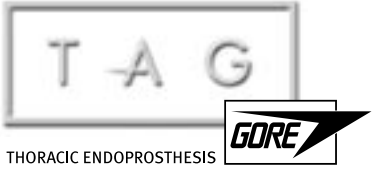
An Endovascular Treatment for Thoracic Aortic Aneurysms

Patient Information Booklet



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

INTRODUCTION

In the US, the incidence of **thoracic aortic aneurysms (TAA)** is approximately 5.9 cases per 100,000 person-years.

The risk of rupturing a thoracic aortic aneurysm is related to the diameter or size of the aneurysm. In a recent series of 133 patients with TAA, the risk of **rupture** at 5 years was 0% for diameters less than 4 cm, 16% for diameters of 4-5.9 cm, and 31% for aneurysms greater than 6 cm in diameter.

(reference: http://www.emedicine.com/emerg/topic942.htm)

A **TAA** 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 thoracic 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 11 and space in this brochure on page 17 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.

WHAT IS A THORACIC AORTIC ANEURYSM (TAA)?

A **thoracic aortic aneurysm (TAA)** is the swelling or ballooning of the thoracic aorta. The **aorta** is the main artery that carries oxygen-filled blood from the heart to all parts of the body. In the **thorax** (chest), once leaving the heart, blood travels upward through the **ascending aorta** turning into the **aortic arch** branching into the **innominant**, **carotid** and **subclavian arteries**. These **branch vessels** carry blood to the heart muscle, arms, shoulders, chest, neck, face, and head (including brain). Once past the aortic arch, the aorta turns downward turning into the **descending aorta** and carries blood to the **intercostal arteries**, **spinal arteries**, and ultimately other lower **organs** and areas of the body (see Figure 1).

An aneurysm is a ballooning of the aorta that results from a weakened section in the artery, which cannot support the force of blood flow and pressure created by the heart (see Figure 2).

Although an **aneurysm** can occur in any artery of the body, it may become dangerous and symptomatic when it occurs in the **thoracic aorta**, **abdominal aorta** and the **iliac arteries**. While the thoracic aorta's diameter normally ranges from 1 to 1.5 inches (2 - 4 cm), 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 leading to internal bleeding.

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.

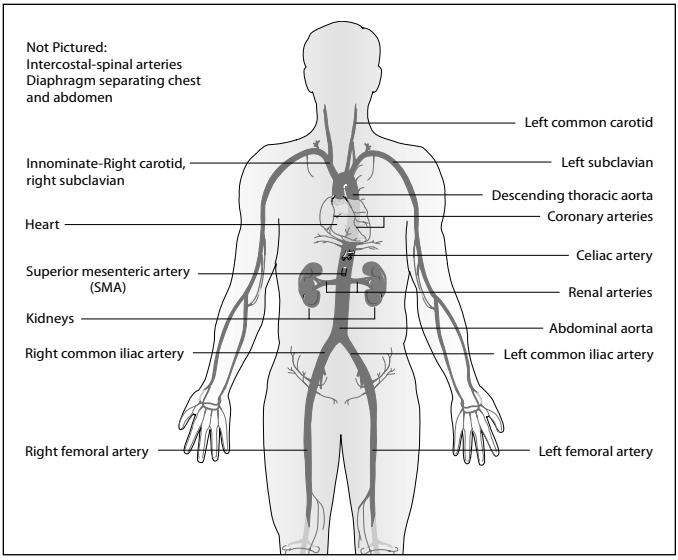

Figure 1
The aorta is the main artery that carries oxygen-filled blood from the heart. It is the largest artery in the body, starting in the chest, branching into the arm, neck, head, and extending down to the abdomen where it then branches into abdominal organs, the iliac arteries and into the legs.

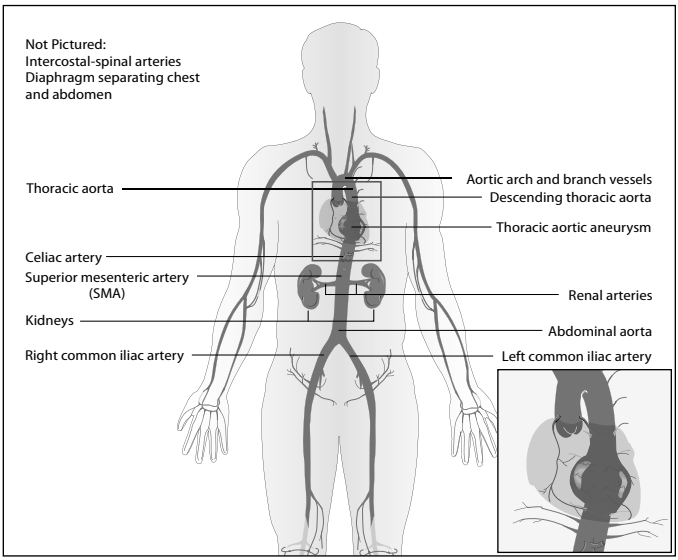

Figure 2
An aneurysm is the ballooning of the thoracic aorta. The weakened sections of the aortic wall are unable to withstand the force of blood flow and blood pressure over time.

