

PATIENT INFORMATION BOOKLET

Thoracic Stent Grafts:

A Treatment for

Thoracic Aortic Aneurysms

TABLE OF CONTENTS

Introduction	1
Glossary	2
Thoracic Aorta	3
Thoracic Aortic Aneurysm (TAA)	4
Causes	5
Symptoms	5
Treatment Options	5
Open Surgical Repair	6
Endovascular Repair	7
Thoracic Stent Graft	8
Is Endovascular Repair Right For You?	9
When Endovascular Repair Is Not An Option	9
Warnings	9
What Symptoms Should Prompt You to Call Your Doctor After the Procedure?	10
Important Safety Information*	10
Possible Complications	11
Possible Benefits of Treatment	12
Endovascular Stent Graft Procedure	13
Follow-Up	15
Implanted Device Identification Card	15
Magnetic Resonance Imaging	15
Lifestyle Changes	16
Questions You May Want to Discuss with Your Doctor	16
Additional Information	17

*See pages 10 to 12 for important safety information.

INTRODUCTION

You have discussed having an **endovascular repair** procedure to treat a **thoracic aortic aneurysm (TAA)** with your doctor. Your doctor has given you this booklet to help you further understand the device and procedure. Only a doctor can determine if you are a good candidate for 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 are defined in the glossary.

GLOSSARY

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

Anatomy: The study of parts of the body.

Aneurysm rupture/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.

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 aneurysm.

Endoleak: Blood flow into the aneurysm after a stent graft is put in it.

Endovascular: Inside or within a blood vessel.

Endovascular repair: A procedure in which a tube-shaped stent graft is placed inside a TAA without cutting open the chest or stomach.

Exclude: To remove or shut off from the main part.

False aneurysm: A collection of blood outside the vessel wall.

Femoral artery: 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.

Iliac artery: blood vessels that carry blood to your pelvis. 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.

Minimally invasive: Involving a small cut of the skin without exposing the organs.

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

Open surgery/Open surgical repair: A procedure in which a doctor makes a large cut in the chest or stomach to remove a TAA and then replaces it with a fabric graft.

Penetrating ulcer: A weak area of the thoracic aorta that causes one side of the diseased vessel to bulge or expand but, unlike a saccular aneurysm, does not go completely through the first layer of the aorta.

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

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

Stent graft/Thoracic stent graft: A fabric tube supported by a metal frame that a doctor puts inside a TAA.

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**).

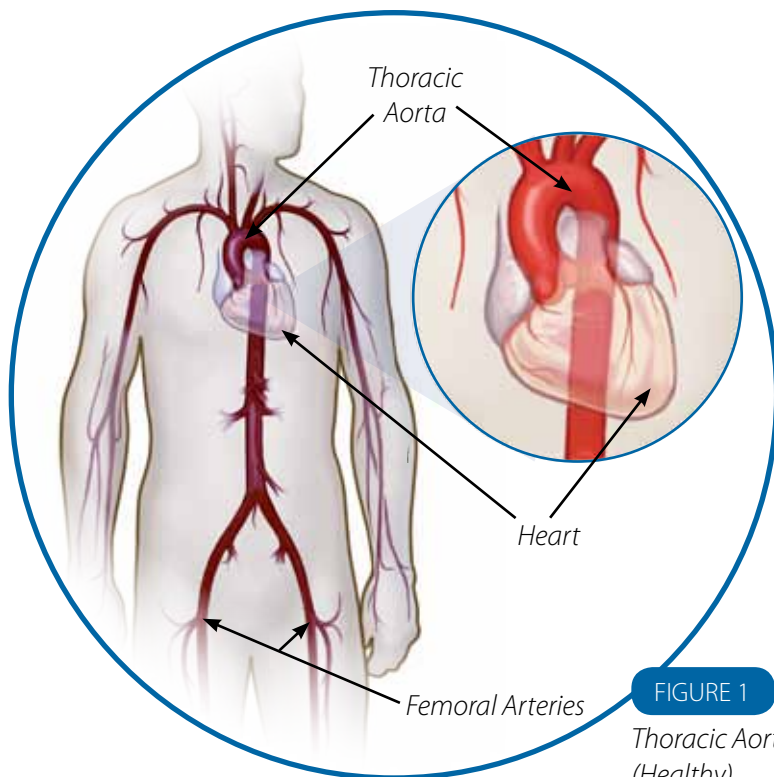


FIGURE 1

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. A **saccular aneurysm** is circular in shape and typically involves only one side of the diseased vessel. 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.

