

DRAFT

YOUR GUIDE TO
Understanding Thoracic
Aortic Aneurysms



Patient Information Guide

Updated August 5, 2021

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Helpful hints

To help you learn more about your Thoracic Aortic Aneurysm, you'll notice some words and terms you might be unfamiliar with. You can find their meanings in the Glossary section near the back of this guide.

Introduction

This educational information is provided by Terumo Aortic to help you make an informed decision about the Relay[®] Pro Thoracic Aortic Stent-Graft System to treat your Thoracic Aortic Aneurysm (TAA).

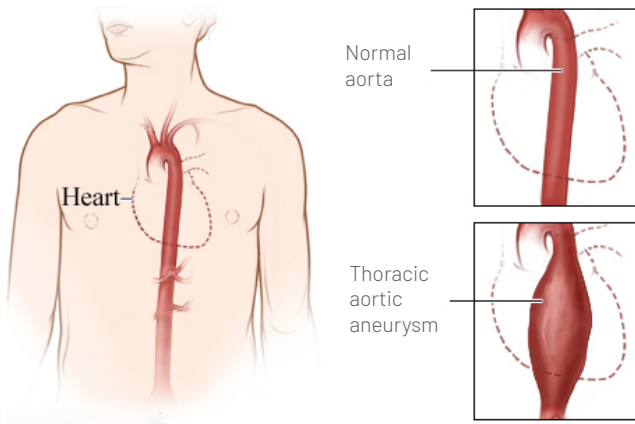
You have been told by your doctor that you have a thoracic aortic aneurysm (TAA) and discussed different types of treatments for this disease, including endovascular repair with a thoracic stent-graft. This booklet will help you understand your condition and what endovascular repair is. This booklet can be used as a reference, but only your doctor can decide what type of procedure is right for you. Please consult your doctor prior to making any decisions regarding your TAA.

While you are reading this information, it may be helpful to write down any questions you may have so you can discuss them with your doctor and healthcare team. There is a note page provided near the end of this booklet.

A glossary is provided at the end to help you understand the medical terms used in this booklet.

What is the Thoracic Aorta?

The aorta is the largest artery in the body. The thoracic aorta is the section of the aorta that sits within your chest and is the first part of the aorta that the blood enters when it leaves the heart to move throughout the body.



Thoracic Aortic Aneurysm

What is a Thoracic Aortic Aneurysm (TAA)?

A TAA is a weakened and bulging area in the upper part of the aorta. Some TAAs are associated with penetrating ulcers. TAAs can continue to get larger, and it is possible for a TAA to burst or rupture. Because the aorta supplies the body with most of the oxygenated blood from the heart, a ruptured TAA can cause life-threatening bleeding.

Most small and slow-growing TAAs do not rupture, but large, fast-growing TAAs may. Depending on the size and rate at which the TAA is growing, treatment may change from watchful waiting to elective surgery to emergency surgery. Once a TAA or penetrating ulcer is found, doctors will closely monitor the area to determine the appropriate treatment.

Prevalence and Causes

What causes TAA?¹

You have a greater chance of having a TAA if are/have:

- ▶ Age 55 years or older
- ▶ Male
- ▶ High blood pressure
- ▶ History of smoking
- ▶ Inherited diseases that cause weakening of the blood vessels, with emphasis on Marfan Syndrome
- ▶ Family history of aortic aneurysm
- ▶ Hardening of the arteries (atherosclerosis)

Symptoms

What are the symptoms of a TAA?¹

Most individuals who have a TAA do not experience any outward symptoms. For those who do have symptoms, 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 order imaging to determine whether a TAA is present.

Treatment

What are the current treatments for TAA??

Medical Management

If your TAA is small and not causing any symptoms, your doctor may watch it by taking images of your TAA for 6 months to make sure it is not getting larger. Your doctor may suggest medical or lifestyle changes to reduce the stress on the TAA, especially if it is small. This may include blood pressure medication and/or lifestyle changes such as smoking cessation.

