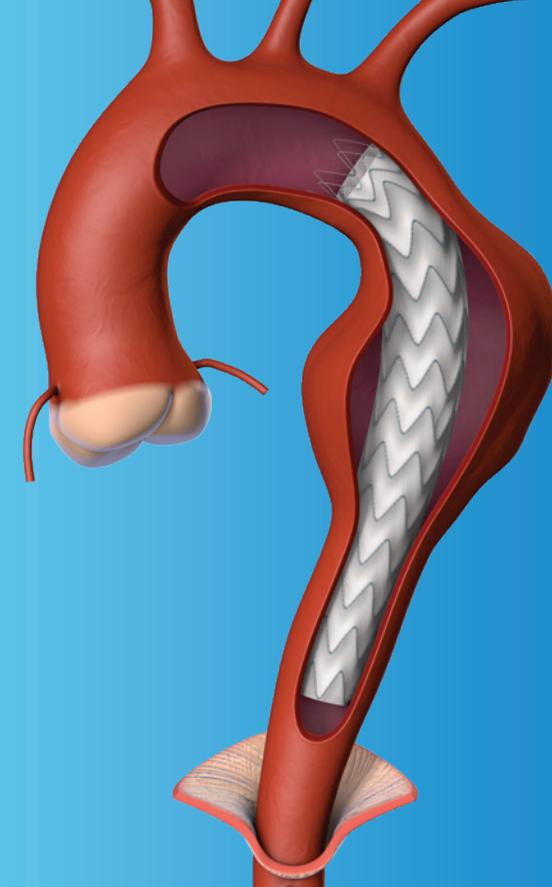


PATIENT INFORMATION BOOKLET



Thoracic Stent Grafts: A Treatment for

- Thoracic Aortic Aneurysms
- Thoracic Aortic Dissection
- Blunt Thoracic Aortic Injuries
and other Isolated Lesions

Medtronic

Aortic | Peripheral | Venous
3576 Unocal Place
Santa Rosa, CA 95403
USA

24-hour Technical Support
Toll free: +1.800.328.2518

Orders
Toll free: +1.877.526.7890
Fax: +1.800.838.3103

CardioVascular LifeLine
Customer Support
Tel: +1.763.526.7890
Toll free: +1.877.526.7890

[medtronic.com/aortic](https://www.medtronic.com/aortic)

UC201810306 EN © 2018 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic. All other brands are trademarks of a Medtronic company. Printed in the USA. For distribution in the USA only. 10/18

Medtronic
Further, Together

TABLE OF CONTENTS

Introduction	1
Glossary	2
Thoracic Aorta	5
Thoracic Aortic Aneurysm (TAA)	6
Causes	7
Symptoms	7
Thoracic Aortic Dissection	8
Causes	9
Symptoms	9
Blunt Thoracic Aortic Injury (BTAI)	10
Causes	11
Symptoms	11
Other Isolated Lesions	12
Treatment Options	13
Open Surgical Repair	14
Endovascular Repair	16
Thoracic Stent Graft	18
Is Endovascular Repair Right For You?	19
When Endovascular Repair Is Not an Option	19
Warnings	19
Important Safety Information*	20
Possible Benefits of Treatment	21
Possible Problems	22
Endovascular Stent Graft Procedure	24
What Symptoms Should Prompt You to Call Your Doctor After the Procedure?	27
Follow-Up	27
Implanted Device Identification Card	28
Magnetic Resonance Imaging	28
Lifestyle Changes	29
Questions You May Want to Discuss with Your Doctor	29
Additional Information	30

*See pages 20-23 for important safety information.

INTRODUCTION

An **endovascular repair** procedure is one option to treat certain diseases or injuries of the **thoracic aorta**, such as **aneurysm**, **dissection** and **blunt injury**.

Your doctor has given you this booklet to help you further understand the **endovascular repair** device and procedure. You and your doctor will decide together whether you should have an **endovascular repair**.

A glossary is provided in the next section to help you understand the medical terms used in this booklet. Words that are bold text in the booklet are defined in the glossary.

GLOSSARY

Aneurysm: See thoracic aortic aneurysm.

Aneurysm rupture: A tear in the blood vessel wall near or in the diseased part of the vessel.

Aorta: The main vessel that carries blood from the heart to the rest of the body.

Blunt injury: See blunt thoracic aortic injury.

Blunt thoracic aortic injury (BTAI): An injury to the thoracic aorta due to traumatic force to the chest (for example, during a car accident).

Congestive heart failure: A condition in which the heart can no longer pump enough blood to other organs of the body.

CT scan: A scan that takes X-rays or pictures of the injured or diseased portion of the aorta.

Dissection: See Thoracic aortic dissection.

Endoleak: Blood flow between the stent graft and the aorta wall.

Endovascular: Inside or within a blood vessel.

Endovascular repair: A procedure in which a tube-shaped stent graft is placed inside the aorta, redirecting blood flow away from the lesion and relining the aortic wall, without cutting open the chest.

False aneurysm: A collection of blood that forms between the two outer layers of the vessel wall that can form in areas of the aorta that have been previously damaged.

Femoral arteries: Blood vessels that carry blood to the thigh region of each leg. Doctors can use these as pathways to reach the aorta.

Fluoroscopy: A real-time X-ray image that allow doctors to see inside the patient.

Fusiform aneurysm: A type of thoracic aortic aneurysm that has a varying diameter and length and typically involves all sides of the diseased vessel.

Groin: Area between the abdomen and thigh on either side of the body.

Iliac arteries: Blood vessels that carry blood to the lower part of your body. Doctors can use these as pathways to reach your aorta.

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

Intramural hematoma: The abnormal collection of blood within the aortic walls. Over time, the collection of blood weakens the aorta and may lead to rupture.

Lesions: Different types of diseased or injured areas of a blood vessel, such as aneurysms, dissections, and blunt traumatic injuries.

Malperfusion: A complication of aortic dissection where not enough blood is flowing to the organs in the body.

Magnetic resonance imaging (MRI): A technique that uses magnetic fields to get pictures of the inside of the body.

Minimally invasive: Involving a small cut in the groin instead of a big cut in the chest.

Open surgery/Open surgical repair: A procedure in which a doctor makes a large cut in the chest to treat a lesion by sewing in a fabric vascular graft.

Other isolated lesions: Other isolated lesions include but are not limited to intramural hematomas and pseudoaneurysms.

Paraplegia: The loss of the ability to move the legs and lower body.

Penetrating ulcer: A weak area like a sore in the wall of the thoracic aorta.

Pneumonia: Swelling and soreness of the lungs usually due to an infection. People with pneumonia often have a fever, cough and trouble breathing.

Pseudoaneurysm: A collection of blood that forms between the two outer layers of the vessel wall that can form in areas of the aorta that have been previously damaged.

Renal failure: A condition where the kidneys fail to adequately filter toxins and waste from the blood.

Retrograde Type A Dissection: A rare complication after endovascular repair where a new tear in the aorta results in blood flowing between the layers of the aorta back toward the heart.

Rupture: A tear in the blood vessel wall near or in the diseased part of the vessel that results in life-threatening internal bleeding.

