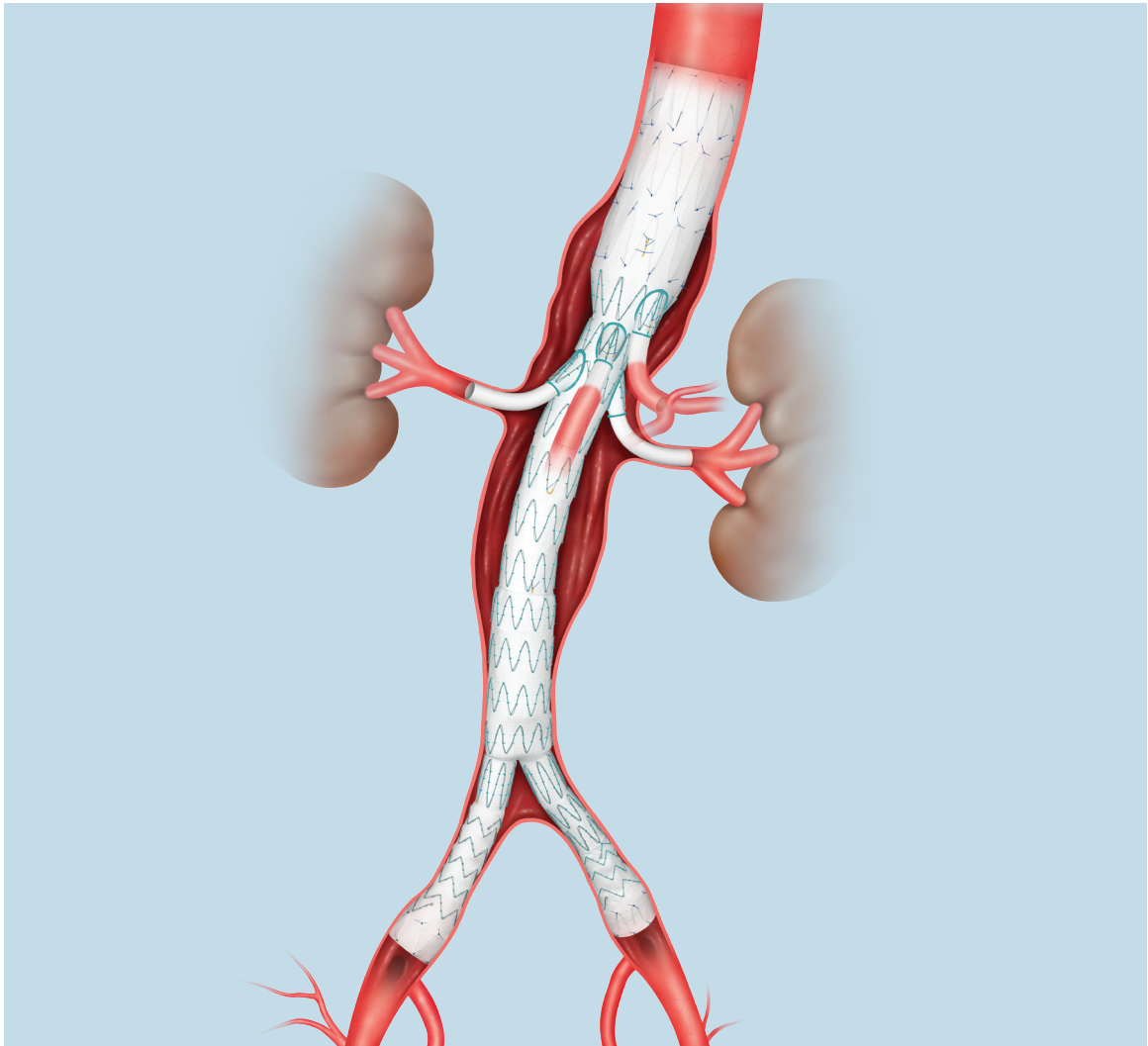


# Treating Your Thoracoabdominal Aortic Aneurysm



**Zenith<sup>®</sup> t-Branch<sup>™</sup>**

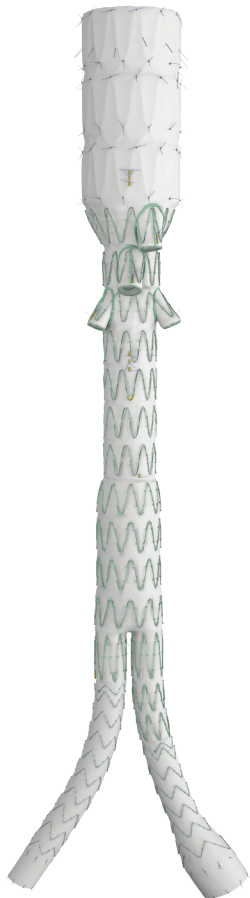
THORACOABDOMINAL ENDOVASCULAR GRAFT

## About This Patient Guide

This patient guide has been provided as a courtesy from Cook Medical and is intended to help you learn more about **thoracoabdominal aortic aneurysms** (TAAA). We hope this information will be helpful to you and your family.

For your convenience, a glossary of medical terms is included on pages 4-6. Words in **bold** throughout this text are defined in the glossary.

This patient guide is only a guideline. It provides basic information about **thoracoabdominal aortic aneurysms** and their treatment with the Cook **Zenith t-Branch**. This information is not intended to diagnose a medical condition. The treatment of **thoracoabdominal aortic aneurysms** may vary according to an individual's unique needs and doctor assessments. As with any surgery or medical procedure, the best source of information and advice is your doctor.



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## Glossary

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

**Aneurysm** – a bulging or ballooning (enlarging and thinning) of a weakened area of a blood vessel.

**Angiography** – an x-ray method that uses contrast (dye) injected into the bloodstream to see blood flow through blood vessels.

**Angiogram** – the image taken during an angiography.

**Branch Vessels** – blood vessels that come off the aorta, such as the renal and superior mesenteric arteries.

**Celiac Artery** – the artery that supplies blood to the liver, stomach, spleen and other organs.

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

