ENDOVASCULAR TREATMENT OF THE THORACIC AORTA

Patient information

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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 31. 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 this blood vessel located within the chest. The **aortic arch** is the top section of the thoracic aorta and connects the **ascending aorta** with the **descending aorta**.

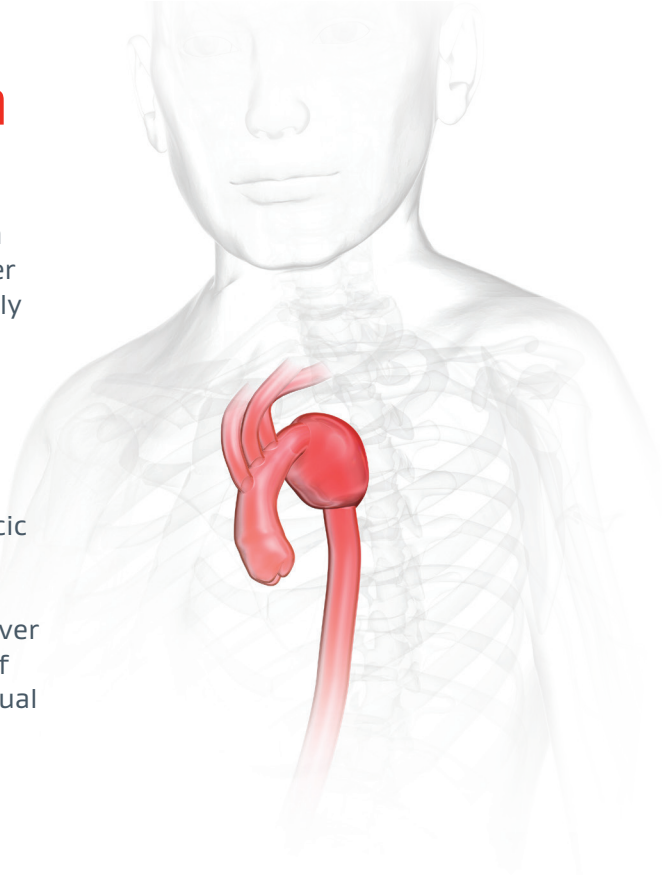
There are many different diseases and injuries of the thoracic aorta. The most common categories are **thoracic aortic aneurysm (TAA)**, **traumatic aortic transection** and **aortic dissection**. These diseases or injuries can sometimes require the **left subclavian artery (LSA)** to be covered. Aneurysm and dissection may affect any area of the thoracic aortic arch or descending aorta, where traumatic transections are typically located in the descending aorta. The location of your aortic disease or injury may require coverage of one of the main arteries that branches off your aortic arch–either your **brachiocephalic artery (BCA), left common carotid artery (LCCA),** or **left subclavian artery (LSA).** These vessels are the main branches of the aorta that supply blood to the brain and arms.

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.

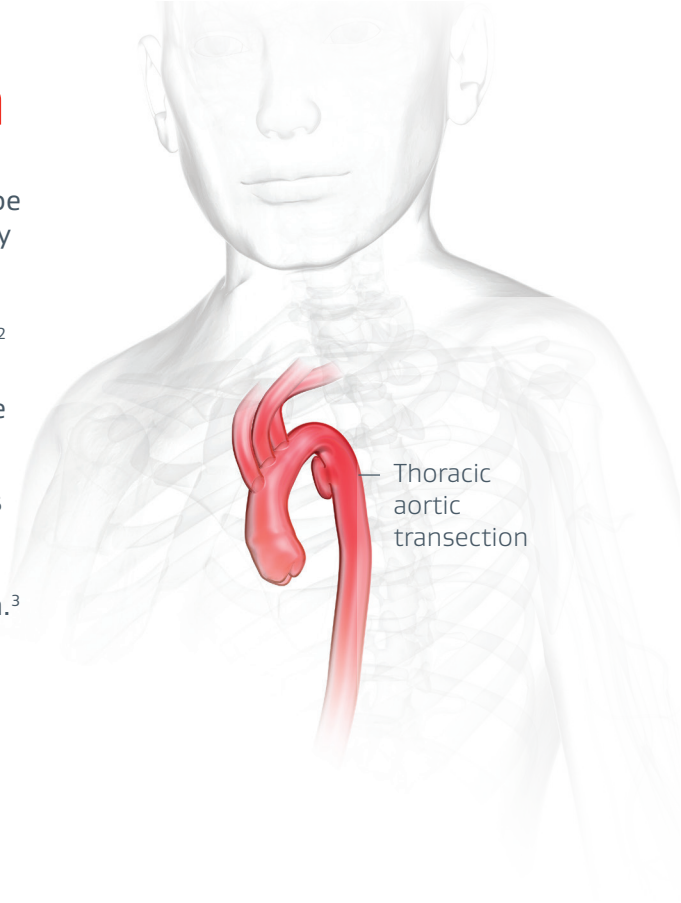
Thoracic aortic aneurysms (TAA) are rare, occurring in approximately 53 cases per every 1 million people. Thoracic aortic aneurysms are known to occur more often in men than women, and the risk increases above the age of 50. Screening is especially recommended in men who have ever smoked and are over the age of 65. The natural history of aneurysm is an increase in sac diameter leading to eventual rupture.[1]