Saccular aneurysm: A type of thoracic aortic aneurysm that is spherical in shape and typically involves only one side of the diseased vessel. Saccular aneurysms are often associated with penetrating ulcers.

Spinal cord ischemia: A lack of blood flow to the vessels that carry blood to the spinal cord.

Stent graft/Thoracic stent graft: A fabric tube supported by a metal frame that a doctor puts inside the injured or diseased portion of the aorta.

Stroke: A loss of brain function due to the loss of blood supply to a part of the brain.

Thoracic aorta: The portion of the aorta that is within the chest and close to the heart.

Thoracic Aortic Aneurysm (TAA): A weak area of the thoracic aorta that causes the diseased vessel to expand or bulge.

Thoracic aortic dissection: A condition in which a tear in the inner layer of the aorta allows blood to flow into the middle layer of the aortic wall, causing the layers to separate (dissect).

Transected aorta: Traumatic aortic rupture.

Transfusion: Receiving blood into circulation from an external source, needed as a result of loss of blood.

Ultrasound: An imaging technique that creates a picture through the use of high frequency sound waves.

THORACIC AORTA

The **aorta** is the largest blood vessel in the body. It carries blood away from the heart to the rest of the body. The **thoracic aorta** is the part of the **aorta** located in the chest (**Figure 1**).

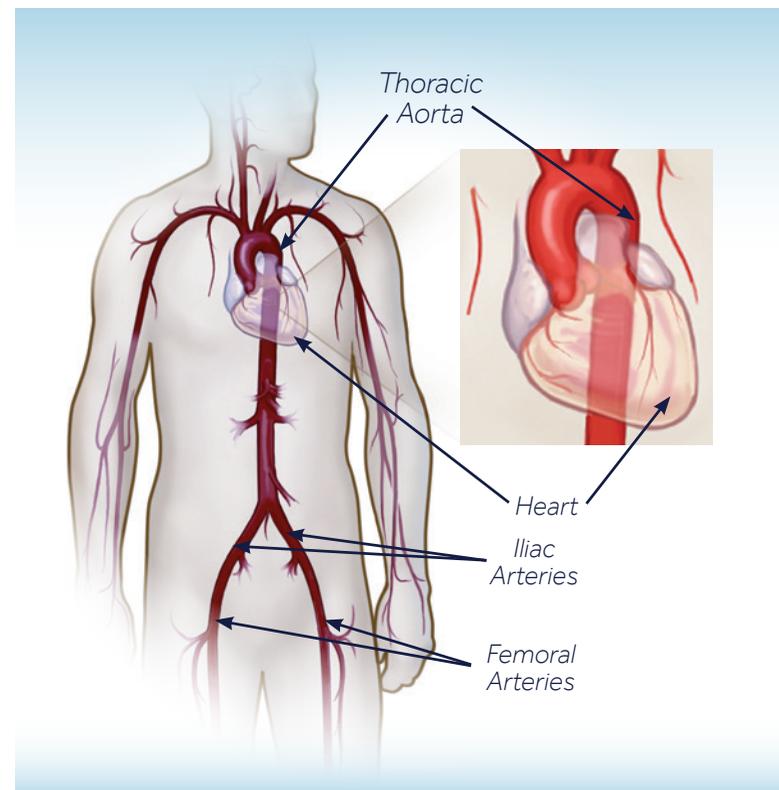


FIGURE 1
Thoracic Aorta
(Healthy)

THORACIC AORTIC ANEURYSM (TAA)

A **thoracic aortic aneurysm (TAA)** is a weak area of the **aorta** that will expand or bulge as blood is pumped through it (**Figure 2**). As the TAA grows, the wall of the **aorta** becomes weaker.

If the **TAA** continues to grow, the **TAA** could **rupture** and this would lead to large amounts of bleeding inside the body. An **aneurysm rupture** needs immediate medical attention because it can lead to death. There are two types of **TAA**, fusiform and saccular. A **fusiform aneurysm** has a varying diameter and length and typically involves all sides of the diseased vessel (**Figure 3**). A **saccular aneurysm** is spherical in shape and typically involves only one side of the diseased vessel (**Figure 4**). **Saccular aneurysms** are often associated with **penetrating ulcers**. You should talk to your doctor about what type of **aneurysm** you have and what that means for you.

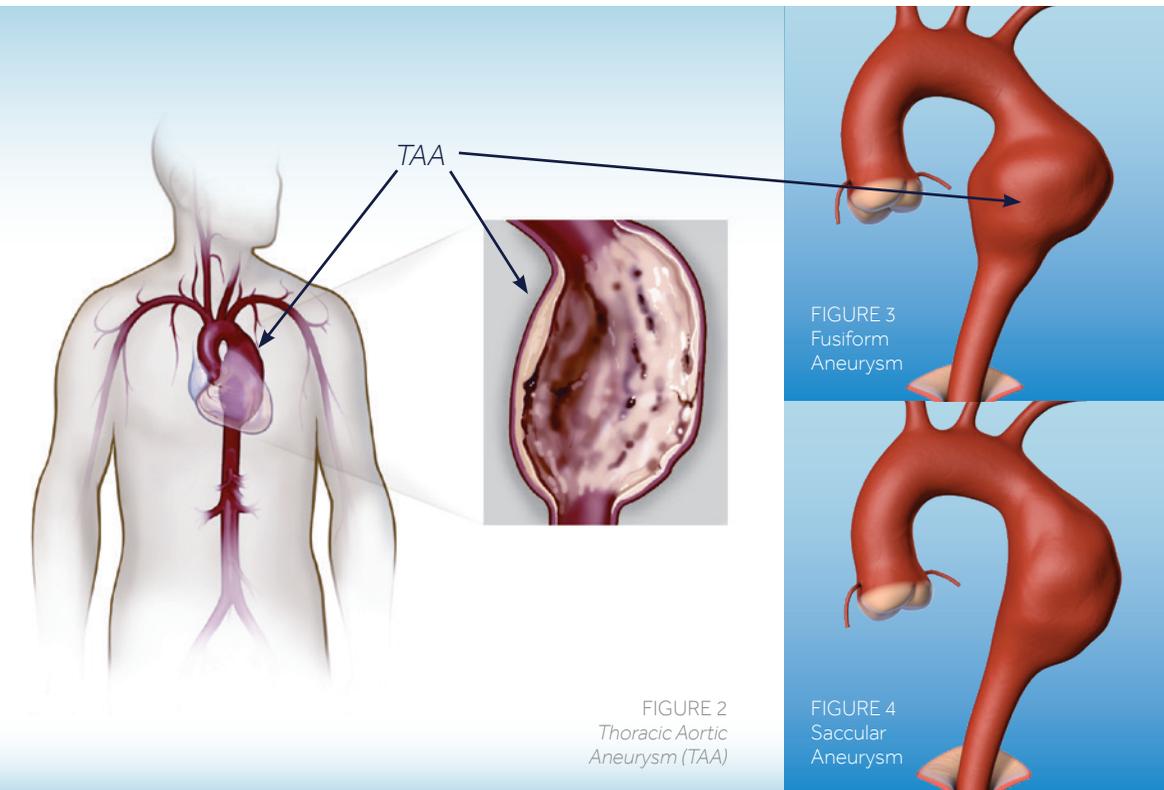


FIGURE 2
Thoracic Aortic
Aneurysm (TAA)

