About this Patient Guide

This patient guide has been provided as a courtesy by Cook Medical Incorporated. It will help you learn more about certain diseases or injuries of the thoracic aorta, such as aneurysm, ulcer and blunt injury. We hope this information will be helpful to you and your family.

For your convenience, a glossary of medical terms is included on pages 25-27. Words that are in bold throughout the text are defined in the glossary.

This patient guide is only a guideline. It provides basic information about thoracic aortic lesions (including thoracic aortic aneurysms, ulcers and blunt injuries), and how aneurysms or ulcers can be treated with a Zenith Alpha Thoracic Endovascular Graft. It is not intended to diagnose a medical condition. The best way to treat a thoracic aortic lesion may depend partly on the patient's needs and the doctor's assessments. As with any surgery or medical procedure, your doctor is the best source for information and advice.
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Introduction

What is a thoracic aortic aneurysm (TAA) or ulcer?
The aorta (see Figure 1) is the main blood vessel that carries blood from the heart to the rest of the body. It starts in the chest and runs down into the abdomen, where it branches into the iliac arteries. The iliac arteries carry blood to lower parts of the body and to the legs. Sometimes, with aging or other changes, a section of the aorta may weaken and begin to bulge.

This bulge can get larger over time as the walls of the aorta get thinner and stretch (like a balloon). This bulge in the aorta is called an aneurysm.

Weakening of the aorta may also lead to formation of a lesion that goes through the inner lining of the aorta. This kind of lesion is called an ulcer, and it causes blood to collect between the layers of the aorta. This abnormal collection of blood may weaken the wall of the aorta and cause one side of the aorta to bulge like an aneurysm.

Sometimes an aneurysm or ulcer occurs in the part of the aorta that runs through the chest (see Figure 2). This is called a thoracic aortic aneurysm (TAA) or ulcer.
Is this a serious condition?

When a TAA is small, it may not be an immediate health risk. However, your doctor will want to check its condition regularly. If the TAA continues to grow, the aorta’s walls can become thin and less able to stretch. Eventually, the stretched sections may become too weak to support the force of blood flow. This type of aneurysm could rupture (burst), causing serious internal bleeding that requires immediate medical attention.

When an ulcer is small, it may not be an immediate health risk. However, if it continues to grow, it may cause an aneurysm or a dissection, or it may cause the aorta to rupture (burst).

What are some of the symptoms of a TAA or an ulcer?

Unfortunately, most patients with a TAA or an ulcer have no symptoms. For people who do have symptoms, the symptoms include, but are not limited to, back and chest pain, trouble breathing or swallowing and hoarse coughing. Many patients feel none of these symptoms, yet may still have a TAA or an ulcer. A TAA or an ulcer is often found during an examination done for other medical reasons. Most often, aneurysms or ulcers are found during a medical test such as a CT scan, MRI, or angiogram (X-ray, see Figure 3).

If you know you have a TAA or an ulcer and you develop back pain, chest pain or dizziness, call your doctor right away.

What causes a TAA or an ulcer?

Over time, vascular disease, injury, or an inherited defect of tissue within the arterial wall can cause the aorta to weaken. Blood pressure against the weakened area can cause it to stretch and grow thinner, like a balloon.

Risk factors for developing an aneurysm or an ulcer include, but may not be limited to, family history, smoking, heart disease, trauma and high blood pressure. If you are at risk for developing an aneurysm or an ulcer, your doctor may suggest periodic checks. The checks could include a physical exam and possibly a CT scan or MRI.
How do doctors treat a thoracic aortic lesion?

When a thoracic aortic lesion is small or the BTAI does not completely tear the aorta, your doctor may want to watch it with periodic checkups. He or she may want to see if it grows and how much it grows. He or she may also suggest medicine to lower your blood pressure and reduce the pressure on the thoracic aortic lesion.

However, if a thoracic aortic lesion becomes larger, or is growing rapidly, it has more risk of rupturing (bursting).