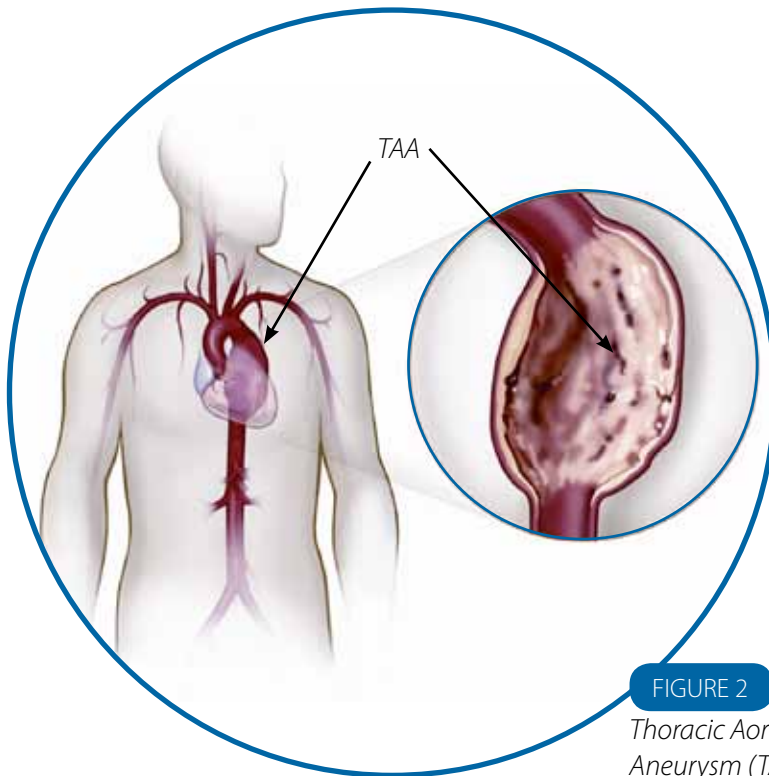


FIGURE 2

Thoracic Aortic Aneurysm (TAA)

CAUSES

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

- are over 50
- are men
- have high blood pressure
- smoke
- 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.

TREATMENT OPTIONS

If the doctor thinks there is a risk that the **TAA** may **rupture**, treatment may be recommended. There are two primary treatment options available depending on your doctor's diagnosis:

- **open surgical repair**
- **endovascular repair**

Both TAA treatment options have possible complications and benefits. Patients should talk with their doctor about which option is best for them. See pages 10 to 12 for important safety information about endovascular repair.

OPEN SURGICAL REPAIR¹:

Open surgical repair is a proven medical procedure. A doctor will cut open your chest or stomach (**Figure 3**), cut out the **TAA**, and replace it with a fabric graft. This reduces the chance of **rupture**.

This procedure takes 4 to 6 hours. After this, you will likely spend 3 to 7 days in the intensive care unit and then 8 to 18 days in the hospital. You will need 12 to 24 weeks to recover.