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.[2] 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 due to 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 elsewhere in the aorta.[3]

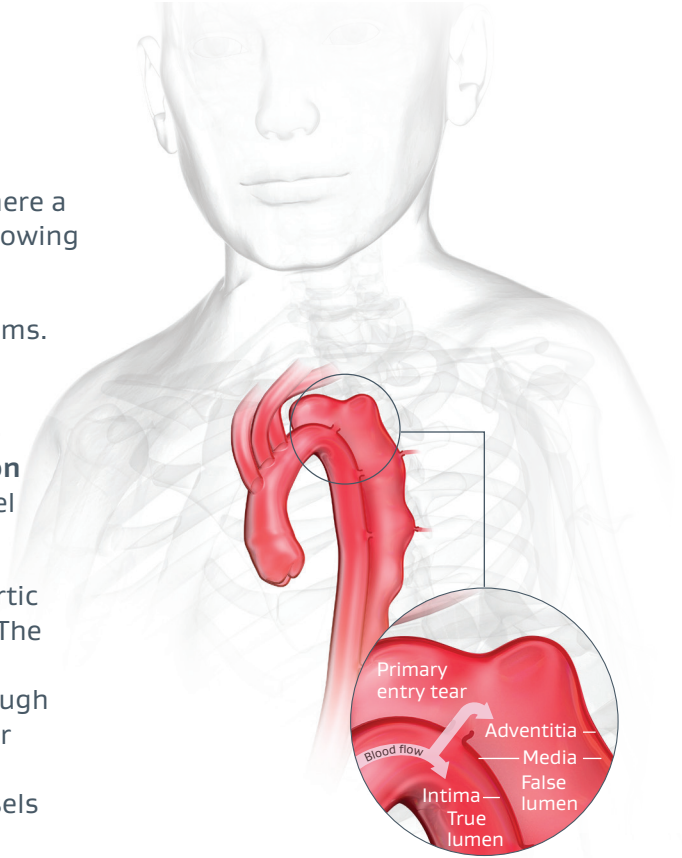


Aortic dissection

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 **malperfusion** (loss of blood flow to vital organs caused by blood vessel obstruction), treatment may be required.[4]

Thoracic aortic dissection (TAD) is the most common aortic catastrophe requiring immediate surgical intervention. The exact population incidence is unknown as up to 30% of aortic dissections may not be clinically diagnosed, although published figures range from 5-30 cases per 1 million per year. Common complications associated with dissection are rupture and blood flow obstruction into branch vessels causing a lack of blood flow to an organ or leg(s).[5-8]



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, 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 has had an accident.

An acute aortic dissection may involve a sudden onset of symptoms, which may include chest pain often described as severe and tearing, accompanied by 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 (computed tomography) scan** or **magnetic resonance imaging (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 potentially 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 the extent of the disease or injury and high blood pressure.

If your doctor feels treatment is necessary, three primary options are available: open surgical repair, **branched endovascular repair,** or branched/non-branched **endovascular repair** requiring bypass.

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 the blood flow through the aorta to be stopped while the graft is being put into place.

