ENDOVASCULAR TREATMENT OF THE THORACOABDOMINAL AORTA

Patient information

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Introduction

This brochure is intended to provide basic information about **thoracoabdominal aortic aneurysm (TAAA)** and **pararenal abdominal aortic aneurysm (PAAA)** disease 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 30. 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.

Thoracoabdominal aortic and pararenal abdominal aortic aneurysms

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 **thoracoabdominal aorta** is the segment of the aorta bridging across the **diaphragm** from the chest to the abdomen involving the **renal arteries**, which supply blood to the kidneys and **visceral branch vessels**. The visceral branch vessels are important arteries that supply blood to organs, including liver, stomach, spleen and intestines. These vessels are critical to maintain blood flow for sustained health.

An **aneurysm** is a ballooning (thinning and enlarging) of the aorta caused by continuous blood pressure against a weakened area of the vessel. 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. When aneurysm rupture occurs it often leads to a fatal event.

Aortic aneurysms that extend through the region of the visceral branch vessels are called thoracoabdominal aortic aneurysms. Aneurysms that only extend up to the renal arteries, but do not include the visceral branch vessels are called pararenal abdominal aortic aneurysms. The treatment approach to both of these conditions is similar.

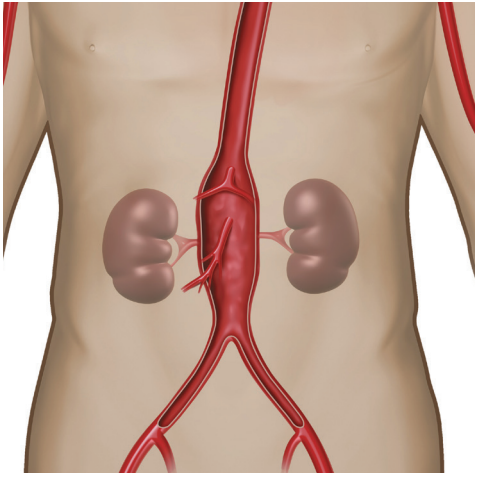


Figure 1. Thoracoabdominal aortic aneurysm with involvement of visceral branch vessels

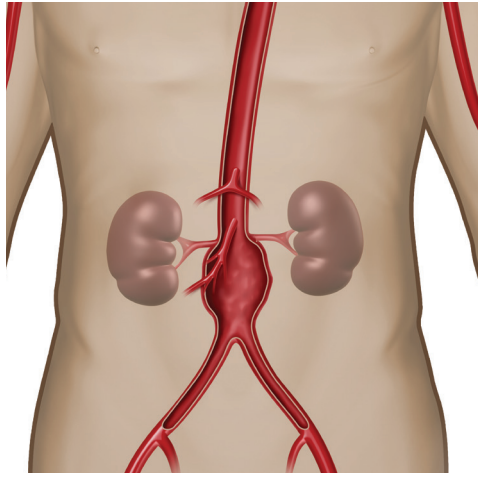


Figure 2. Pararenal abdominal aortic aneurysm at the level of the renal arteries

Causes of aneurysmal disease

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 an aneurysm that requires treatment.

Main risk factors for developing an aneurysm include:

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

Symptoms

Many people do not experience any symptoms when aneurysmal disease is present. Others have expressed feeling the aneurysm as a pulsating or throbbing mass in their abdomen.

When symptoms do occur, pain is most commonly experienced. Some patients describe the pain as anything from mild to severe, or a tenderness that can occur in the neck, shoulders, chest, upper and lower back regions, groin, flank and/or abdomen. The development of symptoms may be associated with expansion or leakage from the aneurysm and should cause one to seek medical attention.

Your doctor may have discovered aneurysmal disease during a routine physical exam or a medical test such as a **computed tomography (CT) scan** or **magnetic resonance imaging (MRI)**.

Treatment options

The size and location of the aneurysm, and your general health, influence which treatment your doctor recommends. When the aneurysm is small, or has a potentially low risk to your health, your doctor may only recommend periodic checkups to monitor your condition. However, a larger or rapidly growing aneurysm poses more risk of rupture and may require treatment. The risk of rupture increases with the size of the aneurysm and high blood pressure.

If your doctor feels treatment is necessary, two primary options are available: Open surgical repair and **endovascular repair**.

