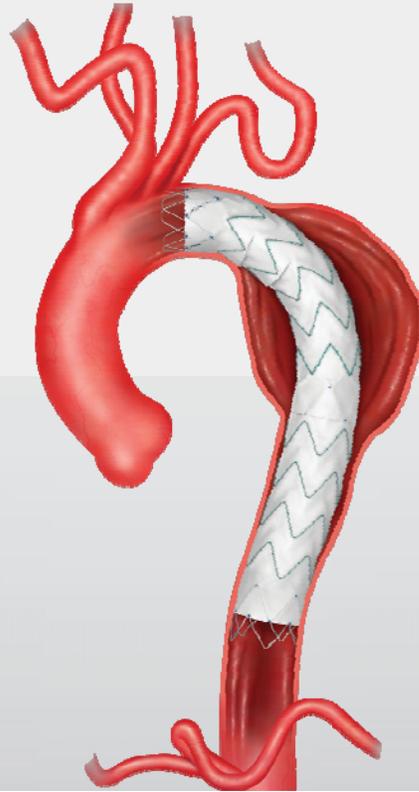


PATIENT GUIDE

Treating Your Thoracic Aortic Lesion



Zenith Alpha™
THORACIC ENDOVASCULAR GRAFT

COOK®

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 24-26*. 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 they 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.

CONTENTS

5-7 INTRODUCTION

What is a thoracic aortic aneurysm (TAA) or ulcer?

Is this a serious condition?

What are some of the symptoms of a TAA? What causes a TAA?

What is a blunt thoracic aortic injury?

Is this a serious condition?

What are some of the symptoms of a TAA?

What causes a TAA?

8-12 TREATMENT OF THORACIC AORTIC LESIONS

How do doctors treat a thoracic aortic lesion?

What is open surgical repair?

What is endovascular repair?

How is the stent graft put in?

13 ABOUT THE ZENITH ALPHA THORACIC ENDOVASCULAR GRAFT

What is a Zenith Alpha Thoracic Endovascular Graft?

13 INDICATIONS FOR USE

14 CONTRAINDICATIONS

14 GENERAL WARNINGS AND PRECAUTIONS

15 RISKS

16 BENEFITS

17 BEFORE-PROCEDURE INFORMATION

18-20 **AFTER-PROCEDURE INFORMATION**

Why is follow-up important?

What kind of follow-up should I expect?

What if I need magnetic resonance imaging (MRI)?

What should I do with my Patient ID card?

21 **CLINICAL STUDY**

22 **WHEN TO CALL THE DOCTOR**

23 **WHERE CAN I FIND MORE INFORMATION?**

24-26 **GLOSSARY**

27 **NOTES**

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 (called an **ulcer**), causing 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**.

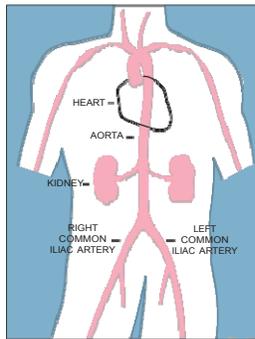


Figure 1: Aortic anatomy

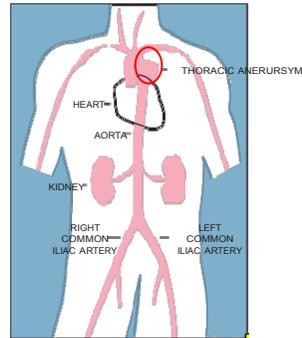


Figure 2: Aortic anatomy with thoracic aneurysm

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, which 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**.

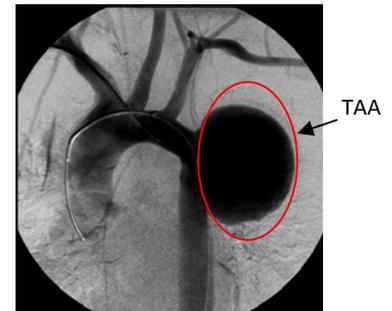


Figure 3. X-ray of an aorta with a TAA

What is a blunt thoracic aortic injury (BTAI)?

A **blunt thoracic aortic injury** (Figure 4) is a **traumatic injury** resulting in a complete or partial tear of the thoracic aorta.

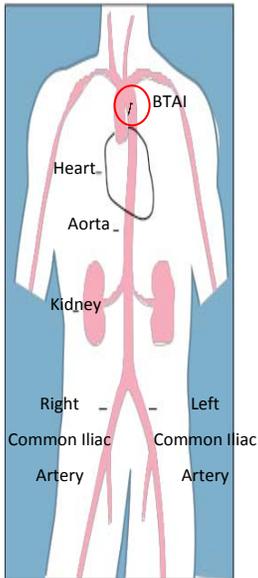


Figure 4. Aortic anatomy with BTAI

Is this a serious condition?

BTAI is life-threatening due to the potential for the tear in the **aorta** to cause bleeding inside the body. Therefore, immediate treatment may be necessary. Both **open surgical repair** and **endovascular repair** are options if treatment is necessary. Patients with **BTAI** may have sustained other injuries during the accident that require treatment prior to the **BTAI**.

What are some of the symptoms of BTAI?

Most people do not have symptoms of **BTAI** and will require an x-ray to determine if the aorta has been injured.

What causes BTAI?

BTAI is often caused by motor vehicle accidents or falls and is often accompanied by additional injuries related to the accident.

Treatment of Thoracic Aortic Lesions

How do doctors treat a thoracic aortic lesion?

