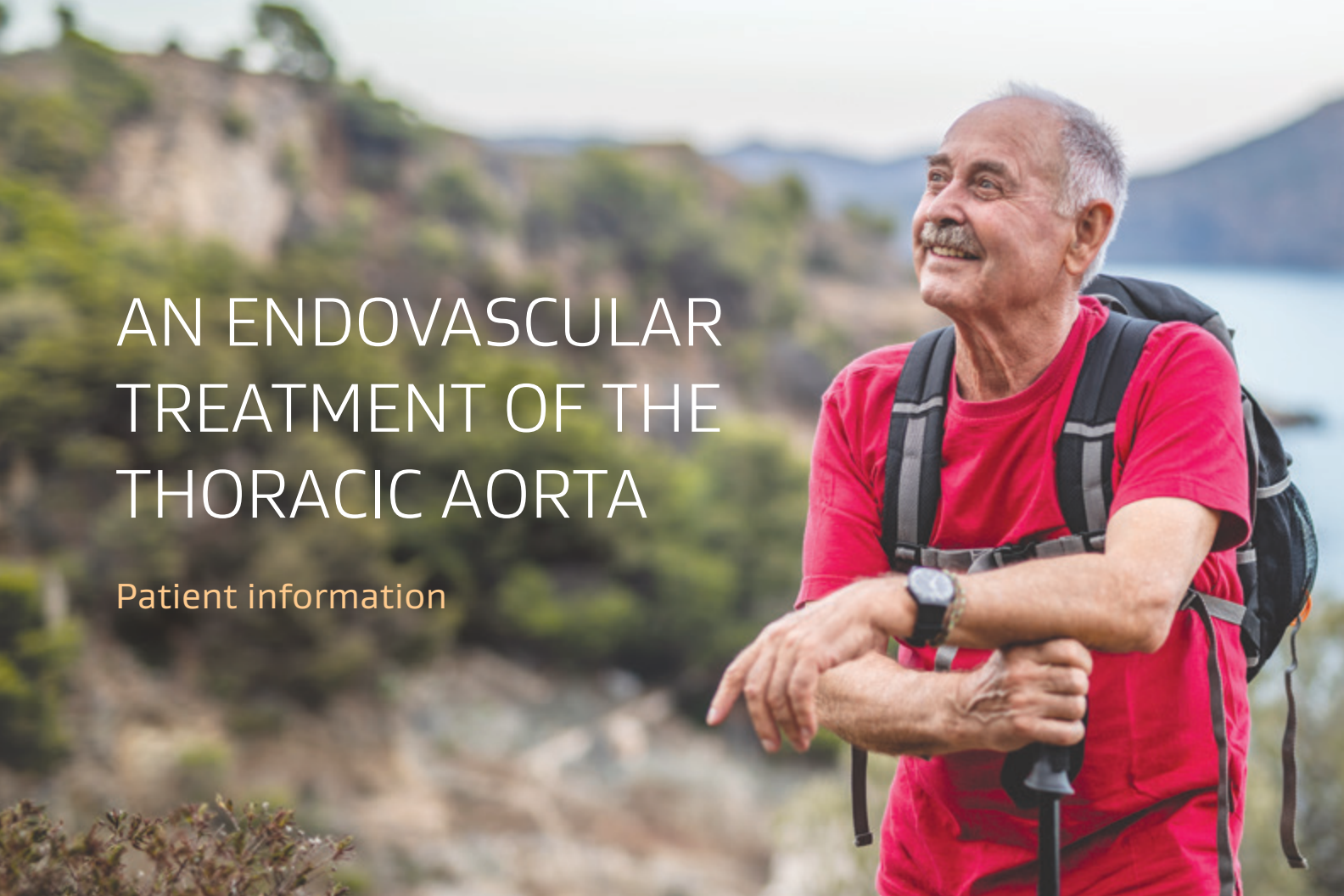


AN ENDOVASCULAR TREATMENT OF THE THORACIC AORTA

Patient information

Table of Contents

Introduction

This brochure is intended to provide basic information about thoracic aortic disease, and to assist you in making an informed decision about your treatment options. If you have any questions or concerns about the diagnosis or treatment of your medical condition, please talk to your doctor. A glossary of medical terms has also been included starting on page 24. Any words that are bold throughout the text can be found in the glossary.