Non-branched thoracic endovascular repair (Non-branched TEVAR with or without bypass procedure)

Non-branched thoracic endovascular repair involves sealing off the disease or injury by placing a non-branched stent graft inside the portion of the affected aorta, making a new path for blood flow. With non-branched TEVAR, the stent graft sometimes covers the left subclavian artery (LSA) or other vessels. To maintain blood flow into the LSA, the LSA must be moved or bypassed to another branch vessel through an open surgical LSA revascularization procedure. The open surgical LSA revascularization procedure can be performed before the TEVAR procedure or at the same time.

Branched thoracic endovascular repair (Branched TEVAR)

For branched TEVAR, the doctor makes a small incision in the groin for delivery catheters (tube-like tools that assist in the delivery and positioning of the stent graft) and stent grafts to be inserted and positioned. The stent grafts seal off the diseased or injured part of the aorta, while maintaining flow into the branch vessel *(Figure 1).*

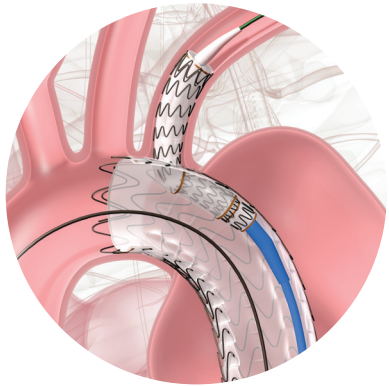


Figure 1. Branched TEVAR

Branched TEVAR requiring bypass

Depending on the extent of the disease, branched TEVAR can also be used to treat the aorta at the level of the BCA or LCCA. However, this treatment requires a surgical bypass procedure prior to implantation of the TEVAR device (similar to what was previously described in the non-branched TEVAR section). During the surgical bypass procedure, the blood vessels to be covered by the stent graft must be moved or bypassed to another branch vessel to maintain blood flow to the brain and arms (see *Figures 2 and 3*). The bypass and TEVAR procedures may either be done in two separate procedures or in one procedure, however the surgical bypass must occur prior to the TEVAR device being deployed.

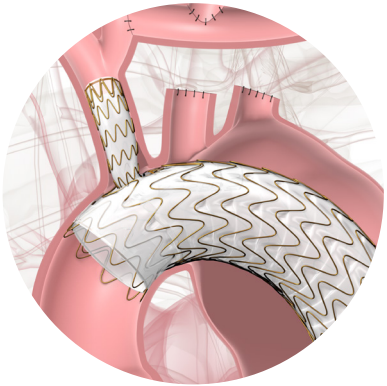


Figure 2. Branched TEVAR requiring bypass of LCCA and LSA

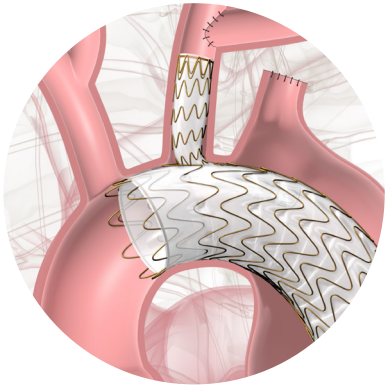


Figure 3. Branched TEVAR requiring bypass of LSA

GORE® TAG® Thoracic Branch Endoprosthesis

The GORE® TAG® Thoracic Branch Endoprosthesis (TBE) is an implantable branched **stent graft** designed for the descending thoracic aorta and/or aortic arch requiring placement into an area of the arch that includes one of the three major branches of the arch. It consists of at least two components which line the thoracic aorta and one of the arch branches. The devices allow blood to flow into one of the branches of the arch and the rest of the aorta while preventing blood from flowing to the damaged area. The device extends from the aortic arch to the descending thoracic aorta.

The GORE® TAG® Thoracic Branch Endoprosthesis is made of expanded polytetrafluoroethylene (ePTFE) with an outer metallic support structure known as a stent. See *Figure 4* for an image depicting the GORE® TAG® Thoracic Branch Endoprosthesis with the branch in the LSA.