If your doctor thinks there is a risk that the thoracic aortic lesion may rupture, he or she may suggest treatment to keep the aorta from bursting or affecting blood supply to other parts of the body. There are two types of treatment for a thoracic aortic lesion:

• Open surgical repair
• Endovascular repair

Important Note: Not every patient is a candidate for endovascular or surgical repair. Both types of repair have pros and cons. The best repair will depend on your condition and needs. Talk about the pros and cons with your doctor.
What is open surgical repair?

In this approach, surgery (see Figure 5) is performed to repair the section of the aorta that has a lesion (aneurysm, ulcer or blunt injury). To reach the lesion, the doctor will cut through the breastbone or the side of the chest. The aorta is repaired by replacing the section containing the lesion with a fabric tube called a graft.

The graft is sewn into place to serve as a “replacement” blood vessel. During graft placement, blood is stopped from flowing through the aorta. The surgery usually takes around four hours to complete.

Open surgical repair is a proven medical procedure, with potential benefits. These potential benefits include providing a permanent repair with no long-term follow-up (compared to endovascular repair, which requires long-term follow-up). However, as shown in a previous clinical study comparing open surgical repair to endovascular repair for thoracic aortic aneurysms and ulcers with a graft similar to the Zenith Alpha Thoracic Endovascular Graft, open surgical repair also has a long recovery time. On average, patients usually stay overnight in the intensive care unit for nine days. They may stay an additional seven days in the hospital before being discharged. Many patients cannot eat or walk for at least five days after the surgery. The overall recovery period can last up to three months.

Like any medical procedure, open surgical repair has a risk of complications. Talk to your doctor about these.
What is endovascular repair?

Endovascular repair is an alternative to open surgical repair. Endovascular means “inside or within a blood vessel.” Instead of cutting open the chest, the doctor makes a small cut near your hip (near the crease where your belly meets your leg) to get to the femoral artery.

The delivery catheter containing the stent graft is inserted into the femoral artery in the groin through a small skin incision (cut). It is carefully guided within the artery into the chest to bridge the site of the lesion in the aorta. The stent graft is then released (deployed), and the stents self-expand to the diameter of the aorta. The stent graft redirects blood flow away from the lesion and relines the artery wall. This can prevent further growth and possible rupture of the lesion.

The cut used for endovascular repair is much smaller than the cut used for open surgical repair, so patients may have less pain and a faster recovery. Patients may have to stay in the hospital for only a few days. They can usually return to normal activity after four to six weeks.

As with any medical procedure, endovascular repair has a risk of complications. You should talk about these with your doctor. Endovascular repair also requires routine follow-up visits with your doctor (see page 19 for follow-up visit information). During these visits, tests will be done to evaluate your health and the stent graft. There is also a chance that you will need further treatment or surgery after your endovascular repair. (For more information, see page 19.)
How is the stent graft put in?

Before the procedure, your doctor looks at pictures of your aorta using CT scans and angiograms. From these pictures, the doctor can choose the proper size of each part of a Zenith Alpha Thoracic Endovascular Graft. The stent graft will be sized to fit your aorta where the thoracic aortic lesion is located. During the procedure, the doctor uses x-rays to see the stent graft and place it correctly.

The stent graft is contained in its own plastic tube (sheath, see Figure 6). The tube allows the stent graft to be inserted and placed in the aorta. The plastic tubes are removed after the stent graft is in place.

To place the stent graft, your doctor makes a cut near the hip (near the crease between the belly and leg) to get to the femoral artery. The doctor then inserts the sheath containing the stent graft through the cut into your bloodstream (see Figure 6). Depending on your anatomy, it may also be possible to insert the stent graft directly through your skin near the hip without making a cut.
If the femoral artery is not large enough, the doctor may have to insert the sheath containing the stent graft into your bloodstream through another graft. This graft is called a conduit, and it gets connected to either your iliac artery or aorta. This was necessary in <1% of patients during the clinical study for the Zenith Alpha Thoracic Endovascular Graft. Sometimes, another, smaller incision may be needed in the neck to help the doctor properly place the stent graft.