Repair

Generally, aneurysms that are large and/or growing quickly may be at higher risk of rupture and usually require treatment. If your doctor feels that your TAA is at an increased risk of rupturing, he or she may recommend repairing it. There are two types of repair:

- ▶ Open Surgical Repair
- ▶ Endovascular Repair

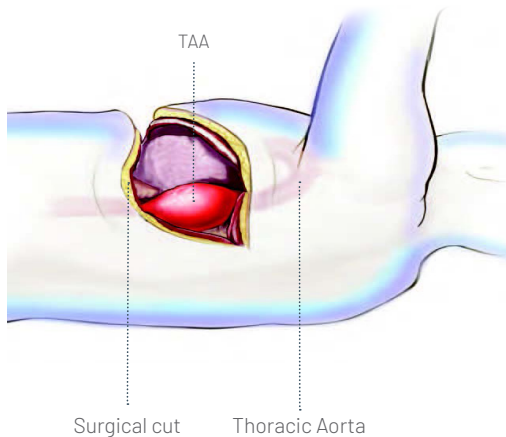
Both TAA repair options have possible complications and benefits. Patients should discuss with their doctor the best option for them.

See pages 8 to 11 for important safety information about endovascular repair.

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 and typically takes 4 to 6 hours to complete. 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 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 5.0 cm 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 0.5 cm 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 your 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 also be inserted into your bladder to drain your 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.

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

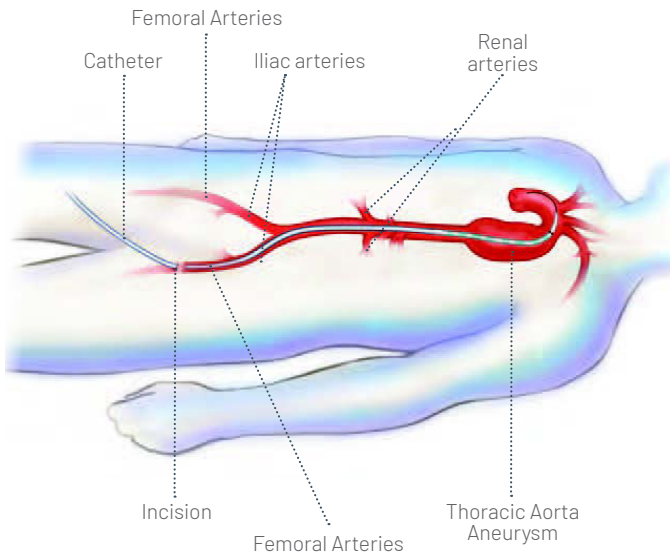
Chest infections can occur following this type of surgery, particularly in smokers, and may require treatment with antibiotics and physiotherapy. Slight discomfort and twinges of pain in your wound are normal for several weeks following surgery. Wounds sometimes become infected and these can usually 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 these 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.

Endovascular Repair

What is endovascular repair?

Endovascular repair is a minimally-invasive way to repair a TAA. During this 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 threaded 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 site of your TAA. The stent-graft (described in the next section) will open inside your aorta and become the new channel for blood flow. The stent-graft is designed to reduce the pressure on the TAA and to prevent further growth of your aneurysm, and prevent your TAA from rupturing.

Following endovascular repair, you may stay 2 or 3 days in hospital. You should speak to your doctor to understand if endovascular repair is the right treatment for you.



What is a thoracic stent-graft?

A thoracic stent-graft is a fabric tube supported by a metal frame which is placed in the diseased aorta through a small groin incision. This seals the TAA by fitting inside the diseased part of the aorta and allows blood to flow normally through your aorta.

Before undergoing endovascular repair

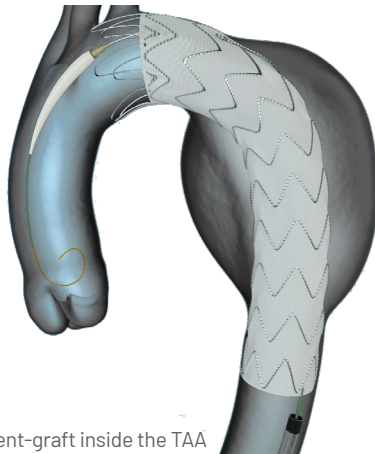
If endovascular repair is recommended, your doctor may ask you to have some further tests done before the procedure, such as CT or MR scans. These tests will allow the doctor to review your aneurysm and determine the proper size stent-graft that is needed for your procedure. The stent-graft selected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

The procedure

Typically, endovascular repair takes 2 to 3 hours to complete. You will be asleep during the procedure and will not feel any pain.

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 your TAA. During the insertion, 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 11 regarding the use of dyes).
3. Once the delivery system reaches the correct location, the stent-graft is deployed (expanded).
4. When your stent-graft is released, it seals the aorta above and below your TAA.
Note: The size and number of stent-grafts used will depend on your anatomy and your doctor's assessment.
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 just before release.