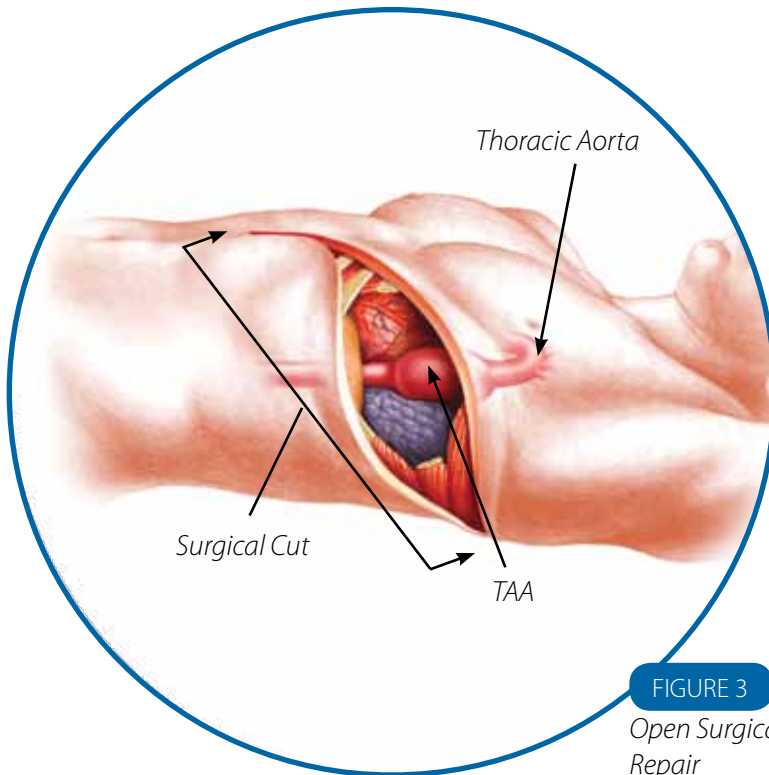


FIGURE 3
*Open Surgical
Repair*

ENDOVASCULAR REPAIR⁴:

Endovascular repair is a newer **minimally invasive** medical procedure. The long-term results of endovascular repair with a **thoracic stent graft** have not been established. A doctor will make a small cut in your groin (**Figure 4**). A catheter holding a fabric and metal stent graft is inserted into the cut, guided to your **TAA** and then released into your **aorta**. This **excludes** your TAA and reduces the chance of **rupture**.

In some patients, the **iliac artery** and **femoral artery** 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 takes 4 to 6 hours. After this, you will likely spend 0 to 1 1/2 days in the intensive care unit and then 2 to 7 days in the hospital. You will need 4 to 6 weeks to recover.

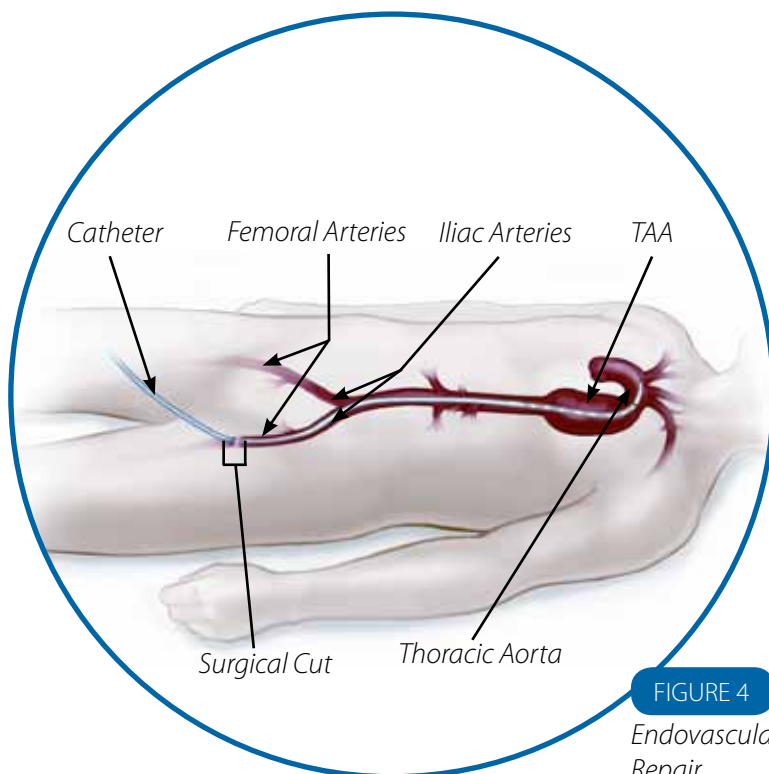
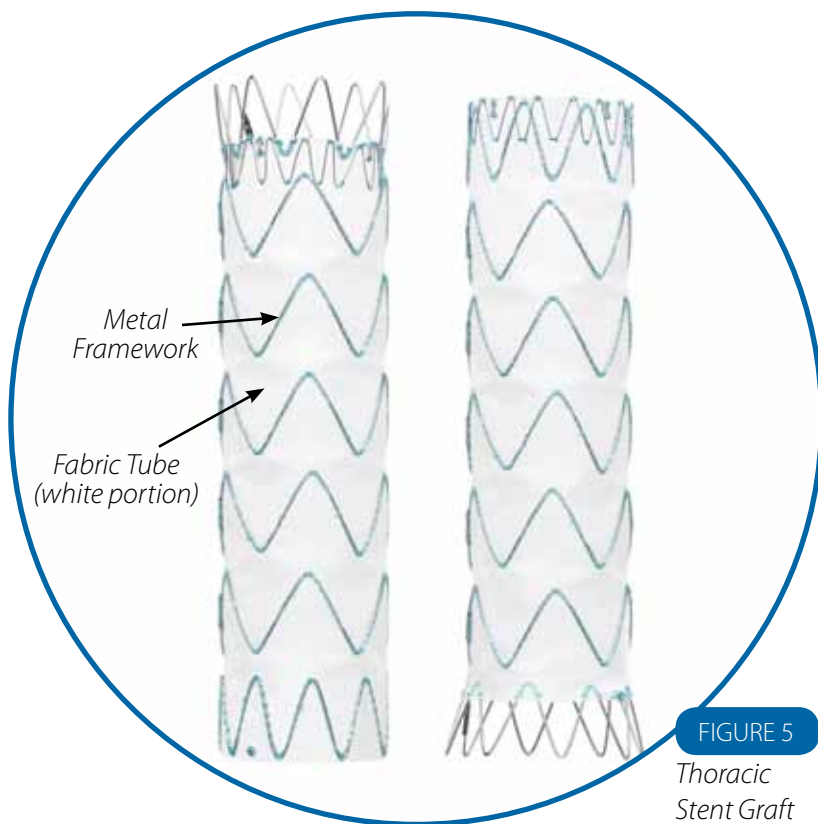


