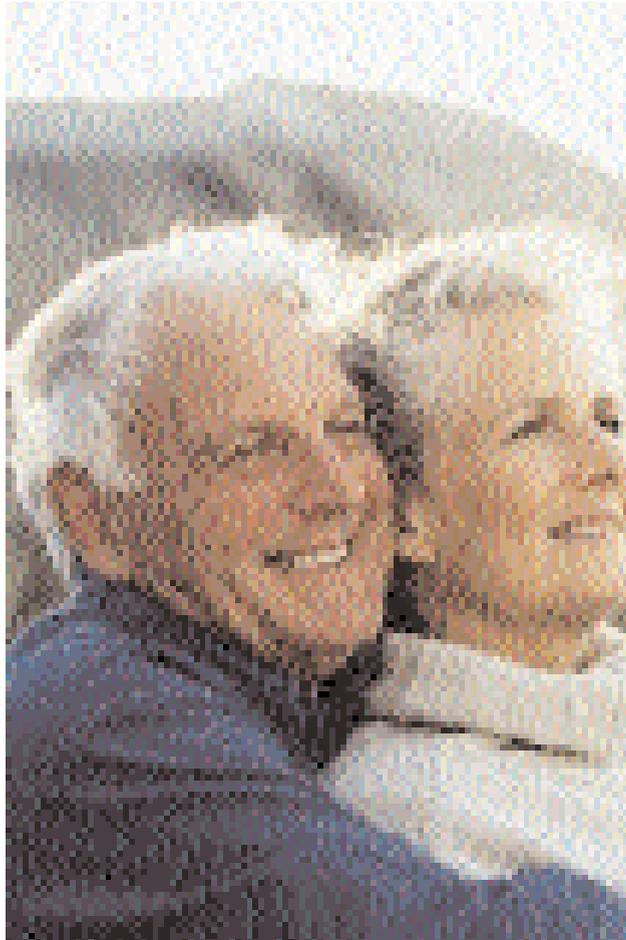


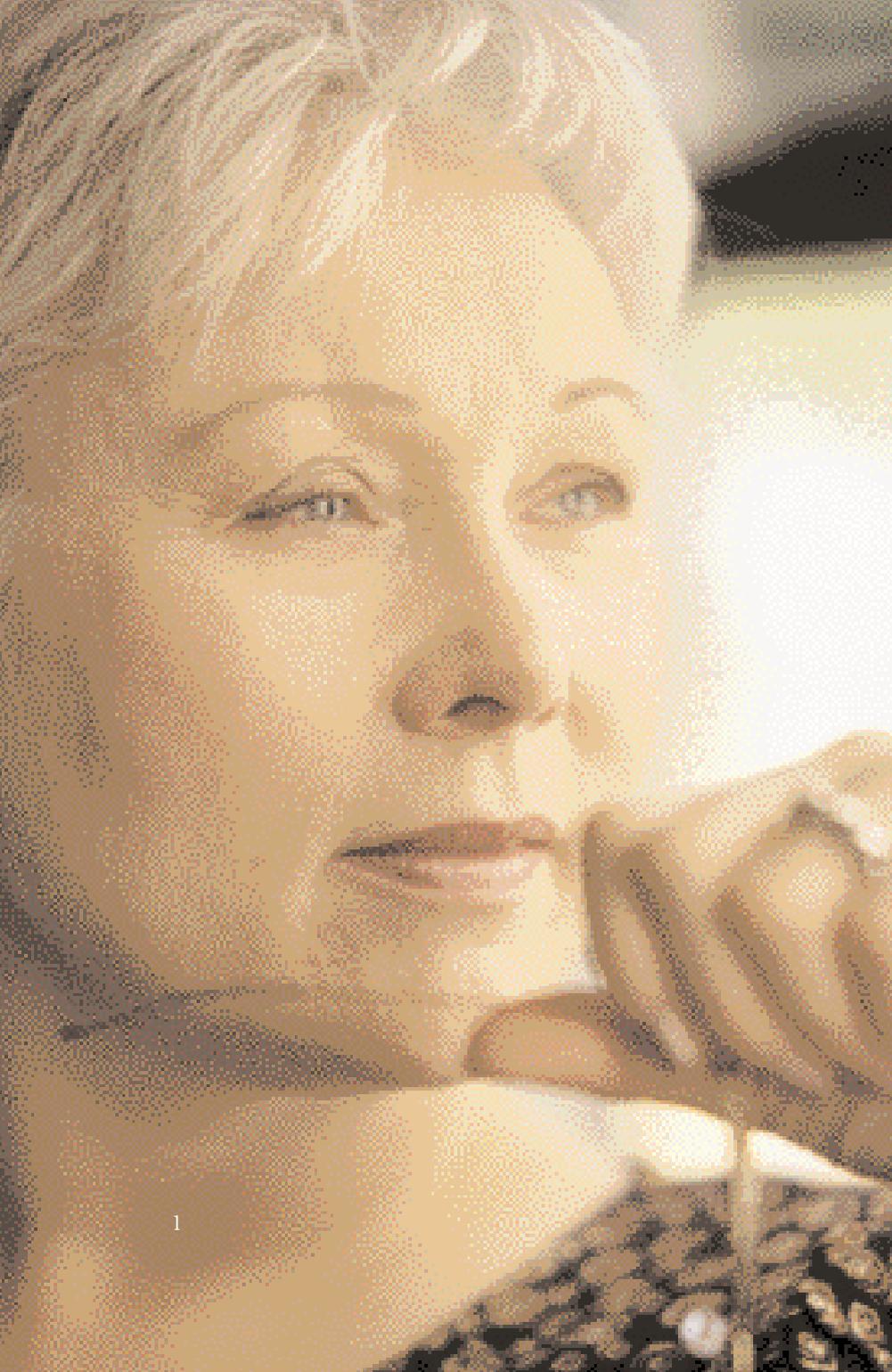
*An Endovascular  
Treatment for  
Abdominal  
Aortic Aneurysms*



