TERUMO AORTIC

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Patient Information Guide

Thoraflex™ Hybrid

Your guide to understanding Thoracic Aneurysms and Dissections.

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 aneurysm.

Introduction

This educational information is provided by Terumo Aortic to help you make an informed decision about the Thoraflex™ Hybrid Frozen Elephant Trunk (FET) device to treat your thoracic aortic aneurysm or dissection.

Since gaining initial European approval in 2012, the Thoraflex™ Hybrid device has been implanted in over **25,000 patients** in **65+ countries.** *

The Thoraflex™ Hybrid device is manufactured by Terumo Aortic, a global medical device company focused on addressing every patient's aortic needs. Our goal is to work together with your doctor to find solutions that best fit your anatomy.

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. Only your doctor can decide if you are a good candidate for a Thoraflex™ Hybrid device.

What is an aorta?

The aorta is an artery and the largest blood vessel in the body. It carries oxygen-rich blood away from the heart to the body.

Doctors refer to the upper part of the aorta as the thoracic aorta and the lower part as the abdominal (related to the belly) aorta. (Figure 1)

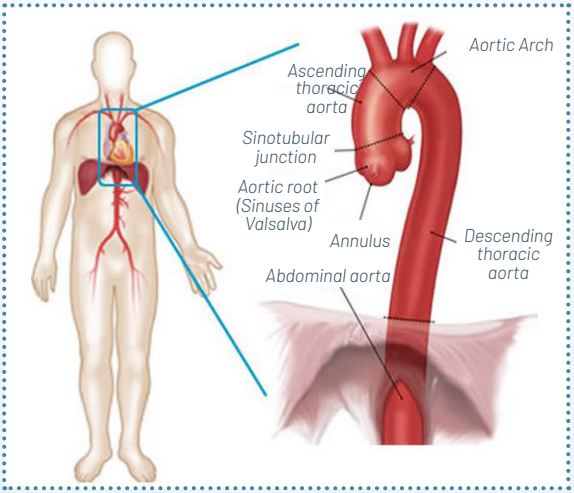

Figure 1 - Diagram of the Aorta

* Based on number of devices sold

What is a Thoracic Aortic Aneurysm?

An aneurysm is a balloon-like bulge in a blood vessel.

It is caused when a section of the blood vessel wall becomes weakened due to trauma or disease caused by; smoking, diet, family history or other reasons. Over time the pressure caused by the blood flowing through the blood vessel expands the weakened section of the wall causing it to bulge outward. (Figure 2)

When an aneurysm occurs in the upper part of the aorta, it is called a thoracic aortic aneurysm.

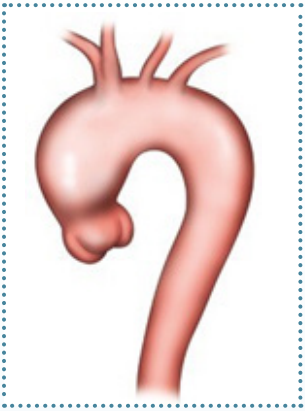

Figure 2 –
Example of an Aortic Aneurysm

Are there risks associated with a thoracic aneurysm?

If an aneurysm expands too much, it can burst or rupture.

Early diagnosis and medical treatment may reduce the risk of an aneurysm expanding too far and causing rupture. If it does rupture then there is a high risk of death.

What are the symptoms associated with a thoracic aortic aneurysm?

As a thoracic aortic aneurysm grows, some people may notice:

- Tenderness or pain in the chest
- Back pain
- Hoarseness
- Cough
- Shortness of breath

www.mayoclinic.org/diseases-conditions/thoracic-aortic-aneurysm/symptoms-causes/syc-20350188

What is a Thoracic Aortic Dissection?

A dissection is a tear in the lining of the aorta, that allows blood to flow between the 3 layers of the aortic wall (Figure 3). This can weaken the wall and potentially lead to an aortic rupture. A dissection can be caused by high blood pressure over a long period of time, if an aortic aneurysm already exists as this weakens the wall, genetic factors (occurs in families) or trauma i.e., a car crash.

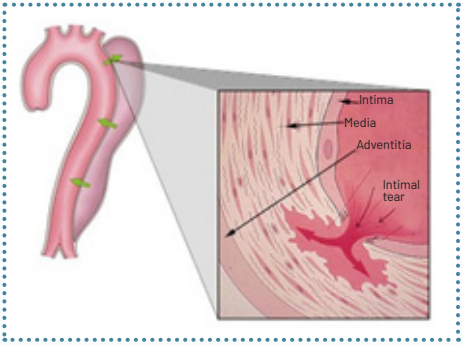

Figure 3 – An Aortic Dissection

Are there risks associated with a thoracic aortic dissection?