FIGURE 3
Fusiform
Aneurysm

FIGURE 4
Saccular
Aneurysm

Causes

People are more likely to have a **TAA** if they:

- Are over 50
- Are men
- Have high blood pressure
- Are smokers
- Have a family member with TAA

Symptoms

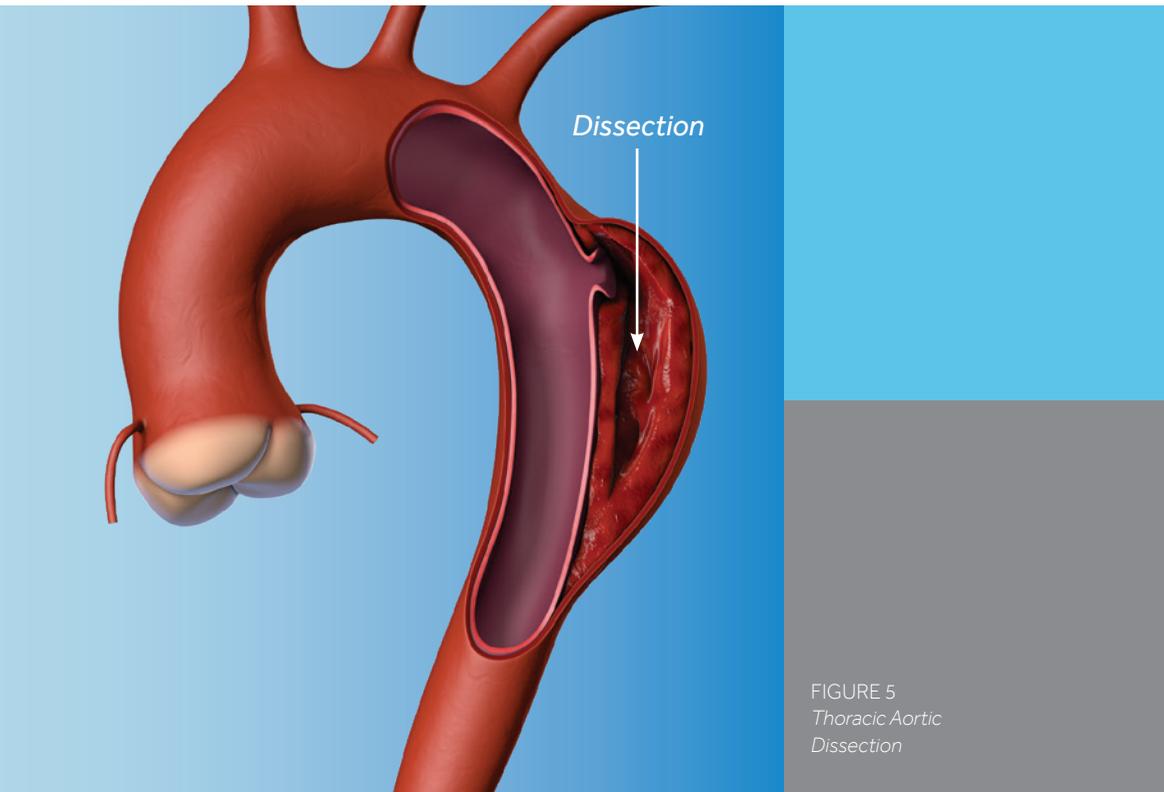
Most people do not have symptoms of a **TAA**. For those with symptoms, the most common are:

- Hoarseness
- Difficulty swallowing
- Pain in the chest, back, side or stomach

The pain may range from mild to severe. A **TAA** is often found during a **CT scan** being done for other unrelated reasons.

THORACIC AORTIC DISSECTION

A **thoracic aortic dissection (Figure 5)** is a condition in which a tear develops in the inner layer of the **aorta**, the main blood-carrying vessel in the chest. Blood flows through this tear into the middle layer of the wall of the **aorta** causing the inner and middle layers to separate (dissect). If the tear goes through the vessel wall (**rupture**), **dissection** can be life threatening due to the potential for bleeding inside the body. Even without a **rupture**, **dissection** may cause a problem of aortic **dissection** where the vessel supplying blood to the organs in the body narrows down or is completely blocked resulting in organ failure (**malperfusion**).



Causes

People are more likely to have a **dissection** if they:

- Are 50 to 70 years old
- Are male
- Have high blood pressure
- Have Marfan syndrome (or other connective tissue disorder)

Symptoms

The most common symptom of **dissection** is severe, sudden chest pain. Less common symptoms include:

- Fainting
- **Stroke**
- Numbness and tingling, pain or weakness in the extremities

BLUNT THORACIC AORTIC INJURY (BTAI)

A **blunt thoracic aortic injury (BTAI)** is an injury to the **thoracic aorta** (the portion of the **aorta** that is within the chest and close to the heart) due to severe injury to the chest. This injury can result in a complete tear in the wall of the **aorta** (the main vessel that carries blood from the heart to the rest of the body) or a partial tear that weakens part of the **aorta** (**Figure 6**). A **BTAI** is life-threatening due to the potential for the tear in the **aorta** to cause bleeding inside the body. This will require you to go to the hospital where the doctor will confirm your injury before any treatment is recommended. Some patients who have other life-threatening injuries may need other surgical interventions prior to the treatment of the **BTAI**.

Causes

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

Symptoms

Most people do not have symptoms of **BTAI** and it is diagnosed using **imaging** (the use of X-rays, **CT scans**, **MRI** scans or other techniques to get pictures of the inside of the body).

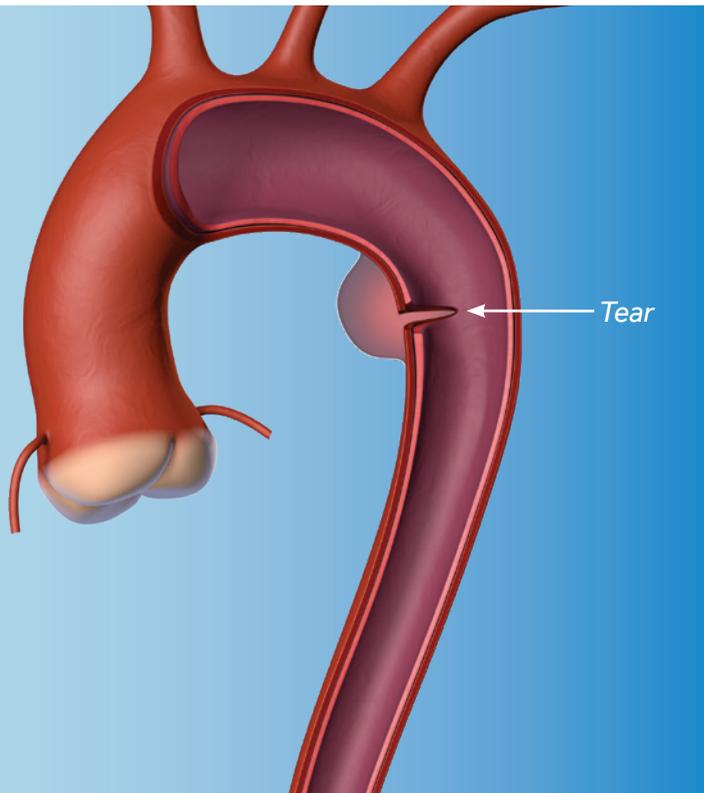


FIGURE 6
Transected Aorta (Aortic rupture or burst of the aorta due to a severe injury in the chest area)

OTHER ISOLATED LESIONS

Other isolated lesions of the **thoracic aorta** include but are not limited to **intramural hematomas**, **pseudoaneurysms** and **penetrating ulcers**.