*W. L. Gore & Associates, Inc., has spent more than 25 years making products for nearly every field of surgery, using unique technology to advance the way procedures are performed. Today, more than 6.5 million Gore expanded polytetrafluoroethylene (ePTFE) medical devices have been implanted worldwide.*

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

**Abdominal aortic aneurysms (AAA)** occur in an estimated 200,000 people per year in the United States. Also known as AAA's, an abdominal aortic aneurysms 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** called the EXCLUDER Bifurcated Endoprosthesis.

For your convenience, we have included a **Glossary of Medical Terms** on page 19 and space in this brochure to jot down questions. 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.

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

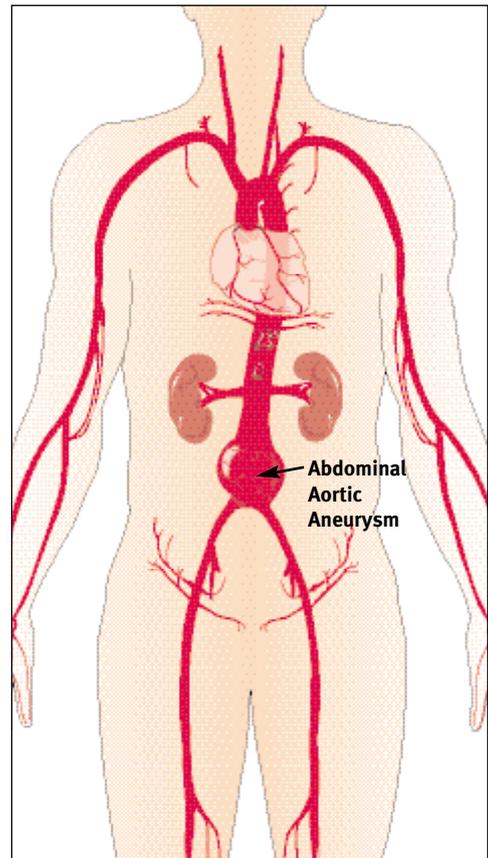
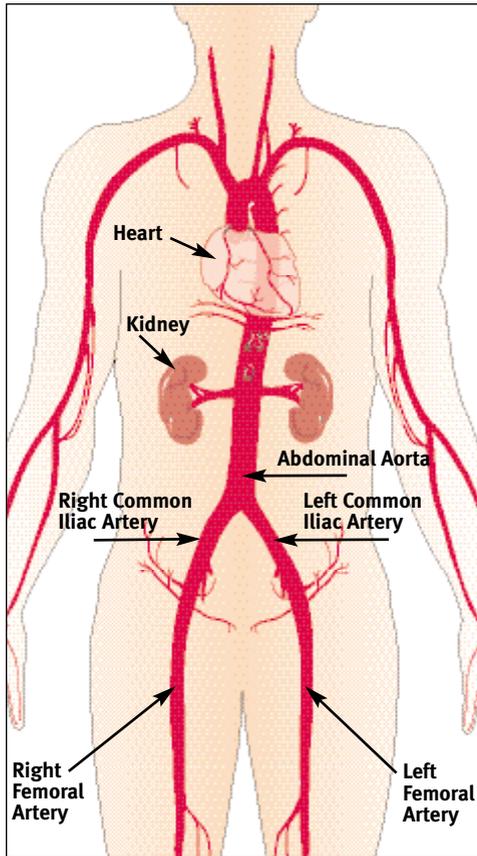
An **abdominal aortic aneurysm** is the swelling or ballooning of the **aorta**.