**CT Scan** – a series of computerized x-rays that form a picture of your aneurysm. Formerly known as a CAT scan.

**Embolization** – the process of purposefully obstructing a blood vessel or organ with a material mass.

**Endovascular** – inside or within a blood vessel.

**Endovascular Graft** – a graft placed inside a diseased vessel without the use of open surgical techniques. The graft makes a new path through which the blood flows.

**Endovascular Repair** – placement of an endovascular graft to seal off (exclude) an aneurysm. Instead of making a large incision in the abdomen, the doctor makes a small cut near each hip (near the crease between the abdomen and thigh) to get to the femoral arteries (blood vessels). Through these small cuts, a graft (fabric tube) is inserted through the femoral arteries. The graft makes a new path through which the blood flows.

**Femoral Arteries** – two blood vessels (one in each leg) that carry blood to the thigh region of each leg. Doctors can use the femoral arteries as a path to reach the iliac arteries and the aorta.

**Iliac Arteries (Common)** – the two large blood vessels that extend from the lower end of the aorta to the internal iliac, external iliac and femoral arteries in each leg.

**Iliac Leg(s)** – the parts of the t-Branch TAAA Endovascular Graft that extend from the main body (in the aorta) to the iliac arteries.

**MRI (Magnetic Resonance Imaging)** – a way of creating detailed pictures of the body. The MRI scanner uses magnetic fields and radio waves to create the pictures.

**Open Surgical Repair** – a type of surgery performed to repair an aneurysm. To reach the aneurysm, a doctor makes a cut through the abdomen or the side of the patient. The doctor 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.

