

*An Endovascular
Treatment for
Isolated Lesions
of the Thoracic
Aorta*



Patient Information



THORACIC
ENDOPROSTHESIS

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*This brochure has been provided as a courtesy by W. L. Gore & Associates, Inc. (Gore). This brochure will help you learn more about **isolated lesions** of the thoracic aorta, such as thoracic aortic aneurysms and traumatic aortic transections, as well as a less-invasive method of treating **isolated lesions**. Whether you are trying to reduce your risk or supporting a loved one diagnosed with an **isolated lesion**, we hope this information will be helpful for you and your family.*

INTRODUCTION

Isolated lesions of the **thoracic aorta** include any **aorta** with a diseased portion that has healthy **aorta** above and below the disease. Two of the most common types of **isolated lesions** are a **thoracic aortic aneurysm (TAA)**, and a **traumatic aortic transection**. Other types of **isolated lesions** include, but are not limited to, penetrating aortic ulcers, ruptured **aneurysms**, pseudoaneurysms, and intramural hematomas. If you or a loved one has one of these diseases, you may be seeking information on how it can be treated. This brochure describes **TAA**s, **transections**, and other **isolated lesions**, and a relatively new way to treat them. This treatment option is **endovascular repair** using an **endovascular graft**.

For your convenience, we have included a **Glossary of Medical Terms** on the following pages. In addition, at the end of this brochure, there are a list of questions that you may wish to discuss with your doctor as well as a space for you to write any additional questions you may have. 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.

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. This method 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 main artery (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*).

Contrast (dye) — A drug injected into the vascular system to show blood flow through the blood vessels on the x-ray image and / or **CT scan**.

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 delivery of an **endovascular graft** through the vascular system.

Descending Aorta — The descending aorta is part of the main artery (**aorta**) that 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.

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 they are placed.

Endovascular Repair — Considered to be less invasive than open surgery, it involves the use of an **endovascular graft** to exclude (seal off) a lesion 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 graft** 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 8*).

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*).

Isolated Lesion — A diseased portion of the **aorta** that has a healthy portion of the **aorta** above and below the diseased portion for the **endovascular graft** to be placed. Isolated lesions include, but are not limited to, **aneurysms**, **transections**, penetrating aortic ulcers, ruptured **aneurysms**, pseudoaneurysms, and intramural hematomas.

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).

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

Thoracic Aorta — The part of the main artery (**aorta**) that is located in the thorax (chest). The thoracic aorta includes the **ascending aorta, aortic arch**, and descending thoracic **aorta**.

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”.

Transesophageal Ultrasound (TEU) — Transesophageal Ultrasound is a useful tool used to evaluate the function and small detailed structures of the heart and associated vessels. The TEU procedure uses ultrasound waves to produce images of the heart and **aorta**. Performing a TEU involves passing a tube into the esophagus.

Traumatic Aortic Transection (Transection) — A tear in the **aorta** that usually occurs in the chest. This tear is often referred to just as a transection.

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

THORACIC AORTIC ANEURYSMS (TAA)

WHAT IS A TAA?

A **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**, and branching into the **innominate**, **left common carotid**, and **left subclavian arteries**. These branch vessels carry blood to the heart muscle, arms, shoulders, chest, neck, face, and head (including the brain). Once past the **aortic arch**, the **aorta** turns downward into the **descending aorta** and carries blood to the intercostal arteries, spinal arteries, and ultimately other lower organs and areas of the body (see *Figures 1* and *2*).

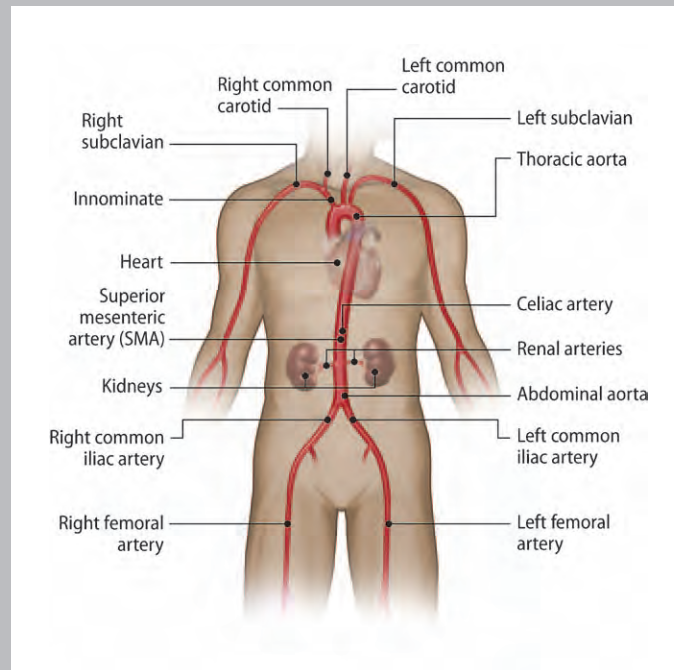


Figure 1.

