

Patient Information Booklet



*Endovascular Stent Grafts:
A Treatment for
Thoracic Aortic Aneurysms*

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Introduction

This booklet is provided to help you and your caregivers decide if a thoracic stent graft is right for you to treat a thoracic aortic aneurysm. Please read the booklet and discuss any questions with your doctor. Only a doctor can determine whether you are a good candidate for the procedure.

*There is a glossary on page 20 that you can use to better understand some of the medical terms in this booklet. Words that are **bolded** in the text are defined in the glossary.*

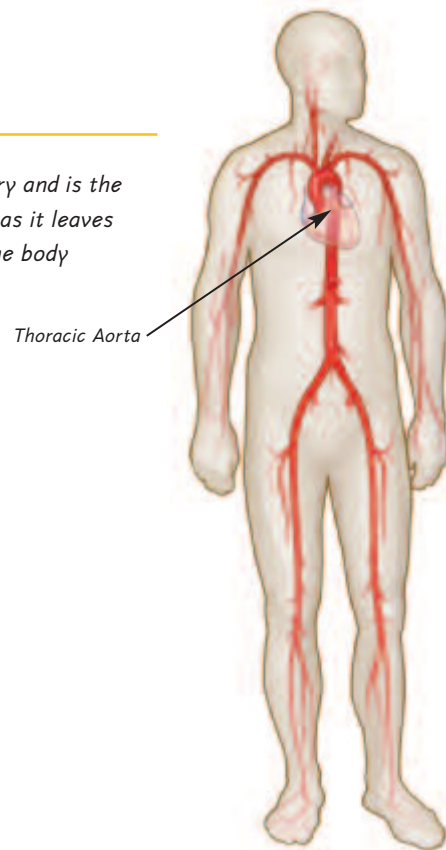
Anatomy of the Thoracic Aorta

The **aorta** is the largest **artery** in the body. An artery is a blood vessel that carries blood away from the heart. The **thoracic aorta** is the first blood vessel that the blood enters when it leaves the heart to circulate throughout the body. The thoracic aorta is the section of the aorta that sits within your chest (see **Figure 1**).

The thoracic aorta has several important blood vessels that provide blood to the heart, head, arms, and spinal cord. The thoracic aorta normally has a diameter (width) of about one inch. This diameter varies among individuals and increases slightly as you age.

FIGURE 1

The aorta is the body's largest artery and is the first blood vessel that blood enters as it leaves the heart to circulate throughout the body



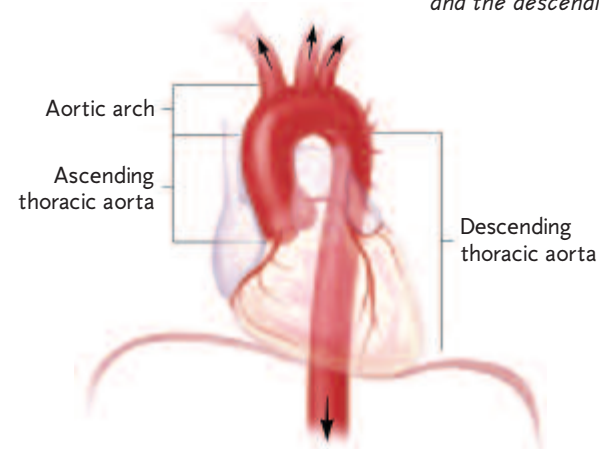
The thoracic aorta has three major sections: the **ascending thoracic aorta**, the **aortic arch**, and the **descending thoracic aorta** (see **Figure 2**). From the heart, the aorta curves upward and blood travels up toward the head. The aorta then curves downward and redirects blood flow to the feet.

The ascending thoracic aorta is the section of the aorta closest to the heart. Blood vessels that branch off from the ascending thoracic aorta also provide blood to the heart. The aorta then curves in the section called the **aortic arch**. Blood vessels that go to the head and arms originate off the aortic arch.

Blood flow is directed toward the feet in the descending thoracic aorta. Multiple blood vessels branch off from the descending thoracic aorta including vessels that send blood to the spinal cord. The Medtronic **Talent™ Thoracic Stent Graft** is designed for use in the descending thoracic aorta.