**Renal Arteries** – two blood vessels that come off the aorta and carry blood to the kidneys.

**Rupture** – a tear in the blood vessel wall that causes serious internal bleeding.

**Sheath** – a long plastic tube that contains the Zenith t-Branch AAA Endovascular Graft. The sheath is advanced inside the blood vessel to the aneurysm site, and the graft is put in place.

**Stents** – surgical steel parts of the endovascular graft that provide support and hold it in place.

**Superior Mesenteric Artery** – also known as the SMA, a major artery that comes off the aorta and supplies blood to the intestine and the pancreas.

**Thoracoabdominal Aortic Aneurysm (TAAA)** – a ballooning or enlargement of the aorta, the main artery that carries blood from the heart to the rest of the body, in the part of the aorta that runs through the thoracic region (chest) and the abdomen (the stomach).

**Ultrasound** – a way to create pictures of parts of the body using high-frequency sound waves.

**Vascular** – composed of, or pertaining to the vessels that convey blood.

**Zenith t-Branch** – a device placed within a thoracoabdominal aortic aneurysm to seal off the aneurysm. The graft is a tube made of polyester graft material (fabric) like that used in open surgical repair. Standard surgical suture is used to sew the graft material to a frame of stainless steel stents. These self-expanding stents provide support. The Zenith t-Branch is made up of three parts: a proximal body (t-Branch), a distal body (universal distal body) and two legs. The proximal body is positioned in the aorta and has carefully positioned branches, so blood can continue to flow to the body's organs. The graft extends from the aorta around the celiac artery, into both iliac arteries. The Zenith t-Branch is placed within the aneurysm using the H&L-B One-Shot Introduction System.

## Introduction

### *What is a thoracoabdominal aortic aneurysm (TAAA)?*

The **aorta** is the main blood vessel that carries blood from the heart to the rest of the body. It extends from the chest to 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, because of aging or other changes, a section of the **aorta** may weaken and begin to bulge.

This bulge can enlarge over time as the walls of the **aorta** become thinner and stretch (like a balloon). This bulge in the **aorta** is called an **aneurysm**. Sometimes an **aneurysm** occurs in the part of the **aorta** that runs through the thoracic region (chest) and the abdomen (the stomach). This is called a **thoracoabdominal aortic aneurysm (TAAA)**. Sometimes an **aneurysm** that occurs in the part of the **aorta** that runs through the thoracic region (chest) and the abdomen (the stomach) can extend into the **iliac arteries**. This is called a **thoracoaortoiliac aneurysm**.

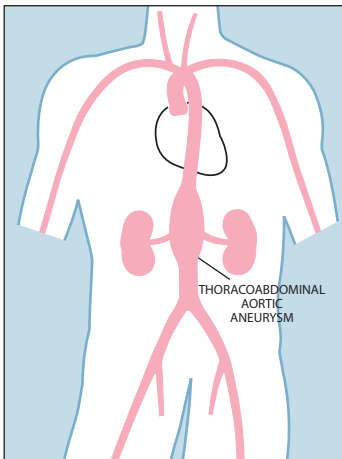
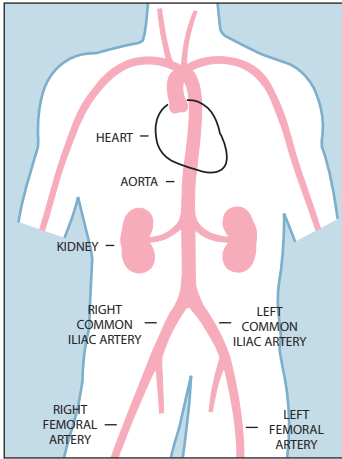
### *Are these serious conditions?*

In its early stages, when a **TAAA** is small, it may not pose an immediate health risk. However, your doctor will want to check the condition of the **aneurysm** regularly.

In later stages, if the **TAAA** continues to grow, the walls of the **aorta** can become thin and lose their ability to stretch. The weakened sections of wall may become unable to support the force of blood flow. Such an **aneurysm** could **rupture**, causing serious internal bleeding and death.