*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, with branches into the arms, neck, head, and extending down to the abdomen where it then branches into the **iliac arteries** and into the legs.*

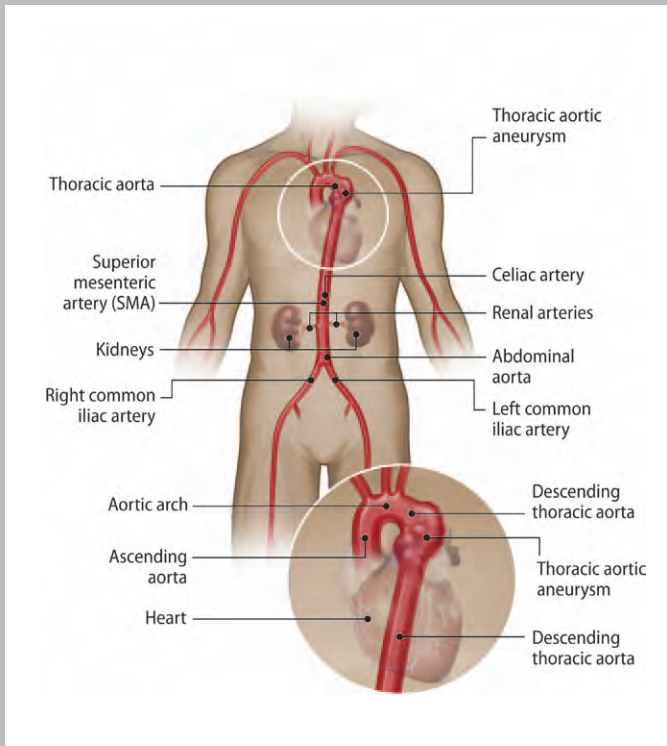


Figure 2.
*An **aneurysm** is the ballooning of the **thoracic aorta**. The weakened sections of the aortic wall may **rupture** (burst).*

An **aneurysm** is a ballooning of the **aorta** that results from a weakened section in the artery (see *Figure 2*).

While the diameter of the **thoracic aorta** 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.

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 Scan** (Computed Tomography or CAT scan), **MRI** (Magnetic Resonance Imaging), or cardiac catheterization (**angiogram**) procedure.

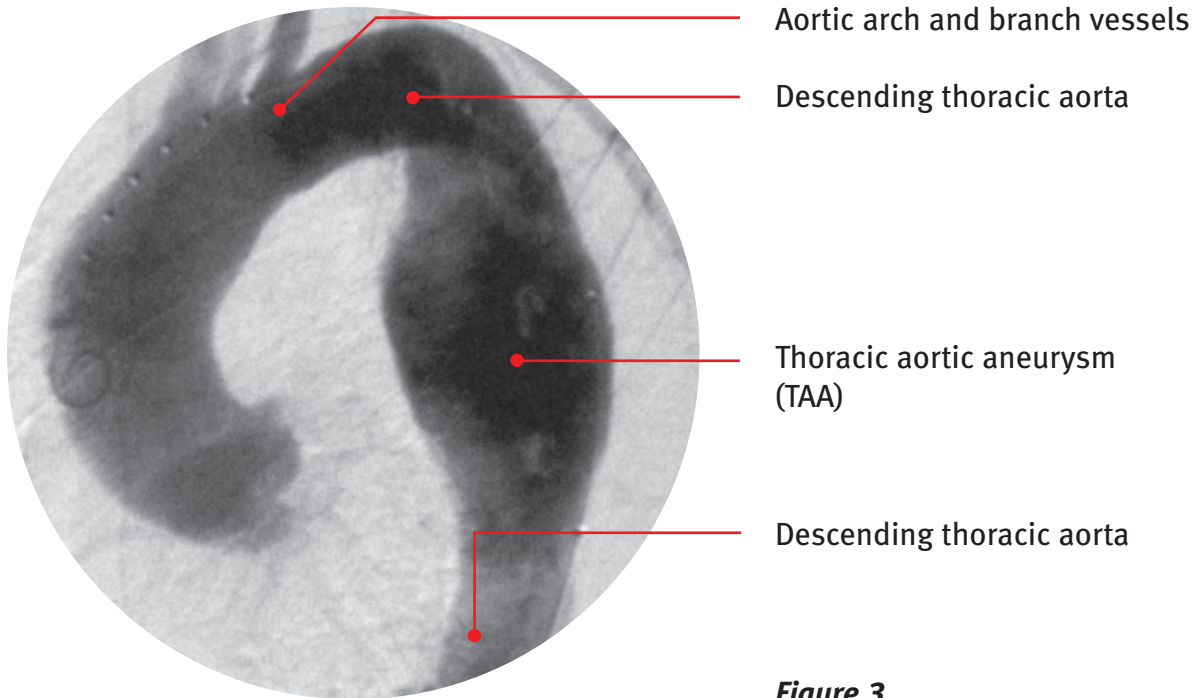


Figure 3.
An angiogram showing an aneurysm of the descending aorta.