FIGURE 2

The thoracic aorta has three major sections: the ascending thoracic aorta, the aortic arch, and the descending thoracic aorta



What Is an Aneurysm?

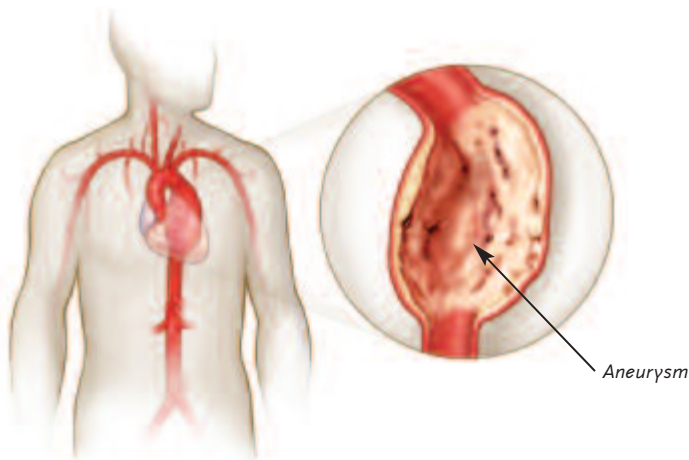
An **aneurysm** is a bulging or ballooning of a weakened area of a blood vessel. Aneurysms usually result when proteins that make the artery elastic break down. Aneurysm formation may also be related to heredity, trauma, or disease that weakens the vessel wall. Over time, the vessel wall loses its strength and the force of normal blood pressure in the aneurysm can cause it to burst.

If an aneurysm forms in the part of the aorta that flows through your chest, it is called a **thoracic aortic aneurysm** (see **Figure 3**). This term is often abbreviated as “**TAA**.”

The descending aorta has an aneurysm when the diameter of the diseased part of the aorta is at least 1.5 times as wide as the healthy part of the aorta. An aneurysm is also likely when its diameter reaches approximately two inches or larger.

FIGURE 3

An aneurysm is a bulging or ballooning of a weakened area of a blood vessel



What Symptoms Are Associated with Thoracic Aortic Aneurysms?

Most people do not have any symptoms from thoracic aortic aneurysms. If symptoms do occur, they include back pain, chest pain, difficulty swallowing, and/or coughing up blood. Most aneurysms are diagnosed when doctors do tests (such as **CT scans** or **MRIs**) for other reasons. As an aneurysm gets wider, it has a higher chance of bursting, also called **aneurysm rupture**. When the aorta ruptures, blood leaks from the vessel and no longer travels to vital organs, and this often leads to death. Thoracic aortic aneurysms are treated when a doctor believes the aneurysm might rupture.

What Are the Current Treatments for Thoracic Aortic Aneurysms?

Not all thoracic aortic aneurysms need surgery. Your doctor may try medical management of your thoracic aortic aneurysm. However, medical management does not treat the aneurysm or the underlying disease, but rather it attempts to reduce the stresses on the diseased vessel. Common medical management includes:

- If your aneurysm is small, your doctor may decide to wait and watch carefully to see if there are any changes.
- If you have high blood pressure, your doctor may prescribe medication to lower it.
- If you smoke, your doctor may suggest that you find help in quitting.
- Your doctor may also ask you to make changes in your diet or exercise habits.

If the doctor feels there is a risk that the aneurysm will burst (or rupture), he or she may recommend one of two aneurysm repair methods:

- Open Surgery
- Thoracic Stent Graft Procedure

What Is Open Surgery?

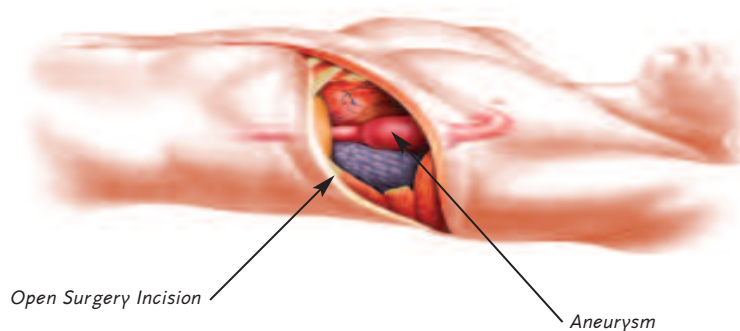
Open surgery (thoracotomy) is the traditional treatment used to replace the part of the vessel where the aneurysm has formed. Open surgery is performed under general anesthesia and typically takes four to six hours to complete.