The doctor advances the stent graft through your blood vessels until it reaches the aorta. The top of the stent graft is placed in the aorta above the thoracic aortic lesion. The body of the stent graft extends down the aorta across the lesion. The bottom of the stent graft is placed at a point below the lesion. When the stent graft is released from its sheath, it opens up and pushes against the inside of the aorta. Once it opens up, the stent graft prevents blood from flowing into the lesion.

Before the procedure is finished, your doctor will take x-rays of your aorta. He or she will look to make sure the blood is flowing through the stent graft and not through the thoracic aortic lesion. Your doctor will then close up the cut on your leg with stitches.

After the procedure, your doctor should give you a filled-out Patient ID Card. You should carry this card with you at all times. If you need to have other procedures, such as an MRI, be sure to show this card to your doctor(s) or other health care provider(s). For an example of a Patient ID Card, see page 21.
About the Zenith Alpha Thoracic Endovascular Graft

What is a Zenith Alpha Thoracic Endovascular Graft?

A Zenith Alpha Thoracic Endovascular Graft (see Figure 7) is a one- or two-part fabric tube. It is sized to fit the part of the aorta that needs to be covered to seal off the thoracic aortic lesion. The stent graft is placed in the aorta across the thoracic aortic lesion to keep blood from flowing into the thoracic aortic lesion.

The stent graft is made of a polyester material like that used in open surgical repair. Suture material, like that used to close a wound, is used to sew the graft material to a frame of self-expanding nitinol stents. These stents provide support. The stent graft has several gold markers placed around its top and bottom. Using x-ray, your doctor can see these gold markers and use them to guide placement of the stent graft in your aorta.

All the materials used to make the device have been used in medical implants for a long time. If you are sensitive or allergic to polyester, polypropylene, nitinol, or gold, be sure to tell your doctor before treatment.

Indications for Use

A Zenith Alpha Thoracic Endovascular Graft is used for the endovascular treatment of patients who have:

1. Aneurysms or ulcers of the descending thoracic aorta; and
2. the right anatomy for endovascular repair.
Contraindications

A **Zenith Alpha Thoracic Endovascular Graft** should not be used in patients:

- with reactions or allergies to polyester, polypropylene, nitinol, or gold
- with a **systemic** infection who may be at increased risk of **endovascular** graft infection

General Warnings and Precautions

- The long-term performance of this **stent graft** is not fully known. Additionally, successful **thoracic aortic lesion** repair does not stop the disease from spreading. Therefore, patients who have an **endovascular repair** must have regular medical follow-up for the rest of their lives. This follow-up will assess your health and how your **stent graft** is performing. Regular follow-up with your doctor is important to make sure your **thoracic aortic lesion** does not require further treatment.

- A **Zenith Alpha Thoracic Endovascular Graft** is not recommended for patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging.

- Your doctor will determine your specific treatment needs and circumstances.

- You should keep your follow-up schedule even when you have no symptoms (e.g., pain, numbness, weakness).

- For more details, see your doctor or the Instructions for Use for the **Zenith Alpha Thoracic Endovascular Graft** at [www.cookmedical.com](http://www.cookmedical.com).
Risks

Endovascular repair of thoracic aortic lesions is a surgical procedure that has risks that include, but are not limited to, death. Other risks include complications involving the following organs:

- brain (for example, stroke)
- spinal cord (for example, paraplegia)
- heart (for example, heart attack)
- lungs (for example, pneumonia)
- kidneys (for example, kidney failure)
- gastrointestinal tract (for example, bowel obstruction)

You should discuss the procedure and all possible risks with your doctor to determine if endovascular repair is right for you.