Your doctor may also recommend an **angiogram** (see *Figure 3*), or additional testing such as **CT Scan** (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 **TAA**.

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 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 **transesophageal ultrasound (TEU)**. Your doctor may also prescribe medication to lower your blood pressure.

TRAUMATIC AORTIC TRANSECTIONS

WHAT IS A TRANSECTION?

A **transection** is a tear in the wall 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 thorax (chest), once leaving the heart, blood travels upward through the **ascending aorta**, turning into the **aortic arch**, and branching into the **innominate, left common carotid, and left subclavian arteries**. These branch vessels carry blood to the heart muscle, arms, shoulders, chest, neck, face, and head (including the brain). Once past the **aortic arch**, the **aorta** turns downward 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*).

A **transection** is a tear in the wall of the **aorta**. This tear can be complete which results in internal bleeding and is frequently fatal. If the tear is not complete, but rather small or a partial tear, this results in a weakened section in the **aorta** and potentially a ballooning of the **aorta** much like an **aneurysm** (see *Figure 4*). This condition, if not treated, could result in a **rupture** (bursting) of the **aorta** leading to internal bleeding. Ruptured **transections** are frequently fatal.

Location of thoracic aortic transection



Figure 4.
A transection is a tear in the wall of the aorta that results in a weakened section of the aorta and potentially a ballooning of the aorta much like an aneurysm.

WHAT CAUSES A TRANSECTION?

Transections most commonly occur in accidents such as motor vehicle accidents, being hit by a motor vehicle, or falls from heights. **Transections** most commonly occur near the **left subclavian artery** in the **descending aorta**, but can occur in other places within the **aorta**.

Diagnosis of **transections** is often not based on symptoms, but rather on the fact that the patient was in an accident. Most often, **transections** are found during a medical test such as a **CT Scan** (Computed Tomography or CAT scan) or **MRI** (Magnetic Resonance Imaging).

Your doctor may also recommend an **angiogram**, or additional testing such as **CT Scan** (Computed Tomography or CAT scan), **MRI** (Magnetic Resonance Imaging), or **IVUS** (Intravascular Ultrasound) to determine the precise location, size, and shape of the **transection** and your surrounding arteries.

OTHER ISOLATED LESIONS

Other **isolated lesions** of the **thoracic aorta** besides **TAA** and **transection** include, but are not limited to, penetrating aortic ulcers, ruptured **aneurysms**, pseudoaneurysms, and intramural hematoma.

- A penetrating aortic ulcer (PAU) is a small area of disease in the **aorta** that leads to a small portion of the **aorta** expanding and forming a bulge or bubble filled with blood on the side of the aortic wall. There is a high risk of PAUs either bursting (**rupturing**) or leading to other life-threatening diseases over time.
- Ruptured **aneurysms** are **aneurysms** that have a hole in the wall of the **aorta** where blood is leaking out of the **aorta** leading to internal bleeding. Ruptured **aneurysms** are frequently fatal.
- Pseudoaneurysms of the **thoracic aorta** are **aneurysms** or bulges in the **aorta** that form at a location of damage to the **aorta**. This damage could be caused by previous surgeries, accidents, or other implanted devices near to or inside of the **aorta**. Pseudoaneurysms expand with time and could lead to **rupture** if left untreated just as **aneurysms**.
- Intramural hematoma is an abnormal pooling of blood inside the wall of the **aorta**. Over time, the blood in the wall of the **aorta** could cause a hole in the **aorta** leading to **rupture** or other life-threatening diseases.

As previously discussed with **TAA**s, there may be no symptoms associated with these and other **isolated lesions**. When symptoms do occur, they are similar to those previously discussed for **TAA**s. Please see “What Are Some of the Symptoms of a **TAA**?” for more information.

HOW DO DOCTORS TREAT ISOLATED LESIONS?

The size and location of the **isolated lesion** and your general health will determine how you should be treated. When the **isolated lesion** is small, your doctor may only recommend periodic check-ups to monitor your condition. However, a larger, or rapidly growing **isolated lesion** 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**.