A surgeon performs an operation to open the chest (see **Figure 4**). Then, the surgeon removes the aneurysm. Finally, the aneurysmal vessel is replaced with a fabric graft that is sewn into place. Surgical patients have follow-up one year later. If the surgery is successful at one year, follow-up is no longer necessary.

Patients typically spend one night in an intensive care unit and then remain in the hospital for five to seven days. It often takes at least three to six months for a patient to return to the quality of life that he or she had before surgery.

FIGURE 4

Open surgery is the traditional treatment for repairing a thoracic aortic aneurysm



What Are the Risks of Open Surgery?

Repairing an aneurysm surgically is a complicated process that requires an extended stay in the intensive care unit as well as a prolonged hospital stay. Please discuss with your doctor if this treatment method is right for you. Complications associated with open surgery include, but are not limited to the following:

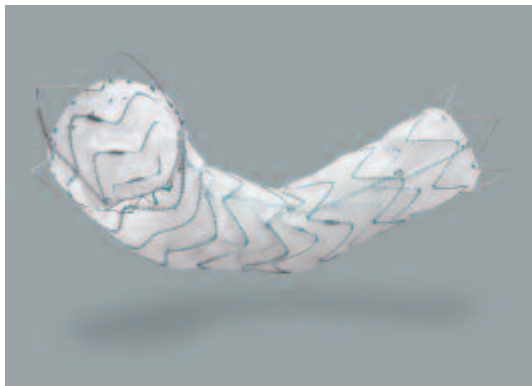
- Neurological complications (for example, stroke or paraplegia)
- Cardiopulmonary complications (for example, heart attack)
- Wound healing complications
- Kidney failure
- Multi-system organ failure
- Infection
- Fever
- Shock
- Sexual dysfunction
- Death

Is There an Alternate Treatment to Open Surgery?

Yes, the alternate treatment is a **thoracic stent graft procedure (endovascular stent grafting)**. A fabric graft (see **Figure 5**) supported by a metal framework is placed within the length of the aneurysm without surgically opening the surrounding tissue. The Talent™ Thoracic Stent Graft System is used to reline the weakened wall of the vessel to prevent the aneurysm from rupturing.

FIGURE 5

The Talent™ Thoracic Stent Graft



Note: The stent graft shown in the figure is not representative of the actual size. The actual size of the Talent™ Thoracic Stent Grafts range from 80 mm to 130 mm in length

Are You a Good Candidate for the Talent™ Thoracic Stent Graft Procedure?

Anyone who is considering the Talent™ Thoracic Stent Graft procedure should:

- Be able to undergo a procedure that lasts one to three hours.
- Be able to attend regularly scheduled doctor's visits and tests after the procedure, including at least one visit annually for life.
- Be fully informed about the risks and benefits of the Talent™ Thoracic Stent Graft procedure as compared to open surgical repair.

Patients who have very large aneurysms and/or vessels with many bends or curves may not be good candidates for the stent graft procedure. Discuss with your doctor which treatment is best for you.



Discuss with your doctor which treatment is best for you

This booklet is not intended as a substitute for a thorough talk with your doctor about whether this procedure is right for you. Please read this page carefully, and then talk with your doctor.

Questions You Might Ask Your Doctor

- What are all of my options for treating my thoracic aneurysm?
- Is the Talent™ Thoracic Stent Graft System an appropriate treatment for my thoracic aortic aneurysm?
- What are the risks of rupture with a stent graft?
- Will I have any symptoms from the Talent™ Thoracic Stent Graft procedure?
- After the procedure, how often will I need to see my doctor?
- What follow-up tests will be needed?
- What if the aneurysm continues to grow after endovascular treatment?
- Will I have to limit my activities after the treatment? If so, for how long?
- How long can the stent graft remain implanted inside my body?
- How many Talent™ Thoracic Stent Graft procedures has this doctor performed?
- What are the advantages and disadvantages of open surgical repair compared to endovascular repair of a thoracic aneurysm?



Ask your doctor to explain all of your options thoroughly

What Are the Contraindications?