WHAT ARE SOME OF THE SYMPTOMS OF A TAA?

Many people do not experience any symptoms of a **TAA**. Because of this, it is very important to speak with your doctor about your risk of having or developing TAA disease. When symptoms do occur, pain is most commonly experienced. This can occur in the chest or back area, shoulders, neck and abdomen. Some patients describe the pain as anything from mild to severe, or a tenderness in the mid or upper chest, back or shoulders. Again, many people may not experience any of these symptoms, yet still be found to have a TAA. Your doctor may discover a TAA during a routine physical exam. Most often, aneurysms are found during a medical test such as a **CT** (Computed Tomography or CAT scan), **MRI** (Magnetic Resonance Imaging Scan) or cardiac catheterization (**angiogram**) procedure.

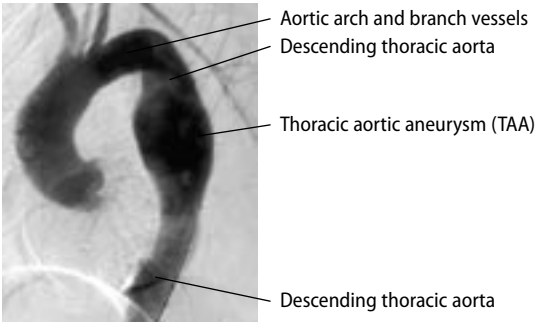

Figure 3
An angiogram of a thoracic aortic aneurysm.

Your doctor may also recommend an **angiogram** (see Figure 3), or additional testing such as CT (Computed Tomography or **CAT scan**), **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 A TAA?

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 a **thoracic 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 high fat diet. Most doctors will advise simple preventative measures such as keeping your blood pressure under control, quitting smoking, reducing cholesterol in your diet and appropriate exercise. These lifestyle changes could also aid in preventing further problems in the future.

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

HOW DO DOCTORS TREAT A TAA?

The size and location of the **thoracic 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 may require treatment.

Two procedural options are available if your doctor feels treatment is necessary; open surgical repair or **endovascular repair**. Medical management is the only option for patients that cannot tolerate the surgical procedure.

WHEN TREATMENT BECOMES NECESSARY, WHAT ARE MY TREATMENT OPTIONS?

Medical Management -

Medical management is generally the first choice for treatment, including **reducing blood pressure** and minimizing other risk factors.

Open Surgical Repair -

Open surgical repair is considered when the **thoracic aortic aneurysm (TAA)** is considered dangerous and at risk for rupture. During this type of operation, the doctor makes an incision (cut) in the chest (front or side) and repairs the aorta by replacing the diseased section (aneurysm) with a **synthetic graft** (tube) that is sewn into place with sutures. 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 spend some time in the intensive care unit **(ICU)** and another several days in the hospital for early recovery. Depending on how quickly your body heals and any other associated health issues, hospitalization and recovery time may take about 3 to 6 months. Currently, medical management and open surgical repair are standard of care for thoracic aortic aneurysms and are proven medical therapies. However, both therapies have their limitations. Medical management does not treat the aneurysm, just reduces the stresses (i.e., blood flow pressure) on the aneurysm. Open surgical repair is invasive and 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 thoracic aortic aneurysms. Less invasive than open surgery, it involves excluding (sealing off) the aneurysm by placing an **endovascular graft** inside of the diseased aorta, re-lining and making a new path for blood flow. An endovascular graft (e.g., GORE TAG Thoracic Endoprosthesis) remains inside the aorta permanently through the use of a metal **stent** creating a tight fit and seal against the wall of the aorta. Endovascular repair may be performed under **general**, **regional** or **local anesthesia**. The procedure 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 2-6 weeks after the procedure.

The endovascular procedure does require regular and routine follow-up visits with your doctor. Tests are performed to evaluate and monitor the status and success of the treatment over time.

Please see the follow-up section on page 9 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 thoracic aortic aneurysms, types of therapy, or more information about the GORE TAG Endoprosthesis, visit the websites listed on page 14.