FIGURE 4

Endovascular
Repair

THORACIC STENT GRAFT

The **thoracic stent graft** is a fabric tube supported by a metal framework (Figure 5). A doctor puts it inside your **TAA** using a catheter. It will reduce the pressure in your aneurysm by making a new path for your blood.



Note: The size of the stent graft in the figure above is not actual size. Medtronic devices are 80 mm (3.15 in) to 220 mm (8.66 in) long.

IS ENDOVASCULAR REPAIR RIGHT FOR YOU?

If you have the right **anatomy**, an **endovascular repair** procedure may be an option to treat your **thoracic aortic aneurysm** or **penetrating ulcer**.

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 your graft could get infected or you could have an allergic reaction, both of which could be life-threatening.

Only your doctor can help you decide which treatment option is right for you.

WARNINGS

The use of **stent grafts** has not been studied in patients who:

- have received a previous stent graft in same area of their **aorta**
- have connective tissue disease
- refuse blood transfusions
- had a recent stroke
- 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.

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

- cannot complete regular follow-up visits and **imaging** examinations
- cannot tolerate imaging dyes
- have bleeding disorders
- have kidney disease
- cannot use blood thinners

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 these symptoms:

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

IMPORTANT SAFETY INFORMATION

To better understand the possible complications and benefits with an endovascular repair procedure, Medtronic conducted two clinical studies in the United States with 355 patients.

These studies included patients between the ages of 18 and 85 years old. Almost all patients had high blood pressure. Many had mild to moderate levels of heart, lung or kidney disease. However, patients who had a recent surgery, infection, heart attack or stroke were not included in the studies. You should talk to your doctor about how your situation may be different or similar.

Many problems experienced after endovascular repair of a **TAA** do not have symptoms associated with them. So, you will have to schedule regular follow-up visits with your doctor. This will allow your doctor to check on your progress.

POSSIBLE COMPLICATIONS

Clinical study patients had these complications within 30 days after their **endovascular repair**:

Possibility (%)	Complications within 30 days ²
10%	Abnormal or irregular heartbeat Significant blood loss
5-10%	Pneumonia or difficulty breathing A blood vessel hole or tear
3-5%	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%	Death False aneurysm 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
1% or less	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 Second procedure to treat continued TAA growth

Possible complications after 30 days

After your endovascular repair, there is a chance that an **endoleak** may cause your TAA to begin to grow again. If this happens, your doctor may recommend a second endovascular repair procedure to fix this. If the aneurysm continues to grow and is not repaired, it could rupture. In the two Medtronic clinical studies, about 5 to 10% of patients had a second endovascular repair procedure to treat this problem. Fewer than 1% of patients experienced a TAA rupture after 30 days.

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

POSSIBLE BENEFITS OF TREATMENT

The biggest benefit of getting your **thoracic aortic aneurysm** treated is a decreased chance of **rupture**. If left untreated, your aneurysm may continue to grow. If your aneurysm grows to 6 cm in diameter there is a 4% chance each year that your TAA could rupture.³ You should talk to your doctor to see if this applies to you. Options for treatment of aneurysms include **endovascular repair or open surgical repair**.