The aorta is the main artery that carries oxygen-filled blood from the heart to all parts of the body. In the abdomen area, 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 your 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 balloon up 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 U.S.

### 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**

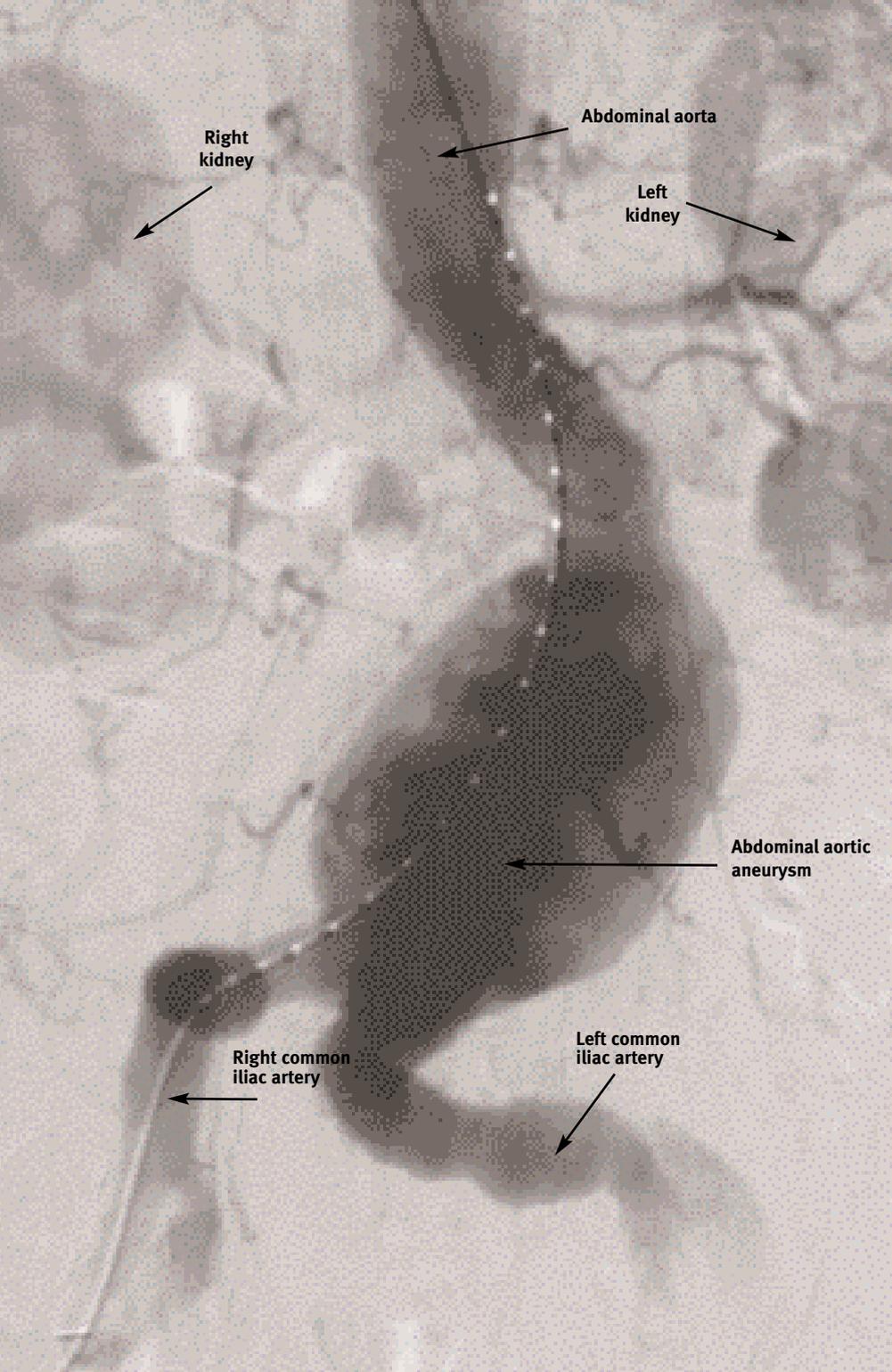
*An aneurysm is the ballooning of the abdominal aorta. The weakened sections of the aortic wall are unable to support the force of blood flow over time.*