### *What are some of the symptoms of a TAAA?*

In most cases patients have no symptoms of a **TAAA**. For people who do have symptoms, the most common one is pain. The pain can be in the abdomen, back or chest. It could be anything from a mild pain to a severe pain or tenderness in the mid to upper abdomen or lower back. Some patients feel the **aneurysm** as a pulsating or throbbing mass in their abdomen. Many patients feel none of these symptoms yet may still have a **TAAA**.



A **TAAA** is often discovered during an examination being done for other medical reasons. Your doctor may feel a bulge or pulsation (throbbing) in your abdomen. Most often, **aneurysms** are found during a medical test such as a **CT Scan** or **ultrasound**.

If you know you have an **TAAA** and you develop back pain, abdominal pain or dizziness, call your doctor immediately.



### ***What causes an aneurysm?***

Over time, **vascular** disease, injury or a hereditary defect of tissue within the arterial wall can cause a weakening of the **aorta** or **iliac arteries**. Blood pressure against the weakened area can cause ballooning (enlarging and thinning) of the vessel.

Risk factors for developing an **aneurysm** include family history, male gender, smoking, heart disease and high blood pressure. If you are at risk for developing an **aneurysm**, your doctor may recommend periodic checks. The checks could include a physical exam and possibly a **CT scan** or **ultrasound**.



## Treatment of Thoracoabdominal Aortic Aneurysm

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### ***How do doctors treat a TAAA?***

When an **aneurysm** is small, your doctor may recommend periodic checkups to monitor it. If an **aneurysm** is larger, or is rapidly growing, it has a greater risk of **rupturing**. If your doctor thinks there is a risk the **aneurysm** may burst, he or she may recommend treatment. There are two types of treatment for **TAAA**:

*Open Surgical Repair*

*Endovascular Repair*

The goal of all **TAAA** repair is to prevent the **aorta** from bursting.

**Important Note:** Not every patient is a candidate for **endovascular repair**. **Open surgical repair** and **endovascular repair** both have advantages and disadvantages based upon each patient's condition and needs. Discuss the advantages and disadvantages with your doctor.

### ***What is an open surgical repair?***

In this approach, surgery is performed to repair the section of the **aorta** that has an **aneurysm**. To reach the **thoracoabdominal aortic aneurysm**, a doctor makes a cut through the abdomen or the side of the patient. The doctor repairs the vessel 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. The blood flow through the **aorta** is stopped while the graft is put in place. The surgery takes about two to four hours to complete.

**Open surgical repair** is a proven medical procedure that works. However, it also has a long recovery period. Patients usually stay overnight in the intensive care unit and stay another five to nine days in the hospital. Many patients are unable to eat normally for five to seven days after the surgery. The overall recovery period can last up to three months.

As with any medical procedure, **open surgical repair** has a risk of complications. Discuss these with your doctor.

### ***What is an endovascular repair?***

**Endovascular** means “inside or within a blood vessel.” Instead of making a large incision in the abdomen, the doctor makes a small cut near each hip (near the crease between the abdomen and thigh) to get to the **femoral arteries** (blood vessels).

Through these small cuts, a **sheath** containing a graft (fabric tube) is inserted into the arteries and positioned inside the appropriate blood vessel (**aorta** and **iliac arteries**). The **endovascular graft** is deployed and seals off the **aneurysm**. The graft makes a new path through which the blood flows. The graft remains inside the vessel permanently. **Endovascular repair** typically takes a few hours to complete.

Because there are smaller cuts than those in **open surgical repair**, **endovascular repair** may result in less discomfort, a shorter hospital stay and faster recovery. Patients may have a hospital stay of only a few days. They can usually return to normal activity within four to six weeks after the procedure.

As with any medical procedure, **endovascular repair** has a risk of complications. **Endovascular repair** also requires routine follow-up visits with your doctor. Tests are done to evaluate the procedure and monitor success of the treatment. Refer to the follow-up section on *page 17* for more information. There is also a possibility that additional treatment or surgery may be required after the initial **endovascular repair**.

