TERUMO AORTIC

FDA APPROVED

Patient Information Guide

Relay®Pro

Your guide to understanding Thoracic Aortic Lesions

Table of Contents

Helpful hints

Some words and terms in this guide might be unfamiliar. You can find explanations in the glossary to help you learn more about your thoracic aortic lesion.

Introduction

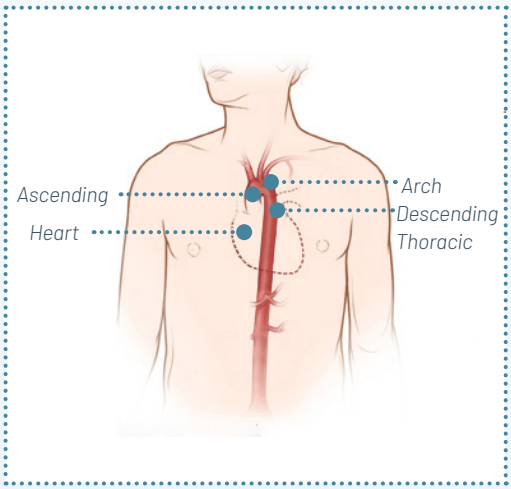
The aorta is the largest and main blood vessel that carries blood from the heart to the rest of the body. The section of the aorta that is in your chest is called the thoracic aorta. Your thoracic aorta includes the ascending aorta (section of the aorta that is next to your heart), aortic arch (top section of the aorta that connects the ascending aorta and descending aorta), and the descending thoracic aorta (section that is in your chest).

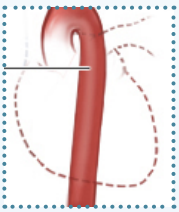
There are many different diseases or injuries (lesions) that can affect the aorta. The more common categories are Thoracic Aortic Aneurysm (TAA), Aortic Dissection, and Blunt Traumatic Aortic Injury (BTAI).

This brochure describes diseases and injuries of the thoracic aorta and a relatively new device that can be used to treat them, namely an endovascular graft (also known as a stent-graft).

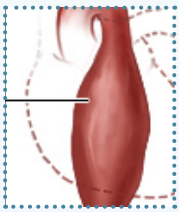
This brochure can be used as a reference, but only your doctor can decide what type of treatment is right for you. Please consult your doctor prior to making any decisions regarding your aortic treatment.

It may be helpful to write down your questions and concerns to discuss later with your doctor and healthcare team. You can use the note page near the end of this brochure.

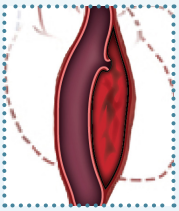




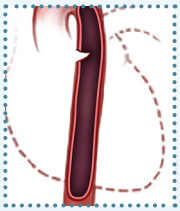
Normal Aorta



Thoracic Aortic Aneurysm



Aortic Dissection



Blunt Traumatic Aortic Injury

What is a Thoracic Aortic Aneurysm?

A thoracic aortic aneurysm (TAA) is a weakened and bulging area in the wall of the thoracic aorta (section of the aorta in the chest). TAAs can grow in size over time further weakening the wall of the aorta and may potentially burst or rupture (causing bleeding inside of the body). As the aorta supplies the body with most of the oxygenated blood from the heart, a ruptured TAA can cause life-threatening bleeding.

Most people with a TAA do not experience any outward symptoms. [1]
For those who do, the most common are:

- Pain in the jaw, neck, chest and/or back
- Coughing, hoarseness and/or difficulty breathing

If you experience any of these symptoms, tell your doctor immediately. Your doctor may have you get imaging done to check what may be causing the symptoms.

What is an Aortic Dissection?

An aortic dissection is a small tear in the inner layer of the aortic wall that allows blood to flow between the layers. An acute aortic dissection has a sudden onset of symptoms similar to a heart attack; for example, symptoms may include chest or back pain, weak pulse, shortness of breath and/or loss of consciousness.

However, the tear may be small or progress slowly so that the aortic dissection becomes chronic. Blood flow between the layers of the aortic wall can cause the same type of ballooning of the aortic wall seen in aneurysms.

Where the tear occurs in the aorta (how close to the heart), how big it is and how far it travels will usually determine whether or not you have symptoms and how urgent treatment is. When deciding when and how to treat the aortic dissection, your doctor will also consider whether there is a risk of rupture or malperfusion (tear in the aorta may decrease or block blood flow to one or more organ(s)).