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

Open surgical repair

Open surgical repair is an operation to reconstruct the aneurysm 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 and/or abdomen to repair the aorta by replacing the aneurysm 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. Patients typically stay in the hospital for 5 to 10 days and continue to recover for 4 to 6 weeks at home or an extended care facility.[1]

Endovascular repair

Endovascular repair involves sealing off the aneurysm by placing a **stent graft** (a specially designed tube) relining the aneurysm, making a new path for the blood to flow. It is a less invasive procedure than open surgery and doesn't require an incision in the chest or abdomen since a stent graft is placed inside the aorta from a small incision(s) made in your body.[2]

Endovascular repair may be performed under general anesthesia. Patients typically stay in the hospital for 1 to 2 days and can usually return to normal activity within 6 weeks.[3]

GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE)

The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) is an implantable branched device designed for use in patients with thoracoabdominal aortic aneurysms (TAAA) and **high-surgical risk patients with pararenal abdominal aortic aneurysm (PAAA)**.[4] The complete device consists of several parts which supply blood to the aorta, visceral branch vessel and lower limbs. See *Figure 3* for an image depicting the complete assembled device showing all the intended parts.

The TAMBE is a graft made with **expanded polytetrafluoroethylene (ePTFE)** with an outer metallic support structure known as a stent.

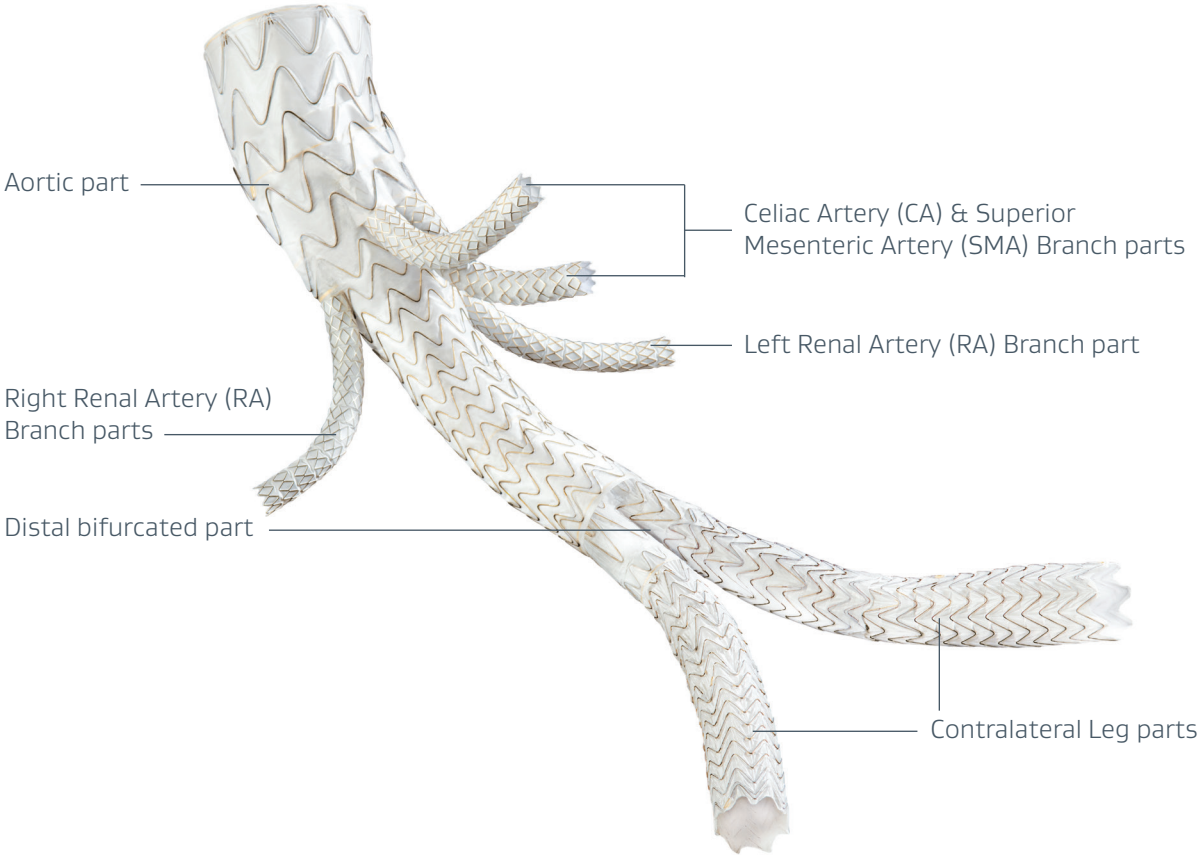


Figure 3. GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE)

TAMBE procedure

The procedure for implanting the TAMBE consists of the delivery of the different parts into the aorta inserted through the **femoral artery** in the leg and the **brachial** or **axillary artery** in the upper arm.