### ***Warnings***

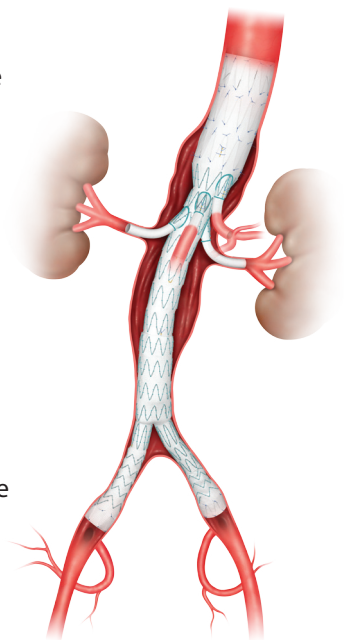
The use of this endovascular graft has not been studied in patients who:

- Are pregnant
- Are less than 18 years old
- Have a **ruptured** aneurysm
- Already have a device in the same location

Your doctor will need to help you decide if it is appropriate to get the device if any of these situations apply.

The device may not be recommended by your physician if you:

- Do not have suitable anatomy
- Cannot complete regular follow-up
- Cannot tolerate imaging dyes



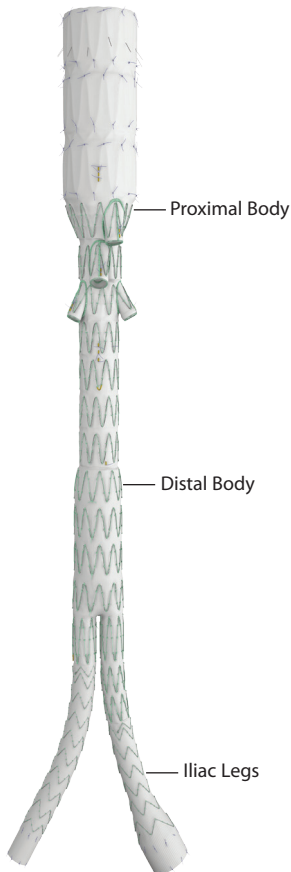
- Have an allergy to the materials used in the device
- Have an infection

## About Zenith t-Branch

### ***What is Zenith t-Branch?***

**Zenith t-Branch** is made up of four parts: a proximal body, a distal body (called Zenith Universal Distal Body), and two legs. The proximal body is positioned in the **aorta** and has carefully positioned **branches**, so blood can continue to flow to the body's organs. The graft extends from the **aorta** above the **celiac artery** into both **iliac arteries**.

The graft itself is made of a polyester graft material like that used in **open surgical repair**. Standard surgical suture is used to sew the graft material to a frame of stainless steel **stents**. These self-expanding **stents** provide support. The graft has several gold markers to help your doctor see the device during placement. All of these materials have a long history of use in medical implants.



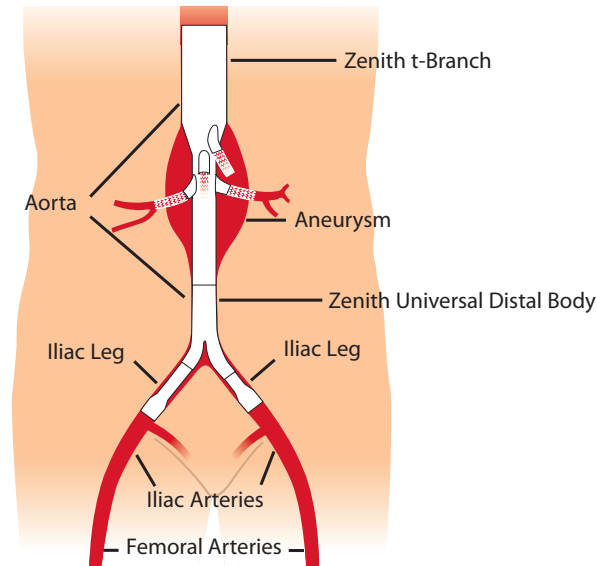
***How are the grafts implanted?***

Before the procedure, your doctor looks at pictures (**CT scan** and **angiogram**) of your **aorta** and **iliac arteries**. From these pictures, the doctor can choose the proper size for each part of the **Zenith t-Branch** so that it will fit in your blood vessels. During the procedure, the doctor uses x-rays to see the grafts and position them correctly.