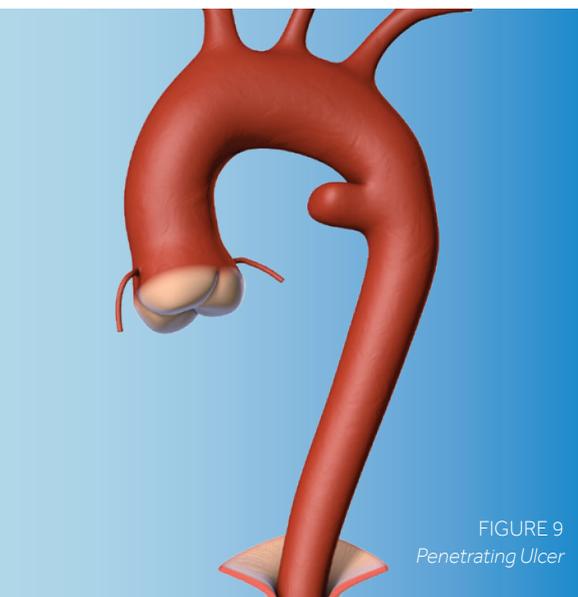
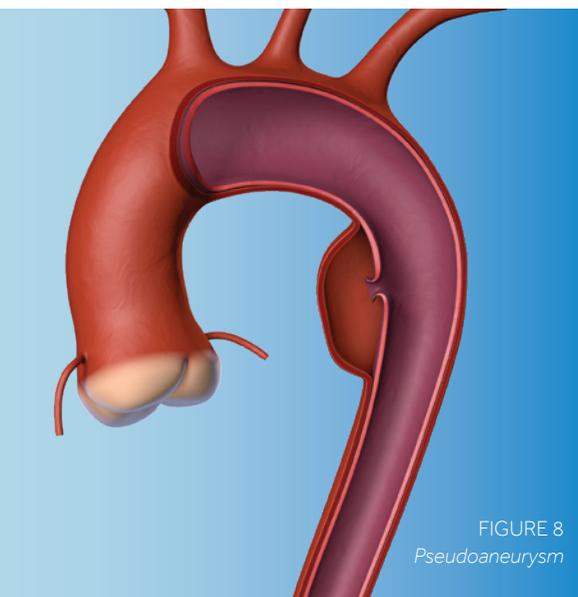
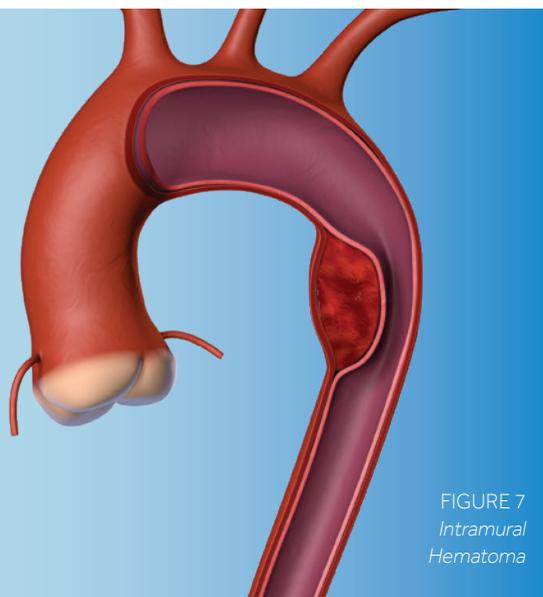
- **Intramural hematoma** is the abnormal collection of blood within the aortic walls (**Figure 7**). Over time, the collection of blood weakens the **aorta** and may lead to **rupture** (a tear in the blood vessel wall near or in the diseased part of the vessel that results in life-threatening internal bleeding).
- **Pseudoaneurysms** of the **thoracic aorta** are bulges in the **aorta**, formed usually at areas in the **aorta** that have been damaged by previous surgery or trauma (**Figure 8**). **Pseudoaneurysms** can enlarge over time and could lead to **rupture** if left untreated.
- **Penetrating ulcers**, a weak area like a sore in the wall of the **thoracic aorta** (**Figure 9**).

TREATMENT OPTIONS

There are three primary treatment options available, depending on your doctor's diagnosis:

- Medical management (medicine to control your heart rate and blood pressure)
- **Open surgical repair** (a procedure in which a doctor makes a large cut in the chest to treat a **lesion** by sewing in a fabric vascular graft)
- **Endovascular repair** (a procedure in which a tube-shaped **stent graft** is placed inside the **aorta**, redirecting blood flow away from the **lesion** and relining the aortic wall, without cutting open the chest)

You will probably need life-long medical management if your **aorta** is diseased. Some injuries to the **aorta** may also be treated with medical management at first. You should discuss your need for medical management over time with your doctor. Even with medical management, your **lesion** may get worse and your doctor may recommend that you have a procedure to treat the **lesion**. The treatment would be either **open surgical repair** or **endovascular repair**. Both of these treatment options have possible problems and benefits. You should talk with your doctor about which option is best for you.



Open Surgical Repair:

If you have an **open surgical repair (Figure 10)**, your doctor will need to make a large cut to gain access to your **aorta** and will repair your **lesion** (different types of diseased or injured areas of a blood vessel, such as **aneurysms, dissections, and blunt traumatic injuries**) by sewing in a vascular graft. The procedure is similar for all types of **lesions**, such as **aneurysms, dissections** (a condition in which a tear in the inner layer of the **aorta** allows blood to flow into the middle layer of the aortic wall, causing the layers to separate (dissect)) and **blunt traumatic injuries**.

This procedure takes 4 to 6 hours. After this, you will likely spend several days in the intensive care unit and then several more days in the hospital. The following estimates are based on experience with patients whose conditions are similar to yours:

- **Thoracic aortic aneurysm (TAA)** (a weak area of the **thoracic aorta** that causes the diseased vessel to expand or bulge): 3 to 7 days in intensive care followed by 8 to 18 days in the hospital
- **Thoracic aortic dissection:** (a condition in which a tear in the inner layer of the **aorta** allows blood to flow into the middle layer of the aortic wall, causing the layers to separate (dissect)) 8 to 20 days in intensive care followed by 10 to 28 days in the hospital
- **BTAI/other lesions:** 10 to 15 days in intensive care followed by 10 to 20 days in the hospital. Depending on the other injuries you have, you may have to stay in the intensive care unit or hospital longer due to treatment of injuries to other parts of your body.

Your doctor will discuss the procedure with you and tell you what to expect based on your condition. For the **open surgical repair**, you will need 12 to 24 weeks to recover.