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

The most common symptom of an **abdominal aortic aneurysm** is pain. 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. However, many people may not experience these types of pain or any of these symptoms yet still be found to have an abdominal aortic aneurysm.

Your doctor may discover an abdominal aortic aneurysm 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 additional tests such as **angiography** (see Figure 3), **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 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 connection), smoking, heart disease, high blood pressure, and poor diet. Most physicians 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 possible **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, the 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 with a **synthetic graft** (tube) that is sewn into place. 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 large operation. Ask your doctor about the risks associated with an open procedure as they relate to your overall health condition.

## **ENDOASCULAR 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 (EXCLUDER Bifurcated 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 not 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 an ideal candidate for endovascular repair. With this in mind, please check with your doctor if you are a candidate for endovascular repair. If you would like to learn more about abdominal aortic aneurysms, types of therapy, or more information about the EXCLUDER Bifurcated Endoprosthesis, visit the websites listed on page 23.

## What is the *EXCLUDER Bifurcated Endoprosthesis*?

The EXCLUDER Bifurcated Endoprosthesis is an implantable device delivered 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 EXCLUDER Bifurcated 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 EXCLUDER Bifurcated 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, which is placed just below the renal arteries, and includes 1 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 full endovascular graft. Together, these 2 pieces form a bifurcated endovascular graft (see Figures 4 and 5).