WHEN TREATMENT BECOMES NECESSARY, WHAT ARE MY TREATMENT OPTIONS?

MEDICAL MANAGEMENT

Medical management is the first choice for treatment, including reducing blood pressure and minimizing other risk factors. Medical management usually includes keeping your blood pressure under control, quitting smoking, and reducing cholesterol in your diet.

OPEN SURGICAL REPAIR

Open surgical repair is an operation to remove the **isolated lesion** when it 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 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 two to four 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 three to six months.

Currently, medical management and open surgical repair are standard of care for **isolated lesions** and are proven medical therapies. However, both therapies have their limitations. Medical management does not fix the **isolated lesion**, just reduces the stresses (i.e., blood flow pressure) on the diseased **aorta**. Although open surgical repair is a proven treatment, 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.

Figure 5a. Artist's rendition of the delivery of a GORE® TAG® Thoracic Endoprosthesis allowing for **endovascular repair of a TAA.**

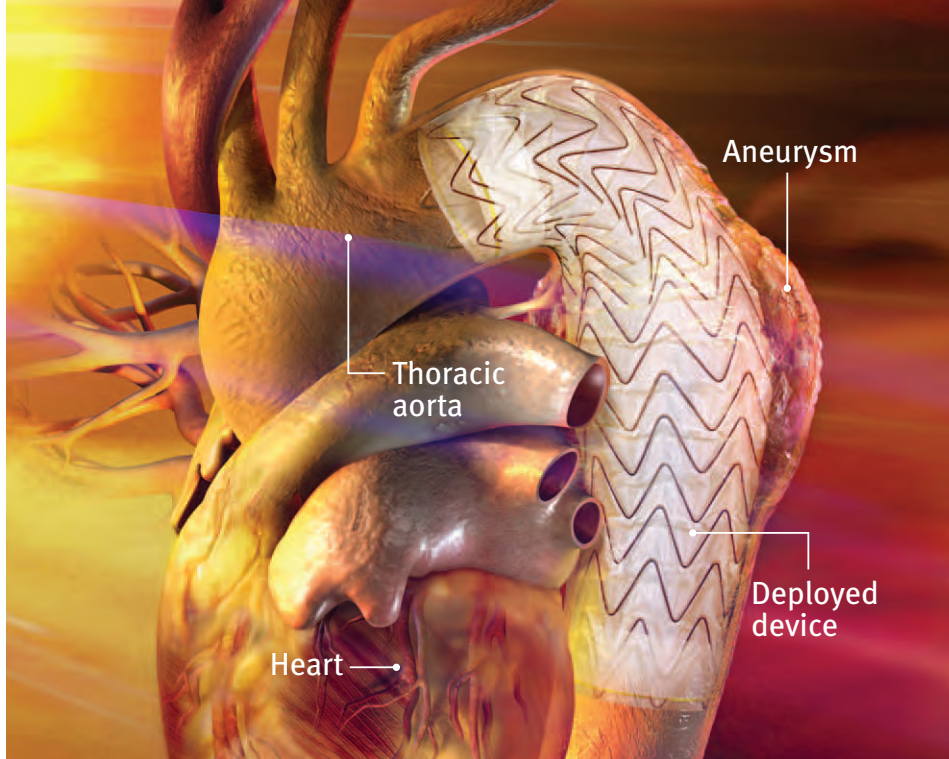
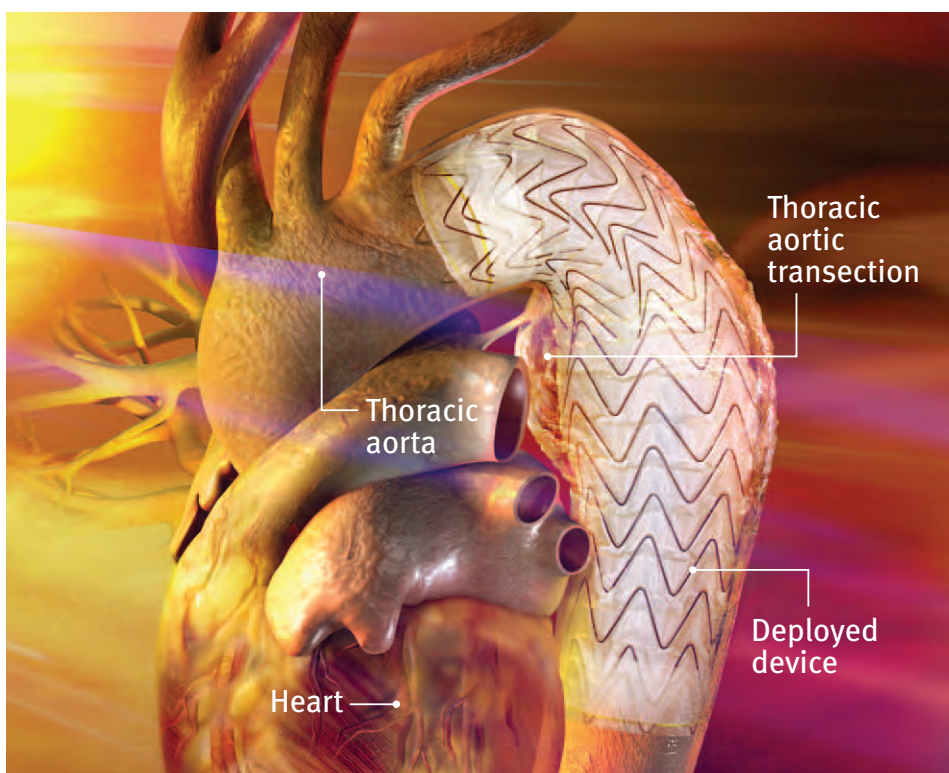