Yes. A dissection can weaken the aortic wall and potentially lead to a rupture. If it does rupture, then there is a high risk of death.

Even without a rupture, dissection can 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).

What are the symptoms of a thoracic aortic dissection?

- Sudden severe chest or upper back pain, often described as a tearing, ripping or shearing sensation that radiates to the neck or down the back
- Sudden severe abdominal pain
- Loss of consciousness
- Shortness of breath
- Sudden difficulty speaking, loss of vision, weakness or paralysis of one side of your body, like those of a stroke
- Weak pulse in one arm or thigh compared with the other
- Leg pain
- Difficulty walking
- Leg paralysis

www.mayoclinic.org/diseases-conditions/aortic-dissection/symptoms-causes/syc-20369496

What are my treatment options?

Your doctor, in consultation with yourself, will determine your best method of treatment based on a number of factors such as your age, current state of health, the size of your aneurysm or dissection and how fast it is progressing. Small aneurysms or dissections that are found early and not causing symptoms may not need immediate treatment or might be treated with medication.

Large or fast-growing aneurysms or dissections will likely need to be repaired to prevent a rupture. One method for repair is a traditional open surgical technique. The extent of aorta that needs to be treated varies patient to patient.

During the procedure, the surgeon makes a large incision (cut) in the chest while the patient is under general anesthesia (a method used to eliminate pain and keep the patient in a controlled state of unconsciousness) and places the patient on a heart-lung machine. This temporarily takes over the function of the heart and lungs during surgery. The surgeon opens the aneurysm and sews a graft to the healthy part of the aorta. The graft is a tube-like device typically made of a woven polyester material (Figure 4). When a second stage is needed to treat disease that extends further toward the abdomen, this is conducted by either open surgery with a surgical graft (Figure 5) or by the addition of stent(s) (Figure 6). In both cases this creates a new channel for blood to flow through.

Figure 4

Figure 5

Figure 6

As with all surgical and endovascular procedures, there are associated risks. Your doctor will discuss the risks and benefits with you. Only your doctor in consultation with yourself can decide the most appropriate course of treatment.

About the Thoraflex™ Hybrid Device

What is the Thoraflex™ Hybrid device?

It is implanted and replaces the aorta using an open surgical technique.

The Thoraflex™ Hybrid device has two main parts, a traditional graft section which is connected to a stented section. The stented section is compacted inside a sheath before it is deployed within the aorta (Figure 7).

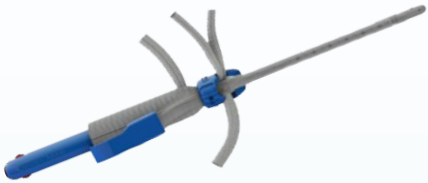

Figure 7 - Compacted stent inside a sheath

The graft section replaces the diseased aortic arch and associated blood vessels which are reattached. The stented section has metal rings that expand when deployed
(Figure 8).

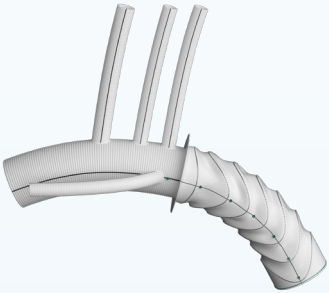

Figure 8 - Graft and expanded deployed stent

The Thoraflex™ Hybrid device comes with a deployment system which keeps the stented section compacted, allowing the surgeon to place this part down inside the aorta during surgery. When deployed the stent section expands to create a channel within the aorta for blood to flow through and supply the body. It also creates a seal inside the aorta preventing blood flowing back into the diseased part of the aorta (Figure 9). In some cases, a physician may decide to complete the sealing as part of a second stage procedure.

How long will the surgery and hospital stay last?

This type of surgery usually takes at least six hours, and you will have to stay in the intensive care unit after surgery. You can expect to stay in the hospital for several days, but maybe longer. The length of surgery and hospital care thereafter will depend on your medical condition, any additional treatment you require, and standard medical care and procedures at the hospital. Your doctor will discuss this with you in detail.