The parts are implanted using **fluoroscopy**, or real-time X-ray images, and is viewed on a monitor following these steps (See *Figures 4-7* illustrating the steps):

1. The aortic part is inserted through the femoral artery and positioned with its top above and just beyond the aneurysm. It is then partially deployed.

2. Branch parts are inserted and deployed through the designed openings of the aortic part and into its corresponding visceral artery.

3. After the aortic part is fully deployed, additional parts such as the distal bifurcated part and contralateral leg parts are inserted and deployed to complete aortic relining.

4. Once all parts are deployed, an **endovascular balloon** may be used to aid in fully expanding and sealing of the device to the vessel walls.

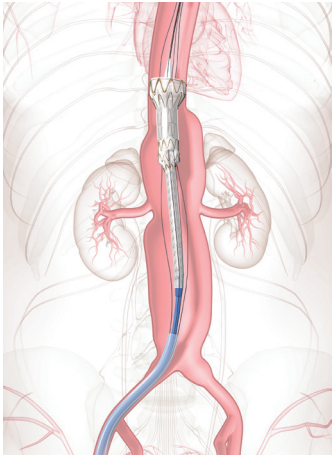
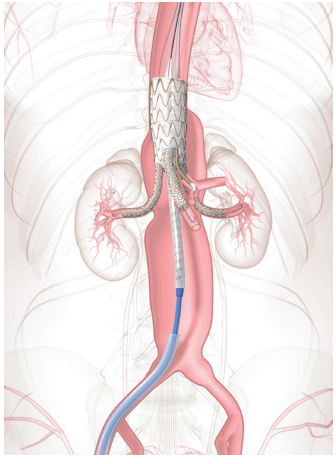


Figure 4.



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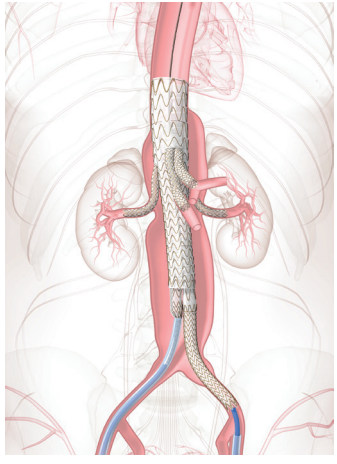

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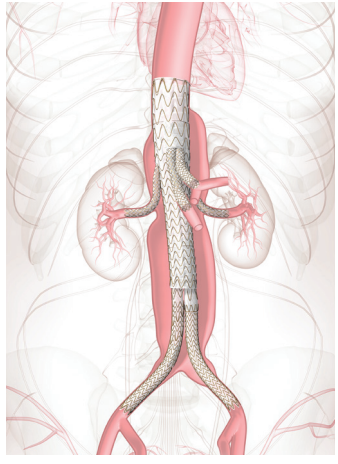

Figure 7.

Clinical data summary

The TAMBE was evaluated for safety and performance in a multicenter clinical study. A total of 102 patients were enrolled at 44 sites in the United States (U.S.) and United Kingdom. Patients in the study treated for either a TAAA or PAAA are being followed for 5 years after initial implant. The primary purpose of the study was to measure the device's technical success and procedural safety events as well as to assess the effectiveness of excluding the aneurysm in the longer term and whether additional interventions were needed to achieve the intended function for these patients.

All required TAMBE parts were able to be implanted with all patients achieving exclusion of the aneurysm. There were no conversions to open surgery that required device explantation and no lesion-related deaths. A total of 16.2% of patients in the study experienced major adverse events through 12 months.

In the TAMBE Pivotal Study, in the first year after the TAMBE placement, 15.6% of patients required a reintervention to allow for the device to continue to function as intended. Most of the reinterventions were related to occlusions in the branch components, with an approximately 12% risk of patients experiencing an occlusion within the first year after the procedure. Occlusions of the branch parts of the TAMBE system may result in end organ complications, notably including bowel complications or loss of kidney function. More branch occlusions were noted in patients treated for PAAA than for TAAA within the first year, and this factored into the decision to only allow use of the device in those PAAA patients who are otherwise at a high risk of complications from open surgery.