The time to recover is expected to be longer than with **endovascular repair**. You would be more likely to have problems related to the procedure because it is a major operation. The benefits of **open surgical repair** as compared to **endovascular repair** are:

- You probably would not need to have additional procedures in the same part of your **aorta**.
- You would not need to go back to your doctor to have lifelong **imaging**.

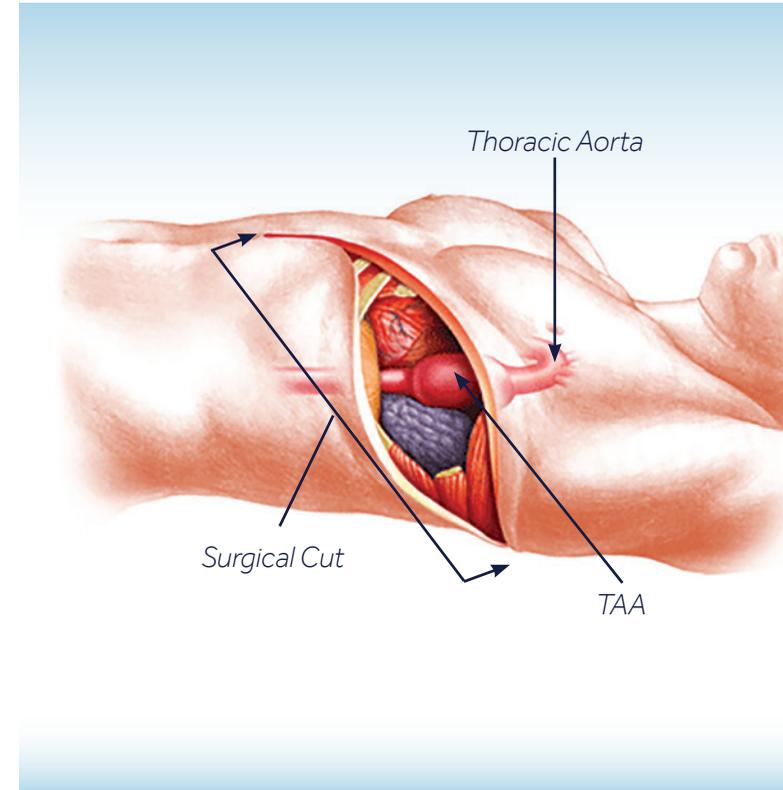


FIGURE 10
Open Surgical Repair

Endovascular Repair:

Endovascular repair is a **minimally invasive** (involving a small cut in the **groin** instead of a big cut in the chest) medical procedure. A doctor will make a small cut in your **groin** (area between the abdomen and thigh on either side of the body) (**Figure 11**). A catheter holding a fabric and metal **stent graft** (a fabric tube supported by a metal frame that a doctor puts inside the injured or diseased portion of the **aorta**) is inserted through the cut into the blood vessel, guided to the diseased or injured location in your **aorta** (the main vessel that carries blood from the heart to the rest of the body) and then released into the **aorta**. **Figure 11** is an illustration of an **endovascular repair** procedure for **thoracic aortic aneurysm**. The procedure is similar for **dissections**, **blunt injuries** and other **lesions**. This procedure protects the diseased/injured area of the **aorta** and reduces the chance of **rupture**.

In some patients, the **iliac arteries** (blood vessels that carry blood to the lower part of your body. Doctors can use these as pathways to reach your **aorta**) and **femoral arteries** (blood vessels that carry blood to the thigh region of each leg. Doctors can use these as pathways to reach the **aorta**) are too narrow for this catheter. In these cases, your doctor will sew a fabric tube to your **iliac artery** and then put the catheter into the vessel.

This procedure can take from 1 to 6 hours, depending on the nature of the disease or injury. After this, you will likely spend some time in the intensive care unit and several more days in the hospital. The following estimates are based on experience with patients whose conditions are similar to yours:

- **Thoracic aortic aneurysm (TAA):** 0 to 1 1/2 days in the intensive care unit and then 2 to 7 days in the hospital
- **Dissection:** 2 to 12 days in intensive care followed by 5 to 18 days in the hospital
- **BTAI/other lesions:** 2 to 9 days in intensive care followed by 5 to 14 days in the hospital. Depending on your other injuries, you may have to stay in the intensive care unit or hospital longer due to treatment of injuries to other parts of your body.

Your doctor will discuss the procedure with you and tell you what to expect based on your condition. You will need 4 to 6 weeks to recover from the **endovascular repair**. You will need to go back to your doctor to have lifelong **imaging** to monitor the device. You may need to have additional procedures in the same part of your **aorta**.

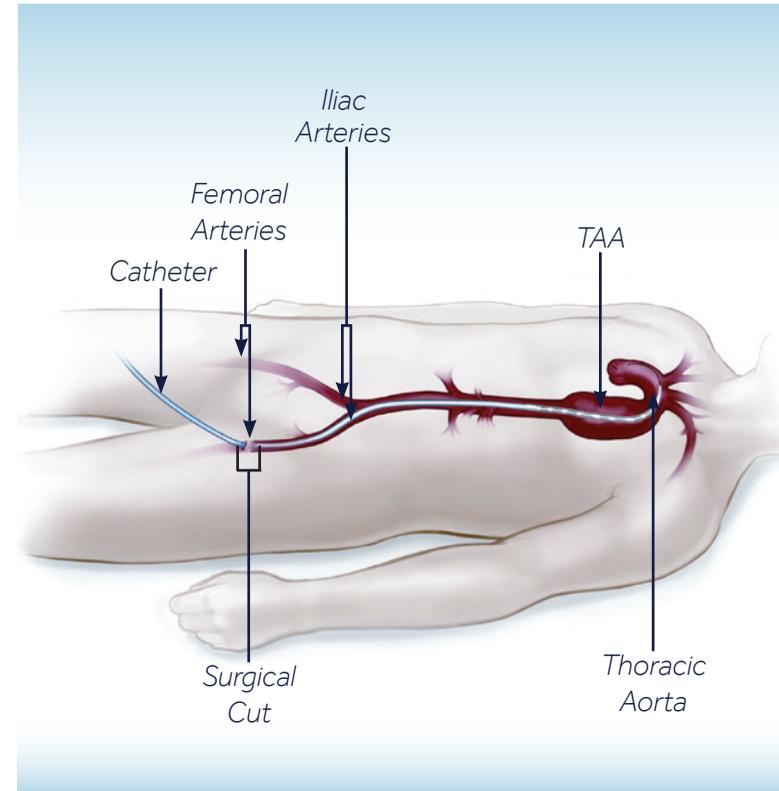


FIGURE 11
Endovascular Repair

THORACIC STENT GRAFT

The **thoracic stent graft** is a fabric tube supported by a metal framework (**Figure 12**). A doctor puts it inside your **aorta** using a catheter (**Figure 13**). It will help repair or protect your diseased/injured **aorta**, restore appropriate blood flow and prevent **rupture** (a tear in the blood vessel wall near or in the diseased part of the vessel that results in life-threatening internal bleeding).