Each component of the device is supplied to the physician in its own **sheath** (plastic tube). The **sheath** of the **Zenith t-Branch** is called the **H&L-B One-Shot Introduction System**. Each **sheath** is removed after the graft is put in place.



To place the graft, your doctor makes a small cut near each hip (near the crease between the abdomen and thigh) to get to the **femoral arteries** (blood vessels). Through these small cuts, each part of the graft is inserted separately into your bloodstream. The proximal body of the **Zenith t-Branch** is positioned in the **aorta**. Smaller covered stents are then used to connect the **t-Branch** to each of your major arteries: the **superior mesenteric artery**, the **celiac artery** and the right and left **renal arteries**. Then the distal body is positioned below the **Zenith t-Branch**. The legs extend from the distal body into the **iliac arteries**. When each part of the graft is released from its tube, it opens up to fill and reinforce the **aorta**. When all graft components are connected, the graft seals off (excludes) the **aneurysm**.



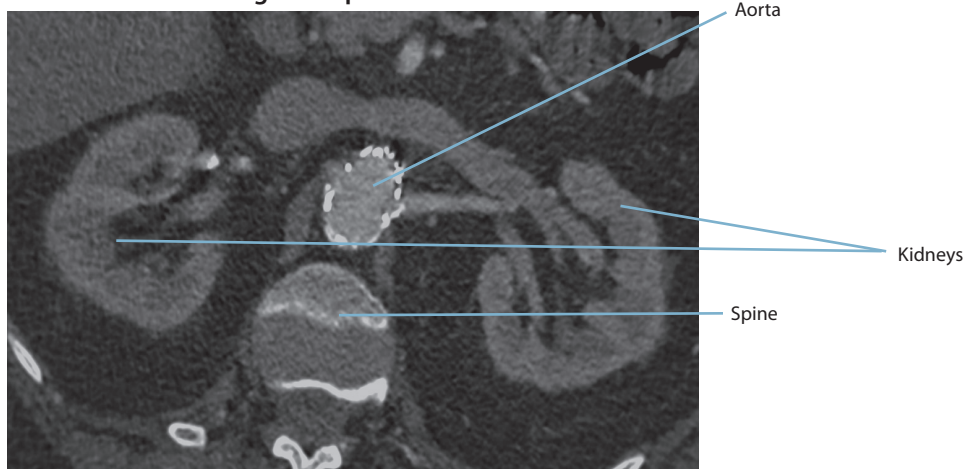
Before the procedure is finished, your doctor uses x-rays to confirm that blood is flowing to the **branch vessels** and **iliac arteries**, and also makes sure that blood is not flowing into the **aneurysm**. Your doctor then closes up the cut in each leg with a few stitches.

## After the Endovascular Procedure

### ***Why is follow-up important?***

If you receive a **Zenith t-Branch**, it is very important that you have regularly scheduled follow-up appointments with your doctor because the long-term results of this endovascular graft have not been established. It is possible for problems to occur that do not cause noticeable symptoms. Therefore, your doctor needs to look at pictures (x-ray, **CT scan**) of your **aneurysm** and graft on a regular basis. If a problem occurs, your doctor may recommend additional procedures.