As with any surgery or medical procedure, the best resource for information and advice is your doctor. We hope this information will be helpful to you and your family.

Thoracic aortic disease or injury

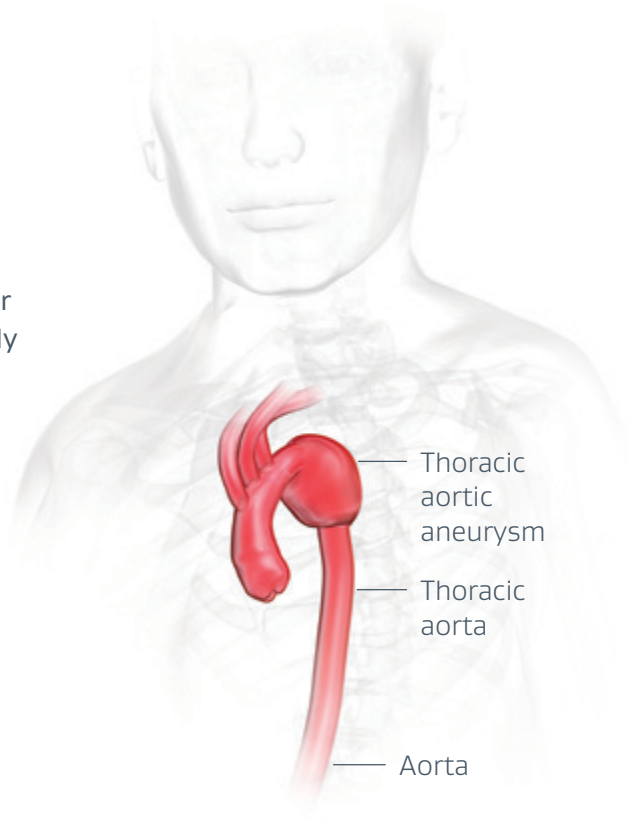
The **aorta** is the largest blood vessel in the body. It carries blood from the heart to the rest of the body through smaller branched arteries. The **thoracic aorta** is the section of the vessel located within the chest.

There are many different diseases or injuries of the thoracic aorta. The most common categories are **thoracic aortic aneurysm (TAA)**, **traumatic aortic transection** and **aortic dissection**.

Thoracic aortic aneurysm

An **aneurysm** is a ballooning (thinning and enlarging) of the aorta caused by continuous blood pressure against a weakened area. Over time an aneurysm may grow, further weakening the wall of the aorta, or it can burst completely causing **rupture**, which is bleeding inside the body.

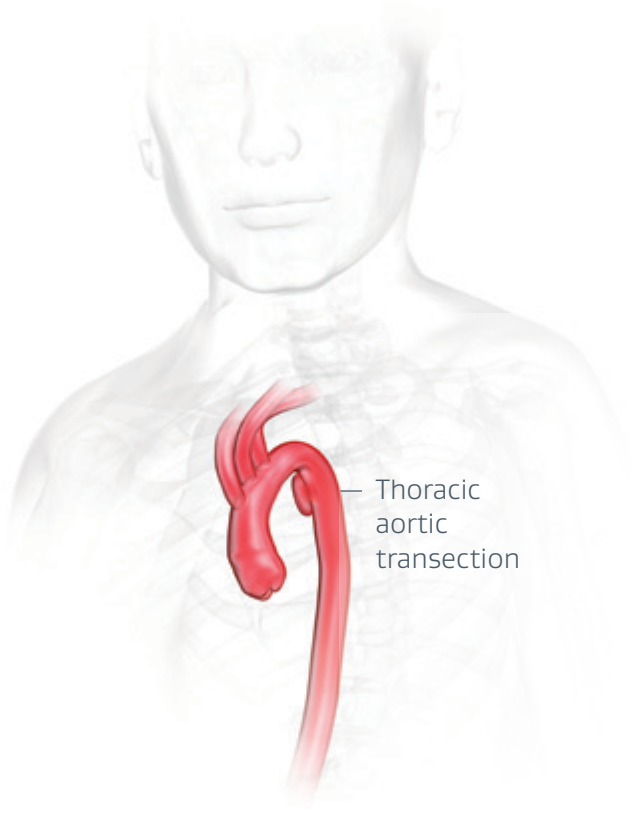
A thoracic aortic aneurysm (TAA) is the swelling or ballooning of the thoracic aorta.