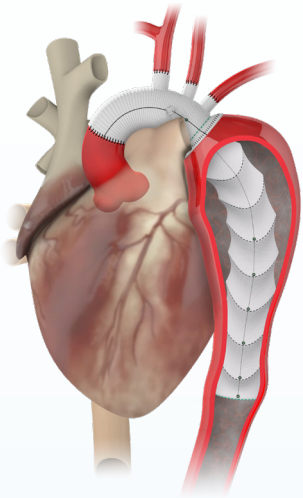

Figure 9 - Implanted Thoraflex™ Hybrid device

Are there risks associated with the Thoraflex™ Hybrid device?

As with any surgery, the FET procedure comes with potential risks. Please discuss all risks with your doctor. The risks associated with using Thoraflex™ Hybrid largely coincide with those of all aortic arch surgery but also include those associated with stented grafts.
These risks include, but are not limited to:

- Endoleaks – blood flow continues to flow into the diseased part of the aorta
- Device - related issues such as breaking of sutures or metal parts, fabric defects/tears or component separation
- Continued disease progression
- Rupture
- Additional endovascular or surgical procedures
- Heart attack
- Stroke
- Kidney failure
- Spinal cord injury
- New dissection
- Death

Your doctor will discuss the risks and benefits with you.

Are there benefits associated with the Thoraflex™ Hybrid device?

There are a number of potential benefits with the Thoraflex™ Hybrid device. Potential benefits include: Thoraflex™ Hybrid reduces the risk of aortic rupture and aortic related mortality in patients diagnosed with a damaged or diseased aortic arch and descending aorta in cases such as aneurysm and dissection; it allows the possibility of treatment in a single-stage procedure; it stabilises the thoracic aorta and facilitates subsequent repairs if a second-stage is necessary.

Thoraflex™ Hybrid Clinical Study Summary

Thoraflex™ Hybrid was assessed for safety and effectiveness in a 65-subject study conducted in the United States.

Patients enrolled in this study were followed for three years.

The device was evaluated based on the percentage of patients without major adverse events in the year after implant. Major adverse events are permanent stroke, permanent paraplegia/paraparesis, unplanned aortic reoperation, and death: 15 out of 65 subjects in the study experienced these events. That means that the percentage of patients without these events was 77%.

Although the types of risks are similar to open surgical procedures, please talk to your doctor to better understand how Thoraflex™ Hybrid compares to the other types of treatment.

Seven patients (11%) died in the year following treatment in this study, there were five disabling strokes (8%) in the year after the operation, three patients (5%) required reoperation and three patients (5%) experienced permanent paraplegia or paraparesis.

Your risk of having these events may be higher or lower. You should discuss the likely risk of these events throughout your life with your doctor and discuss how the risks and benefits of Thoraflex™ Hybrid may apply to you.

Your recovery

What happens after the procedure?

Before you are released from hospital, your doctor or nurse will discuss your follow-up care and ensure all your concerns are addressed. A series of follow-up appointments will be organised so you can meet with your surgeon and local doctor.

Will I need more surgery later?

Some patients who undergo FET subsequently require further treatment lower in the aorta (the descending thoracic aorta or thoracoabdominal aorta) because their disease continues to progress beyond the initial area of treatment or is already extensive and staged treatment is planned to reduce the risk of spinal cord injury. This is called distal extension and is typically performed using endovascular repair.

The Relay®Pro NBS stent-graft is approved for distal extension of Thoraflex™ Hybrid and can be implanted via an incision in the groin.

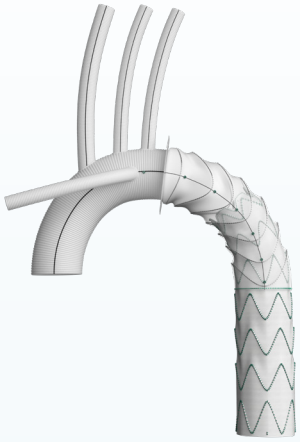

Figure 10 - Thoraflex™ Hybrid Extended with a Relay®Pro NBS Stent-Graft

If further treatment with a Relay®Pro NBS device is required, a patient guide that presents of overview of that device will be provided to you.

Post-operative care

Follow-up

Depending on the type of **intervention, localisation and type of aortic disease**, different follow-up appointments are required.

The first year of post-operative care serves to monitor the outcome of the operation and the review of complications that can arise from the surgery. Thereafter the follow-up serves to identify new aortic changes.

After surgery

A CT angiography is the best imaging method to examine the aortic arch and thoracoabdominal aorta.

If there is a reason why you should not have a CT then Magnetic Resonance Imaging (MRI) can be used to carry out the follow-up examination.

The first follow-up examination usually takes place before you leave the hospital. Further imaging is recommended **after 6 months** and following that, annually.