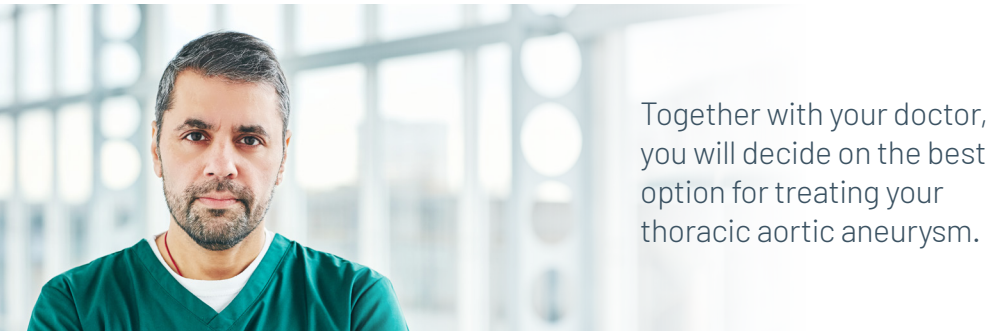
The stent-graft inside the TAA

After the procedure

After the endovascular repair, you will go to a recovery room where you will lie down for a few hours. This will allow the cut in your groin to start healing. You may have some pain or discomfort for up to two days and will probably stay in hospital 2 to 7 days². Your doctor will provide you with instructions on how to care for yourself after this procedure.

Possible benefits of endovascular repair³

TAA repair may reduce the risk of rupture. As with any procedure, there are benefits and risks with either approach. Using endovascular repair to treat your TAA may have additional benefits. Please discuss the possible benefits and risks with your doctor as they apply to your specific case.



Together with your doctor, you will decide on the best option for treating your thoracic aortic aneurysm.

Possible risks of endovascular repair

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 aneurysm
- ▶ 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 aneurysm
- ▶ Aneurysm rupture
- ▶ Additional endovascular or surgical procedures
- ▶ Heart attack
- ▶ Stroke
- ▶ Kidney failure
- ▶ Access site incision complications
- ▶ Conversion to open surgical repair
- ▶ Death

Who should not have endovascular repair (Contraindications)?

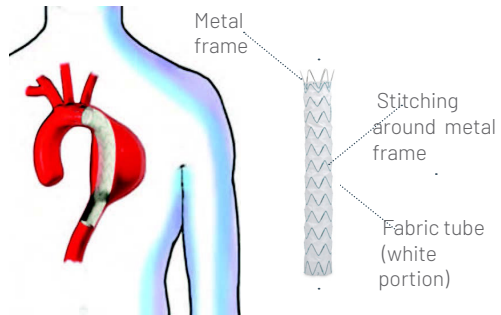
The Relay[®]Pro Thoracic Stent-Graft System is contraindicated for the following:

- ▶ Patients with a known allergy or intolerance to device materials 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 a connective tissue disease
- ▶ Have a torn, ruptured, or bleeding aorta
- ▶ Have blood clotting diseases
- ▶ Have a systemic infection
- ▶ Are pregnant
- ▶ Are less than 18 years old
- ▶ Are morbidly obese