Risks that may occur with the use of a Zenith Alpha Thoracic Endovascular Graft are listed below:

- If your thoracic aortic lesion continues to become larger or is at risk for becoming larger due to a leak in the stent graft or movement of the stent graft, it may be necessary to perform further endovascular treatments or to have open surgery.

- If you have an infection in your bloodstream or other organs of your body, you may have an increased risk of developing an infection in the stent graft.

- The stent graft has been tested to see how it reacts during an MRI. Based on the results of these tests, the device is labeled as MR Conditional. If the scanner settings are outside of those provided in the Instructions for Use, there may be potential risks. Ask your doctor before having an MRI. (For more information, see page 20.)
• **Thoracic aortic lesion** growth or **ruptures** are rare following **endovascular** treatment. However, they are still possible. Symptoms of growth or **ruptures** are not always present. Common symptoms of growth or **ruptures** include, but may not be limited to:

- pain (back or chest)
- persistent cough
- dizziness

- fainting
- rapid heartbeat
- sudden weakness

If you have any of the symptoms listed above, call your doctor right away. For more details, please see your doctor or the Instructions for Use for the **Zenith Alpha Thoracic Endovascular Graft** at [www.cookmedical.com](http://www.cookmedical.com).
Benefits

A study was conducted to compare open surgical repair to endovascular repair with a thoracic stent graft similar to the Zenith Alpha Thoracic Endovascular Graft. The study showed that the benefits of endovascular repair of thoracic aortic aneurysms and ulcers compared to open surgery may include, but may not be limited to:

• quicker recovery following surgery, including:
  ■ shorter overall hospital stay
    - endovascular patients 5.0 days, surgical patients 16.1 days
  ■ shorter time to return to regular diet
    - endovascular patients 1.9 days, surgical patients 5.2 days
  ■ shorter time to return to walking
    - endovascular patients 1.6 days, surgical patients 5.5 days

• fewer blood transfusions before discharge from the hospital
  - endovascular patients 0.3, surgical patients 1.7

In addition, the generally less invasive nature of endovascular repair offers the following potential benefits:

• much smaller surgical incision

• less frequent need for general anesthesia

• lower chance of heart and lung complications within 30 days following surgery

These endovascular repair results from the previous study were similar to the results from a clinical study of the Zenith Alpha Thoracic Endovascular Graft for the treatment of thoracic aortic aneurysms and ulcers.

For more information please visit: www.cookmedical.com
Before-Procedural Information

Before the procedure you will meet with your doctor to talk about the possible treatments for your thoracic aortic lesion. These may include endovascular treatment with a Zenith Alpha Thoracic Endovascular Graft (or another commercially available device), medical therapy, open surgery, or no treatment. Your doctor may ask you to have some further tests before your procedure.
After-Procedure Information

Why is follow-up important?
If you receive a Zenith Alpha Thoracic Endovascular Graft, it is very important to have regularly scheduled follow-up appointments with your doctor. This is because the long-term results of endovascular repair with this device are not fully known. Your doctor needs to look at pictures (x-ray, CT scan) of your thoracic aortic lesion and stent graft on a regular basis. This will help him or her make sure that the stent graft is not leaking and has not moved and that your thoracic aortic lesion is not growing. Your doctor may suggest further procedures and tests based upon this regular follow-up.

What kind of follow-up should I expect?
Recommended follow-up includes, but may not be limited to checkups at:

• 1 month
• 6 months
• 12 months
• yearly after the 12-month point*

Follow-up exams usually include, but may not be limited to, routine blood tests, x-rays (see Figures 8 and 9), a CT scan and a physical exam. These tests carry a low risk of complications. For example, there is a slight risk of allergic reactions to the contrast dye used in the CT scan. However, the benefits of these tests are usually greater than the possible risks. Talk with your doctor if you are concerned about follow-up exams. He or she may suggest special precautions.