Your care team will provide more details on when you can return to normal activities.

In addition, if you need to take blood thinners (eg. warfarin) some professions and hobbies should be stopped.

The breastbone should heal after **about three months** and you can again take up exercise. Take care to exert yourself steadily. Endurance exercise (walking, bicycle riding, jogging, swimming) and moderate strength training are suitable.

Driving

You should **refrain** from **driving a car for the first six weeks** because glancing over your shoulder and turning the steering wheel will put pressure on the chest that can cause pain.

As a passenger, take time getting in and out of a car to protect your chest. Using a seat belt is still mandatory after an operation.

Medication

Next to surgery, medication plays an important role. Risk factors like too high blood sugar or high blood pressure must be addressed as part of your treatment.

After an aortic intervention, you should take a platelet aggregation inhibitor, like **aspirin 100mg (once daily) for the rest of your life.** An exception is when warfarin is necessary for blood thinning.

Travel and wellness

Long trips can be taken **three months after surgery** at the earliest.

Take an **adequate supply of medicine** as well as a copy of your **medical report.** Also, use **caution when carrying** heavy luggage.
Flying after being discharged from the hospital is possible.

Sauna visits should first be enjoyed no earlier than **three months after** the operation.

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
- Manufacturers name and contact information
- MRI safety conditions

Keep this card with you at all times.
Please share this information with your healthcare providers and make them aware you have been treated with a Thoraflex™ Hybrid device.

Possible questions to ask your doctor

- Are you familiar and comfortable performing a Frozen Elephant Trunk Technique procedure and how many procedures have you conducted?
- What are my best options for treating my aneurysm or dissection?
- Am I a candidate for this type of open surgery or would more conventional open or even endovascular surgery be better?
- What are the benefits and risks of performing a Frozen Elephant Trunk, more conventional surgery or endovascular surgery?
- Could an endovascular approach be an alternative option for me?
- What should I expect after my procedure and how often do I need to follow up with you or my family doctor?
- How critical is it for me to continue the prescribed treatment plan?
- How long will the device be implanted in my body?
- What should I expect if my aneurysm or dissection disease is not resolved?
- How much of the cost of my procedure will be covered by my health insurance?
- Will I have to change my lifestyle activities after the procedure? If so, for how long?
- Where can I get more information?

VISION & MISSION

Committed to Aortic Care

Together with our customers, we strive to create effective management of aortic disease and drive the evolution of our cardiovascular solutions for our patients.

Where can I get more information?

Aneurysms and Dissection

The Aortic Dissection Charitable Trust.

aorticdissectioncharitabletrust.org/

The Aortic Dissection Charitable Trust are a UK & Ireland charity uniting patients, families and the medical community in a shared goal of improving diagnosis, increasing survival and reducing disability due to aortic dissection.

Aortic Dissection Awareness

aorticdissectionawareness.org/about

Aortic Dissection Awareness's mission is to save lives by improving diagnosis of Aortic Dissection and ensuring that every family affected by this disease has access to the best available information, care and support. They measure their success by the increasing number of aortic dissection survivors, relatives and healthcare professionals joining the organisation and by the changes they see happening in the aortic dissection healthcare landscape.

The Aortic Centre Trust

www.aorticcentretrust.co.uk/

Diseases of the aorta cause 5,000 deaths per year in the UK. That compares with 11,000 deaths from prostate cancer and a similar number of deaths from breast cancer. The Aortic Centre Trust want people who are at risk to be aware of the risk and those who have aortic problems to get the treatment that they need before it becomes an emergency. The Trust seeks to help with research into better treatment and prevention.

European Heart Network (EHN)

ehnheart.org/

EHN is a Brussels-based alliance of foundations and associations dedicated to preventing and reducing cardiovascular diseases throughout Europe. Many national patient organisations supporting people with cardiovascular diseases, including aortic conditions, are members of EHN.

VASCERN (European Reference Network on Rare Multisystemic Vascular Diseases)

vascern.eu/network/patient-representation/heritable-thoracic-aortic-diseases-htad-epag/

VASCERN is a European Reference Network (ERN) that addresses rare vascular diseases, including Heritable Thoracic Aortic Diseases (HTAD). It works to provide highly specialised care and guidance across Europe. It has a dedicated Heritable Thoracic Aortic Diseases European Patient Advocacy Group (ePAG) to ensure the patient voice is included in care and research.