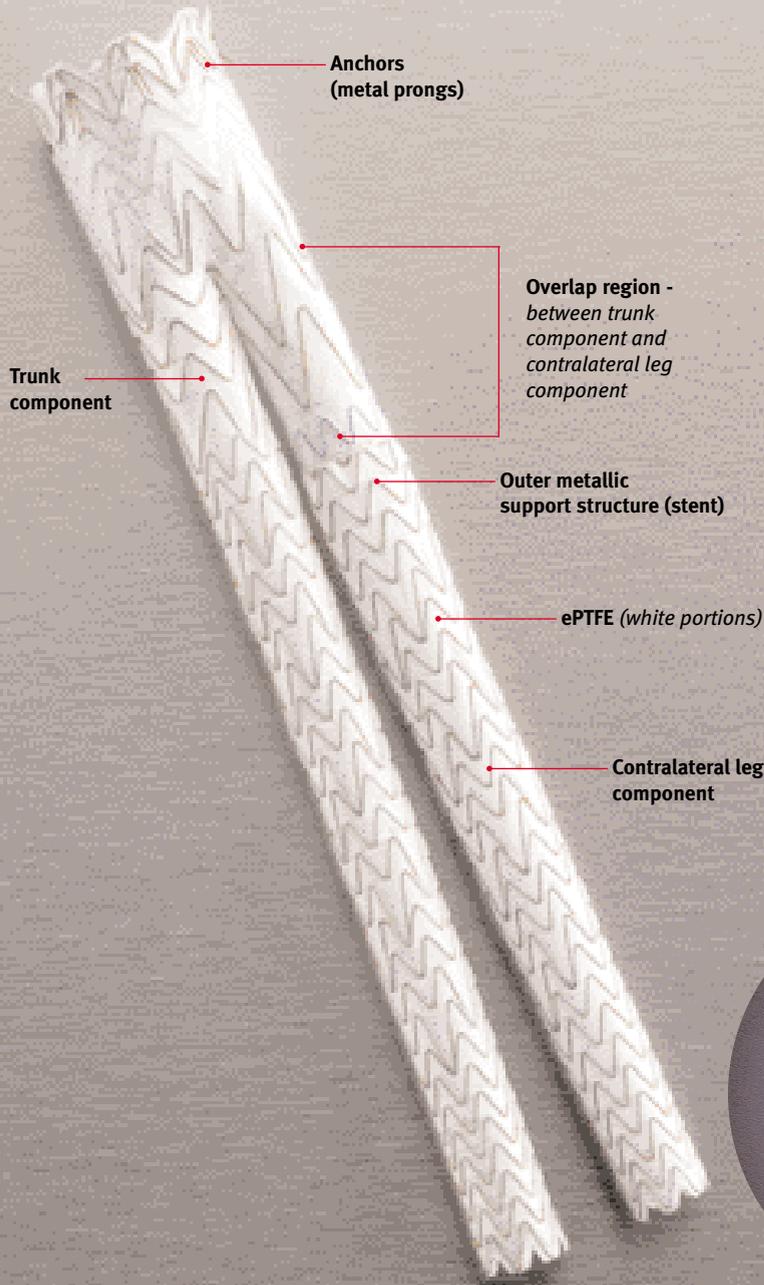


Figure 4

## EXCLUDER Bifurcated Endoprosthesis

Consists of two components:

- Trunk
- Contralateral Leg

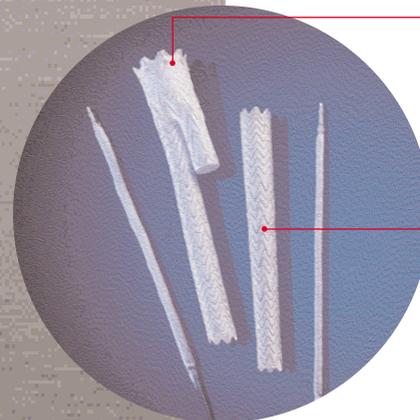


Figure 5



**Figure 7**

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

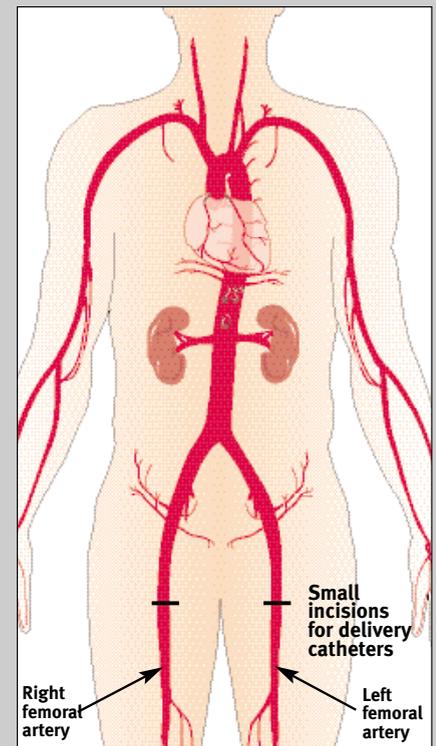
## What is the *EXCLUDER Bifurcated Endoprosthesis?*

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 6). 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 6**