1. Penn Medicine: https://www.pennmedicine.org/conditions/thoracic-aortic-aneurysm. As of 08/28/2025

What causes a TAA or an Aortic Dissection? [2]

Weakening of the aorta over time may be caused by many factors, including vascular disease and genetic conditions. For both aneurysms and aortic dissections, the main risk factors include the following:

- High blood pressure (hypertension)
- Smoking
- Family history of aortic disease (inherited diseases that cause weakening of the blood vessels, Marfan Syndrome, for example)
- Hardening of the arteries (atherosclerosis)
- High cholesterol (hypercholesterolemia)

Also, your risk of having a TAA is greater if you are a man over 55 years of age. You may also get a aortic dissection if you already have an aortic aneurysm.

2. American Heart Association: https://www.heart.org/en/health-topics/aortic-aneurysm/your-aorta-the-pulse-of-life. As of 08/28/2025

What is a Blunt Traumatic Aortic Injury (BTAI)?

A Blunt Traumatic Aortic Injury (BTAI) is a tear in wall of the aorta. The tear may be a complete tear (a tear that goes through the whole wall of the aorta). This causes internal bleeding and is fatal in most cases. The tear may not be a complete tear of the wall of the aorta. The aorta is weakened at the location of the smaller or partial tear and may potentially be ballooned (similar to what is described in the aneurysm section). If the tear is not treated, the aorta could rupture resulting in life-threatening bleeding in the body.

Most often, Blunt Traumatic Aortic Injury occurs because of blunt force trauma and massive deceleration (extremely fast stopping) that causes significant injury to the chest. For example, this may happen due to an car or motorcycle crash or a fall from a very high height.

What are the current treatments for Aortic Lesions?

Medical Management

The size and extent of your aortic lesion will impact which treatment option that your doctor recommends for you. If the disease or injury to your aorta is small, your doctor may recommend regular follow-up visits to monitor your lesion (check whether it grows in size or extent). Your doctor may also recommend medical or lifestyle changes to lower the stress on the aortic wall such as blood pressure medication and/or stop smoking.

Repair

If your lesion is quickly growing in size or is of a certain size, there is a higher risk of rupture. This risk of rupture will continue to increase as the lesion size and extent increase.

If your doctor recommends that treatment is needed for your lesion, there are two options that are available:

- Open surgical repair
- Endovascular repair

Both repair options have possible risks (complications) and benefits. You should discuss the best option for you with your doctor.

Each of these options are discussed in more detail in the pages that follow.

Open Surgical Repair

What is open surgical repair?

During open surgical repair, your doctor will make a cut in your side so that the aneurysm can be replaced with a fabric tube (graft) that is sewn in place in your aorta above and below your aneurysm. Blood will then flow through the graft. This surgery reduces the likelihood of vessel rupture.

Open surgical repair is performed under general anesthesia. After surgery, you may stay in hospital for 7 to 10 days.[3] If your TAA is complicated or if you have other conditions such as heart, lung or kidney disease, you may require 2 to 3 months for a complete [3] recovery.

Do I need open surgery?

Not all aneurysms require treatment. The risk of rupture and, therefore, the need for repair depends on the size of the aneurysm. If the aneurysm is large (more than 5.0cm in diameter), your doctor may prefer to treat the condition with open surgery rather than taking a less invasive approach. This protects the aorta from rupture. Your doctor may prefer to "wait and see" by taking images at 6 to 12 month intervals if your aneurysm is small. These images will allow the doctor to observe whether the aneurysm grows with time to a size that might be more dangerous. Average enlargement is about 0.5cm per year, so surgery may be required at a later stage. Your doctor will explain the various options and recommend the preferred treatment for you.

The open surgical operation

You will initially be taken to a reception area, then to the anesthetic room where you will be given anesthetic, and then into the operating room.

While asleep, you may have a small tube placed in your back (epidural) to help with pain relief following surgery. Also, tubes will be inserted into your bladder to drain urine, into your stomach (via your nose) to prevent nausea and into a vein in your neck for blood pressure measurements and administration of fluid following surgery. You will have a cut either down or across your abdomen. Occasionally, it is necessary to make a smaller cut on one or both sides of your groin.

3. https://vascular.org/your-vascular-health/vascular-conditions/thoracic-aortic-aneurysm As of 08/28/2025.