Thoracic aortic 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. This condition, if not treated, could result in a rupture of the aorta leading to internal bleeding. Ruptured transections are frequently fatal.

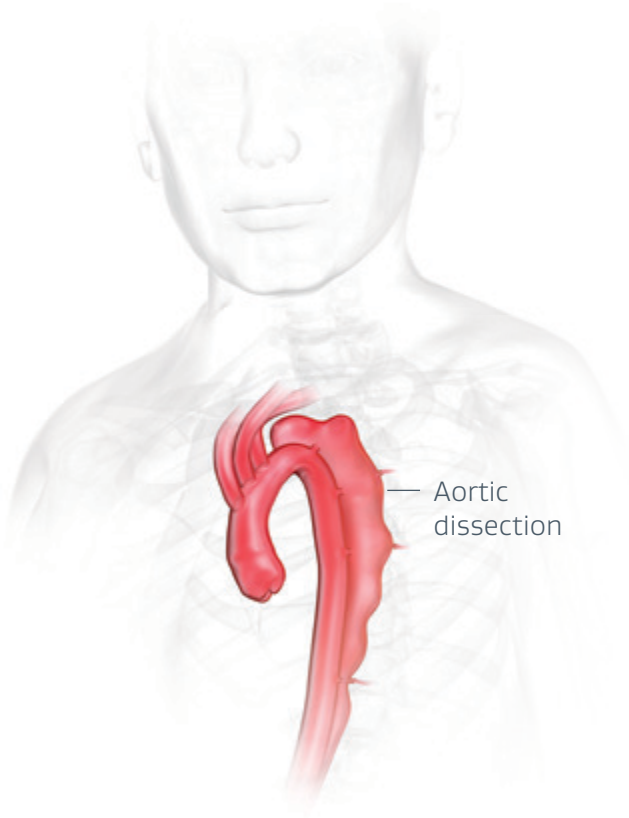
Transections most commonly occur in accidents such as motor vehicle accidents, being hit by a motor vehicle, or falls from heights. Transections most commonly occur in the **descending aorta** but can occur in other places within the aorta.



Aortic dissection

An aortic dissection is 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.

An acute aortic dissection is a sudden onset of symptoms. 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. If there is a risk of rupture or complications with blood flow to the lower body, treatment may be required.



Causes

Over time, weakening of the aorta due to vascular disease, injury (trauma), or a genetic (hereditary) defect of the tissue within the aortic wall can cause thoracic aorta conditions that require treatment.

Risk factors for developing thoracic aortic disease include:

- Heredity (family history)
- Smoking
- High blood pressure
- Heart disease

Symptoms

Many people do not experience any symptoms when thoracic disease is present. 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.

Diagnosis of transections is often not based on symptoms, but rather on the fact that the patient was in an accident.

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

Your doctor may discover thoracic disease during a routine physical exam or a medical test such as a **CT scan** or **MRI**.

Treatment options

The size and location of the disease or injury and your general health influence which treatment your doctor recommends. 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 rupture and may require treatment. The risk of rupture increases with size of the disease or injury and high blood pressure.

Two primary options are available if your doctor feels surgical treatment is necessary: Open surgical repair or **endovascular repair**.