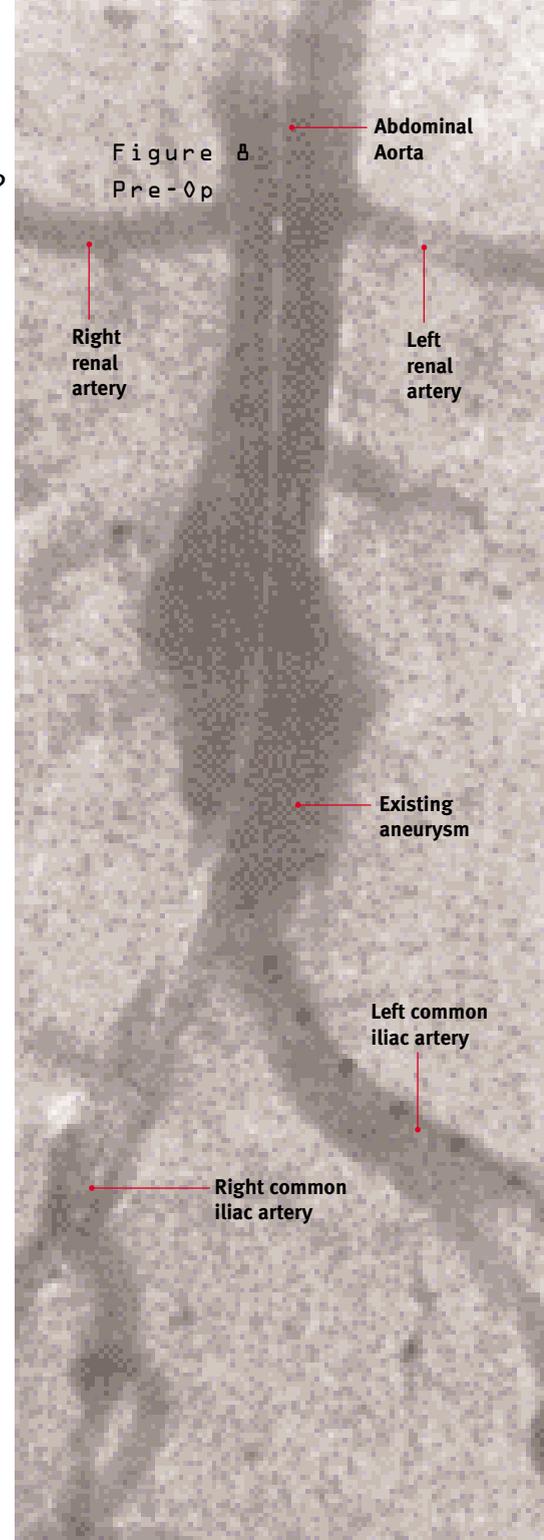
*Insertion sites of delivery catheters for placement of an EXCLUDER Bifurcated Endoprosthesis.*



## What is the *EXCLUDER Bifurcated Endoprosthesis Procedure?*

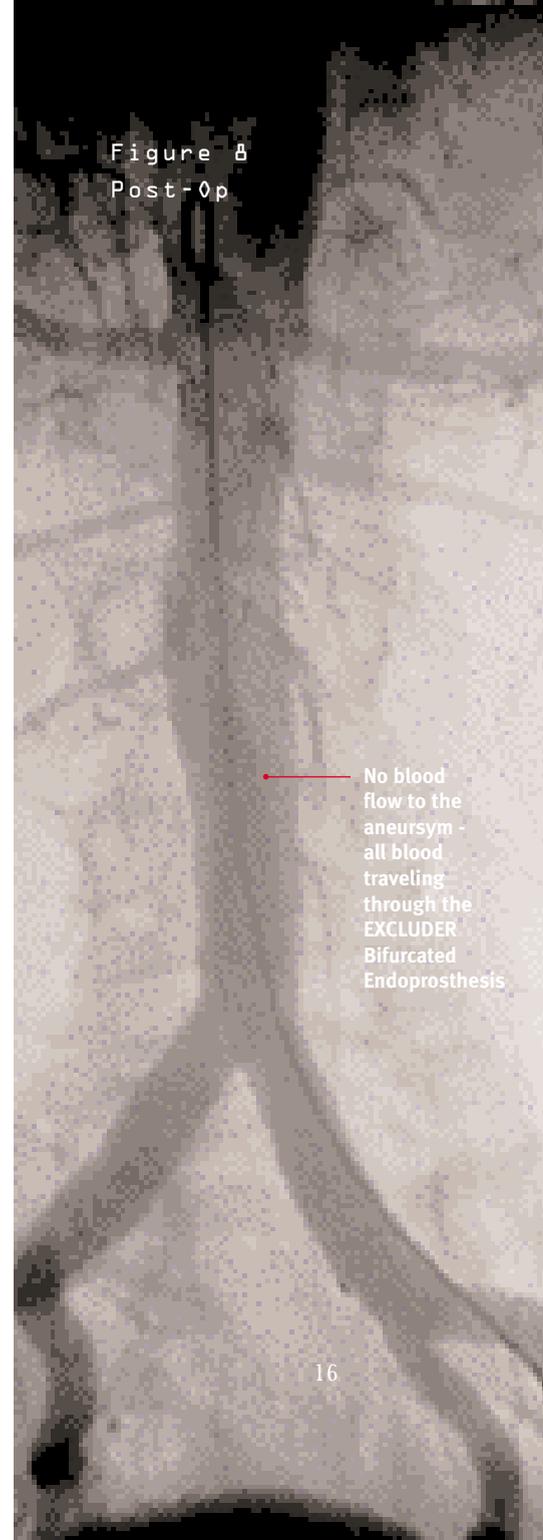
The EXCLUDER Bifurcated Endoprosthesis procedure consists of the implantation of the EXCLUDER Bifurcated Endoprosthesis to exclude an **abdominal aortic aneurysm (AAA)**. The **endovascular graft** is implanted using **fluoroscopy** (real time x-ray images) viewed on a monitor in these simple steps:

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.



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 figure 8). 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 8  
Post-Op



No blood flow to the aneurysm - all blood traveling through the EXCLUDER Bifurcated Endoprosthesis



**Be Sure to Ask...**

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 of the original symptoms associated with your abdominal aortic aneurysm. Remember, the most common symptom is pain, occurring in the abdomen, back, chest area, or tenderness in the mid or upper abdomen, lower back or side.

## What Follow-Up Evaluations *Will I Have?*

Currently, follow-up is advised to include 1 month, 6 months and annual visits thereafter. Your doctor may recommend more frequent follow-up visits depending on your medical condition.

The follow-up exams may consist of routine blood tests, x-rays, a physical exam, and possibly an abdominal **ultrasound**, **CT** or **MRI** scan. The exposure related to these follow-up exams carries 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 studies. Please ask your doctor if you have any concerns regarding these tests and exams.

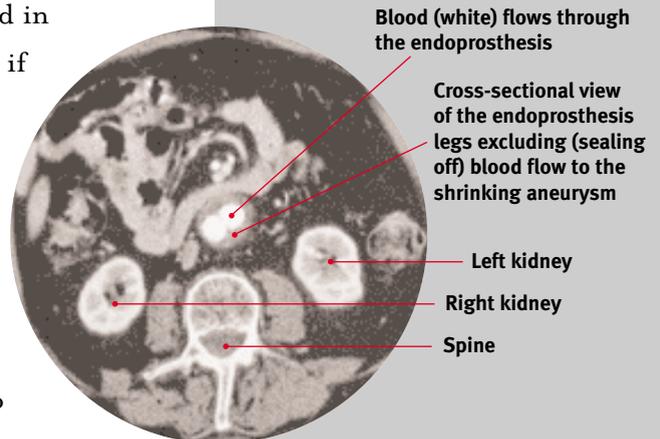
These tests and exams are performed because they are helpful in evaluating the outcome of your treatment and any changes over time. Your doctor may also request additional follow-up evaluations

based on findings at the follow-up visits. These may include finding a return of blood flow in the aneurysm and/or growth of the **aneurysm**.

This type and frequency of monitoring is generally not required after open surgical repair.

Figure 9

*A CT Scan of an abdominal aortic aneurysm.*



**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**

A method whereby dye is injected into the bloodstream to view blood vessels under x-ray. Utilizes contrast (dye) and small **radiation** exposure.

**Contrast (dye)**

A drug injected into the vascular system to show 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.

### **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 femor or thigh region of each leg. Physicians 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.

**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](http://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/home](http://www.mayoclinic.com/home)

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](http://www.sirweb.org)

The Society of Interventional Radiology (SIR) is a professional society for physicians 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.

