Endovascular Treatment of the Thoracic Aorta

Patient Information
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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 risk factors and common symptoms, as well as a less-invasive method of treating diseases and injuries of the thoracic aorta. Whether you are trying to reduce your risk or supporting a loved one diagnosed with a thoracic aortic disease or injury, we hope this information will be helpful for you and your family.

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.
There are many different diseases or injuries of the **thoracic aorta**. The most common categories are **isolated lesions** and **aortic dissections**. **Isolated lesions** of the **thoracic aorta** include any **aorta** with a diseased portion that has healthy **aorta** above and below the disease or injury. 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. **Aortic dissections** are a disease in the **thoracic aorta** where a small tear occurs in the inner layer of the **aortic wall** allowing blood to flow between the layers of the **aortic wall**.

If you or a loved one has one of these diseases or injuries, you may be seeking information on risk factors, common symptoms, and how it can be treated. This brochure describes diseases and injuries of the **thoracic aorta**, 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**. 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.
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 oxygenated 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).

**Aortic Dissection** — The tearing of the inner layer of the aortic wall, allowing blood to flow into the wall itself and cause the separation of the inner and outer layers.
**Aortic Wall** — The wall of the aorta is made up of three layers; the thin outer layer (adventitia), the thick, elastic middle layer (media) and the thin inner layer (intima).

**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 aortic arch (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, runs down through the chest and the abdomen, and ends by splitting into the two 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 aortic arch to the diaphragm, has numerous branches that supply oxygenated blood to the chest and the organs within the chest.

Endoleak — Unwanted blood flow into the diseased or injured portion of the aorta after placement of an endovascular graft.

Endovascular Graft — A graft supported by a metal stent that is implanted within a diseased vessel intended to relieve weakened vessel walls without the use of open surgical techniques. Endovascular grafts are delivered to the diseased or injured aorta at a small size, compressed on a delivery catheter, and then are deployed or expanded to the size of the vessels in which they are placed.
Endovascular Repair — The use of real time x-ray (fluoroscopy) and guidewires to treat unhealthy arteries with an endovascular graft delivered through small incisions in the iliac or femoral arteries. The endovascular graft excludes (seals off) the lesion inside the diseased or injured aorta, making a new path for blood to flow. Through this less invasive technique, physicians can treat certain conditions through small incisions in the skin that might otherwise require open surgery.

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 grafts 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 a portion of the chest, and the right common carotid artery which supplies blood to the right side of the head and neck (see Figure 2).

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 catheter, long thin tube advanced into the body over a guidewire, 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 2*).

**Left Subclavian Artery** — One of the main branches off the **aortic arch** that supplies blood to the left arm and a portion of the chest (see *Figure 2*).

**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 tube-shaped graft made of a man-made material that is sewn into place with sutures to replace diseased human vessels. Open surgical repair of a diseased or injured portion of the aorta often uses a synthetic graft.

**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 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.

**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. Transections are most commonly caused during motor vehicle accidents.

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

WHAT IS THE AORTA?
The aorta is the main artery that carries oxygen-filled blood from the heart to all parts of the body through smaller branched arteries. In the thorax (chest), blood travels from the heart through the ascending aorta into the aortic arch and branches 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 becoming the descending aorta which carries blood to the spine, organs, and lower 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 to all parts of the body through smaller branch vessels.

Figure 2.
The aorta 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 3.
An aneurysm is the ballooning of the thoracic aorta. The weakened sections of the aortic wall may rupture (burst).

Thoracic Aortic Aneurysms (TAA)

WHAT IS A TAA?
A TAA is a swelling or ballooning of the thoracic aorta that results from a weakened section in the artery (see Figure 3).

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.

Your doctor may also recommend an angiogram (see Figure 4), or additional testing such as CT scan, MRI, or IVUS (Intravascular Ultrasound) to determine the precise location, size, and shape of the aneurysm and your surrounding arteries.
Figure 4.
An angiogram showing an aneurysm of the descending aorta.
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 aorta.

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.
WHAT IS A TRANSECTION?
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 5). This condition, if not treated, could result in a rupture (bursting) of the aorta leading to internal bleeding. Ruptured transections are frequently fatal.

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 or MRI.

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.

Figure 5. 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.
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 **TAAs**, there may be no symptoms associated with these and other **isolated lesions**. When symptoms do occur, they are similar to those previously discussed for **TAAs**. Please see “**What Are Some of the Symptoms of a TAA?**” for more information.
WHAT IS AN AORTIC DISSECTION?
Aortic dissection is the tearing of the inner layer of the aortic wall, allowing blood to flow into the wall itself and cause the separation of the inner and outer layers. The flow of blood between the layers could lead to a ballooning of the outer layer of the aorta, much like an aneurysm (see Figure 6).

Aortic dissections of the descending thoracic aorta, or Type B dissections, are often initially stabilized with medical treatment. However, if there is a risk of rupture or complications with blood flow to the lower body, treatment may be required.

WHAT ARE THE SYMPTOMS OF AN AORTIC DISSECTION?
An acute aortic dissection is a sudden onset of symptoms which include chest pain often described as severe and tearing along with cold sweats. The pain may be localized to the front or back of the chest. Typically the pain moves as the dissection worsens.
As aortic dissections age and become chronic, the flow of blood between the layers of the aortic wall could lead to a ballooning of the outer layer of the aorta, much like an aneurysm.

Many people may not experience any of these symptoms, but just as with aneurysms, 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.

Other symptoms and signs of both acute and chronic aortic dissections depend on the branch vessels involved and the effect on nearby organs.

Figure 6. Type B Dissection.
How Do Doctors Treat Diseases and Injuries of the Thoracic Aorta?