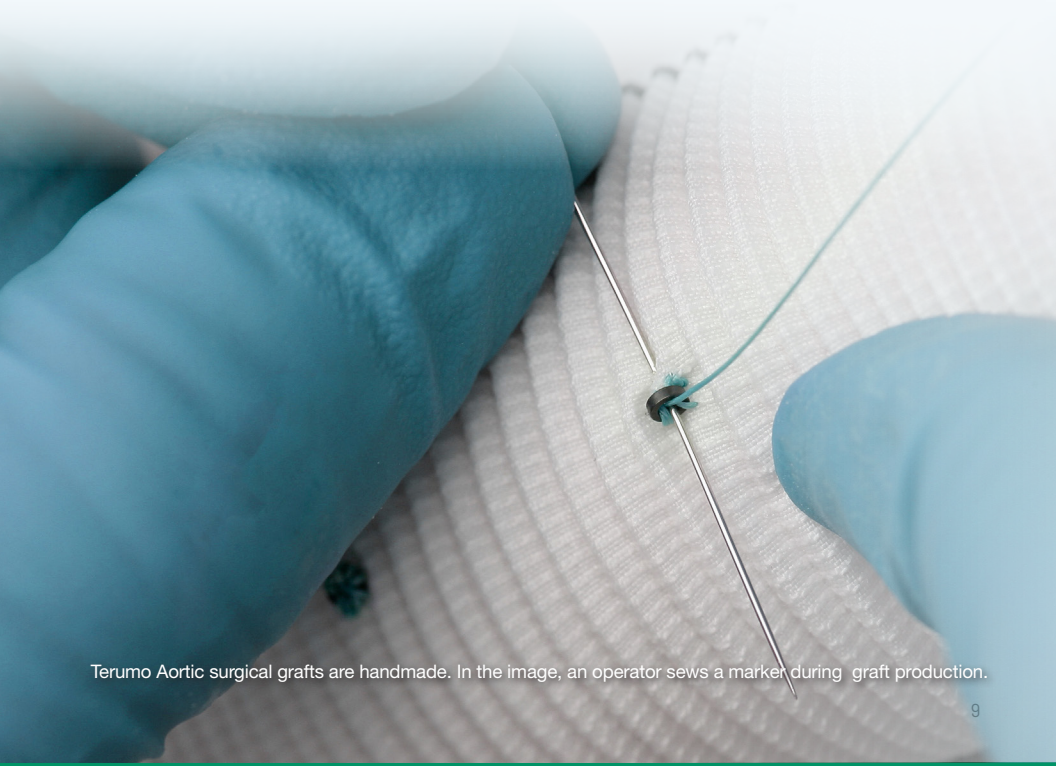
Is open surgery successful?

If aneurysms are repaired before they rupture, there is a high overall chance of successful repair and a return to normal life expectancy. However, you should discuss the risks of open surgery in your particular case with your doctor.

Complications with open surgery

Chest infections can occur following this type of surgery, particularly in smokers, and may require treatment with antibiotics and physiotherapy. Slight discomfort and twinges of pain in your wound are normal for several weeks following surgery. Wounds sometimes become infected and these can usually be successfully treated with antibiotics. Also, the groin wound can fill with a fluid called lymph that may leak between the stitches but this usually decreases with time.

As with any major operation, there is a small risk of medical complication such as a heart attack. The doctors and nurses will try to prevent such complications and deal with them rapidly should they occur. Occasionally, the bowel is slow to start working again, but fluids will be provided in a drip until your bowels return to normal. Sexual activity may be affected due to nerves in your abdomen being cut during the operation.



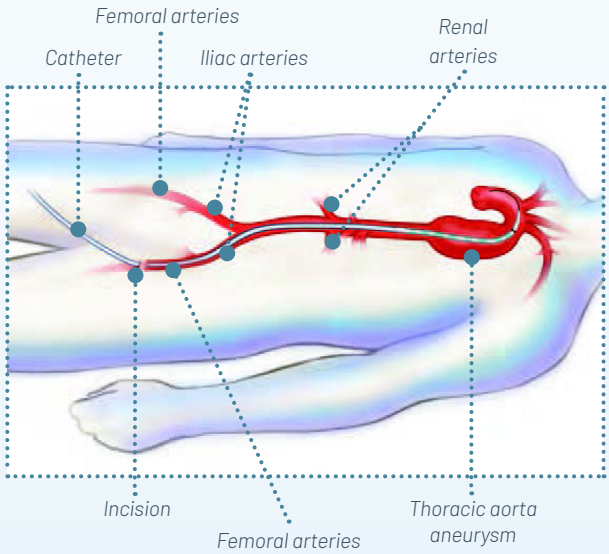
Terumo Aortic surgical grafts are handmade. In the image, an operator sews a marker during graft production.

What is Endovascular Repair?