A **contraindication** is a specific situation in which a drug, procedure, or surgery should not be used, because it may be harmful to the patient. The Talent™ Thoracic Stent Graft is contraindicated in patients:

- Who have a condition that can infect the stent graft.
- Who are allergic to the stent graft materials.^a

Your doctor can help determine if the Talent™ Thoracic Stent Graft is safe for you.

Warnings and Precautions

Warning: All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft and aneurysm size. Follow-up is important because you may not have symptoms when there is a problem with your stent graft.

Warning: The use of this device requires administration of contrast dye used in imaging. Patients with preexisting kidney problems may have an increased risk of kidney failure after procedure.

Warning: The long-term risks of prolonged fluoroscopy have not been established.

Caution: A MRI may only be used on the graft under specific conditions. Please refer to the "Patient Implant Card" section (page 17) for information on MRI scans.

^a The Talent Thoracic Stent Graft is made up of the following materials: nitinol, polyester, and platinum-iridium wire.

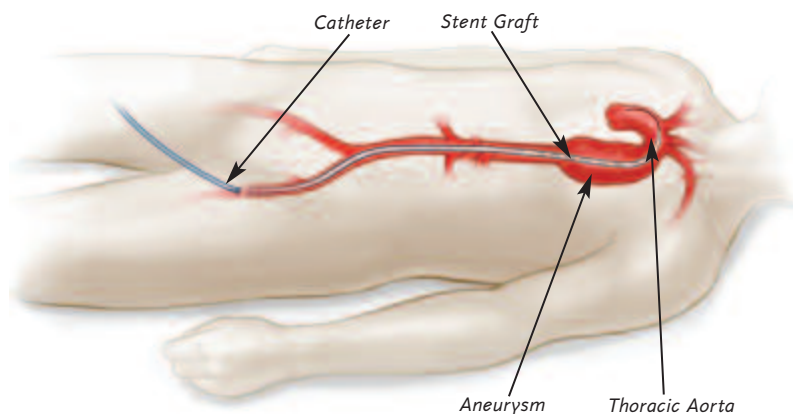
How Is the Talent™ Thoracic Stent Graft Procedure Performed?

The procedure is performed under regional or general anesthesia. Before the procedure, several tests are performed that let your doctor see the aneurysm and the area around it. These tests are usually performed using imaging such as a CT scan. A CT scan is an imaging technique that creates a series of X-rays that are used to form a picture of your aneurysm and adjacent blood vessels. A CT scan does not hurt and you will be awake for this testing.

To prepare for the stent graft procedure, a small cut is made in your groin to allow access for the stent graft **delivery catheter** into the **femoral artery**. Sometimes the doctor will use a **conduit** (a surgical graft attached to a larger artery in your pelvis) if the artery in your groin is too small to deliver the device. The doctor uses **fluoroscopy** (video-like X-rays) to see the device move through the blood vessel in your groin. The doctor also uses fluoroscopy to correctly position the device over the aneurysm in your descending thoracic aorta (see **Figure 6**).

FIGURE 6

The Talent™ Thoracic Stent Graft



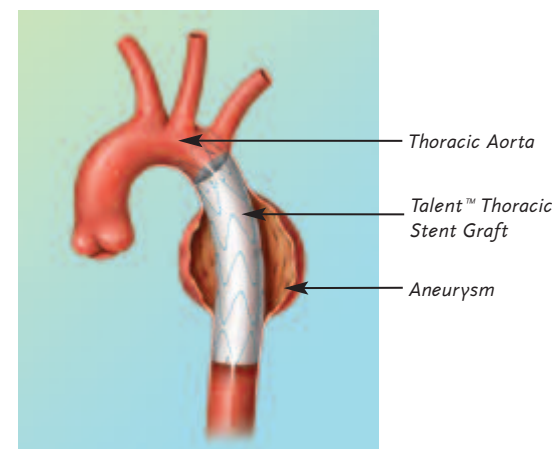
When the delivery catheter is properly placed, the Talent™ Thoracic Stent Graft is released slowly from the delivery catheter into the aorta. As the stent graft is released, it expands automatically to its proper size (see **Figure 7**) so that it fits snugly to the aorta both above and below the aneurysm.