If medically indicated, these events were treated with additional, minimally invasive procedures to attempt to restore blood flow in the branch vessels. Through 12 months, 5 patients were identified as having lost > 50% of kidney function, including the need for dialysis in 3 patients.

This study demonstrated that the TAMBE is safe and effective as a treatment option for the endovascular treatment of TAAA and high-surgical risk PAAA patients with appropriate anatomy. This procedure can be performed with low risk of surgical death and other safety events when compared to open surgical repair. Consult with your treating physician on your risk factors for open surgical repair and if endovascular treatment is right for you.

Risks

Like surgery, endovascular repair with a stent graft(s), see *Figure 7* for the TAMBE example, 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:

Abnormal blood connection between an artery and a vein (arteriovenous fistula)

Allergic reaction (anaphylactoid) and/or response to x-ray contrast dye, anti-platelet therapy

Bleeding, bruising or inability of the blood to clot (hematoma or coagulopathy)

Blockage or closing of the device or blood vessel (occlusion)

Movement of clots or atherosclerotic material down stream to cause temporary or permanent blockage (micro-embolization or macro-embolization with transient or permanent ischemia)

Blood vessel spasm or trauma such as vessel dissection, bleeding, injury or bursting (vascular spasm or trauma)

Risks *(continued)*

Bowel problems such as paralysis or temporary lack of bowel motion, decreased blood flow to the intestines, abdominal pain or tenderness, nausea, vomiting or diarrhea

Breakage or tear of the aorta and aortic branches (dissection, perforation or rupture of the aortic vessel and surrounding vasculature)

Bursting of the aneurysm (rupture)

Catheter breakage

Clotting (arterial or venous thrombosis and/or pseudoaneurysm)

Clotting of blood inside the stent graft (prosthetic thrombosis)

Death

Deficiency of healthy red blood cells in blood (anemia)

Endoprosthesis (stent graft): improper placement; incomplete deployment; movement; material failure; stent fracture; blood flow outside the stent graft

Erectile dysfunction

Excess fluid in tissues (edema)

Fever

Heart problems such as chest pain, arrhythmia, myocardial infarction, congestive heart failure, low or high blood pressure

Increased size of the aneurysm (aneurysm enlargement)

Infection of the aneurysm, device or skin entry sites

Inflammatory reaction to the stent graft (post implantation syndrome)

Injury to spleen (splenic injury – e.g., infarction, ischemia)

Kidney dysfunction or failure requiring temporary or permanent dialysis treatment

Loss of seal at the ends of the branched stent graft or blood vessel directly feeding the aneurysm potentially leading to aneurysm expansion and/or rupture **(endoleak)**

Leaking lymph fluid (lymph fistula/complications)

Loss of a limb (amputation)

Low platelet count (heparin induced thrombocytopenia (HIT))

Lung complications such as pneumonia, persistent progressive breathlessness and cough, collapse of one or both lobes of the lungs or respiratory failure

Narrowing of a blood vessel (stenosis)

Nausea or vomiting (anesthetic complications)

Nervous system complications such as stroke (permanent or temporary), inability to move and/or feel parts of the body, numbness, nerve damage in the spine or poor blood supply to the spine resulting in loss of motor function and/or weakness in the lower extremities

Risks *(continued)*

Obstruction of blood flow to arms and legs (extremity ischemia or neurologic complications)

Open surgical intervention or conversion

Organ failure

Reoperation or intervention

Stretching and/or breaking of the stent grafts (prosthetic dilatation/rupture)

Swelling, redness (irritation/inflammation)

Urinary tract issues such as incontinence, urinary retention, blood in urine or infection

Wearing of the device (erosion)

Wound complications such as infection, abscess and opening of wound

X-ray burn (radiation injury)

Benefits

Overall clinical study results supported that the TAMBE has a favorable risk-benefit balance. The TAMBE is a less invasive treatment option which can be performed with potentially lower rates of surgical complications, blood loss and death. Additional potential benefits can include a shorter hospital stay and overall, a quicker recovery compared to open surgical repair.