The rates below are from two Medtronic clinical studies of TAA repair. The results for patients in the open surgery group were selected to allow for comparison. Clinical study results in the table below suggest an improvement in specific outcomes.

Complication	Endovascular Repair ⁴	Open Surgery ¹
Death in the first 30 days	2% to 3%	8%
Major complications in the first 30 days	38% to 41%	84%
Patients requiring blood transfusion	10% to 23%	94%
Blood loss during procedure	1/2 to 3/4 pints	6 1/2 pints
Length of procedure	2 to 3 hours	4 to 6 hours
Time in ICU	0 to 1 1/2 days	3 to 7 days
Total time in hospital	2 to 7days	8 to 18 days

Experts are still studying the long-term results of endovascular stent graft repair.⁵

For detailed clinical study information, go to www.ClinicalTrials.gov and search for VALOR and VALOR II or contact Medtronic at 877-526-7890.

ENDOVASCULAR STENT GRAFT PROCEDURE

Before the procedure:

Prior to the procedure, **imaging** tests are performed. These tests allow the doctor to assess your **aneurysm**.

During the procedure:

Typically, the **endovascular procedure** takes 2 to 3 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.
2. A catheter holding your **thoracic stent graft** is inserted into the cut and advanced through your **femoral artery** to reach your **TAA**.

*Note: **Fluoroscopy** is used to guide the catheter to your TAA. 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** (**Figure 6**).

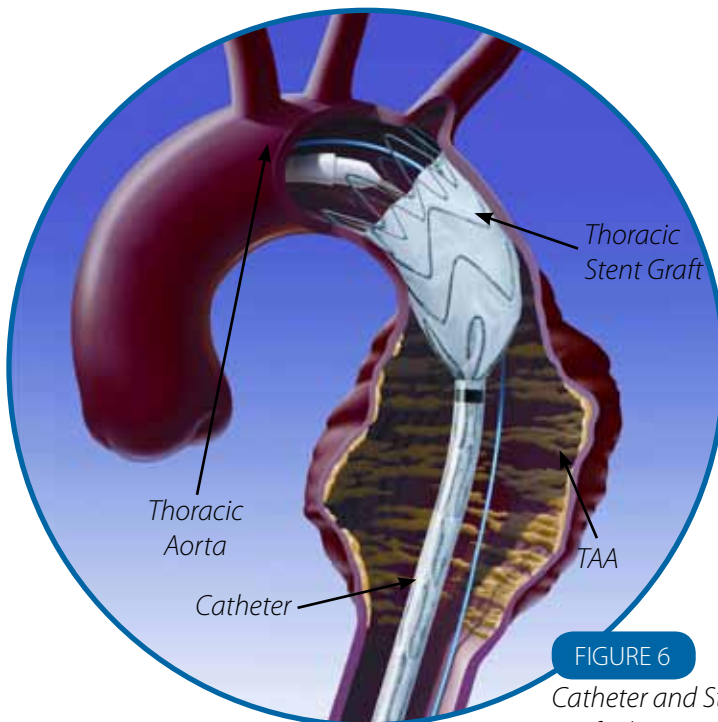


FIGURE 6

Catheter and Stent Graft Placement

4. When your **stent graft** is released, it expands to its proper size to fit in your **aorta**, both above and below your **TAA (Figure 7)**
*Note: Additional stent grafts may be required to completely **exclude** your aneurysm.*
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.

After the procedure:

After the **endovascular repair**, 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 2 to 7 days. Your doctor will provide you with specific care instructions.