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

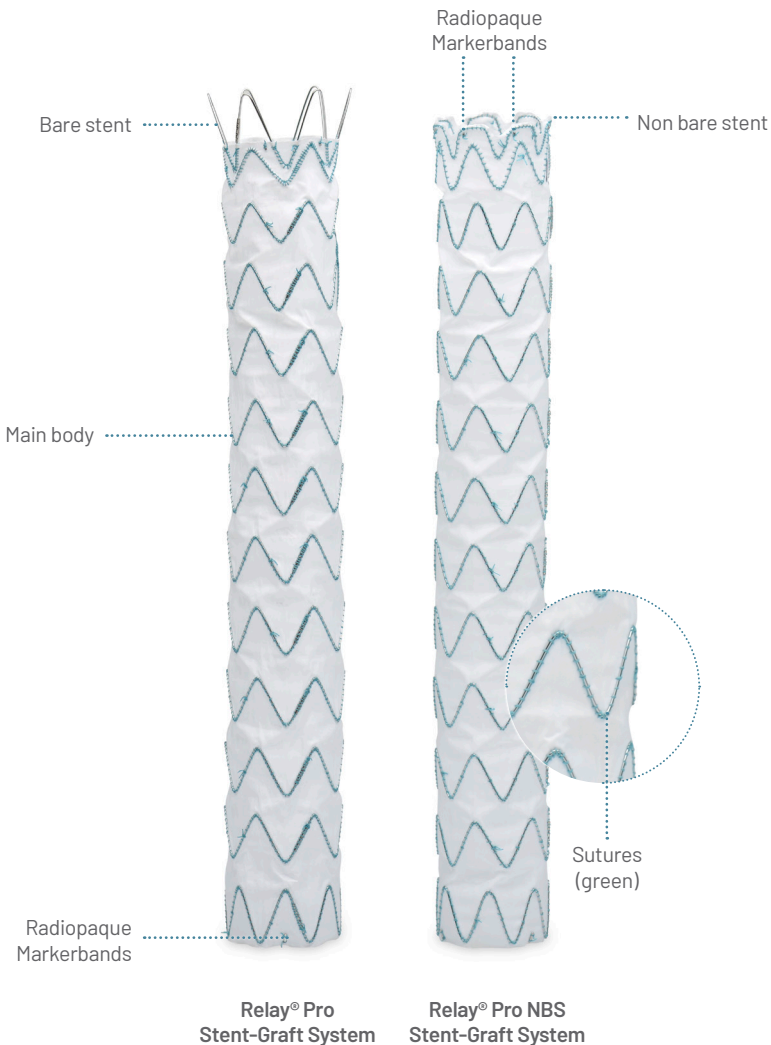
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The Terumo Aortic Difference

Thoracic Stent-Grafting 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 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) thus preventing the need for a major surgical incision.

The Relay[®]Pro Stent-Graft is available in two configurations: a bare metal stent and covered stent (NBS). Once you and your doctor agree to proceed, your doctor will determine the exact size and configuration of the device to implant.



Relay[®] Pro Clinical Study Summary

The Relay[®]Pro Study was a 110 subject study conducted in the United States and Japan to assess the safety and effectiveness of the Relay[®]Pro Thoracic Stent-Graft System.

Patients enrolled in this study will be followed for five years. Currently one-year and two-year data is available on 93 and 48 subjects, respectively. Safety success was defined as absence of Major Adverse Events through 30 days. Of the 110 subjects evaluated at 30 days, 103 (93.6%) had a successful safety outcome. Seven patients experienced 7 MAEs through 30 days, specifically 2 strokes, 1 renal failure, 2 paralysis events, and 2 procedural blood loss > 1,000 cc requiring transfusion. Effectiveness success was defined as successful aneurysm treatment at one year. The treatment success at one year was 89.2% (74 out of 83 subjects).

Please talk to your doctor to better understand how the Relay[®]Pro Thoracic Stent-Graft System compares to other endovascular devices.

Of the subjects evaluated at one year, 100% had the device successfully delivered and expanded at the TAA.

One year of clinical study follow-up has shown the following:

- ▶ 4 subjects experienced leakage of blood around the stent-graft (Type I endoleak)
- ▶ 7 subjects had additional procedures related to the treated disease or for reasons related to the stent-graft
- ▶ 2 subject deaths related to the treated disease have occurred (>30 days after the treatment)
- ▶ 1 subject had an increase in size of their aneurysm after the treatment
- ▶ No subjects in the study have had a rupture/burst of the aneurysm
- ▶ No subjects in the study experienced unintended device movement, breaks in their device or the need to replace the device

In longer term data (after 1 year), the following events/observations have been reported:

- ▶ 5 subjects had an increase in size of their aneurysm
- ▶ No subject deaths related to the device or procedure
- ▶ 2 subjects experienced leakage of blood around the stent-graft (Type I endoleak)
- ▶ 2 subjects had additional procedures related to the treated disease or for reasons related to the stent-graft
- ▶ No subjects have had a rupture/burst of the aneurysm or death related to the treated disease
- ▶ No subjects experienced unintended device movement, breaks in their device, or the need to replace the device

Your risk of having these events may be higher or lower.

In summary, the totality of evidence provides a reasonable assurance of safety and effectiveness and an appropriate benefit-risk balance for use of the Relay[®]Pro Stent-Graft System, in patients with aneurysms of the descending thoracic aorta or penetrating ulcers.

You should discuss the likely risk of these events throughout your life with your doctor and discuss how the risk and benefits of the Relay[®]Pro Thoracic Stent-Graft System may apply to you.