The size and location of the disease or injury and your general health will determine how you should be treated. When the disease or injury is small, or has a low risk to your health, your doctor may only recommend periodic check-ups to monitor your condition. However, a larger or rapidly growing disease or injury poses more risk of bursting (rupture), and may require treatment. In addition, aortic dissections that involve other branch vessels or affect your organs may require immediate 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 diseased or injured portion of the aorta 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 or injured 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 treatment of the thoracic aorta and are proven medical therapies. However, both therapies have their limitations. Medical management does not fix the diseased or injured aorta; it just reduces the stresses (i.e., blood flow pressure) on the diseased or injured area. 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 7a.** Artist’s rendition of the delivery of a GORE® TAG® Thoracic Endoprosthesis allowing for endovascular repair of an isolated lesion.

**Figure 7b.** Artist’s rendition of the delivery of a GORE® TAG® Thoracic Endoprosthesis allowing for endovascular repair of an aortic dissection.
**When Treatment Becomes Necessary, What are My Treatment Options? (continued)**

**ENDOVASCULAR REPAIR**

*Endovascular repair* is a relatively new procedure for the treatment of diseases or injuries of the *thoracic aorta*. 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*. See *Figures 7a and 7b* for illustrations of an endovascular graft used for treatment of an isolated lesion and an aortic dissection, respectively.

*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 thoracic aortic disease or injury, types of therapy, or more information about the GORE® TAG® Thoracic Endoprosthesis, visit the websites listed in the back of this brochure.
What is the GORE® TAG® Thoracic Endoprosthesis?

The GORE® TAG® Thoracic Endoprosthesis (see *Figure 8*) is an implantable device positioned by a delivery catheter. The endovascular graft is intended to exclude (seal off) the diseased or injured portion of the aorta 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 the thoracic aorta. 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.

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 7a and 7b*).
Figure 8. GORE® TAG® Thoracic Endoprosthesis.
Each endovascular graft is compressed onto the end of a long, thin, tube-like device called a delivery catheter (see Figure 9). The delivery catheter is used to deliver the endovascular graft by making a small incision into the femoral or iliac artery in the groin (see Figure 10).

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 9. GORE® TAG® Thoracic Endoprosthesis (on and off delivery catheter).
Figure 10. 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 diseased or injured aorta (see Figure 10).

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. 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 may be balloononed, which aids in sealing / seating of the device in the aorta.

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 diseased or injured aorta by using x-ray angiography (see Figures 11a and 11b). The doctor will then be able to determine whether the diseased or injured portion 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 diseased or injured aorta 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 including, but not limited to:

- **Endoleak** – An endoleak occurs when blood from the aorta continues to leak into the diseased or injured portion of the aorta.

- **Aortic growth or rupture** – Symptoms of aortic 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 arm(s), hand(s), or leg(s).
Gore conducted numerous clinical studies in the United States to understand the benefits and possible complications of endovascular repair of the thoracic aorta. Ten clinical studies, treating a total of 642 patients with endovascular grafts, were conducted to establish the safety and effectiveness of the device for the treatment of various diseases and injuries 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 and aortic dissections 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 treatment of diseases or injuries of the thoracic aorta 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 (including the aorta)
- Kidney complications / failure
- Abnormal or irregular heart beat
- Bowel / intestine obstruction or other disorders
- Pneumonia or difficulty breathing
- Blood leaking around the device

Other possible complications could include:

- Additional procedure to treat blood leaking around device or aortic growth
- Chest, back, or abdominal pain
- Infection
- Lymphatic system complications
- Anemia
- Hole or tear in blood vessel
- Aortic enlargement

- Respiratory failure / complications
- Wound complications including infection
- Heart disorders
- Temporary or permanent loss of feeling in both legs
- Stroke
- Death

- Increased white blood cell count
- Shock
- Muscle weakness
- Mental status change
- Fever
- Blood pressure complications (including high and low blood pressure)

It is anticipated that possible complications for endovascular repair of other diseases or injuries, besides TAA, transection, and aortic dissection 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 aorta 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

Diseased and injured portions of the thoracic aorta could grow / expand and eventually rupture with life-threatening results if left untreated. The larger the diseased or injured portion 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.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Endovascular Repair</th>
<th>Open Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death in the first 30 days</td>
<td>0–2%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Major complications in the first 30 days</td>
<td>15.7–28.6%</td>
<td>70.2%</td>
</tr>
<tr>
<td>Blood loss during procedure</td>
<td>$\frac{1}{3}$ – $\frac{1}{2}$ pint</td>
<td>4 pints</td>
</tr>
<tr>
<td>Time in ICU (intensive care unit)</td>
<td>1.2–1.9 days</td>
<td>3 days</td>
</tr>
<tr>
<td>Time in hospital</td>
<td>3–4 days</td>
<td>9 days</td>
</tr>
<tr>
<td>Time to return to normal daily activities</td>
<td>18–30.5 days</td>
<td>80 days</td>
</tr>
</tbody>
</table>

Possible benefits of treating aortic dissections and isolated lesions other than aneurysms cannot be anticipated as similar data to that displayed above is not available for these other 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 aortic growth, device movement, etc.
- The possibility that an additional endovascular repair 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.

As with any surgery or medical procedure, there are potential complications with **endovascular repair**. 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 diseased or injured **aorta**. 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, Transections, and Aortic Dissections

www.emedicine.medscape.com
(reference search — thoracic aneurysm or aortic dissection)

www.vascularweb.org
(search — thoracic aneurysm, transection, or aortic dissection)

www.webmd.com
(search — thoracic aneurysm or aortic dissection)

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 condition?
- Is endovascular repair an option for treating my condition?
- Which endovascular grafts are approved for treatment of my condition?
- What are all the possible complications of endovascular repair?
- What are all the possible complications of open surgical repair?
- 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 disease or injury 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