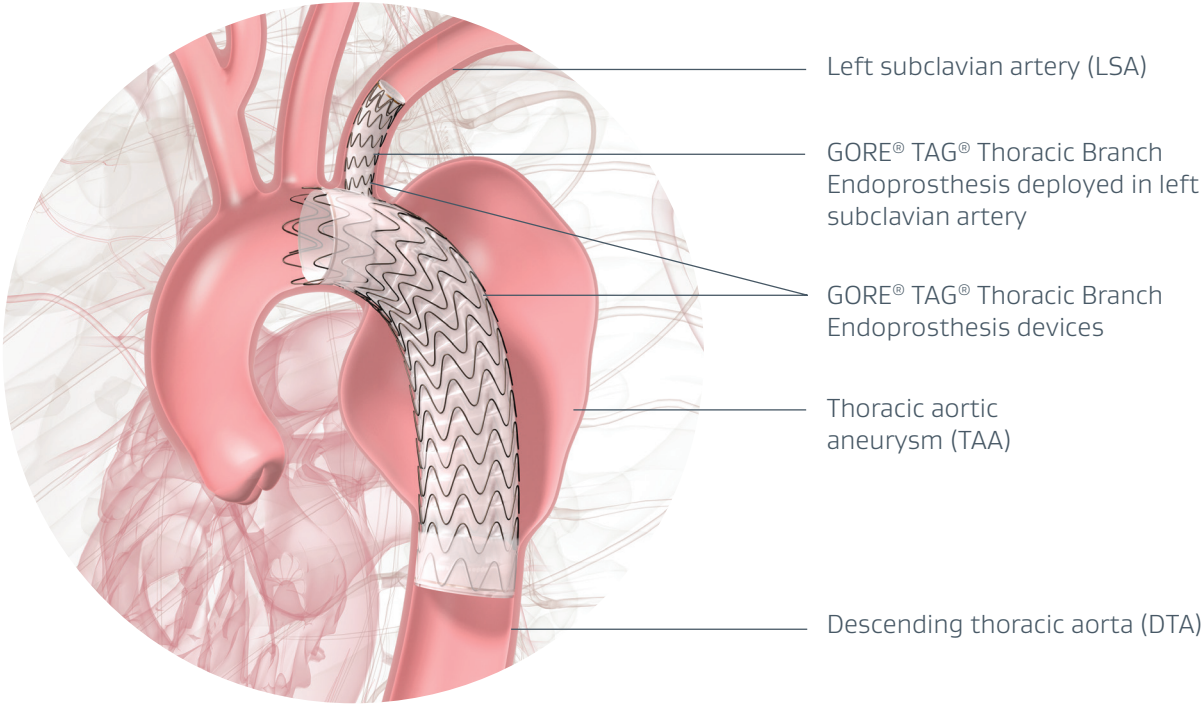


Figure 4. GORE® TAG® Thoracic Branch Endoprosthesis deployed in the left subclavian artery and the descending thoracic aorta.

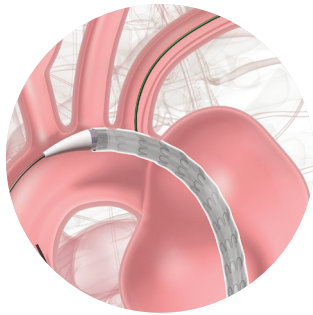
GORE® TAG® Thoracic Branch Endoprosthesis procedure

The procedure for implanting the GORE® TAG® Thoracic Branch Endoprosthesis consists of the delivery of the stent grafts into the aorta and one of the branch vessels of the aortic arch. While the endovascular procedure is similar for trauma or dissection repair, below is an example of the steps included in an aneurysm repair of the LSA. This procedure will be similar when treating the BCA or the LCCA.

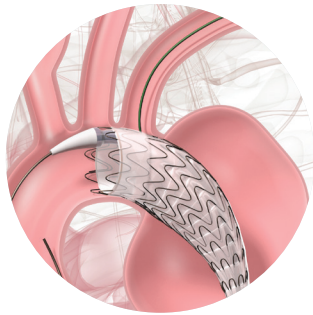
The main body stent graft is implanted using **fluoroscopy**, or real-time X-ray images, and is viewed on a monitor following these steps:

1. The **delivery catheter**, which contains the stent graft, is inserted into the **femoral** or **iliac artery** and carefully guided through the abdomen into the chest to the site of the diseased or injured aorta.