Figure 5b. Artist's rendition of the delivery of a GORE® TAG® Thoracic Endoprosthesis allowing for **endovascular repair of a transection.**



WHEN TREATMENT BECOMES NECESSARY, WHAT ARE MY TREATMENT OPTIONS?

continued

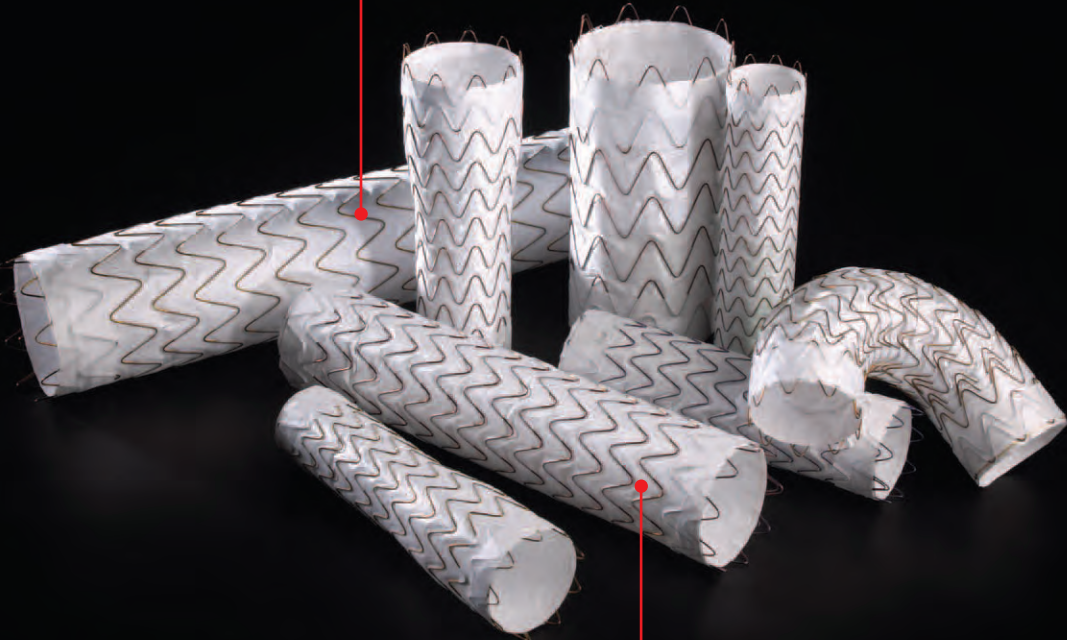
ENDOASCULAR REPAIR

Endovascular repair is a relatively new procedure for the treatment of **isolated lesions**. Less invasive than open surgery, it involves excluding (sealing off) the diseased segment by placing an **endovascular graft** inside of the diseased **aorta**, relining and making a new path for blood flow. The **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 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 two to six weeks after the procedure, depending on other health conditions.

The endovascular procedure does require regular and routine follow-up visits with your doctor. As the long-term results of **endovascular repair** with an **endovascular graft** have not been established, tests are performed to evaluate and monitor success of the treatment over time.

Please see the section “*What Follow-Up Evaluations Will I Have?*” 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 a specific **isolated lesion**, types of therapy, or more information about the GORE® TAG® Thoracic Endoprosthesis, visit the websites listed in the back of this brochure.

Outer metallic
support structure
(stent)



ePTFE graft
(white portions)
component — in
its expanded size

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 **isolated lesion** 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 an **isolated lesion**. The **endovascular graft** is a one-piece, tube-shaped device that relines 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 made of ePTFE (expanded polytetrafluoroethylene), a material similar to plastic, with an outer metallic support structure known as a stent.