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 in the chest to repair the aorta by replacing the diseased or injured section with a **synthetic graft** that is sewn into the aorta. This procedure requires stopping blood flow through the aorta while the graft is being put into place.

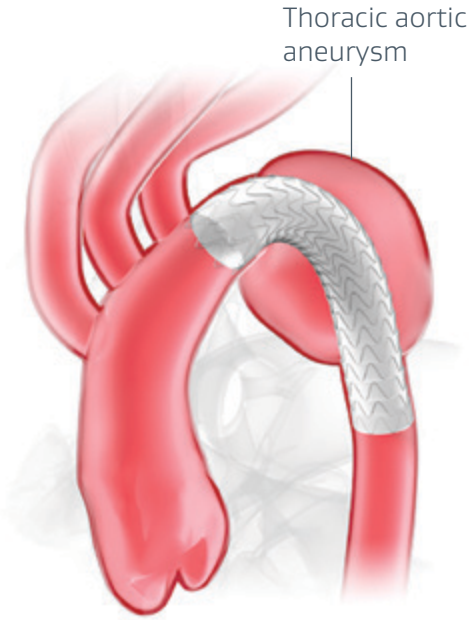
This procedure is typically performed under general anesthesia and takes about two to four hours to complete. Patients usually stay overnight in the intensive care unit and about one week in the hospital. Recovery time can take about three to six months.

Endovascular repair

Endovascular repair involves sealing off the diseased or injured portion of the aorta by placing a **stent graft** inside the affected area, making a new path for the blood to flow. The stent graft remains inside the aorta permanently through the use of a metal stent creating a tight fit and seal against the wall of the aorta. It is a less invasive procedure than open surgery and does not require an incision in the chest, since a stent graft is placed inside the aorta from a small incision made in each leg.

Endovascular repair may be performed under general, regional or local anesthesia and typically takes one to three hours to complete. Patients typically stay in the hospital for only one to two days and can usually return to normal activity within six weeks.

As with any surgery or medical procedure, there are potential serious complications with the treatment. Discuss the risks and benefits with your doctor to determine which option is best for you or your family member.



GORE® TAG® Conformable Thoracic Stent Graft

The GORE® TAG® Conformable Thoracic Stent Graft is an implantable stent graft designed for endovascular repair of the thoracic aorta. It is a tube-shaped device that 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® Conformable Thoracic Stent Graft is made of ePTFE (expanded polytetrafluoroethylene) with an outer metallic support structure known as a stent.

While the procedure is similar for trauma or dissection repair, below is an example of the steps included in an aneurysm repair.

Procedure steps

The stent graft is implanted using **fluoroscopy**, real-time x-ray images, and is viewed on a monitor while the physcian is following these steps:

1. The **delivery catheter**, which contains the stent graft, is inserted into the **femoral** or **iliac artery** and carefully guided through the artery, then through the abdomen into the chest to the site of the diseased or injured aorta.
2. Once the stent graft is correctly positioned in the aorta, it is released or deployed from the delivery catheter.
3. The stent graft self-expands to the diameter of the aorta. The placement of the stent graft is designed to exclude (seal off) the diseased segment and reline the aortic wall.
4. The delivery catheter is withdrawn from the body.
5. Following deployment, the stent graft may be ballooned, which aids in sealing the device in the aorta.

More than one GORE® TAG® Conformable Thoracic Stent Graft may be placed in your thoracic aorta. The devices are placed to fit above, across and below the diseased portion of the aorta.

Clinical Data Summary

Three separate studies were conducted in the United States to assess the device safety and effectiveness.

Thoracic aortic aneurysms: A 51-patient study was conducted to assess the safety and effectiveness in patients presenting with thoracic aortic aneurysms. The study met the predefined endpoints of treatment success at one month after the device was implanted, defined as the ability to place the device as intended and the patient not experiencing any major device events within 30 days post procedure. Of the 50 patients evaluated at 30 days post procedure, 98% of patients had the device placed and were free of a major device event. Patients were continued to be followed for five years. At five years, patients had an 93% freedom from aneurysm related death and 92% did not experience a major device event.