These exams should be part of your lifelong plan for health and wellbeing. They are needed to evaluate your treatment and to watch for any changes over time. Your doctor may ask for additional tests based on what he or she finds at the follow-up visits.

* For additional information see “Risks” on page 15.
What if I need magnetic resonance imaging (MRI)?

Zenith Alpha Thoracic Endovascular Grafts meet standard testing requirements for MRI safety, supporting the labeling of the device as MR Conditional. This means that testing indicates that a patient can be safely scanned within the scan parameters provided in the Instructions for Use and Patient ID Card. Additional risks may exist if the MR scan is performed outside of the parameters provided.

If you receive a Zenith Alpha Thoracic Endovascular Graft, be sure to tell all of your health care providers that you have the stent graft. Show them your Patient ID card. This card contains information about MRI procedures for patients with this device. If you are concerned about MRI, talk to your doctor about potential risks and benefits of the test.
What should I do with my Patient ID Card?

You will receive a **Zenith Alpha Thoracic Endovascular Graft** Patient ID card. The card provides valuable information about:

- the type of device you have implanted
- the date your device was implanted
- your doctors
- information about **MRI**

Be sure to tell all your health care providers that you have the **stent graft** and show them your Patient ID Card. Keep the card with you at all times.

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**Before MRI, you must show this card to your doctor who should assess potential risks and consider the MRI information in the device labeling on www.cookmedical.com. Because unforeseen variations in patient anatomy or scanners may increase risk, the MRI facility should allow for prompt intervention if necessary.**

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**Cook recommends that the patient register the MR conditions with the MedicAlert Foundation. The MedicAlert Foundation can be contacted in the following manner:**

- Mail: MedicAlert Foundation International
  2323 Colorado Avenue
  Turlock, CA 95382
- Phone: 888.633.4298 (toll free) or 209.668.3333 (from outside the U.S.)
- Fax: 209.669.2450
- Web: www.medicalert.org

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**Nonclinical testing has demonstrated that the Zenith Alpha Thoracic Endovascular Graft is MR Conditional. A patient with the endovascular graft may be safely scanned in an MR system meeting the following conditions:**

- **Static magnetic field of 1.5 tesla or 3.0 tesla only.**
- **Maximum spatial gradient of 1600 gauss/cm (16.2 T/m) or less.**
- **The product of the spatial gradient and static magnetic field should not exceed 48.0 T²/m.**
- **Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of ≤ 2.0 W/kg (Normal Operating Mode) for 15 minutes of scanning (i.e., per scanning sequence).**

The image artifact extends approximately 5 mm from the Zenith Alpha Thoracic Endovascular Graft as found during nonclinical testing when imaged with a gradient echo pulse sequence and a 3.0 tesla MR system.
Clinical Study

A clinical trial for the Zenith Alpha Thoracic Endovascular Graft used to treat thoracic aortic aneurysms and ulcers was conducted at 23 hospitals in the United States and other countries. The goal of the trial was to compare the safety and effectiveness of endovascular repair with the Zenith Alpha Thoracic Endovascular Graft to results from endovascular repair with a different graft. This other graft, the Zenith TX2 TAA Endovascular Graft, was previously approved, based on results from a study that compared it to open surgical repair in patients with descending thoracic aortic aneurysms or ulcers.

One hundred and eight (108) patients received the Zenith Alpha Thoracic Endovascular Graft.

Patients treated with the stent graft received clinical assessment and/or x-ray follow-up before leaving the hospital, at 30 days, at 6 months, and at 12 months. They are also being followed yearly through 5 years. The safety results (major adverse events within 30 days) and effectiveness results (successful placement of the stent graft and prevention of rupture, conversion, aneurysm growth, and endoleak requiring reintervention at 12 months) for patients treated with the Zenith Alpha Thoracic Endovascular Graft were similar to the results from patients treated with the Zenith TX2 TAA Endovascular Graft. Major adverse events within 30 days occurred in 3.6% of patients following treatment with the Zenith Alpha Thoracic Endovascular Graft. Unsuccessful placement of the stent graft, conversion, aneurysm growth, or endoleak requiring reintervention at 12 months occurred in 7.3% of patients following treatment with the Zenith Alpha Thoracic Endovascular Graft.