WHAT IS THE GORE TAG THORACIC ENDOPROSTHESIS?

The GORE TAG Thoracic 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 TAG Thoracic Endoprosthesis is a device that allows for endovascular repair of a **thoracic aortic aneurysm (TAA)**. The endovascular graft is a 1-piece, tube-shaped stent-graft that re-lines the aorta and extends from as high as the **aortic arch**, to as low as the **abdomen** above the **celiac artery**. The GORE TAG Thoracic Endoprosthesis is comprised of ePTFE (expanded polytetrafluoroethylene), FEP (fluorinated ethylene propylene), nitinol wire and gold. All materials have a long history of use in medical products.

The GORE TAG Thoracic Endoprosthesis is placed in the thoracic aorta as one or more devices. The devices are placed to fit above, across and below the aneurysm portion of the aorta (see Figures 4, 5 and 6).

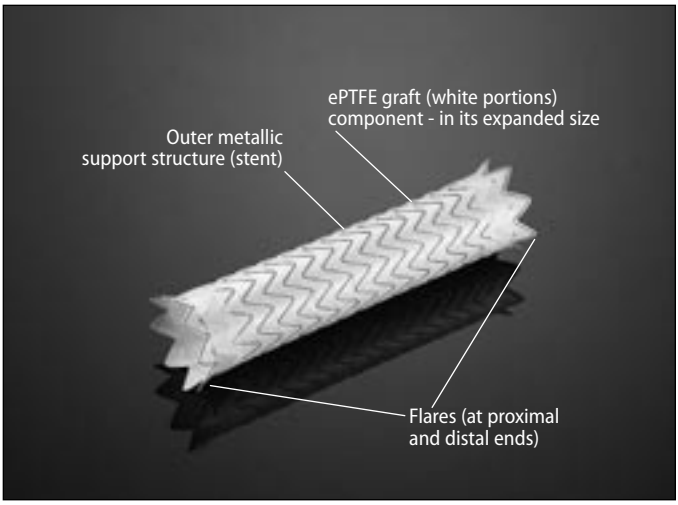

Figure 4
GORE TAG Endoprosthesis

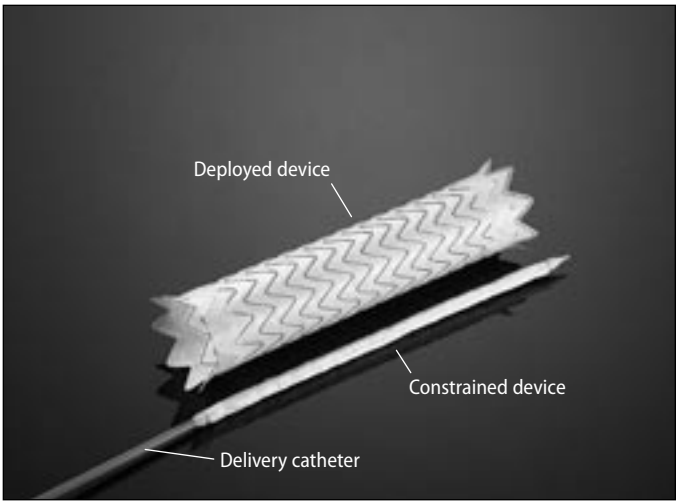

Figure 5
GORE TAG Thoracic Endoprosthesis (on and off catheter)

Figure 6
Artist's rendition of the delivery of a GORE TAG Thoracic Endoprosthesis allowing for endovascular repair of a thoracic aortic aneurysm. The device has been delivered and deployed from the left common iliac artery on a delivery catheter.

WHAT IS THE GORE TAG THORACIC ENDOPROSTHESIS (continued)?

Each **endovascular graft** is compressed into the end of a long, thin, tube-like device called a **delivery catheter**. The delivery catheter is inserted into the aorta by making a small incision, or puncture in one of the **femoral** or **iliac arteries** in the groin or lower abdominal area (see Figure 7). For example, the device delivery catheter is inserted through the right femoral artery (see Figure 7).

Diagnostic measurements (**CT, MRI**, **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.