Aortic dissections: A 50-patient study was conducted to assess the safety and effectiveness in patients presenting with acute (< 14 days from onset) and complicated (clinical symptoms) Type B dissections. The study met the predefined endpoints of treatment success at one month after the device was implanted, defined as the ability to place the device as intended to cover the primary entry tear of the dissection and the patient not experiencing any major device events within 30 days post procedure. Of the 40 patients evaluated at 30 days, 98% of patients had primary entry tear coverage. Four patients not evaluated at 30 days were due to

mortality and six had insufficient information available for evaluation. Patients were continued to be followed for five years. At five years, 96% of patients available for evaluation did not experience deaths related to the aortic dissection after 30 days.

Traumatic transections: A 51-patient study was conducted to assess the safety and effectiveness in patients presenting with traumatic transections. The study met the predefined endpoints of treatment success at one month after the device was implanted, defined as the ability to place the device as intended and the patient not experiencing any major device events within 30 days. Patients were continued to be followed for five years. Of the 47 patients evaluated at 30 days post procedure, all were free of a safety event (100%). The four patients not evaluated at 30 days were due to death not related to the aortic transection. At five years, none of the patients who were available for evaluation, died related to the aortic transection.

Although the device events reported in these studies are similar to other (TEVAR) procedures and stent grafts, please talk to your doctor to better understand how the GORE® TAG® Conformable Thoracic Stent Graft compares to the other TEVAR devices. Your experiences may vary, and you may have higher or lower risks with regard to these types of events. You should discuss the likely risk of these events throughout your life with your doctor and discuss how the risks and benefits of the GORE® TAG® Conformable Thoracic Stent Graft may apply to you.

Potential risks

Like open surgery, endovascular repair with a stent graft comes with risks. It is important to discuss the risks and benefits of treatment with your doctor. Some of the potential risks associated with stent grafts include:

Endoleaks — When blood from the aorta continues to leak into the thoracic aortic aneurysm. Most endoleaks do not require treatment.

Stent graft movement — Movement of the stent graft from its original position over time.

Stent graft failure-related issues — These issues may be detected using imaging techniques such as X-rays.

Aneurysm growth.

Aneurysm 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).

The use of this device requires fluoroscopy and use of dyes for imaging. Patients with kidney problems may be at risk of kidney failure due to the use of dyes.

Swelling of the groin area.

Nausea and vomiting.

A hole or a tear of the blood vessels are risks associated with any catheter-based procedure.

Formation of an abnormal passage between your arteries and veins.

Bowel complications including death of a portion of your bowel tissue requiring surgical removal.

Formation of blood clots that block the flow of blood to your organs.

Fever and inflammation.

Infection of the aneurysm and device access site, pain or bleeding.

Complications of the nervous system including total or partial paralysis of the lower half of the body with involvement of both legs, confusion, stroke and transient ischemic attack.

Blockage of the device or blood vessel.

Surgical conversion to open surgical repair.

Kidney problems.

Death.

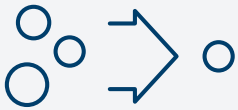
Potential benefits

There are a number of potential benefits to having an endovascular repair with a stent graft compared to open surgical repair:

The procedure is

minimally invasive.

and can be performed under local anesthesia.[1]



Lower surgical complication rate.[2,3]

Less loss of blood

during the procedure, reducing the risk of needing a blood transfusion.[1]

Less time

spent in the intensive care unit after the procedure, and the potential for a shorter hospital stay.[2]

Follow-up

After endovascular repair with the GORE® TAG® Conformable Thoracic Stent Graft, follow-up exams will typically consist of a physical examination and imaging, such as a CT scan, to check the repair and evaluate the stent graft performance.

Follow-up will be scheduled with your doctor on a regular basis. These visits commonly occur at one month, six months and annually thereafter.

When should I call my doctor?