Figure 6. GORE® TAG® Thoracic Endoprosthesis.

One or more GORE® TAG® Thoracic Endoprostheses may be placed in your **thoracic aorta**. The devices are placed to fit above, across, and below the diseased portion of the **aorta** (see *Figures 5a, 5b, and 6*).

Each **endovascular graft** is compressed onto the end of a long, thin, tube-like device called a **delivery catheter** (see *Figure 7*). The **delivery catheter** is used to deliver the **endovascular graft** by making a small incision into the **femoral** or **iliac artery** in the groin.

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

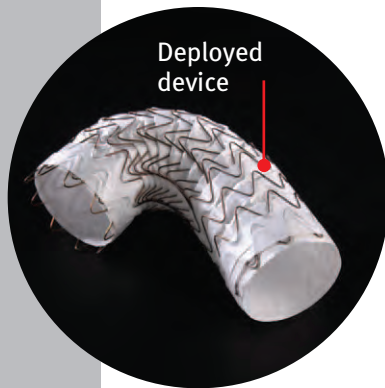
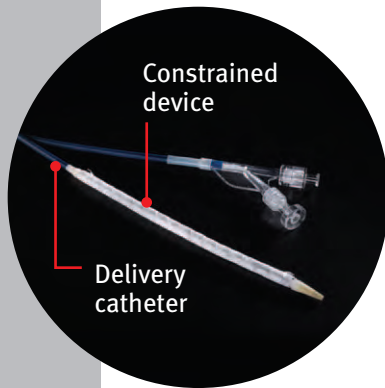


Figure 7. GORE® TAG® Thoracic Endoprosthesis (on and off **delivery catheter**).

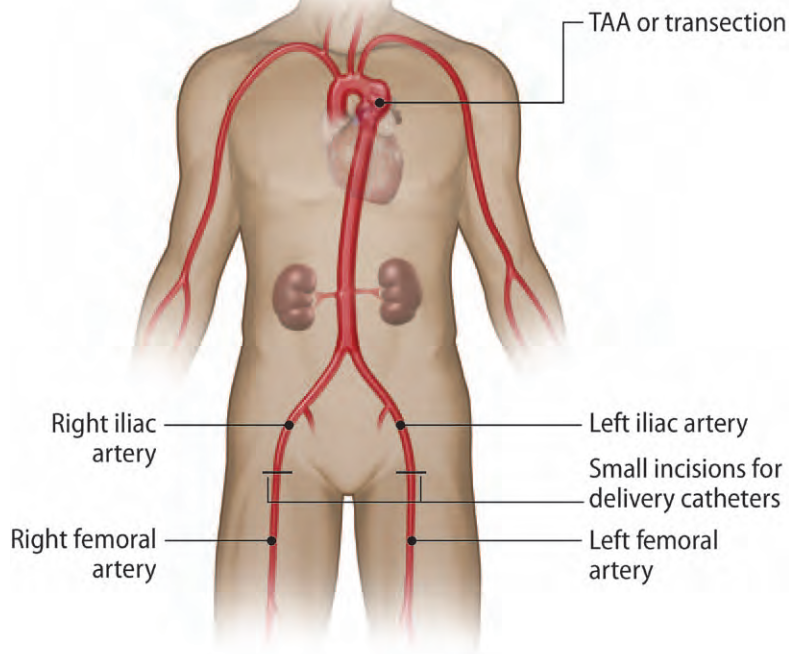


Figure 8.
*Insertion sites of
delivery catheters
for placement of
GORE® TAG® Thoracic
Endoprosthesis.*

WHAT IS THE GORE® TAG® THORACIC ENDOPROSTHESIS PROCEDURE?

The GORE® TAG® Thoracic Endoprosthesis procedure consists of the implantation of a GORE® TAG® Thoracic Endoprosthesis to exclude an aortic lesion. 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** through a small incision (cut) in the groin and carefully guided up the leg artery through the abdomen into the chest (near the heart) to the site of the **isolated lesion** (*Figure 8*).
2. Once the **endovascular graft** is correctly positioned in the **aorta** (across the **isolated lesion**), 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 diseased segment and reline the artery wall.
4. The **delivery catheter** is withdrawn from the body.
5. Following deployment, the device is ballooned, which aids in sealing / seating of the device in the **aorta**.