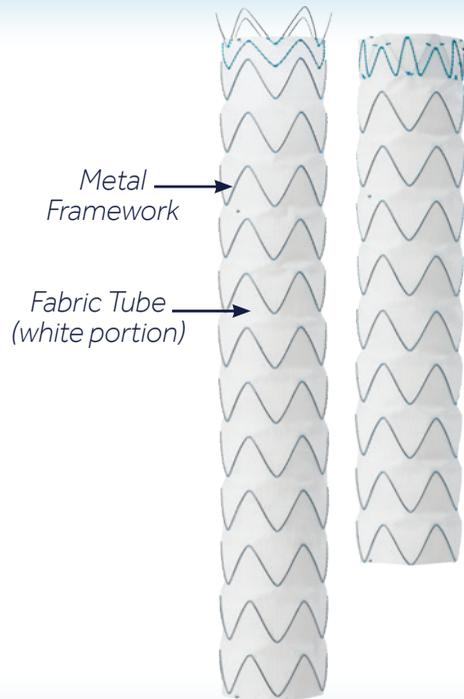


FIGURE 12
Thoracic Stent Graft

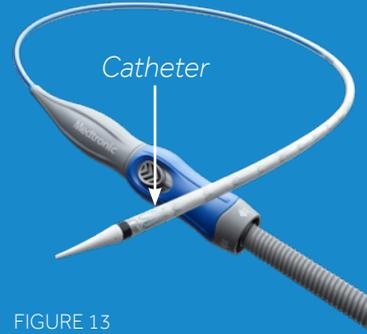


FIGURE 13

Is Endovascular Repair Right For You?

Not everyone can get an **endovascular repair** (a procedure in which a tube-shaped **stent graft** is placed inside the **aorta**, redirecting blood flow away from the **lesion** and relining the aortic wall, without cutting open the chest). Your doctor will need to image your blood vessels to see if the catheter would be able to go through your blood vessels to get the **stent graft** where it is needed to cover the **lesion** and to see if there is a good place for the **stent graft** to attach to the **aorta**. Also, you and your doctor will need to talk about whether you are good with having life-long **imaging** (the use of X-rays, **CT scans**, **MRI** scans or other techniques to get pictures of the inside of the body) and if you are willing to have other procedures in the future if needed.

When Endovascular Repair Is Not An Option

If you have a condition that can infect the **stent graft** or you are allergic to the **stent graft** materials, you should not have an **endovascular repair** because the graft could get infected or you could have an allergic reaction, both of which could be life-threatening.

The **thoracic stent graft** may not be recommended by your physician if you:

- cannot complete regular follow-up visits and **imaging** (the use of X-rays, **CT scans**, **MRI** scans or other techniques to get pictures of the inside of the body) examinations
- cannot tolerate **imaging** dyes
- have bleeding disorders
- have kidney disease
- cannot use blood thinners

Your doctor can help you decide if you are not a good candidate for **endovascular repair**.

Warnings

You should also talk to your doctor if any of the items in the list below apply to you because the use of **stent grafts** has not been studied in patients who are described in the list.

- have received a previous **stent graft** in the same area of their **aorta**
- have connective tissue disease
- refuse blood **transfusions** (receiving blood into circulation from an external source, needed as a result of loss of blood)
- had a recent **stroke** (a loss of brain function due to the loss of blood supply to a part of the brain)
- are pregnant
- are less than 18 years old

Your physician will need to help you decide whether it is appropriate for you to get a **thoracic stent graft** if any of these situations apply to you.

Note: The size of the **stent graft** in the figure above is not actual size. Medtronic devices are 52 mm (2.05 in) to 229 (9.015 in) in covered length.

IMPORTANT SAFETY INFORMATION

Endovascular repair of the **thoracic aorta** (the portion of the **aorta** that is within the chest and close to the heart) was studied by Medtronic to better understand the possible problems and benefits of the overall procedure. Medtronic conducted three clinical studies in the United States with 442 patients with **thoracic aortic aneurysm (TAA)** (a weak area of the **thoracic aorta** that causes the diseased vessel to expand or bulge) treated using **thoracic stent grafts**.

Medtronic conducted smaller clinical studies with patients with **blunt traumatic aortic injury** (50 patients were included in this clinical study) and patients with **thoracic aortic dissection** (50 patients were included in this clinical study).

These studies included patients between the ages of 18 and 85 years old. The health and medical history of the patients in the studies may or may not be similar to yours. You should talk to your doctor about how your situation may be different or similar.

Many problems experienced after **endovascular repair** of a diseased or injured **aorta** do not have symptoms associated with them. You will have to schedule regular follow-up visits with your doctor. This will allow your doctor to check on your progress.

Possible Benefits of Treatment

The biggest benefits of treatment of your diseased or injured **aorta** (the main vessel that carries blood from the heart to the rest of the body) are decreased chance of **rupture** and restoration of normal blood flow. If left untreated, aortic **lesions** (different types of diseased or injured areas of a blood vessel, such as **aneurysms**, **dissections**, and **blunt traumatic injuries**) can expand and **rupture**, resulting in bleeding inside the body, which is life-threatening. You should talk to your doctor to see if you are at risk for **rupture**. Options for treatment of serious **lesions** of the **aorta** include **endovascular repair** or **open surgical repair** (a procedure in which a doctor makes a large cut in the chest to treat a **lesion** by sewing in a fabric vascular graft).

Comparison of Endovascular Repair to Open Surgery for Treatment of Thoracic Aortic Aneurysm (TAA)

Endovascular repair requires regular follow-up visits and sometimes requires additional procedures to treat possible problems such as blood flow between the graft and the vessel (**endoleak**), infection from the surgery, **stroke** or the loss of the ability to move the legs and lower body (**paraplegia**).

Studies comparing **open surgical repair** with **endovascular repair** concluded that the less invasive **endovascular repair** is less likely to cause complications or death and is associated with shorter hospital stays and quicker return to normal activities after surgery.

Comparison of Endovascular Repair to Open Surgery for Treatment of Thoracic Aortic Dissection and Blunt Traumatic Aortic Injury (BTAI)

Medtronic has also conducted clinical studies of **endovascular repair** of **dissection** and **BTAI**. These studies were smaller so there is not as much data available regarding the outcomes. In general, when compared to a surgical procedure, patients who have been treated for **dissection** or **BTAI** with **endovascular repair** need fewer hospital days to recover, have a lower risk of death and have a lower risk of problems.

Treatment outcomes may differ depending on individual circumstances. Your doctor will discuss the particulars of your case with you.

For detailed clinical study information, go to www.ClinicalTrials.gov and search for VALOR, VALOR II, RESCUE, Medtronic Dissection Trial, the Valiant Evo IDE study or contact Medtronic at 877-526-7890.

Possible Problems

The **endovascular repair** procedure is a surgical procedure; as such, there are possible problems. Before deciding if the procedure is right for you, please review the possible problems with your doctor. Most problems associated with repair of **lesions** in the descending **thoracic aorta** occur within the first 30 days after treatment.

Problems of Endovascular Repair for Treatment of Thoracic Aortic Aneurysm (TAA)

Below is a list of some of the more common possible problems that may occur within 30 days of **endovascular repair** of **thoracic aortic aneurysm (TAA)**.