Endovascular repair is a minimally-invasive way to treat aortic lesions. Endovascular repair uses a stent-graft. A stent-graft is a fabric tube supported by a metal frame which is placed in the diseased aorta (section of your aorta where the lesion is located). The stent-graft is designed to allow blood to flow normally through your aorta and is designed to protect the diseased aorta from blood pressure and flow.

During an endovascular procedure, a stent-graft, which is compressed inside a narrow plastic tube called a delivery system, is inserted through a small cut in your groin and tracked through your blood vessels. During the procedure, your doctor will use live x-ray pictures viewed on a video screen to guide the stent-graft to the section of your aorta where the lesion is located. The stent-graft is designed to open inside your aorta and become the new channel for blood flow. The stent-graft is designed to reduce the pressure on the aortic wall and to prevent further growth of your lesion and prevent rupture of your aorta.

Following endovascular repair, you can expect to go home within one day to one week.[4] Because many patients that get a BTAI are a result of a car crash or high fall, patients may have other non-aortic injuries that need attention and your hospital stay may be extended to address those other injuries. You should speak to your doctor to understand if endovascular repair is the right treatment for you. Endovascular repair requires yearly lifelong imaging and regular follow-up.



The above picture shows a thoracic aortic aneurysm (TAA). A similar approach would be taken for other lesions, such as aortic dissections and BTAI.

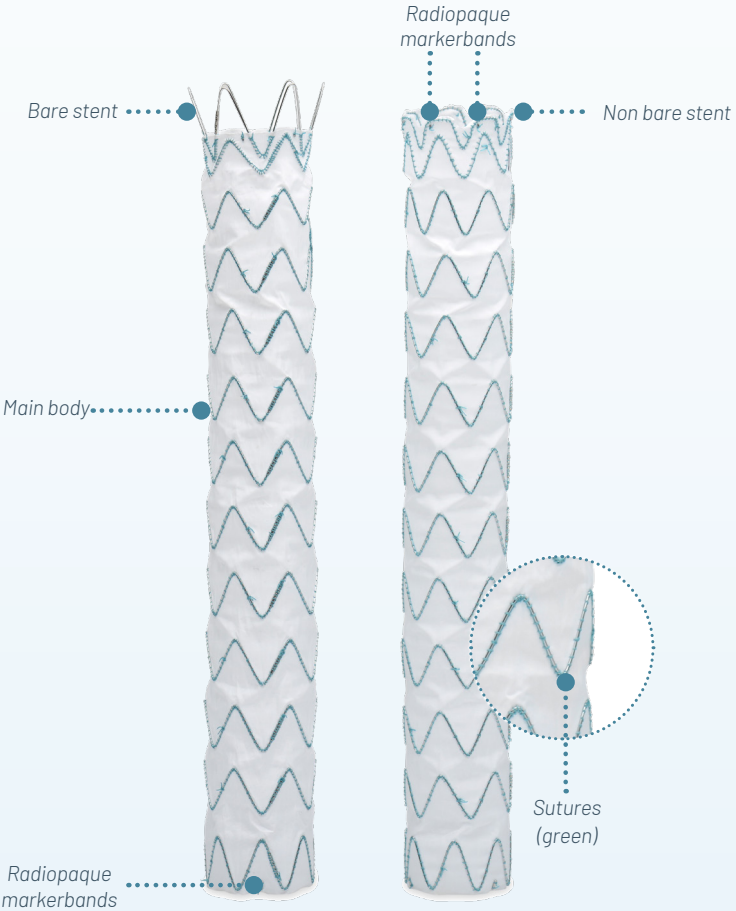
4. Cleveland Clinic: https://my.clevelandclinic.org/health/treatments/16962-endovascular-repair-of-thoracic-aortic-aneurysms. As of 08/28/2025.

The Terumo Aortic difference

Endovascular repair with the Relay®Pro Thoracic Stent-Graft System

The Relay®Pro Stent-Graft is a woven polyester graft (fabric tube) that is supported by a series of stents (metallic rings) which are made from a strong, thin metal called Nitinol. The stent-graft is placed inside the thoracic aorta using a delivery system (thin tubes that contain and deliver the compressed stent-graft).

The Relay®Pro Stent-Graft is available in two configurations: a bare metal stent and covered stent (NBS). Once you and your doctor agree that endovascular repair with the Relay®Pro Stent-Graft is right for you, your doctor will determine the exact size and configuration of the device to use.