The short-term benefits of the device should be carefully weighed with the need to return on an annual basis for imaging studies and routine follow up, as well as the likely need for additional, minimally invasive interventions in the longer term. Also, the uncertainty with regard to longer term outcomes (e.g., the need for dialysis if renal artery occlusions are observed) should be carefully considered.

Follow-up

After endovascular repair with the TAMBE, follow-up exams will typically consist of a physical examination and imaging, such as a CT scan, to check the repair, evaluate the device's performance and ensure the aneurysm remains excluded.

Follow-up will be scheduled with your doctor on a regular basis. Regular follow-ups will be required even in the absence of obvious symptoms (e.g., pain, numbness, weakness). Endoleaks can repressurize the aneurysm and may lead to aneurysm expansion or rupture. After device placement, it is very important to attend follow-up appointments to support your ongoing health.

These visits commonly occur at 1 month, 3 months, 6 months and annually thereafter. If you are unwilling or unable to commit to annual imaging, then endovascular repair may not be a good option to consider.

When should I call my doctor?

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

- Pain, numbness, coldness or weakness in the legs or buttocks
- Any back, chest, flank (kidney area), abdominal or groin pain
- Dizziness, fainting, rapid heartbeat or sudden weakness
- Any other unusual symptoms

Other patient considerations

Certain patients should not receive the TAMBE device. This includes patients with known sensitivity or allergy to device materials (ePTFE, FEP, nickel titanium alloy, stainless steel and gold), patients who have a condition that threatens to infect the graft, and patients with known hypersensitivity to heparin.

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

- Consult your doctor about your ability to safely perform strenuous physical activities, like exercise or work that involves lifting.
- An implanted device typically will not trigger screening or metal detectors, like those at airports or secure building entrances, but consult your doctor about your specific case.
- 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 implants.

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

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

Be sure to tell all your health care providers that you have an endovascular device and show them your implanted device ID card. This is particularly important if you should need any future procedures involving vascular catheterization. You should always keep your implanted device ID card available.

Magnetic resonance imaging

Under certain conditions, you can safely have MRI procedures. 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

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 wall
The wall of the aorta is made up of 3 layers: the thin outer layer, the thick, elastic middle layer and the thin inner layer.

Axillary arteries
An artery located in each shoulder region, which carry oxygenated blood to the upper arms.

Brachial arteries
An artery in each upper arm that are a direct continuation of the axillary arteries.

Computed tomography (CT) 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.

Diaphragm
A thin muscle separating the chest and abdominal cavities.

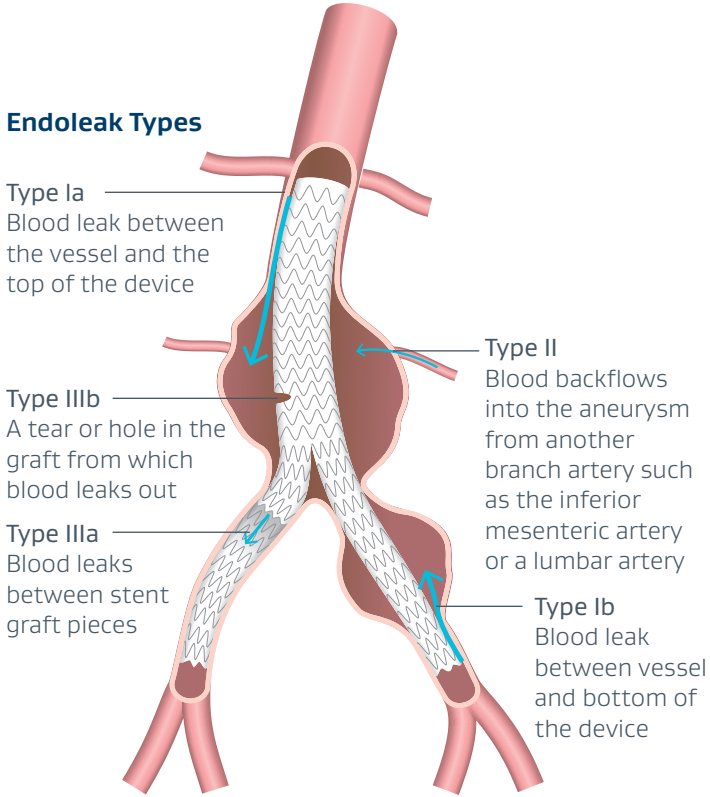

Figure 8. Endoleak types

Endoleak

Persistent or recurrent blood flow into the aortic aneurysm after endovascular device placement. *Figure 8* represents an endovascular device aneurysm treatment illustrating various types of endoleak sources. (Note: TAMBE is not specifically shown in the image.)