For more information please visit: www.cookmedical.com
When to Call the Doctor

If you have any of the symptoms below, please contact your doctor right away:

- pain
- pulse-less legs
- ischemia of intestines
- persistent cough
- dizziness
- cold arms or legs
- fainting
- rapid heartbeat
- sudden weakness

Remember, your doctor can help answer any questions you may have regarding treatment of a thoracic aortic lesion and can discuss potential adverse effects and potential benefits of this treatment based upon your medical history and condition.
Where Can I Find More Information?

**Cook Medical Incorporated**
www.cookmedical.com

Customer Service Representatives may be reached Monday-Friday between the hours of 8:00 a.m. to 7:00 p.m. EST. - Phone 800.468.1379.

**VascularWeb Patient Information**
www.vascularweb.org

VascularWeb is a global source of information and services for improving vascular health. VascularWeb is owned by the Society for Vascular Surgery (SVS), a nonprofit organization.

**Society of Interventional Radiology**
www.sirweb.org

The Society of Interventional Radiology (SIR) is a professional group for doctors who specialize in interventional or minimally invasive procedures. SIR is a nonprofit, national scientific organization committed to improving health and quality of life through the practice of cardiovascular and interventional radiology.

**U.S. National Library of Medicine**
www.medlineplus.gov

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.

**U.S. Department of Health and Human Services**

**Food and Drug Administration**
www.fda.gov

This is a U.S. government agency intended to promote and protect 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.
Glossary

Aorta - the main artery that carries blood from the heart to the rest of the body.

Aneurysm - a bulge or ballooning (enlarging and thinning) of a weakened area of a blood vessel.

Angiography/Angiogram - an x-ray method that uses liquid dye injected into the bloodstream to show blood flowing through blood vessels. This type of image is called an angiogram.

Blunt Injury - see blunt thoracic aortic injury

Blunt Thoracic Aortic Injury (BTAI) - a traumatic injury that causes a tear in the thoracic aorta, which can extend completely or partially though the wall of the aorta.

Cardiac Arrhythmia - irregular heartbeat.

Contrast (dye) - a liquid dye injected into the bloodstream to show blood vessels under x-ray or CT scan.

Conversion - treatment with open surgery after an endovascular treatment that was not successful in repairing the thoracic lesion.

CT Scan - a series of computerized x-rays that form a picture of your organs, blood vessels and aneurysm. The images look like slices of the body on a television screen. This is also known as a "CAT" scan.

Dissection - a type of lesion where a tear in the lining of the aorta causes blood to flow in between the layers of the aorta.

Endoleak - blood flow into the thoracic aortic aneurysm after placement of a stent graft.

Endovascular - inside or within a blood vessel.

Endovascular Repair - placement of a stent graft to seal off or reline the thoracic aortic lesion. Instead of opening up the chest, the doctor makes a small cut near the hip (near the crease between the belly and thigh) to get to the femoral artery (blood vessel). Through this small cut, a graft (metal and fabric tube) is inserted through the femoral artery and gently moved into place inside the lesion. The graft makes a new path through which the blood flows.
Femoral Arteries - two blood vessels that run down each leg and carry blood to the thighs and lower body. Doctors can use the femoral arteries as a path to reach arteries in the chest and belly.

Iliac Arteries - the two large blood vessels that connect the lower end of the aorta to the femoral arteries in each leg.

Ischemia - lack of blood in an area of the body due to mechanical obstruction or functional constriction of a blood vessel.

Lesion - see thoracic aortic lesion.