Clinical Data Summary

The Relay®Pro Thoracic Stent-Graft System was evaluated in over 200 patients in three clinical studies to better understand the safety and benefits of the procedure with the Relay®Pro device. The primary study had 110 patients thoracic aortic aneurysms (TAAs)[5] treated in the United States (US) and Japan. Two additional clinical studies were completed in the US treating patients with aortic dissections[6] (56 patients) and blunt traumatic aortic injuries[7] (50 patients).

These studies included patients between the ages of 19 and 94 years old. The health and medical history of these patients may or may not be similar to yours. Discuss with your doctor how your situation may be different or similar. In the thoracic aortic aneurysm study, 100% remained free from device technical failure and 87.4% were free from major safety events followed out through 1-year. The results from the aortic dissection and blunt traumatic aortic injuries studies also confirmed the safety and effectiveness of the Relay®Pro Thoracic Stent-Graft System. No new safety risks were identified in these studies with the use of the Relay®Pro Thoracic Stent-Graft System.

All three clinical studies support the safety and effectiveness of the Relay®Pro Thoracic Stent-Graft System in the endovascular repair of lesions (diseases or injuries) in the descending thoracic aorta (portion of the aorta in your chest), including thoracic aortic aneurysms, aortic dissections, and blunt traumatic aortic injuries.

Many problems experienced after repair of a diseased or injured aorta do not have symptoms and you will have to schedule regular follow-up visits with your doctor to check on your progress and requires yearly lifelong imaging.

5. Szeto, Wilson Y. “One-year results with a low-profile endograft in subjects with thoracic aortic aneurysm and ulcer pathologies Discussion.” JOURNAL OF THORACIC AND CARDIOVASCULAR SURGERY 163.5 (2022): 1749-+.
6. Rossi, Peter J., et al. “One-year results of a low-profile endograft in acute, complicated type B aortic dissection.” The Annals of thoracic surgery 117.2 (2024): 336-343.
7. Starnes, Benjamin W., et al. “Early survival benefit of a low-profile endograft in blunt traumatic aortic injury.” Journal of Vascular Surgery 80.3 (2024): 678-684.

A brief overview of the outcomes of the studies through 1-year are presented below:

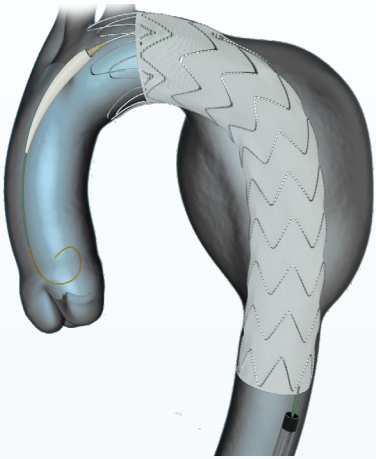
Aneurysm & Penetrating Atherosclerotic Ulcers (PAU) Study [5] *(110 patients treated)*	Aortic Dissection Study [6] *(56 patients treated)*	Blunt Traumatic Aortic Injuries Study [7] *(50 patients treated)*
98.2% Freedom from Aneurysm-Related Death	98.2% Freedom from Aortic Dissection Related Death	98% Freedom from Aortic-Related Mortality
87.4% Freedom from Major Safety Events *(death, heart attack, stroke, kidney failure, respiratory failure, paralysis not including paraparesis, bowel ischemia, high procedural blood loss)*	89.1% Freedom from Major Safety Events *(disabling stroke, kidney failure (not pre-existing), paraplegia, paraparesis)*	95.8% Freedom from Major Safety Events *(death and paralysis)*
6 subjects had additional procedures related to the treated disease or for reasons related to the stent-graft	12 subjects had additional procedures related to the treated disease or for reasons related to the stent-graft	4 subjects had additional procedures related to the treated disease or for reasons related to the stent-graft
No subjects had to have their device replaced	3 subjects had open surgery to treat their Aortic Dissection	No subjects had to have their device replaced
1 subject had an increase in size of their aneurysm after the treatment	2 subjects had an increase in size of their aorta after the treatment	No subjects had an increase in size of their aorta after the treatment
No subjects in the study have had a rupture/burst of the aneurysm	No subjects in the study have had a rupture/burst of the lesion	No subjects in the study have had a rupture/burst of the lesion
No subjects in the study experienced breaks in their device	No subjects in the study experienced breaks in their device	No subjects in the study experienced breaks in their device
		One subject developed blood clots in their device and acute paralysis of the legs and lower body

Before undergoing Endovascular Repair

If endovascular repair is recommended, your doctor may ask you to have some further tests before the procedure, such as CT or MR scans. These tests will allow the doctor to review your aorta and determine the proper size of stent-graft that is needed; the stent-graft will be sized to fit your aorta.