2. Once the stent graft is correctly positioned in the aorta and aligned with the left subclavian artery, it is released, or deployed, from the delivery catheter. The device self-expands to the diameter of the aorta and the delivery catheter is withdrawn from the body.



Positioning Aortic Component at left subclavian artery



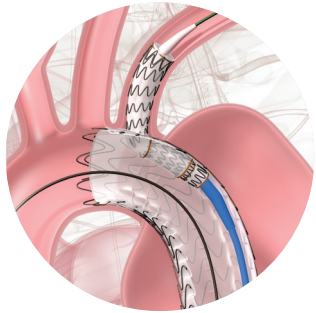
Deployment of Aortic Component

3. A second, smaller stent graft is inserted into the femoral or iliac artery and positioned through the opening of the first stent graft into the left subclavian artery.

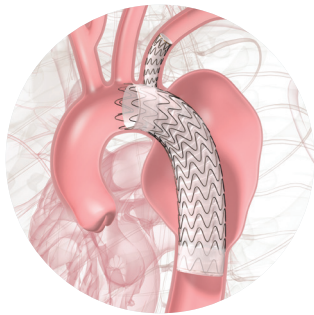
4. Once the second stent graft is correctly positioned within the left subclavian artery, it is released, or deployed, from the delivery catheter. The delivery catheter is then removed.

5. Following deployment, an endovascular balloon may be inflated inside the device to aid the device in opening completely, allowing the device to achieve a better seal.

6. In some cases, an additional component may need to be used to extend higher into the aortic arch or lower into the descending aorta.



Positioning of Side Branch Component into left subclavian artery



Final GORE® TAG® Thoracic Branch Endoprosthesis

Clinical data summary

The GORE® TAG® Thoracic Branch Endoprosthesis was evaluated for safety and performance in a multicenter pivotal study for all areas of the aortic arch. The primary purpose of the study was to measure the technical success of the device and safety events for aneurysm patients. Two patient groups (patients with aneurysms that required a branched TEVAR into the LSA and aneurysms that required a branched TEVAR into the BCA or LCCA) had a performance goal to meet while the other groups (dissection, and other types of lesions) only collected the information.

For the repairs that included the LSA, a total of 244 patients were enrolled at 40 sites in the United States (U.S.). Patients are being followed up for five years after implant. Patient groups were separated by type of aortic disease (aneurysm, dissection, traumatic transection and other isolated lesions). Of the aneurysm patients treated with the GORE® TAG® Thoracic Branch Endoprosthesis, 83.8% remained free from device technical failure and safety events followed out to one year. The results from the other patient groups treated in this study also demonstrated the safety and effectiveness of the TBE device.

For repairs that included the BCA and LCCA, a total of 77 patients were enrolled at 26 sites in the United States (U.S.) and five (5) in Japan. Patients are being followed-up for five years after implant. Patient groups were separated by type of aortic disease

(aneurysm, dissection, and other isolated lesions). Of the aneurysm patients treated with the GORE® TAG® Thoracic Branch Endoprosthesis, 74.5% remained free from device technical failure and safety events followed out to one month. The results from the other patient groups treated in this study also demonstrated the safety and effectiveness of the TBE device.

Occurrence of safety events such as **strokes,** life-threatening bleeds, laryngeal or phrenic nerve injury, **ischemia,** fistula formation and lesion-related death, as well as events that resulted in patients requiring additional procedures (e.g., **endoleaks, new dissection**) were reported in the clinical study. We recommend you discuss the known risks and potential benefits of the procedure and TBE device for your specific condition with your physician, as well as those of the potential alternative treatment options.

This study demonstrated that the GORE® TAG® Thoracic Branch Endoprosthesis is safe and effective as a treatment option for the endovascular treatment of aortic disease in the descending thoracic aorta or aortic arch while maintaining blood flow to one of the branches of the aortic arch.