Major Adverse Event - death or other serious complication involving the brain (stroke), heart (cardiac arrest or heart attack), lungs (blood clot, or need for either a breathing tube or ventilator), spinal cord (paraplegia), kidneys (renal failure), gastrointestinal tract (bowel resection), blood vessels (leak or occlusion requiring operation), lower extremities (amputation), or incision site (need for operation).

MR Conditional - status indicating that a patient can be safely scanned within the scan parameters provided in the Instructions for Use and Patient ID Card. Additional risks may exist if the MR scan is performed outside of the parameters provided.

(MRI) Magnetic Resonance Imaging - a way of creating detailed pictures of the inside of the body. The MRI scanner uses magnetic fields and radio waves to create the pictures similar to the way a television works.

Occlusion - a blockage or closing of a blood vessel or stent graft.

Open Surgical Repair of a TAA - a type of surgery performed to repair a thoracic aneurysm. To reach the aneurysm, a doctor cuts open the chest and repairs the aorta by replacing the aneurysm section with a fabric tube called a graft. The graft is sewn into place and acts as a replacement blood vessel.

Rupture - when a blood vessel bursts, causing serious internal bleeding.

Sheath - a long plastic tube with the stent graft collapsed inside. The sheath is advanced inside the blood vessel to where the aneurysm is located, and the stent graft is positioned in place.
**Stent graft** - a metal and fabric tube placed inside a diseased vessel without the use of open surgery. The graft makes a new path for the blood to flow through, re-lining the diseased vessel.

**Stents** - metal parts of the stent graft that spring outward toward the vessel walls and provide support to the stent graft.

**Systemic** - relating to or affecting the entire body.

**Thoracic Aortic Aneurysm (TAA)** - an aneurysm in the part of the aorta that runs through a person’s chest.

**Thoracic Aortic Lesion** - disease or injury of the aorta including aneurysms, ulcers and blunt thoracic injuries. The Zenith Alpha Thoracic Endovascular Graft is indicated for treatment of only aneurysms or ulcers.

**Traumatic Injury** - an injury that occurs suddenly and requires immediate medical attention.

**Ulcer** - a lesion that goes through the inner lining of the aorta, causing blood to collect within the wall of the aorta. An ulcer may cause one side of the aorta to bulge as the wall becomes weakened due to abnormal blood collection in the diseased section.

**Vascular** - referring to the vessels that carry blood.

**Zenith Alpha Thoracic Endovascular Graft** - a device, made by Cook Medical, that is placed inside the aorta to seal off a thoracic aortic lesion. The stent graft is made of polyester material. Surgical suture is used to sew the graft material to a frame of nitinol stents. The stent graft has one or two parts that are put in the body through long tubes called sheaths.

**Zenith TX2 TAA Endovascular Graft** - a device, made by Cook Medical, that is placed inside the aorta to seal off an aneurysm or ulcer. The stent graft is made of polyester material. Surgical suture is used to sew the graft material to a frame of stainless steel stents. The stent graft has one or two parts that are put in the body through long tubes called sheaths. The Zenith TX2 TAA Endovascular Graft received FDA approval for use before the Zenith Alpha Thoracic Endovascular Graft.
Notes

If you have questions about your thoracic aortic lesion or treatment, talk to your doctor. He or she should always be your main source of information about this procedure and its impact on your health.

Questions to Discuss with your Doctor

• What are the options to treat my thoracic aortic lesion?
• What are the complications associated with endovascular repair of my thoracic aortic lesion?
• What are the complications associated with open surgical repair of my thoracic aortic lesion?
• How many endovascular repair procedures has this facility performed?
• How long will I need to limit my activities following treatment?
• After endovascular treatment, what type of follow-up with a doctor is required?

Use the space below to record your doctor’s name and phone number. You may also want to write down questions, take notes or keep a record of talks with your doctor.

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<th>Doctor’s Phone #:</th>
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<th>Other notes and questions:</th>
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