The procedure

Typically, Thoracic Endovascular Aortic Repair takes about two hours to complete.[8] You will be asleep during the procedure and will not feel any pain. An overview of the procedure is briefly discussed below; please discuss any questions that you have on the procedure with your doctor.



*The stent-graft inside the TAA **

1. A small cut is made on one side of your groin.
2. A delivery system is inserted into the opening and guided through your femoral artery to reach the part of your aorta that needs to be treated. Throughout the procedure, the doctor will view live x-ray pictures of your aorta to make sure the stent-graft is properly placed. This requires the use of dyes (see warning section on page 18 regarding the use of dyes).
3. Once the delivery system reaches the correct location, the stent-graft is deployed (expanded to its full size). When your stent-graft is released, it is designed to seal the aorta above and below the section where your disease/lesion is located from blood flow.
   Note: The size and number of stent-grafts used will depend on your lesion and your doctor's assessment.
4. The delivery system is removed from the body.
5. Once the delivery system is removed, the doctor will recheck that your stent-graft is working properly.
6. The opening in the groin is closed and the procedure is complete.

** In this picture, the stent-graft is shown after it is positioned in your aorta and before delivery system is removed from your body. Please note that a thoracic aortic aneurysm (TAA) is shown in the picture. The device will be similarly positioned for the other aortic lesions.*

8. Cleveland Clinic: https://my.clevelandclinic.org/health/treatments/16962-endovascular-repair-of-thoracic-aortic-aneurysms. As of 08/28/2025.

What should I expect after the procedure?

Immediately after treatment

Immediately after recovery from the stent-graft procedure you may be required to lie flat for several hours.[9] This allows for the healing to begin in your groin. Some patients experience mild discomfort such as swelling of the groin area or fever, but this usually resolves in a few days.

Other side effects may include:

- Numbness or weakness of the legs
- Nausea
- Vomiting
- Leg pain or Throbbing
- Endoleak (blood flow into the lesion after placement of a stent-graft)
- Absence of bowel movement for 1 to 3 days

When to call your doctor

Call your doctor immediately or visit the nearest emergency room if you experience any of the following symptoms:

- Pain, numbness, or weakness in the legs, back, chest or abdomen
- Discoloration or coldness in the leg
- Dizziness
- Fainting
- Rapid heartbeat or sudden weakness
- Pain or swelling at the access site incision

If you do not seek medical attention for these symptoms, they could seriously harm you or cause death.

9. Johns Hopkins Medicine: https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/thoracic-endovascular-aortic-repair. As of 08/28/2025.

Follow-up

Your doctor will discuss your follow-up plan which may include check-ups at 1 month, 6 months, 12 months and annually thereafter for the rest of your life. Endovascular repair requires that you continue to see your doctor regularly for the rest of your life to make sure that your device is working properly. This is important as some problems do not show symptoms and you may not feel them.

During your follow-up examinations, you may routinely receive:

- X-rays
- CT scans
- Physical examinations
- Blood tests
- Ultrasound or MR system scans

Maintaining regularly scheduled follow-up examinations is necessary for your doctor to find out if your stent-graft is working properly and to monitor any changes in your condition over time.

If you do not attend follow-up examinations, your doctor will not know if:

- blood is leaking into your lesion (endoleak)
- the stent-graft has moved (migrated)
- the stent-graft has other issues

During examination, your doctor may also request evaluations to see if additional treatment may be required.

Implant card

Before leaving the hospital, you will be given a patient implant card. Along with your personal information, the following is included:

- Your implant(s) model and ID number
- Hospital name
- Doctor's name
- Nurse's name
- Date of implant
- Manufacturer's name and contact information
- MR system safety conditions

Keep this card with you at all times. Please share this information with your health care providers and make them aware you have been treated with a Relay® Pro Thoracic Stent-Graft.

It is also important to show this implant card to your doctor before you undergo imaging in an MRI machine. Your implant card contains safety information that your doctor needs in order to make sure that you are safely imaged.

Possible risks of Endovascular Repair [10]

As with any endovascular repair, repair with a thoracic stent-graft comes with potential risks. Please discuss all risks with your doctor. Major risks associated with thoracic endovascular stent-grafts include, but are not limited to:

- Endoleak – when blood continues to flow into the lesion
- Migration – movement of the stent-graft from its original position
- Device-related issues such as breaking of the sutures or metal portion of the stent- graft, fabric defects/tears or component separation
- Continued growth of the lesion
- Additional endovascular or surgical procedures
- Stent-Graft thrombus
- Aortic rupture
- Heart attack
- Stroke
- Paraplegia
- Kidney failure
- Access site incision complications
- Conversion to open surgical repair
- Death

10. Relay®Pro Thoracic Stent-Graft System IFU, 2844-8324 Revision H. Always refer to eifu.terumoaortic.com for the latest IFU.