##### **U. S. National Library of Medicine**

[www.medlineplus.gov](http://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.**

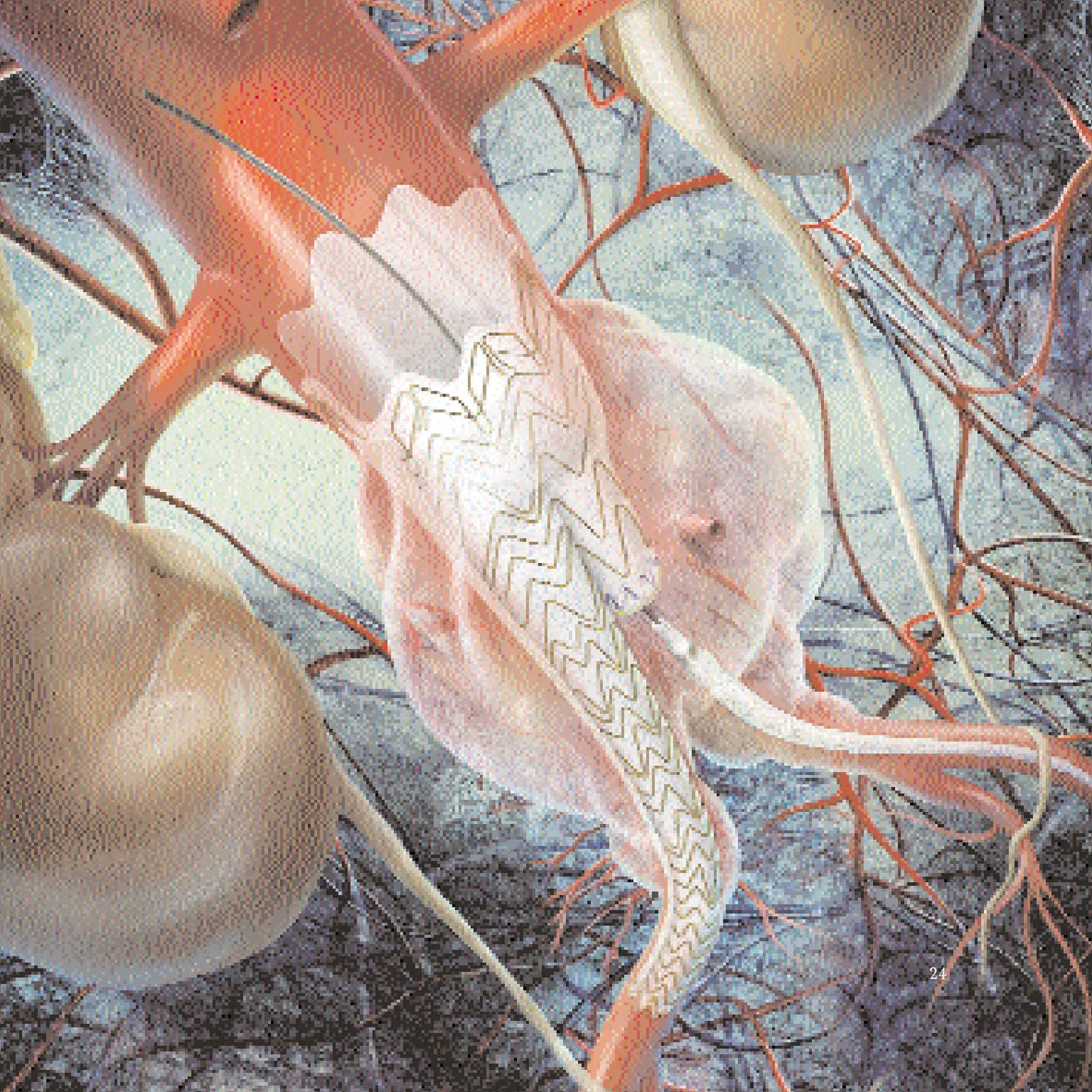
[www.goremedical.com](http://www.goremedical.com)

The Gore Medical Products Division provides creative healing solutions to complex medical problems and provides such products as synthetic vascular grafts, interventional technologies, surgical meshes for hernia repair, and sutures for use in vascular, cardiac, general surgery and orthopedic procedures. With over 6.5 million implants, these devices have been saving and improving the quality of lives worldwide for the past 26 years.

##### **U.S. Department of Health and Human Services Food and Drug Administration**

[www.fda.gov](http://www.fda.gov)

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