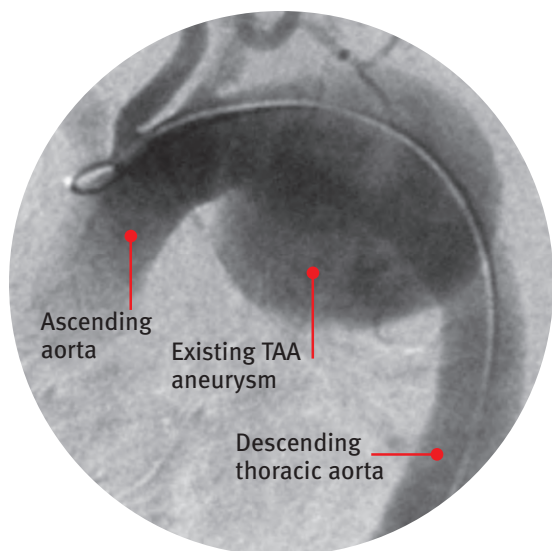


Figure 9a. Pre-Operative TAA.

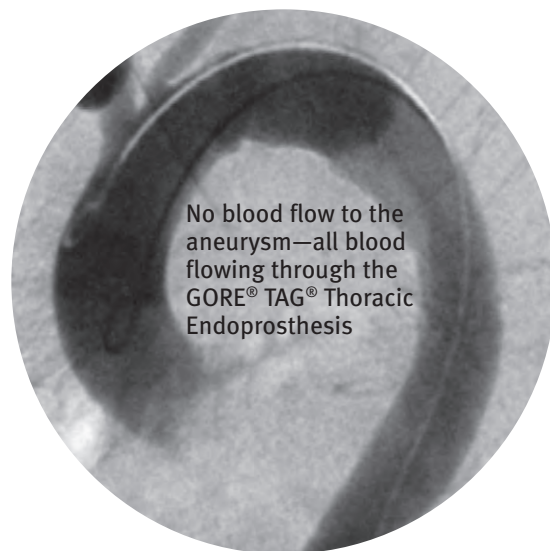


Figure 9b. Post-Operative TAA.

These steps are the same for each device. At the end of the procedure, your doctor will confirm the position of the device and exclusion of blood flow to the **isolated lesion** by using x-ray **angiography** (see *Figures 9a* and *9b*). The doctor will then be able to determine whether the **isolated lesion** has been successfully excluded before closing up the groin incision with a few sutures.

After the GORE® TAG® Thoracic Endoprosthesis procedure, you will receive a card to be kept in your wallet that contains information on the device(s) implanted, date of implant, implanting physician information, and **MRI** information for the device(s) implanted. It is safe to have **MRI** procedures after implant of the device(s) under specific conditions. These conditions are on the wallet card you will be provided and should be shown to your healthcare provider prior to having an **MRI** procedure.

WHAT FOLLOW-UP EVALUATIONS WILL I HAVE?

Currently, follow-up is advised to include check-ups at 1 month, 6 months, 12 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**, 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.

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 **isolated lesion** and / or growth of the diseased segment. This type and frequency of follow-up visits are generally not required after open surgical repair.

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 **isolated lesion**. While most **endoleaks** do not cause any medical problem, a small number require additional treatment.
- **Isolated lesion** growth or **rupture** – Symptoms of **isolated lesion** growth are not always present, but when they are, the most common symptoms are pain, numbness, and weakness in the legs, back, chest, or abdomen. **Rupture** symptoms include dizziness, fainting, rapid heartbeat, or sudden weakness.
- Vessel **occlusion** – Symptoms include pain, numbness, or weakness in the arm(s), hip(s), or leg(s), or discoloration or coolness of the arms(s), hand(s), or leg(s).

IMPORTANT SAFETY INFORMATION

Gore conducted numerous clinical studies in the United States to understand the benefits and possible complications of **endovascular repair** of the **thoracic aorta**. Nine clinical studies, treating a total of 592 patients with **endovascular grafts**, were conducted to establish the safety and effectiveness of the device for the treatment of **isolated lesions** of the **thoracic aorta**.

Patients treated in these studies were between the ages of 21 and 93 years old. Many of the patients treated for **aneurysms** in these studies had high blood pressure, high cholesterol, and a history of cigarette smoking. Most patients treated for **transections** were relatively healthy prior to the accident that caused their **transection**. You should discuss with your physician how your conditions may correspond with those of the patients in these studies and how that may affect your recovery from **endovascular repair**.

POSSIBLE COMPLICATIONS

Most complications associated with repair of a **TAA** or **transection** occur within the first 30 days after treatment. Below is a list of some of the more common possible complications that may occur within 30 days of **endovascular repair**.