Depending on the shape and size of your aneurysm, additional stent grafts may be used. This ensures that the stent grafts span the full length of the aneurysm and blood is no longer flowing into the aneurysm. Fluoroscopy is then performed to allow your doctor to see that the stent graft has been placed properly. The procedure typically takes one to three hours to complete.

Patients often leave the hospital within one or two days of the procedure. Patients can usually return to their normal quality of life within a few weeks.

FIGURE 7

Placement of the Talent™ Thoracic Stent Graft



What Are the Risks of a Thoracic Stent Graft Procedure?

There are a number of risks that are related to having a thoracic stent graft procedure. Complications associated with the use of the Talent™ Thoracic Stent Graft System include, but are not limited to the following:

Clinically Associated Events:

The endovascular stent graft procedure is a surgical procedure; as such, there are possible complications associated with the procedure. Before deciding if the procedure is right for you, please review the list of possible procedural complications with your doctor:

- Vascular complications (for example, blood clot)
- Neurological complications (for example, stroke or paraplegia)
- Cardiopulmonary complications (for example, heart attack)
- Gastrointestinal complications (for example, bowel obstruction)
- Pulmonary complications (for example, lung damage)
- Wound healing complications
- Kidney failure
- Bleeding
- Conversion to open surgery
- Death

Device Related Events:

Endovascular stent grafting is a new therapy. Therefore, long term safety and effectiveness of the Talent™ Thoracic Stent Graft has not been established. Please discuss with your doctor if this therapy is right for you. Possible complications of the device may include, but are not limited to the following:

- Leaking of blood around the graft ("**Endoleak**")
- Movement of the graft away from the desired location ("**Migration**")
- Additional procedures

What Are the Benefits of a Thoracic Stent Graft Procedure?

There are a number of benefits that are related to having a thoracic stent graft procedure:

- A lower risk of death compared to open surgery.^b
- The patient loses less blood during the procedure.
- The patient will spend less time in the intensive care unit after the procedure.
- The patient will have a shorter hospital stay with faster recovery time compared with open surgery.¹

Please discuss the benefits of all treatment options with your doctor so that you can determine which procedure is right for you.

^b VALOR trial all cause mortality at 1 year was 16.1% for endovascular compared to 29.8% for open repair.

Reference: 1. Lopera J, Patino JH, Urbina C, et al. Endovascular treatment of complicated type-B aortic dissection with stent-grafts: mid-term results. *J Vasc Interv Radiol.* 2003;14(2):195-203.

What Can I Expect After the Thoracic Stent Graft Procedure?

Patients have reported feeling discomfort for the first few days after the procedure. Just after the procedure, your physician may tell you to lie flat for four to six hours to let your leg wound begin healing. You may feel side effects such as swelling at the incision at your groin, nausea, vomiting, leg pain or throbbing, lack of appetite, and/or absence of bowel movement for one to three days.

Follow-up After the Procedure

Scheduling Doctor Visits

Follow-up is an important part of determining the success of the Talent™ Thoracic Stent Graft. Your doctor will schedule follow-up visits after one month, six months, one year, and once each year for the rest of your life. At each appointment, an imaging study will be conducted to determine the performance of the stent graft. **Imaging** is defined as the use of X-rays, CT scans, MRI scans, or other techniques in order to obtain pictures of the inside of the body. If you have poor kidney function, you should make sure to ask your doctor about the dyes used in some of these imaging studies, as they may be harmful.

CT imaging may detect an endoleak in some patients. An endoleak means that a small amount of blood is still flowing into the **aneurysmal sac**. If your doctor thinks the endoleak needs treatment, it can often be treated with an additional thoracic stent graft procedure. Sometimes an endoleak cannot be treated with another stent graft. The doctor may need to repair the endoleak with open surgery.

Patient Implant Card

After your Talent™ Thoracic Stent Graft operation, your doctor will fill out a temporary patient implant card. You get one copy, your doctor gets one copy, and the third copy is mailed to Medtronic. The temporary patient implant card will tell you the size and number of your thoracic aortic implants.

Medtronic will mail you a permanent patient implant card to carry in your wallet. Your permanent card will list information about implant sizes, quantities, and MRI compatibility. It is important to know that the Talent™ Thoracic Stent Graft is "**MR Conditional**." MR Conditional means under specific conditions it is safe for you to undergo an MRI scan after receiving a Talent™ Thoracic Stent Graft. Show your Medtronic patient implant card to your doctor before having surgery or undergoing an imaging procedure. Your doctor will consult with Medtronic to determine if it is safe for you to have the surgery or procedure.