When a **thoracic aortic lesion** is small or does not completely tear the aorta in BTAI patients, 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.



Figure 5: Open surgical procedure

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 that 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 and 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 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 (see page 18 for follow-up visit information) with your doctor. 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 18.)

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.

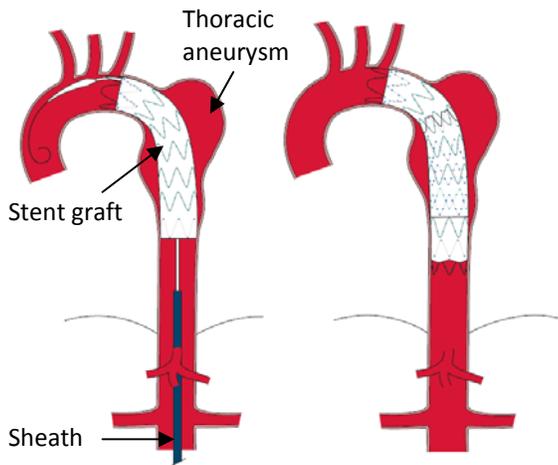


Figure 6. Thoracic aorta with stent graft being placed.

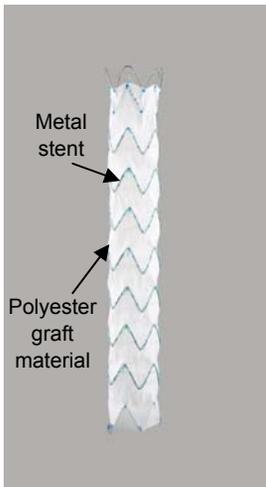
The **stent graft** is contained in its own plastic tube (**sheath**, see Figure 6). The tube allows the **stent graft** to be inserted and placed in the **aorta**. The plastic tubes are removed after the **stent graft** is in place.

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 the skin near the hip. If the femoral artery is not large enough, the doctor may be required to insert the **sheath** containing the **stent graft** into your bloodstream through another graft (referred to as a conduit) that gets connected directly 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**.

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 **thoracic aortic lesion**. The bottom of the **stent graft** is placed at a point below the **thoracic aortic 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 **thoracic aortic lesion**. Sometimes, another, smaller incision may be needed in the neck to help the doctor properly place the **stent graft**.

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 20*.



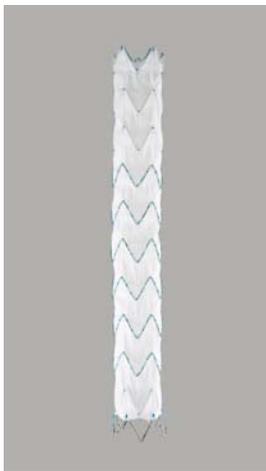
About the Zenith Alpha Thoracic Endovascular Graft

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. **Thoracic Aortic Lesions** (including **aneurysms**, **ulcers** or **blunt injury**) of the descending thoracic **aorta**; and
2. the right anatomy for **endovascular repair**.

Figure 7. Zenith Alpha Thoracic Endovascular Graft (the proximal part is shown in the top image; the distal part is shown in the bottom image)

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 process 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.

Risks

Endovascular repair of thoracic aortic lesions is a surgical procedure that has risks, which include, but are not limited to death as well as **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**.
- Testing supports the device being 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 19.)
- **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.

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**. The potential for experiencing similar benefits following endovascular repair of **BTAI** depends on other injuries that may have occurred as a result of the accident.

For more information please visit: www.cookmedical.com



Before-Procedure 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 to 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 well-being. 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.



Figure 8. X-ray of an aorta with a TAA



Figure 9. X-ray of same aorta after endovascular repair



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.

This patient has received a

COOK MEDICAL Zenith®
ENDOVASCULAR GRAFT

Cook Incorporated 750 Daniels Way Bloomington, IN 47404 U.S.A. 812.339.2235	William Cook Europe ApS Sandet 6, DK-4632 Bjæverskov, Denmark +45 56 86 86 86	William Cook Australia Pty. Ltd. 95 Brandl Street Eight Mile Plains, QLD 4113 Australia +61 7 38 41 11 88
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MRI information on back side.

Patient Name Implant Date

Implanting Facility Name

Implanting Physician

Implanting Physician Phone #

Follow-up Physician

Follow-up Physician Phone Number

Product Catalog #

Product Catalog # Thoracic

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.



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

Mall: MedicaAlert 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

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 MRI system.

AL-1309-441

Patient ID Card

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**.

An additional clinical trial of the **Zenith Alpha Thoracic Endovascular Graft** was conducted at 17 hospitals in the United States. The goal of the additional trial was to evaluate 30-day outcomes following use of the **Zenith Alpha Thoracic Endovascular Graft** in patients with BTAI. Fifty (50) patients received the **Zenith Alpha Thoracic Endovascular Graft**, one of which required an additional procedure within 30 days (to keep blood from flowing through the tear in the aorta).

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 through 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.

Complications – a condition or disease that occurs after initial treatment

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 re-line 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 Events – 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 - 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

(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, which include aneurysms, ulcers and blunt thoracic aortic injuries

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 the 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 the 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 lesion?
- What are the complications associated with endovascular repair of my thoracic lesion?
- What are the complications associated with open surgical repair of my thoracic 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.

Patient Name:	
Date of Graft Placement:	
Hospital:	
Doctor's Name:	
Doctor's Phone #:	
Other notes and questions:	



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