Who should not have Endovascular Repair (Contraindications)?

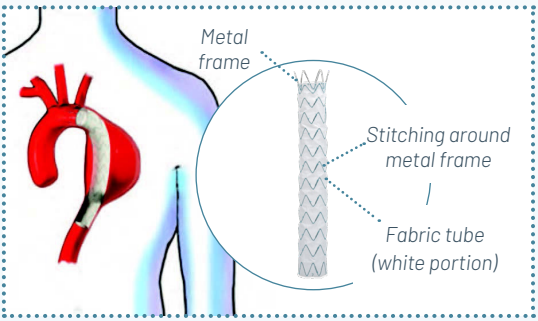
The Relay®Pro Thoracic Stent-Graft System is contraindicated for the following:

- Patients with a known allergy or intolerance to device materials as listed

Implant Component	Material
Stent	Nitinol (including nickel)
Graft	Woven polyester
Sutures	Braided polyester
Radiopaque Markers	Platinum (90%) – Iridium (10%)

- Patients with a condition that threatens to infect the graft

These are general contraindications and only your doctor can say if endovascular repair is the right treatment for you.



Important warnings and precautions

The following are general warnings and precautions. Please discuss with your doctor all warnings and precautions related to endovascular repair. Data is not available on patients who have or are:

- Connective tissue disease
- Blood clotting diseases
- Torn, ruptured, or bleeding aorta
- Pregnant
- Morbidly obese
- Systemic infection
- Less than 18 years old

Your doctor will help you decide whether it is appropriate for you to get a stent-graft if any of the following situations apply to you:

- Cannot complete regular follow-up visits and imaging examinations
- Cannot tolerate injectable dyes needed for imaging examinations
- Have bleeding disorders
- Cannot use blood thinners

Questions to ask your Doctor

- What are all of my treatment options?
- What are the advantages and disadvantages of endovascular repair compared to open surgical repair?
- What are the risks of rupture with a stent- graft?
- Will I have any side effects from the procedure?
- After the procedure, how often will I need to see my doctor?
- What follow-up tests will be needed?
- Why is it important to continue to see my doctor after I get an endovascular procedure even if I have no symptoms?
- What if the lesion 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 inside my body?
- How many endovascular repair procedures has my doctor performed?
- Is the Relay®Pro Thoracic Stent-Graft an appropriate treatment for me?

Your questions

Glossary

Anatomy
The structure of parts of the human body.

Aneurysm/Thoracic Aortic Aneurysm (TAA)
A widening or ballooning (thinning and enlarging) of a portion of the thoracic aorta caused by a weakness in the wall of the blood vessel.

Aorta
The main artery that carries blood away from the heart distributing it to the rest of the body.

Artery
A blood vessel that carries blood away from the heart.

Blunt Traumatic Aortic Injury (BTAI)
A tear in the thoracic aorta (the portion of the aorta that is within the chest and close to the heart) that is often due to severe injury to the chest.

Bowel Ischemia
Conditions that occur when blood flow to your intestines decreases.

Contraindication
A specific situation where the device may not be used because it may be harmful to the person.

Computed Tomography Scan (CT/CAT Scan)
An imaging technique that creates very precise, thin, cross-sectional views of the human body.

For patients under consideration for aortic lesion treatment, this scan will focus on the chest, abdomen and aorta. This technique often utilizes contrast (dye) and always requires limited radiation exposure.

Endoleak
The presence of a persistent flow of blood into the lesion after a stent-graft is placed.

Endovascular
Inside or within a blood vessel.

Endovascular Repair
A less invasive option for the repair of a thoracic aortic lesion as compared to open surgical repair.

It involves the use of an endovascular graft (also called a stent-graft) that excludes (seals off) the lesion, thereby creating a new path for blood to flow.

The technique uses real time X-rays allowing the doctor to see the location of the device and lesion to ensure proper device placement.

The doctor will also use a variety of other temporarily placed devices (such as guidewires) to perform the treatment. Please ask your doctor if you have questions on these other devices that will help to place the stent-graft.