Risks

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

Your risks will vary depending on the circumstances surrounding your procedure; however, possible complications you may experience from the implant procedure or receiving the implanted stent grafts include:

Anesthetic complications

Aortic rupture related to procedure or original aortic disease or injury

Bleeding during or after the treatment procedure

Blocking the treated branch vessel or another important blood vessel

Blood clots in the lungs

Bowel complications such as paralysis or temporary lack of bowel motion or decreased blood flow to the intestines

Breakage of any part of the stent grafts

Breakage of the delivery catheters

Breathing difficulty

Bruising

Bulging of blood vessel walls

Change in mental status

Change in the shape or size of the arteries which may cause changes in the stent grafts

Collapse of the stent grafts

Risks (continued)

Complications with the arteries or veins such as blockage of blood flow in an artery or vein due to blood clotting, vessel rupture or damage to the vessels which could lead to amputation

Complications with the lymph system

Complications with the nervous system such as nerve injury, **stroke** (permanent or temporary), inability to move and/or feel parts of the body, nerve damage in the spine or poor blood supply to the spine resulting in paralysis and/or weakness in the lower extremities

Death

Dysfunction or failure of the kidneys

Erectile dysfunction

Fever

Fistula (an abnormal connection between the aorta and other tissue/organs)

Heart complications such as chest pain, irregular heartbeat, inadequate pumping of the heart muscle or heart attack

Inability to place the stent graft in the correct location, placing it incorrectly, problems releasing the device from the delivery catheter or problems inserting or removing the delivery catheter.

Infection

Infection or blood clots in the stent grafts

Inflammatory reaction to the stent grafts

Risks (continued)

Leak between the implanted devices or between the implanted devices and aortic wall, or a leak from a blood vessel into the injured area of aorta (endoleak)

Lengthening of existing aortic dissection

Lung complications such as pneumonia

Metal part of the stent grafts wearing through the artery wall

Movement of the stent grafts within the aorta

Narrowing of blood vessels

Pain due to inadequate blood supply to the heart

Partial or complete collapse of the lungs

Problems with the blood clotting

Radiation injury

Reaction to the X-ray dye used for the angiogram

Reaction to the drug (heparin) used during the procedure

Reoperation (need for another operation)

Rupture or tear (dissection) of the aorta

Stretching and/or breaking of the stent grafts

Swelling of clotted blood within tissue

Tear (new dissection) of the aorta or branch vessel*

Urinary tract issues

Wound complications such as swelling of the leg and infection

*An increased incidence of branch vessel new dissection and endoleak was noted in the clinical study

Benefits

The main potential benefit to having a branched endovascular repair with a stent graft, compared to non-branched endovascular repair, is that the GORE® TAG® Thoracic Branch Endoprosthesis offers a treatment method that minimizes (when treating the BCA and LCCA with the branch) or avoids (when treating the LSA) the open surgical procedure to bypass arch branches and the associated risks. The TBE device also offers a potential benefit for some patients when used for branching into the BCA and LCCA in that it does not require **deep hypothermic circulatory arrest (DHCA)** or **cardiopulmonary bypass (CPB).**

Follow-up

After endovascular repair with the GORE® TAG® Thoracic Branch Endoprosthesis, 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. Regular follow-ups are required even in the absence of obvious symptoms (eg, pain, numbness, weakness). These visits commonly occur at one month, six months and annually thereafter, but your follow-up visits may differ depending on your specific circumstances as determined by your doctor.

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

The table below has been provided to record the dates of your procedure and follow-up visits.

VISIT	DATE	NOTES
Procedure		
1 month		
6 month		
1 year		
2 year		
3 year		
4 year		
5 year		
6 year		
7 year		
8 year		
9 year		
10 year		
Cont.		

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 card will tell you the size and number of your 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 health care providers that you have a 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 health care providers.

Glossary of medical terms

Acute aortic dissection
A phase of dissection occurring within the first 0-14 days.

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.

Ascending aorta
An artery that starts in the upper surface of the left ventricle (left side of the heart) and passes upward and turns into the aortic arch.

Brachiocephalic artery (BCA)
One of two main arteries that branches off your aortic arch and supplies blood to the brain and right arm.

Branched endovascular repair
A procedure in which a stent graft is placed inside a diseased vessel and one branch vessel without surgically opening the tissue surrounding the weakened vessel to exclude (seal off) a disease or injury inside the aorta, making a new path for blood to flow.