Interventional Therapy

European Association for Cardio-Thoracic Surgery

www.eacts.org/about/our-structure/domains/aortic-disease/

EACTS is the leading membership organisation in Europe devoted to cardiothoracic surgery. Founded in 1986, EACTS supports the global cardiothoracic community with first-class education, cutting-edge learning opportunities, world-renowned journals and publications by championing pioneering research.

European Society of Vascular Surgery

esvs.org/about-esvs/the-society/

The European Society for Vascular Surgery® (ESVS) is a not-for-profit professional medical society, seeking to advance excellence and innovation in vascular health through education, advocacy, research and public awareness.

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.

The Medicines and Healthcare products Regulatory Agency

www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

The MHRA is a UK government agency that regulates medicines, medical devices and blood components for transfusion.

Health Canada

www.canada.ca/en/health-canada.html

Health Canada is the department of the Government of Canada responsible for national health policy and for helping Canadians maintain and improve their health. While the provinces and territories are primarily responsible for delivering most healthcare services, Health Canada plays a key role in administering the Canada Health Act and regulating products and activities that affect public health and safety nationwide.

Glossary

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

Aneurysm
Occurs when part of an artery wall weakens, allowing it to balloon out or widen abnormally - resulting in the weakening of the vessel wall. Aneurysms can occur anywhere. An Aortic Aneurysm occurs in the major artery from the heart.

Angiography/Angiogram
Angiography is a method whereby dye is injected into the bloodstream to view blood flow through the blood vessels under X-Ray. Angiography utilises contrast (dye) and small doses of radiation. The resulting images are angiograms.

Contrast (dye)
A liquid injected into the vascular system that allows a doctor to see a patient's blood flow when the patient is exposed to X-Ray.

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

Dissection
A serious condition in which the inner layer of the aorta, the large blood vessel branching off the heart, tears. Blood surges through the tear, causing the inner and middle layers of the aorta to separate (dissect).

dSINE
Pronounced "dee-sign". Distal stent-graft induced new entry is a technical term to describe damage to the aorta caused by the placement of a stent-graft. The metal may tear the vessel wall because of, for example, friction (rubbing) or oversizing of the device.

Endoleak
Unintended blood flow into the Aortic Aneurysm after placement of an endovascular graft.

Endovascular Repair
A less invasive option for the repair of an 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.

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

Malperfusion
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.

Paraplegia
Inability to voluntarily move the lower parts of the body.

Paraparesis
Partial paralysis (limited ability to complete voluntary movement) in the lower body due to disrupted nerve signals from the brain to the muscles.

Platelet Aggregation Inhibitor
A member of a class of pharmaceuticals that decrease platelet aggregation and inhibit thrombus formation.

Spinal cord injury (or ischemia)
The spinal column sends and receives signals from the brain to and from the rest of the body. Damage can occur to these nerve roots in the spinal column that can result in temporary or permanent changes in feeling, movement, strength, and body functions. The spinal cord gets blood from several sources, among them small arteries that come directly from the thoracic aorta. SCI can occur after interventions of the thoracic aorta because these small vessels are blocked by the replacement graft.

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.

Synthetic Graft
A graft manufactured to replace the vessel. They are created by using man-made materials such as polyester.

X-Ray
A form of energy allowing medical providers to see anatomical structures in the body, as well as the stent-graft components in your body.

Indications For Use

Thoraflex™ Hybrid is indicated to treat a damaged or diseased aortic arch and descending aorta in cases such as aneurysm and dissection, with or without involvement of the ascending aorta.

Contraindications for Use

This device should not be implanted in patients who exhibit:

- Known allergy or intolerance to device materials (polyester, Nitinol, tantalum or materials of bovine origin.)
- Active infection

Magnetic Resonance Imaging (MRI) Safety

Conditions for MR Safety

A person with the Thoraflex™ Hybrid alone or in combination with the Relay®Pro NBS Thoracic Stent Graft System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

MR Conditional

Device Name	Thoraflex™ Hybrid and Relay®Pro NBS Thoracic Stent Graft System
Static Magnetic Field Strength (Bo)	1.5T or 3.0T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarised (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
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 and Wait Time	15 continuous minutes of scan duration with 5 minutes wait time before additional scanning.
MR Image Artifact	In non-clinical testing, the image artifact caused by the device extends approximately 6mm from the Thoraflex™ Hybrid and Relay®Pro NBS Thoracic Stent Graft System when imaged with a gradient echo pulse sequence and a 3.0 T MR system.

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.

Product availability subject to local regulatory approval.

PM-10159

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TERUMO AORTIC