Exclude the Lesion
The stent-graft is designed to exclude the lesion, meaning that when it is placed within the aorta it provides an alternate blood flow path.

Femoral Artery
The main artery within each leg between the area of the hip and knee that brings blood to the lower part of your body (limbs)

Doctors perform many endovascular procedures, including treatment of thoracic aortic aneurysms, using the femoral artery as the primary access site (location where the stent-graft enters the blood vessels).

Iliac Artery
The main artery on each side of the body that takes blood from the abdominal aorta to the femoral artery. In addition to bringing blood to the lower extremities, the iliac artery also provides blood to the pelvic regions of the body.

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

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

Magnetic Resonance Imaging (MRI)
A diagnostic technique that uses magnetic fields and radio waves to visualize structures inside the body.

Minimally-invasive
Involves one or more small incisions to perform a procedure versus one large incision.

Open Surgical Repair
A procedure in which a doctor makes a large cut in the chest or stomach to remove an aneurysm and then replace it with a fabric graft.

Paralysis
The loss of the ability to move some or all of your body.

Paraparesis
When you are partially unable to move your legs and can also refer to weakness in your hips and legs.

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

Penetrating Ulcers
A rare condition that most commonly develops in the aorta when plaque starts to penetrate the aortic wall, putting it at risk for rupture.

Plaque
A fatty material deposit on the inner lining of an arterial wall that may or may not be calcified.

Rupture
A tear in the wall of a blood vessel that allows blood to leave the vessel and flow into areas of the chest around the heart, lungs, or abdomen. This could be a potential life-threatening event.

Stent-graft/thoracic stent-graft
A fabric tube supported by a metal framework that a doctor uses to treat a lesion in the thoracic aorta. A stent-graft is also known as an endovascular graft.

Thoracic Aorta
The section of the aorta located in the chest.

Where can I get more information?

Useful sites

WebMD
www.webmd.com/heart-disease/heart-disease-aortic-aneurysm
The WebMD Medical Team works closely with a team of over 100 doctors and health experts nationwide across a broad range of specialty areas to ensure WebMD's content is up to date, accurate, and helps you live a healthier life.

National Library of Medicine
www.medlineplus.gov
The National Library of Medicine (NLM), on the campus of the National Institutes of Health in Bethesda, Maryland, is the world's largest medical library. The library collects materials in all areas of biomedicine and healthcare, as well as works on biomedical aspects of technology, the humanities, and the physical, life, and social sciences.

Society for Vascular Surgery
www.vascular.org/patients
The Society for Vascular Surgery (SVS) is a not-for-profit professional medical society, seeking to advance excellence and innovation in vascular health through education, advocacy, research and public awareness. It is the national advocate for more than 5,800 specialty-trained vascular surgeons and other professionals dedicated to the prevention and cure of vascular disease.

Aortic Trauma Foundatation
www.aortictrauma.org
The Aortic Trauma Foundation (ATF) is a non-profit professional medical society, composed primarily of vascular surgeons, cardiothoracic surgeons, trauma surgeons and radiology physicians, dedicated to providing educational resources to aid in the early detection, treatment, and survival after Traumatic Aortic Injuries.

Product Information

Terumo Aortic
www.terumoaortic.com
Terumo Aortic is a global medical device company dedicated to developing solutions for aortic vascular disease.

Food and Drug Administration
www.fda.gov
A US government agency intended to promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use.

US Department of Health and Human Services
www.hhs.gov
HHS helps families and individuals stay safe and informed about food, drugs, medical devices, and more. Information is available about medical device safety for consumers, healthcare providers and regulated industry, including device recalls.

MRI System Safety Information

MR Conditional

A person with the Relay®Pro Thoracic Stent-Graft may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Relay®Pro Thoracic Stent-Graft
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole-body transmit coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/ scan without breaks)
MR Image Artifact	The presence of the Relay®Pro Thoracic Stent-Graft may produce an image artifact at 5mm. Some manipulation of scan parameters may be needed to compensate for the artifact.

Your notes

Our goal is to work together with your doctor to find solutions that best fit your anatomy.

This leaflet gives only general information for patients.
Your medical practitioner will be able to answer any specific questions you may have on your condition.
This information was produced as a service to medicine by Terumo Aortic.

Discover our patient education hub
terumoaortic.com/patients

LinkedIn VuMedi X

View IFU at **eifu.terumoaortic.com** for more information on use, indications, contraindications and warnings/precautions. Caution: Federal Law (US) restricts this device to sale by or on the order of a physician.

Product availability subject to local regulatory approval.

PM-08408

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TERUMO AORTIC