Possibility (%)	Problems within 30 days
10%	<ul style="list-style-type: none"> Abnormal or irregular heartbeat Significant blood loss
5 - 10%	<ul style="list-style-type: none"> Pneumonia (swelling and soreness of the lungs usually due to an infection. People with pneumonia often have a fever, cough and trouble breathing) or difficulty breathing A blood vessel hole or tear
3 - 5%	<ul style="list-style-type: none"> Temporary loss of feeling in both legs Unable to breathe without assistance Blood clotting issue Kidney failure Abnormal collection of blood around the surgical cut Loose blood clot Stroke (permanent or temporary)
1 - 3 %	<ul style="list-style-type: none"> Death False aneurysm (a collection of blood that forms between the two outer layers of the vessel wall that can form in areas of the aorta that have been previously damaged) Worsening of congestive heart failure Bleeding in the stomach Blood vessel blockage Abnormal fluid build up in the lungs Decreased kidney function Heart attack Permanent loss of feeling in both legs Decreased blood flow to the intestine Secondary intervention to treat complications Secondary procedure to treat continued aneurysm growth Open surgery to treat complications
1% or less	<ul style="list-style-type: none"> Blockage of the main artery in the lung Reduced blood flow and oxygen to the heart Abnormal connection between an artery and vein Formation of blood clot Aneurysm rupture (a tear in the blood vessel wall near or in the diseased part of the vessel)

Problems of Endovascular Repair for Treatment of Thoracic Dissection and Blunt Traumatic Aortic Injury (BTAI)

Possible problems resulting from the **endovascular repair** of other **lesions** such as **dissection** and **blunt injury** (an injury to the **thoracic aorta** due to traumatic force to the chest (for example, during a car accident)) are expected to be similar to the problems shown above for **aneurysm** repair.

Procedural Risks

Problems that can happen because of the procedure include:

- Infection
- Fever
- Wound healing problems
- Pain/discomfort associated with the implant procedure (usually temporarily)
- Stomach/intestinal problems (for example, bowel obstruction)
- Acute radiation injury
- **Retrograde Type A Dissection** (a rare complication after **endovascular repair** where a new tear in the **aorta** results in blood flowing between the layers of the **aorta** back toward the heart)
- Conversion to **open surgery**

Possible Problems of Endovascular Repair after 30 days

Stent grafts are not sewn in place, so it is important for your doctor to look at **imaging** on a regular basis to make sure that the problem in your **aorta** has not continued and to make sure that your graft does not show any signs that could lead to problems with your **aorta**. The device events that can happen include the following:

- **Endoleak** (blood flows between the graft and **aorta**)
- Migration (the graft moves away from where it needs to be which can lead to **endoleak**)
- Fracture of the stent material (which could lead to migration, but this is rare).

You should ask your doctor about the likelihood of your having later problems with your aorta or graft. Treatment may not be durable in the long term, and you may need to undergo additional procedures to maintain the effectiveness of the **stent graft**. Long term follow-up is important to monitor the effectiveness of the device. **Endovascular** (inside or within a blood vessel) treatment requires lifelong, regular follow-up to assess your health and the performance of **stent graft**. If your doctor finds problems related to the **stent graft** then additional follow-up would be required. It is important to adhere to the follow-up schedule, both during the first year and at yearly intervals thereafter. You should be informed that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of **endovascular** treatment of **thoracic aortic lesions**.

Problems may be different for each patient. You should ask your doctor to help you understand and use this information.

ENDOVASCULAR STENT GRAFT PROCEDURE

BEFORE THE PROCEDURE:

Prior to the procedure, **imaging** (the use of X-rays, **CT scans**, **MRI scans** or other techniques to get pictures of the inside of the body) tests are performed. These tests allow the doctor to assess your diseased or injured **aorta**.

DURING THE PROCEDURE:

Typically, the **endovascular** procedure takes 1 to 6 hours to complete. You are usually asleep during the procedure and won't feel any pain.

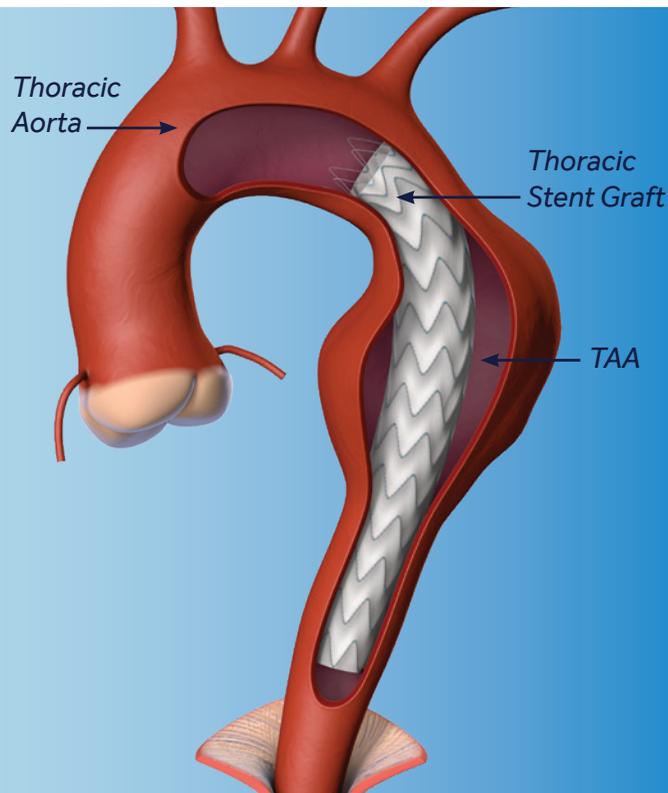
1. A small cut is made on one side of your **groin** (area between the abdomen and thigh on either side of the body).
2. A catheter holding your **thoracic stent graft** (a fabric tube supported by a metal frame that a doctor puts inside the injured or diseased portion of the **aorta**) is inserted into the cut and advanced through your **femoral artery** (blood vessel that carries blood to the thigh region of each leg. Doctors can use this as a pathway to reach the **aorta**) to reach the **lesions** (**aneurysm**, **dissection**, **BTAI**, etc.) in your **aorta**.

Note: A special kind of X-ray (**fluoroscopy**) is used to guide the catheter. This requires the use of dyes. If you have kidney problems, you should speak with your doctor.

3. Once the catheter is placed, the **stent graft** is released into your **aorta**.
4. When your **stent graft** is released, it expands to its proper size to fit in your **aorta**, both above and below the diseased or injured area (**Figures 14-16**).