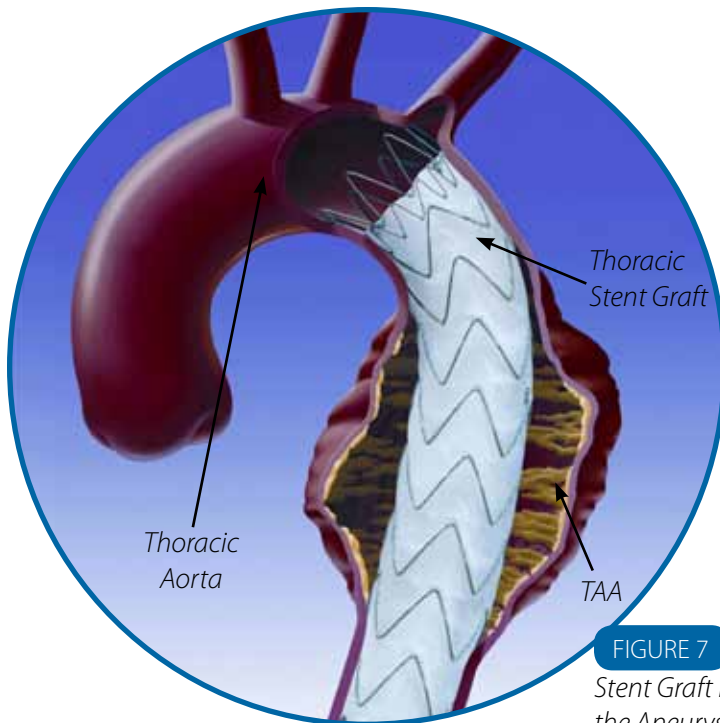


FIGURE 7
Stent Graft Inside
the Aneurysm

FOLLOW-UP

It is important to schedule regular follow-up visits with your doctor. Again, the long-term effects of **thoracic stent grafts** are not known and since most problems with **endovascular repair** also do not have symptoms, you will need to let your doctor check on your progress regularly. See pages 10 to 12 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)** information

Be sure to tell all of your healthcare providers that you have a stent graft 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 **TAA**?
- Which **stent grafts** are approved for treatment of my **TAA**?
- What are all of the possible complications of an **endovascular repair procedure**?
- What are all of the possible complications of an **open surgical repair procedure**?
- Will my health insurance pay part or all of the cost associated with my endovascular repair procedure?
- 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 facility 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.

ADDITIONAL INFORMATION

Additional information regarding TAA can be found at:

www.medlineplus.gov

www.fda.gov

www.vascularweb.org

CONTACTING MEDTRONIC:

If you have any questions concerning a Medtronic thoracic stent graft, you should contact your doctor. It is Medtronic's mission to alleviate pain, restore health and extend life. If there is anything that we as a company can do to assist you, please feel free to contact us at:

Medtronic, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
USA
Tel: 707.525.0111

Product Services
Tel: 800.961.9055
Fax: 800.929.2133

CardioVascular LifeLine
Customer Support
Tel: 877.526.7890
Tel: 763.526.7890
Email: rs.cstechsupport@medtronic.com

ENDNOTES:

¹Open surgical repair procedure information is from 3 centers of excellence and was used in the Medtronic VALOR clinical study as a comparison to endovascular repair. Values for death in the first 30 days, major complications in the first 30 days, patients requiring blood transfusion, and blood loss during procedure are averages. The ranges for procedure length, total time in the ICU, and total time in hospital are restricted ranges; as such, one quarter of patients will spend less time and one quarter will spend more time. Estimated recovery times are from reference sources.

²Average rates of Major Adverse Events within 30 days of procedure of the Medtronic VALOR and VALOR II clinical studies of endovascular repair of thoracic aortic aneurysms.

³Svensson LG, Miller DG et al. Expert consensus document on the treatment of descending thoracic aortic disease using endovascular stent-grafts. *Ann Thorac Surg* 2008;85:S1-41.

⁴Clinical utility and Major Adverse Events from the VALOR and VALOR II clinical studies of endovascular repair of thoracic aortic aneurysms. Values for death in the first 30 days, major complications in the first 30 days, patients requiring blood transfusion, and blood loss during procedure are averages of the Medtronic VALOR and VALOR II clinical studies. Values for length of procedure, time in ICU, and total time in hospital are restricted ranges as such that a quarter of patients will spend less time and a quarter will spend more time.

⁵Thoracic Aortic Aneurysm resource page. Society for Vascular Surgery website. Available at: <https://www.vascularweb.org/vascularhealth/Pages/thoracic-aortic-aneurysm.aspx>. Accessed March 3, 2011.

www.medtronic.com

Medtronic, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
USA
Tel: 707.525.0111

**CardioVascular LifeLine
Customer Support**
Tel: 877.526.7890
Tel: 763.526.7890
Email: rs.cstechsupport@medtronic.com

Product Services

Tel: 800.961.9055
FAX: 800.929.2133