Glossary of medical terms (continued)

Cardiopulmonary bypass (CPB)
A technique that temporarily takes over the function of the heart and lungs during surgery, maintaining the circulation of blood and the oxygen content of the body.

Chronic aortic dissection
A phase of dissection occurring more than 90 days from disease onset.

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.

Deep hypothermic circulatory arrest (DHCA)
A surgical technique that involves cooling the body of the patient and stopping blood circulation.

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
When blood from the aorta continues to leak into the diseased area of the chest.

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 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.

Ischemia
Lack of blood supply to a part of the body.

Left common carotid artery (LCCA)
One of two main arteries that branches off your aortic arch and supply blood to the brain.

Left subclavian artery
A main artery that branches off your aorta and supplies blood to your left arm and head.

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

Malperfusion
Loss of blood supply to a vital organ caused by blood vessel obstruction secondary to a dissection.

New dissection
A dissection created in the aorta or branch vessel as a result of device placement or the endovascular procedure.

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.

Glossary of medical terms (continued)

Stent graft
A synthetic graft implanted within a weakened blood vessel to seal it from the inside. Compressed stent grafts are delivered to the weakened area via a catheter and, once in position, are expanded to fit the size of the vessels in which they are placed.

Stroke
Damage to the brain from interruption of its blood supply.

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 tear in the aorta that usually occurs in the chest, often referred to just as a transection.

Where can I get more information?

Background information on thoracic disease

American Heart Association	heart.org
Society for Vascular Surgery	vascular.org/patients

Interventional therapy

Society of Interventional Radiology	sirweb.org
U.S. National Library of Medicine	medlineplus.gov

Product information

W. L. Gore & Associates, Inc.	goremedical.com/conditions
U.S. Department of Health and Human Services Food and Drug Administration	fda.gov

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 the TBE device (branched TEVAR or branched TEVAR requiring bypass), non-branched TEVAR, and open surgical repair.
- Potential advantages of open surgical repair.
- Potential advantages of non-branched TEVAR.
- Potential advantages of branched TEVAR.
  - Including risks associated with debranching procedure, for BCA or LCCA treatment.
- 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 postoperative follow-up as necessary to ensure continuing safe and effective results.

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Consult Instructions for Use
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Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

INDICATIONS FOR USE: The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the aortic arch and descending thoracic aorta, while maintaining flow into a single aortic arch branch vessel in patients who have: **Adequate iliac/femoral access; Proximal Aortic Landing Zones:** For Isolated Lesion Patients: Proximal landing zone cannot be aneurysmal, dissected, heavily calcified or heavily thrombosed; For Dissection Patients: Primary entry tear must be distal to the target branch vessel and the proximal extent of the landing zone must not be dissected; Aortic inner diameter range 16–42 mm; Proximal segment length (length from distal edge of target branch vessel to the midpoint of any proximal branch vessel) of at least 2.0–4.0 cm, depending on Aortic Component selection; Proximal covered length (measured from distal edge of target branch vessel to the distal edge of any proximal branch vessel) of at least 15–36 mm, depending on Aortic Component selection; For patients with prior ascending aorta or aortic arch repair with surgical graft: at least 2 cm landing zone proximal to the distal anastomosis; **Target Branch Vessel Landing Zone:** Landing zone cannot be aneurysmal, dissected, heavily thrombosed and severely tortuous (180 degree turn within the treated length); Target branch vessel inner diameter of 6–18 mm, depending on Side Branch Portal diameter selected; Target branch vessel minimum length of 2.5–3.0 cm, depending on Side Branch Portal diameter selected. **Distal Landing Zone (Isolated Lesion Patients only):** Outer curve length must be ≥ 2 cm proximal to celiac artery; Aortic inner diameter range 16–42 mm; Cannot be aneurysmal, dissected, heavily calcified or heavily thrombosed; Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft. **CONTRAINDICATIONS:** The GORE® TAG® Thoracic Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials [ePTFE (polytetrafluoroethylene), FEP (fluoroethylpropylene), Nitinol (nickel, titanium), Gold, SB Component only – Heparin (CBAS® Heparin Surface)]; Patients who have a condition that threatens to infect the graft; Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II.

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