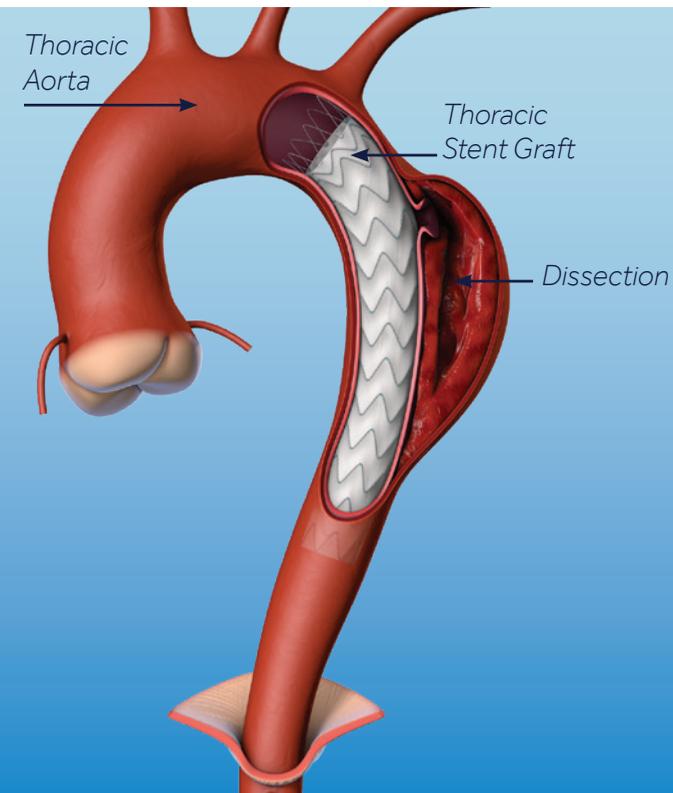
Note: Additional **stent grafts** may be required to treat the diseased/injured **aorta**.

5. The catheter is removed and the doctor will test to make sure your **stent graft** is working properly.
6. The cut in the **groin** is closed and the procedure is complete.



THORACIC AORTIC ANEURYSM

FIGURE 14
Stent Graft Inside the Aneurysm

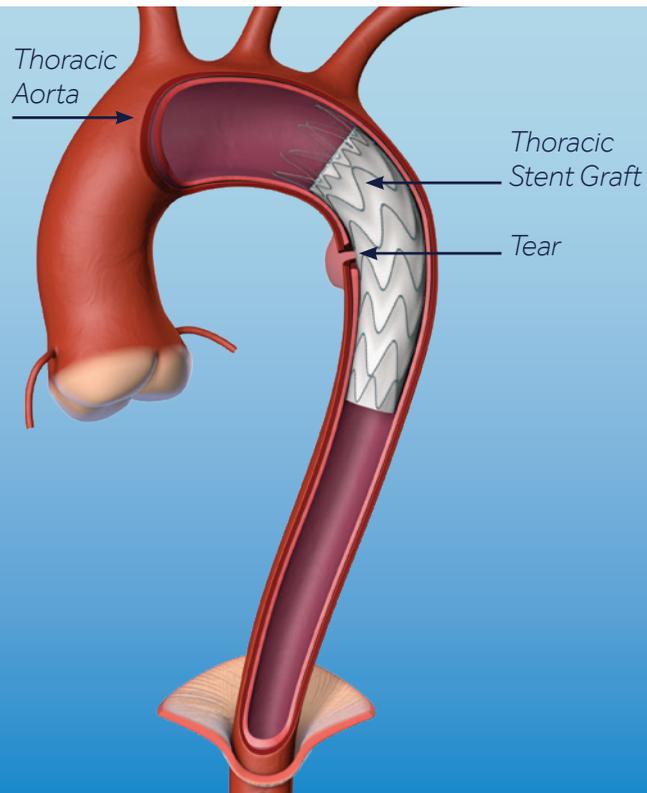


THORACIC AORTIC DISSECTION

FIGURE 15
Stent Graft Inside the Aorta

AFTER THE PROCEDURE:

After the **endovascular repair**, (a procedure in which a tube-shaped **stent graft** is placed inside the **aorta**, redirecting blood flow away from the **lesion** and relining the aortic wall, without cutting open the chest) you will go to a recovery room where you will have to lay flat for up to six hours. This will allow the cut in your **groin** to start healing. You may feel some discomfort for up to two days. You will likely need to stay in the hospital for several days depending on your condition. For more details, please refer to page 16. Your doctor will provide you with specific care instructions.



BLUNT THORACIC AORTIC INJURY (BTAI)

FIGURE 16
Stent Graft Inside
the Aorta

What Symptoms Should Prompt You to Call Your Doctor After the Procedure?

If you have any of these symptoms after your **endovascular repair**, call your doctor immediately to discuss them:

- pain in your back, chest, or **groin**
- dizziness
- fainting
- rapid heartbeat
- sudden weakness
- pain, numbness, coldness, or weakness in your legs, buttocks or other extremities

Follow-Up

It is important to schedule regular follow-up visits with your doctor since most problems with **endovascular repair** do not have symptoms. You will need to let your doctor check on your progress regularly. See pages 20 to 23 for important safety information.

Your doctor will schedule follow-up visits depending on your condition. Most often these will occur at one month, one year and then each year thereafter. **Imaging** tests are required to monitor device performance.

IMPLANTED DEVICE IDENTIFICATION CARD

After your procedure, your doctor will give you a temporary implanted device identification (ID) card. This card will tell you the size and number of your **thoracic stent graft** implants.

Medtronic will mail you a permanent implanted device ID card to carry in your wallet. Your permanent ID card will list the following information:

- Type of device implanted
- Date of implant
- Your doctor's information
- **Magnetic resonance imaging (MRI)** (a technique that uses magnetic fields to get pictures of the inside of the body) information

Be sure to tell all of your healthcare providers that you have a **stent graft** (a fabric tube supported by a metal frame that a doctor puts inside the injured or diseased portion of the **aorta**) and show them your implanted device ID card. You should keep your ID card with you at all times.

MAGNETIC RESONANCE IMAGING

After being implanted with a Medtronic **thoracic stent graft** it is safe to have **Magnetic resonance imaging (MRI)** procedures, under certain conditions.

MRI information is provided on your implanted device ID card. Show this ID card to your healthcare providers.

LIFESTYLE CHANGES

- You will need to go for regular follow-up visits to check your **stent graft**. Please consult your doctor to reschedule any follow-up visits if you are traveling.
- The **thoracic stent graft** is not expected to trigger any passenger screening devices such as airport security scanners.
- Please consult your doctor about your ability to perform strenuous physical activities.

QUESTIONS YOU MAY WANT TO DISCUSS WITH YOUR DOCTOR

- What are the other options for treating my diseased or injured **aorta** (the main vessel that carries blood from the heart to the rest of the body)?
- Which **stent grafts** are approved for this treatment?
- What are all of the possible problems of an **endovascular repair** procedure?
- What are all of the possible problems of an **open surgical repair** (a procedure in which a doctor makes a large cut in the chest to treat a **lesion** by sewing in a fabric vascular graft) procedure?
- Will my health insurance pay part or all of the cost associated with my **endovascular repair** procedure?
- What kind of anesthesia will I need and what are the risks of that?
- How will the cut in my **groin** be made and fixed?
- After the **endovascular repair** procedure, how often must I follow-up with a doctor, and what tests will be done?
- Do I have to limit activities after treatment? If yes, for how long?
- How long can the **stent graft** remain implanted in my body?
- How many **endovascular repair** procedures has this doctor performed?

This guide is not a substitute for detailed talks with your doctor. Only your doctor can decide if this procedure is right for you. This therapy is not for everyone. Please consult your doctor. A prescription is required.