Endovascular balloon

A catheter with a balloon to assist in fully opening an endovascular device used during endovascular repair.

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.

Glossary of medical terms *(continued)*

Expanded Polytetrafluoroethylene (ePTFE)
A highly durable and biocompatible material that is often used in medical procedures.

Femoral arteries
The main artery located in each leg, which carry blood to the femoral or thigh region of each leg.

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

High-surgical risk patients with pararenal abdominal aortic aneurysms (PAAA)
A patient who would not be considered an ideal candidate for open surgery to repair for PAAA due to an increased risk of complication or treatment failure during and/or after the procedure.

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

Pararenal abdominal aortic aneurysm (PAAA)
A ballooning (enlarging and thinning) of the aorta due to a weakening in the arterial wall that extends from the abdomen to the level of the renal arteries.

Renal arteries
The arteries that carry blood to kidneys. Most often there is one main renal artery coming off each side of the aorta.

Rupture
A tear in the vessel wall near or at the location of the weakened area of the aneurysm allows 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) the aneurysm. 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.

Thoracoabdominal aorta
An area of the aorta bridging across the chest and abdomen involving smaller branch vessels that provide blood to organs in the abdomen.

Thoracoabdominal aortic aneurysm (TAAA)
A ballooning (enlarging and thinning) of the aorta due to a weakening in the arterial wall that extends from the chest through the diaphragm into the abdominal aorta. The TAMBE is indicated for endovascular repair in patients with TAAA extending up to 6.5 cm above the celiac artery.

Visceral branch vessels
Two major aortic branch vessels that carry blood to the abdominal organs. The celiac artery supplies the stomach, liver and spleen. The superior mesenteric artery or SMA supplies blood to the small and large intestines.

Where can I get more information?

Background information on aortic thoracoabdominal and pararenal 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/medical-devices

Questions for my doctor

You and your doctor should review the risks and benefits when discussing your treatment options including:

- Potential advantages of open surgical repair of TAAA or PAAA.
- Potential advantages of endovascular TAAA or PAAA repair.
- Risks and differences between treatment of TAAA or PAAA with open surgical repair or with the TAMBE.
- The possibility that additional endovascular treatment or surgery may be required after an initially successful endovascular repair.

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

References

1. *Aneurysm Surgery: Traditional Open Surgery. Cleveland Clinic*. Accessed November 14, 2023. https://my.clevelandclinic.org/health/treatments/16735-aneurysm-surgery-traditional-open-surgery

2. King EG, Farber A, Rybin D, *et al*. Preoperative risk factors predict protracted hospital length of stay after elective endovascular abdominal aortic aneurysm repair. *Annals of Vascular Surgery* 2017;43:73-78.

3. Oderich GS, Forbes TL, Chaer R, *et al*. Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries. *Journal of Vascular Surgery* 2021;73(1):4S-52S.

4. GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc.; 2023. MD193085.

Notes

Together, improving life

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is indicated for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy as described below: Adequate iliac/femoral access and brachial/axillary access; Proximal (supraceliac) aortic neck treatment diameter range over 2 cm seal zone of 22–34 mm for aneurysms extending up to 6.5 cm or less above the origin of the most proximal branch vessel; Aortic neck angle ≤ 60° at the Aortic Component proximal seal zone; Iliac artery treatment diameter range of 8–25 mm and iliac artery seal zone length of at least 10 mm; Renal artery seal zone diameters between 4.0–10.0 mm; Celiac and superior mesenteric artery seal zone diameters between 5.0–12.0 mm, ≥ 15 mm seal zone length in renal arteries, superior mesenteric artery, and celiac artery; Visceral segment of aorta (3 cm proximal through 9.5 cm distal to the most proximal visceral artery) must be ≥ 20 mm in diameter. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the TAMBE Device materials including ePTFE, FEP, nickel titanium alloy (Nitinol), stainless steel, and gold. Patients who have a condition that threatens to infect the graft. Patients with known hypersensitivity to heparin, including patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II and cannot receive the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. ℞ Only

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.

Products listed may not be available in all markets.

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