Your recovery

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 4 to 6 hours. 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 of the legs
- ▶ Nausea
- ▶ Vomiting
- ▶ Leg pain or throbbing
- ▶ Lack of appetite
- ▶ Endoleak (blood flow into the Thoracic aortic aneurysm 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
- ▶ 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 your death.

Follow up

Your doctor will discuss your follow-up plan, which will include check-ups at one month, six months, twelve months and annually thereafter. 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
- ▶ Blood tests
- ▶ CT Scans
- ▶ Ultrasound or MR System scans
- ▶ Physical examinations

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 go, your doctor will not know if:

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

During examination, if the size of the aneurysm shows an increase and/or it is identified that blood flow has returned to the aneurysm, 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
- ▶ Date of implant
- ▶ Hospital name
- ▶ Manufacturer's name and contact information
- ▶ Doctor's name
- ▶ MR System safety conditions
- ▶ Nurse's name

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.

RELAY[®] PRO Have the Relay[®] Pro Thoracic Stent-Graft implanted in my abdominal aorta

Model / lot numbers	Date of implant

Name: _____
 Address: _____
 Phone #: _____
 Date of birth: _____
 Doctor: _____
 Hospital / Clinic: _____
 Nurse: _____
 Phone #: _____

Medtronic AVEA Thoracic Stent-Graft
 11100 North Central Expressway, Jacksonville, FL 32256
 1-800-368-7000
 www.medtronic.com

Questions to ask your doctor

- ▶ What are all of my options for treating my TAA?
- ▶ What are the advantages and disadvantages of endovascular repair of a TAA compared to open surgical repair?
- ▶ What are the risks of rupture of my TAA 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?
- ▶ What if the TAA 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 my TAA?

Your questions

Where can I get more information?

www.webmd.com/heart-disease/tc/aortic-aneurysm-overview

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

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 health care, as well as works on biomedical aspects of technology, the humanities, and the physical, life, and social sciences.

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. SVS 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.

Product Information

Terumo Aortic

www.terumoaortic.com

Terumo Aortic is a global medical device company dedicated to developing solutions for aortic and peripheral 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.

Glossary

Anatomy

The study of the parts of the body.

Aneurysm/Thoracic Aortic Aneurysm (TAA)

A widening or ballooning 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.

Contraindication

A medical reason to withhold a certain medical treatment.

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 TAA treatment, this scan will focus on the abdomen and aorta. This technique often utilises contrast (dye) and always requires limited radiation exposure.

Endoleak

The presence of a persistent flow of blood into the aneurysm sac 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 Aneurysm as compared to open surgery. It involves the use of an endovascular graft that excludes (seals off) an aneurysm of a diseased aorta, thereby creating a new path for blood to flow.

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

The doctor will also use a variety of other temporarily placed devices (such as guidewires) to perform the treatment.

Exclude

To seal.

Femoral Artery

The main artery within each leg between the area of the hip and knee that brings blood to the lower extremities.

Doctors perform many endovascular procedures, including treatment of Thoracic Aortic Aneurysms, using the femoral artery as the primary access site.

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.

Iliac arteries are often included in the treatment of Abdominal Aortic Aneurysms.

Imaging

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

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 in the abdomen.

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.

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

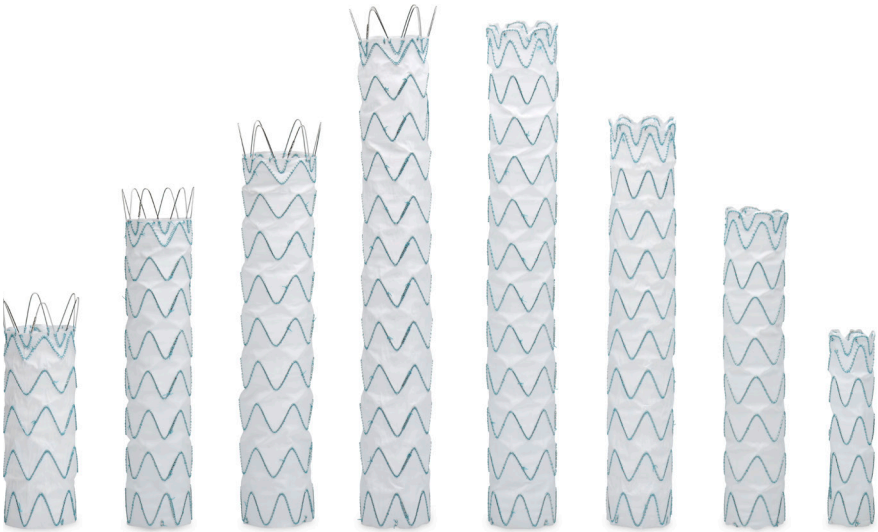
A tear in the wall of an artery that allows blood to exit the blood vessel and could be a potential life-threatening event. The common term for this is hemorrhage.