What Symptoms Would Prompt Me to Call My Doctor?

If you experience any of the following symptoms, contact your doctor immediately:

- Pain, numbness, coldness, weakness, or loss of sensation in your legs.
- Any back, chest, abdominal, or groin pain.
- Dizziness, fainting, rapid heartbeat, or sudden weakness.

Additional Information

Medtronic Patient Information

If you have questions about your particular condition and the Talent™ Thoracic Stent Graft, contact your doctor. If you have additional questions about the Talent™ Thoracic Stent Graft, feel free to contact Medtronic by mail, phone, or fax.

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- The Society for Vascular Surgery (www.vascularweb.org)
633 N. St. Clair, 24th Floor
Chicago, IL 60611
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- The Society of Thoracic Surgeons (www.sts.org)
633 N. St. Clair, Ste. 2320
Chicago, IL 60611
Tel: 312.202.5800
- The National Library of Medicine (www.nlm.nih.gov)
- WebMD (www.webmd.com)

Notes

Glossary

Aneurysm: A bulging or “ballooning” of a weakened area of a blood vessel.

Aneurysmal sac: The dilated area of the artery where an aneurysm is located.

Aneurysm rupture: A tear in the vessel wall near or at the location of the bulging or “ballooning” of the weakened area of the blood vessel (ie, thoracic aortic aneurysm).

Aorta: The main blood vessel of the arterial system of the body.

Aortic arch: The section of the aorta from which the blood vessels lead to the head and arms branch.

Artery: A blood vessel that carries blood from the heart to the rest of the body.

Ascending thoracic aorta: The section of the aorta closest to the heart.

Conduit: A fabric tube sewn onto a major blood vessel that provides an alternate way to insert the stent graft delivery system. A conduit is used if the femoral artery is too small to allow access.

CT scan (Computed Tomography): An imaging technique that creates a series of X-rays that are used to form a picture of your aneurysm and adjacent blood vessels.

Contraindication: A specific situation in which a drug, procedure, or surgery should not be used, because it may be harmful to the patient.

Delivery catheter: A long tube-like device that contains the stent graft. The device is used to deploy the stent graft in the aorta.

Descending thoracic aorta: The segment of the thoracic aorta in which blood flows down toward the feet.

Endoleak: Blood flow into the aneurysm after placement of a stent graft.

Femoral artery: A large artery in the muscles of the thigh. The delivery system for a stent graft is usually inserted via the femoral artery.

Fluoroscopy: A real-time X-ray imaging technique that is viewed on a monitor.

Imaging: The use of X-rays, CT scans, MRI scans, or other techniques in order to obtain pictures of the inside of the body.

Migration: The movement of the graft away from the desired location.

MR Conditional: A standard used to determine when it is safe to undergo an MRI Scan after receiving a Talent™ Thoracic Stent Graft.

MRI (Magnetic Resonance Imaging): An imaging technique that uses magnetic fields to form images of structures within the body.

Open surgery (Thoracotomy): A procedure in which a patient undergoes general anesthesia and the doctor accesses the aneurysm by opening the patient’s chest. Then, the aneurysmal vessel is replaced with a fabric graft that is sewn into place.

Rupture: See “Aneurysm rupture.”

TAA: See “Thoracic Aortic Aneurysm.”

Talent™ Thoracic Stent Graft: A woven polyester tube (graft) supported by a tubular metal framework (stent). The stent graft is placed inside a thoracic aortic aneurysm without surgically opening the tissue surrounding it.

Thoracic aorta: The upper portion of the main artery in the body that extends through the chest.

Thoracic Aortic Aneurysm: A bulging or “ballooning” of a weakened area of the thoracic aorta. This term is often abbreviated as “TAA.”

Thoracic Stent Graft Procedure (Endovascular stent grafting): A procedure in which a tube-shaped device is placed inside a diseased vessel non-surgically opening the tissue surrounding the diseased vessel. The patient is placed under regional or general anesthesia. The physician accesses the aneurysm through 2 small incisions at the patient’s groin.

Thoracotomy: See “Open surgery.”



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