- Bleeding complications including blood loss
- Injury to blood vessels
- Kidney complications / failure
- Abnormal or irregular heart beat
- Bowel / intestine obstruction or other disorders
- Pneumonia or difficulty breathing
- Blood leaking around the device
- Respiratory failure / complications
- Wound complications including infection
- Heart disorders
- Temporary or permanent loss of feeling in both legs
- Stroke
- Death

Other possible complications could include:

- Additional procedure to treat blood leaking around device or **TAA** growth
- Chest pain
- Infection
- Lymphatic system complications
- Anemia
- Hole or tear in blood vessel
- **Aneurysm** enlargement
- Increased white blood cell count
- Shock
- Muscle weakness
- Mental status change
- Fever

It is anticipated that possible complications for **endovascular repair** of other **isolated lesions**, besides **TAA** and **transection**, are similar to those listed above.

POSSIBLE COMPLICATIONS AFTER 30 DAYS

In addition to the possible complications on the previous page, **endovascular grafts** require regular and routine follow-up to ensure that the device is functioning properly long-term. One long-term complication that could occur after your **endovascular repair**, is a chance of blood leaking around the **endovascular graft (endoleak)** which could cause your **isolated lesion** to grow and burst (**rupture**) if untreated. If you have blood leaking around the device, your physician may recommend an additional **endovascular repair** or open surgical procedure to stop the leaking.

As always, please consult your physician for more information and to aid in understanding this information to be used in your treatment decisions.

POSSIBLE BENEFITS OF TREATMENT

Isolated lesions of the **thoracic aorta** could grow / expand and eventually **rupture** with life-threatening results if left untreated. The larger the lesion grows, the higher the risk of **rupture** over time. Two options for treatment include **endovascular repair** and open surgery. The rates for both **endovascular repair** and open surgery from the Gore clinical studies evaluating treatment of low risk **aneurysm** patients are shown below.

COMPLICATION	ENDOASCULAR REPAIR	OPEN SURGERY
Death in the first 30 days	0–2%	6.4%
Major complications in the first 30 days	15.7–28.6%	70.2%
Blood loss during procedure	$\frac{1}{3}$ – $\frac{1}{2}$ pint	4 pints
Time in ICU (intensive care unit)	1.2–1.9 days	3 days
Time in hospital	3–4 days	9 days
Time to return to normal daily activities	18–30.5 days	80 days

Possible benefits of treating **isolated lesions** other than **aneurysms** cannot be anticipated as similar data to that displayed above is not available for these other **isolated lesions**.

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; vascular trauma, **endoleak**, continued **isolated lesion** growth, device movement, etc.
- 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 **isolated lesion**. 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 **isolated lesion**. 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.

WHERE CAN I GET MORE INFORMATION?

Background Information on Thoracic Aneurysms and Transections

www.emedicine.com/emerg/topic942.htm

www.emedicine.com/MED/topic2783.htm

www.vascularweb.org/Pages/default.aspx
(search – thoracic aneurysm)

www.webmd.com
(search – thoracic aortic aneurysm or traumatic aortic transection)

www.trauma.org/archive/thoracic/CHESTaorta.html

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.nlm.nih.gov/medlineplus

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.

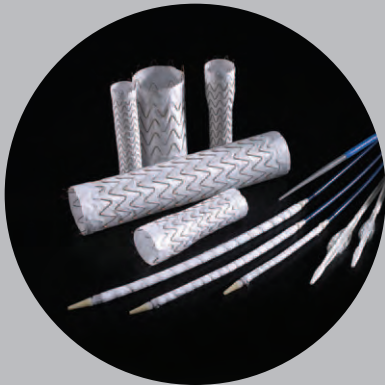
www.goremedical.com

The Gore Medical Products Division has provided creative therapeutic solutions to complex medical problems for more than 35 years. During that time, more than 30 million innovative Gore Medical Devices have been implanted, saving and improving the quality of lives worldwide. The extensive Gore Medical family of products includes vascular grafts, endovascular and interventional devices, surgical meshes for hernia repair, soft tissue reconstruction, staple line reinforcement, and sutures for use in vascular, cardiac, and general surgery.

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 YOU MAY WANT TO ASK YOUR DOCTOR

- What are the options for treating my **isolated lesion**?
- Is **endovascular repair** an option for treating my **isolated lesion**?
- Which **endovascular grafts** are approved for treatment of my **isolated lesion**?
- What are all the possible complications of **endovascular repair** of my **isolated lesion**?
- What are all the possible complications of open surgical repair of my **isolated lesion**?
- After the **endovascular repair**, how often will I need to return for follow-up with my doctor? What exams will be done at these appointments?
- What should I expect after treatment with regards to recovery?
How long will recovery take?
- Are there limitations to my normal daily activities after treatment?
If yes, for how long?
- How many **endovascular repairs** for my type of **isolated lesion** have you (i.e., your doctor) performed?
- Will my health insurance pay all or part of the cost associated with the **endovascular repair**?

ADDITIONAL QUESTIONS FOR MY DOCTOR

ADDITIONAL QUESTIONS FOR MY DOCTOR



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