Stent-graft/Thoracic stent-graft

A fabric tube supported by a metal framework that a doctor uses to treat a TAA.

Thoracic Aorta

The section of the aorta located in the chest.



References

1. EMedicineHealth Online 2020.
2. Harris, C. et al. (2016) 'Thoracic aortic aneurysm', *Ann Cardio thorac Surg*, Jul;5(4), p. 407.
3. Society for Vascular Surgery: <https://vascular.org/patient-resources/vascular-conditions/thoracic-aortic-aneurysm> Retrieved 7/22/2019.

Your notes

Indications For Use

The Relay® Pro Thoracic Stent-Graft System is indicated for the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers in the descending thoracic aorta in patients having appropriate anatomy, including:

- ▶ Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- ▶ Non-aneurysmal aortic neck diameter in the range of 20 – 42mm;
- ▶ Non-aneurysmal proximal aortic neck lengths of:
 - 15mm for the 24 – 28mm device diameters (**Bare Stent Configuration**)
 - 20mm for the 30 – 38mm device diameters (**Bare Stent Configuration**)
 - 25mm for the 40 – 46mm device diameters (**Bare Stent Configuration**)
 - 25mm for the 24 – 38mm device diameters (**Non-Bare Stent Configuration**)
 - 30mm for the 40 – 46mm device diameters (**Non-Bare Stent Configuration**)
- ▶ Non-aneurysmal distal aortic neck lengths of:
 - 25mm for 24 – 38mm device diameters
 - 30mm for 40 – 46mm device diameters

Contraindications

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

- ▶ Patients with a known allergy or intolerance to device materials 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

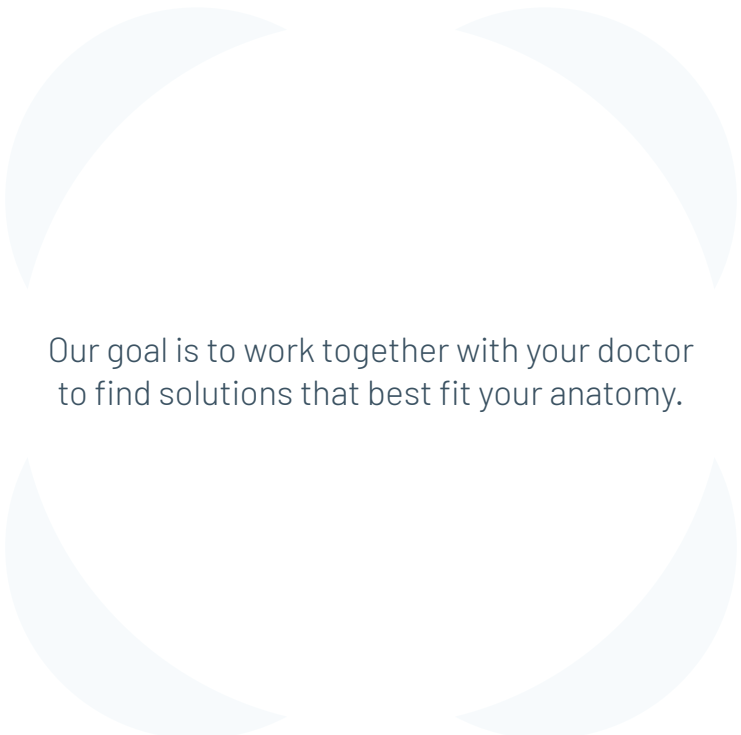
MRI System Safety Information

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 (B0)	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.

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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.

terumoortic.com

Discover solutions for every segment of the aorta

Visit our website for more information on use, indications, contraindications, warnings/
precautions and availability within your market.

Product availability subject to local regulatory approval. Caution: Federal Law (US) restricts this
device to sale by or on the order of a physician.

 Manufactured by: Bolton Medical Inc, 799 International Parkway, Sunrise, Florida 33325, USA

USA_0163-A Aug21 • PM-04962

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