### **CT scan of aorta with graft implanted**



***If at any point following treatment you experience one of the following symptoms, you should call your doctor immediately:***

- Pain in the legs, back, chest or abdomen
- Numbness in the legs, back, chest or abdomen
- Weakness in the legs, back, chest or abdomen
- Dizziness
- Fainting
- Rapid heartbeat
- Leg discoloration or coolness
- Decreased urination

***What follow-up should I expect?***

Recommended follow-up includes checkups at:

- 1 month
- 6 months
- 12 months
- Yearly thereafter

Follow-up exams usually include routine blood tests, x-rays, a **CT scan** and a physical exam.

These follow-up exams carry some minimal potential risk. However, the benefits of these tests clearly outweigh any potential risks. There is a rare risk of allergic reaction related to the **contrast** dye used in the **CT scan**. Talk with your doctor if you have any concerns regarding these exams. These exams should be considered a lifelong commitment to your health and well-being.

They are necessary to evaluate your treatment and any changes over time. Your doctor may request additional evaluations based on findings at the follow-up visits.

***What if I need magnetic resonance imaging (MRI)?***

If you receive a **Zenith t-Branch**, be sure to tell all of your healthcare providers that you have the graft. More information is available at: [www.cookmedical.com](http://www.cookmedical.com). Discuss the potential risks and benefits of an **MRI** with your healthcare providers if you have any concerns about this diagnostic test.

### Questions to Discuss with Your Doctor

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- How long can the graft remain implanted in my body?
- How many endovascular repair procedures has this facility performed?
- How many thoracoabdominal endovascular repair procedures has this facility performed?
- How long will I need to limit my activities following treatment?



## Where can I find more information?

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### ***Abdominal Aortic Aneurysms***

#### **Vascular Web Patient Information**

**[www.vascularweb.org](http://www.vascularweb.org)**

VascularWeb is an internet-based global resource of information and services for individuals interested in improving vascular health worldwide. VascularWeb is sponsored and owned by the Society for Vascular Surgery (SVS), and is governed by a board of directors and managed by an editorial board.

### ***Interventional Therapy***

#### **Society of Interventional Radiology**

**[www.sirweb.org](http://www.sirweb.org)**

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

#### **U.S. National Library of Medicine**

**[www.medlineplus.gov](http://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 healthcare, as well as works on biomedical aspects of technology, the humanities, and the physical, life and social sciences.

### ***Product Information***

#### **Cook Medical**

**[www.cookmedical.com](http://www.cookmedical.com)**

With international headquarters in Bloomington, Indiana, Cook is a leading designer, manufacturer and global distributor of minimally invasive medical device technologies for diagnostic and therapeutic procedures. Since its founding in 1963, Cook has been a privately held company that creates innovative technologies for stents and stent grafts, catheters, wire guides, introducer needles and sheaths, embolization coils, medical biomaterials, vena cava filters, implanted cardiac lead extraction equipment and other minimally invasive medical devices.

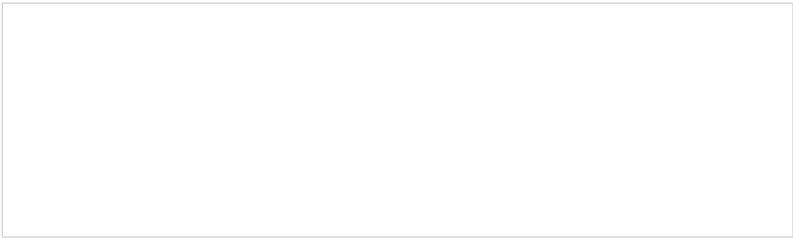
Notes

If you have any questions about your **thoracoabdominal aortic aneurysm** or treatment, we encourage you to talk to your doctor. He or she should always be your primary source of information. Talk to your doctor about the details of this procedure and its impact on your health.

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

Patient Name	
Implantation Date	
Device Implanted	<input type="checkbox"/> Zenith t-Branch.
Implanting Facility's Name (Hospital)	
Implanting Physician	
Implanting Physician Phone #	





AORTIC INTERVENTION  
CRITICAL CARE  
ENDOSCOPY  
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