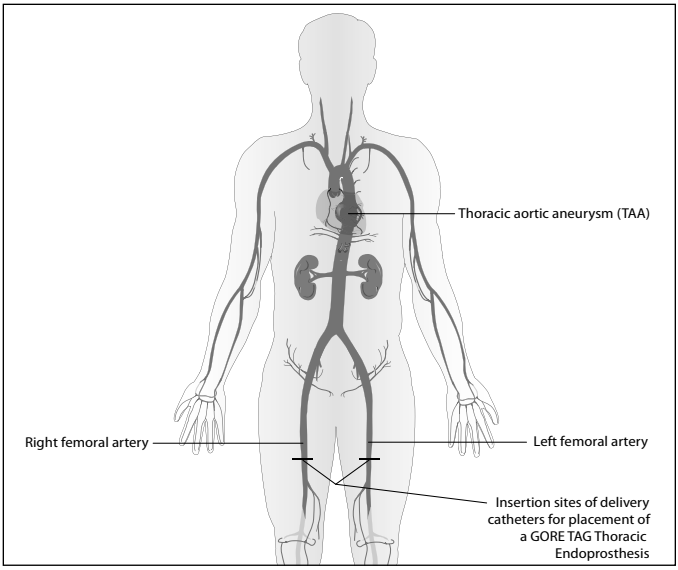

Figure 7

WHAT IS THE GORE TAG THORACIC ENDOPROSTHESIS PROCEDURE?

The GORE TAG Thoracic Endoprosthesis procedure consists of the implantation of a TAG Endoprosthesis to exclude a **thoracic aortic aneurysm (TAA)**. The **endovascular graft** is implanted using **fluoroscopy** (real-time x-ray images) viewed on a monitor in these steps:

1. A **delivery catheter** is inserted into the **femoral** or **iliac artery** and carefully guided up the leg artery through the abdomen into the chest (near the heart) to the site of the thoracic aortic aneurysm.

2. Once the endovascular graft is correctly positioned in the **aorta** (across the aneurysm), it is released or deployed from the delivery catheter.

3. The device self-expands inside the aorta to the diameter of your aorta. The placement of the endovascular graft is designed to exclude (seal off) the aneurysm and reline the artery wall.

4. In most cases, an additional step is performed. This step is a ballooning of the device, which aids in sealing/seating of the device in the aorta.

5. The delivery catheter is withdrawn from the body.

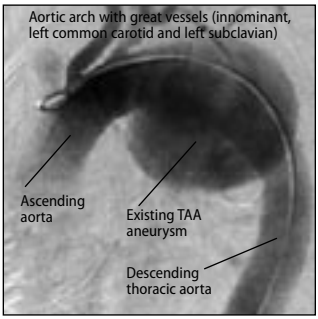

Figure 8a Pre-Op TAA

Figure 8b Post-Op TAA

These steps are the same for each device 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.

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, which should be discussed with your doctor. 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.

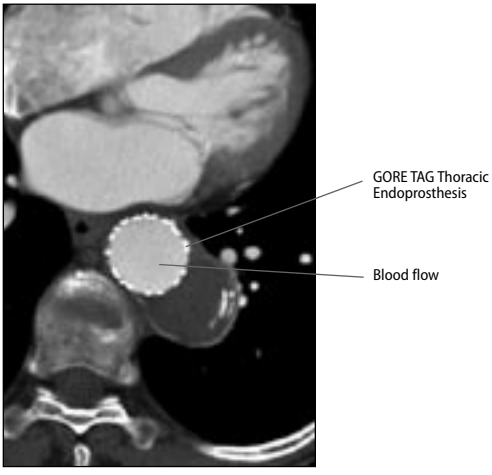

Figure 9
A CT Scan of a thoracic aortic aneurysm with a GORE TAG Thoracic Endoprosthesis.

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 are generally not required after open surgical repair.

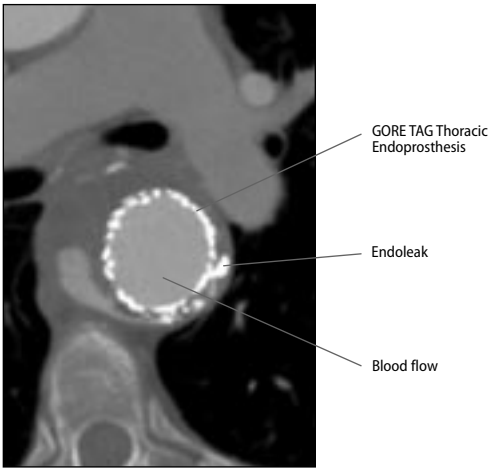

Figure 10
Follow-up CT scan is showing an endoleak.

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 thoracic 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, and weakness in the legs, back, chest, or abdomen. Aneurysm rupture symptoms include dizziness, fainting, rapid heartbeat or sudden weakness.

Vessel **occlusion** – Symptoms include pain, numbness or weakness in the hip(s) or leg(s) during walking, or discoloration or coolness of the leg(s).