Contact your doctor immediately if you experience any of the following symptoms after your procedure:

- Pain, numbness and weakness in the arms, legs, back, chest or abdomen
- Dizziness, fainting, rapid heartbeat or sudden weakness
- Discoloration or coolness of the arms, hands or legs
- Any other unusual symptoms

Other patient considerations

After undergoing an endovascular repair procedure, there are some lifestyle changes that you should be aware of:

- Consult your doctor about your ability to safely perform strenuous physical activities.
- An implanted stent graft typically will not trigger screening or metal detectors, like those at airports or secure building entrances, but consult your doctor about your specific device.
- You should carry your permanent implanted device identification (ID) card in your wallet.

Implanted device identification card

After the procedure, your doctor will give you a temporary implanted device ID card. The temporary implanted device ID card will tell you the size and number of your thoracic aortic stent graft implants.

A permanent ID card will be provided later and will list the following information:

- Type of device implanted
- Date of implant
- Your doctor's information
- Magnetic resonance imaging (MRI) information

Be sure to tell all of your healthcare providers that you have the stent graft and show them your implanted device ID card. You should keep your patient ID card available at all times.

Magnetic resonance imaging

It is still safe to have **MRI** procedures, under certain conditions. MRI information is provided on your implanted device ID card. Before having an MRI, always show your implanted device ID card to your healthcare providers.

Glossary of medical terms

Aneurysm
A ballooning (thinning and enlarging) of a weakened area of a blood vessel.

Aorta
The main artery (blood vessel) that carries blood from the heart to the rest of the body.

Aortic arch
A part of the main artery (aorta) that connects the ascending aorta with the descending aorta.

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, the thick, elastic middle layer and the thin inner layer.

CT (computed tomography) scan
An imaging technique that uses multiple scans to create a very precise view of your abdomen and aorta. Also known as a CAT scan.

Delivery catheter
A long, thin, tube-like tool that assists in the delivery and positioning of a stent graft.

Descending aorta
Part of the main artery (aorta) that begins at the aortic arch and runs down through the chest and abdomen.

Endoleak
Unwanted blood flow into the diseased or injured portion of the aorta after placement of a stent graft.

Endovascular repair
A procedure in which a stent graft is placed inside a diseased vessel without surgically opening the tissue surrounding the weakened vessel to exclude (seal off) an aneurysm inside the aorta, making a new path for blood to flow.

Femoral arteries
Two arteries located in each leg, which carry blood to the femur or thigh region of each leg.

Fluoroscopy
A real-time X-ray image that is viewed on a monitor used during endovascular repair.

Iliac arteries
The iliac arteries begin from the bifurcation (separation) of the aorta in your abdomen. These arteries connect the aorta to the femoral arteries delivering blood to the legs.

Magnetic resonance imaging (MRI)
A technique that uses magnetic fields to form images of structures within the body.

Occlusion
The blocking of an artery, causing the stop of normal blood flow.

Rupture
A tear in the vessel wall near or at the location of the weakened area of the aneurysm allowing blood to flow into the areas around the heart, lungs, or abdomen.

Stent graft

A synthetic graft implanted within a weakened blood vessel to exclude (seal off) from the inside. Compressed stent grafts are delivered via catheter to the weakened area, and once positioned, expanded to fit the size of the vessels in which it is placed.

Synthetic graft

A man-made material in tube form intended to replace damaged blood vessels.

Thoracic aorta

The part of the aorta that is located in the chest.

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.

Traumatic Aortic Transection (Transection)

A ballooning (enlarging and thinning) of the aorta due to a weakening in the arterial wall that occurs in the chest area.

Questions for my doctor

You and your doctor should review the risks and benefits when discussing this stent graft and procedure including:

- Risks and differences between endovascular repair and open surgical repair.
- Potential advantages of traditional open surgical repair.
- Potential advantages of endovascular repair.
- The possibility that additional endovascular treatment or surgery may be required after initial endovascular repair.

In addition to the potential risks and benefits of an endovascular repair, your doctor should consider your commitment to and compliance with post-operative follow-up as necessary to ensure continuing safe and effective results.

Together, improving life

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