PATIENT COUNSELING INFORMATION

You and your doctor should review the following risks and benefits when discussing the endovascular graft and procedure:

- Risks and differences between endovascular repair and open surgical repair.
- Potential advantages of traditional open surgical repair.
- Potential advantages of endovascular repair.
- Potential risks of endovascular repair including; endoleak, continued aneurysm growth, and device movement.
- 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 a **thoracic aortic aneurysm (TAA)**. 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 thoracic aortic aneurysm. Remember, symptoms are not always present, but when they are, the most common symptom is pain, occurring in the chest, back, neck shoulders or abdominal area.

GLOSSARY OF MEDICAL TERMS

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.

Aorta
The main artery that carries blood away from the heart to the rest of the body. It is the largest artery in the body.

Aortic Arch
A part of the aorta that connects the ascending aorta with the descending aorta. Contains three branches: innominate, left common carotid and left subclavian arteries (see Figure 1).

Ascending Aorta
An artery that starts at the origin in the upper surface of the left ventricle (left side of the heart). It passes upward and turns into the arch of the aorta (see Figure 1).

Catheter
A slender, hollow, flexible tube that is inserted into the body.

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)
A computerized axial tomography scan is more commonly known by its abbreviated name, CAT scan or CT scan. It is an x-ray procedure that often utilizes contrast (dye) and combines many x-ray images with the aid of a computer to generate cross-sectional views and, if needed, three-dimensional images of the internal organs and structures of the body.

Delivery Catheter
A long, thin, tube-like tool that assists in the positioning and delivering of an endovascular graft through the vascular system. Also referred to as a Catheter.

Descending Aorta
The descending aorta starts at the aortic arch and runs down through the chest and the abdomen. The descending aorta starts after the arch of the aorta and ends by splitting into two great arteries (the common iliac arteries) that go to the legs. The descending aorta, by convention, is subdivided into the thoracic aorta and the abdominal aorta. The thoracic aorta, the part of the aorta that runs from the arch of the aorta to the diaphragm, gives off numerous branches that supply oxygenated blood to the chest cage and the organs within the chest.

Dilatation
The increase in size of a blood vessel.

Endoleak
Unwanted blood flow into the 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. Also referred to as an Endoprosthesis.

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.

Through this technique, physicians can treat certain conditions through the skin that might otherwise require surgery.

Endovascular Treatment
The use of real time x-rays and guidewires to treat unhealthy arteries with an endovascular device delivered through small incisions in the iliac or femoral arteries.

Femoral Arteries
Two arteries located in each leg which carry blood to the femoral 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 imaging method that helps physicians gain access to the vasculature and guide endovascular devices to their intended treatment area.

Guidewire
A long, flexible wire that is placed in an artery to track (or guide) a delivery catheter and other endovascular accessories used 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.

Innominate Artery
This is the first vessel to branch off the aortic arch. It divides into the right subclavian artery, which provides blood to the right arm and other areas, and the right common carotid artery which supplies blood to the right side of the head and neck (see Figure 1).

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.

Left Common Carotid Artery
One of the main branches off the aortic arch that supplies blood to the left side of the head and neck (see Figure 1).

Left Subclavian Artery
Provides blood for the left arm and portion of the thoracic area (see Figure 1).

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 stoppage of normal blood flow.

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

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 leak into the areas around the heart, lungs or abdomen (hemorrhage).

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

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

Trans Esophageal Ultrasound (TEU)
Trans Esophageal Ultrasound is a useful tool used to evaluate the function and small detailed structures of the heart and associated vessels.

Trans Esophageal Ultrasound Examination
The TEU procedure uses ultrasound waves to produce images of the heart and aorta. Performing a TEU involves passing a tube into the esophagus.

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

WHERE CAN I GET MORE INFORMATION?

Background Information on Thoracic Aneurysms

http://www.emedicine.com/emerg/topic942.htm

http://www.emedicine.com/MED/topic2783.htm

http://www.heartcenteronline.com/myheartdr/home/index.cfm (search - Aneurysm Center)

http://my.webmd.com/webmd_today/home/default.htm (search - aneurysm)

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/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

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.
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 devices, surgical patches for hernia repair, and sutures for use in vascular, cardiac, general surgery and orthopedic procedures. With over 10 million implants, these devices have been saving and improving the quality of lives worldwide for nearly 30 years.

US Department of Health and Human Services
Food and Drug Administration
www.fda.gov

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.

QUESTIONS FOR MY DOCTOR

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