YOUR GUIDE TO

Thoraflex™ Hybrid

Patient Information Leaflet

thoraflex™ hybrid

TERUMO Aortic

Table of Contents

Device Manufacturer: 4

Device Name and Models: 4

Models of the Device: 4

Device Description: 5

Intended Purpose of the Device: 6

Any Special Operating Instructions for Use of the Device: 8

Intended Performance of the Device and Any Undesirable Side Effects That Could Be Caused by Use of the Device: 9

Warnings and Precautions: 10

Post-surgery Follow-Up, Monitoring, Examination and Maintenance: 11

Medicinal Substances and Manufacturing Residuals: 11

Serious Incidents: 11

Device Manufacturer:

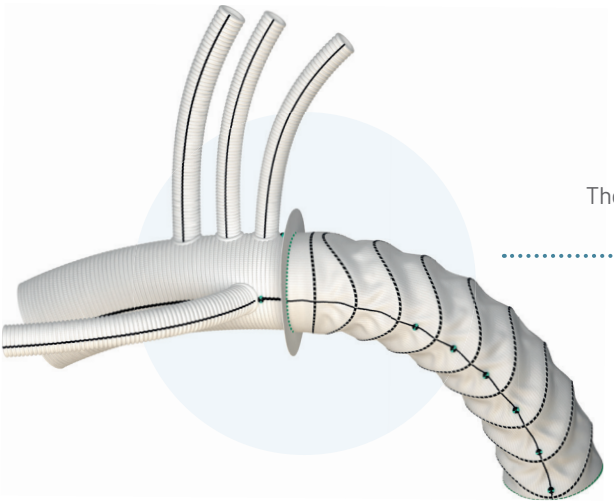
Vascutek Ltd Newmains Avenue, Inchinnan, Renfrewshire, PA4 9RR, United Kingdom

Device Name and Models:

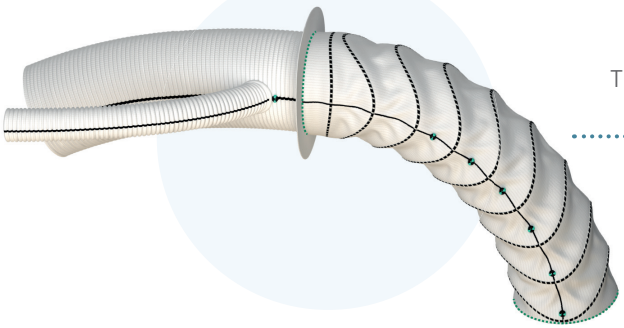
Thoraflex™ Hybrid

Models of the Device:

- Thoraflex Hybrid Ante-Flo
- Thoraflex Hybrid Plexus



Thoraflex Hybrid
Plexus



Thoraflex Hybrid
Ante-Flo

Device Description:

Thoraflex Hybrid is made up of a device and a delivery system.

The device is a fabric tube, known as a graft, made of woven polyester fabric. The graft has two sections, a stented (contains metal rings) and non-stented (does not contain metal rings) section. The entire graft is coated with gelatin to help stop blood leaking through.

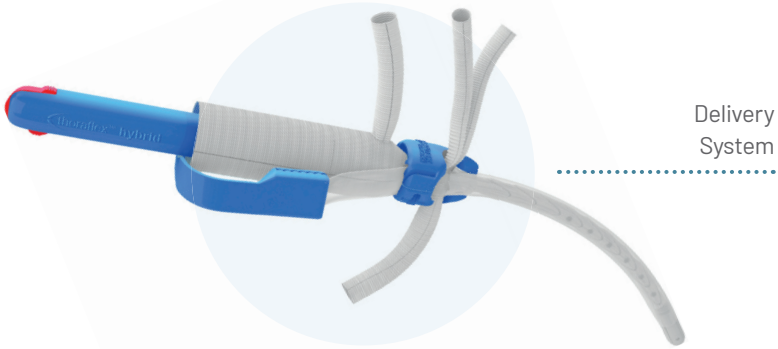
The non-stented section is available in two designs: Plexus and Ante-Flo.

The Plexus has 4 branches and the Ante-Flo only has one branch. The clinician chooses which design is most suitable for each patient.

The non-stented section also has a 'collar' made of polyester fabric. The collar helps the clinician to easily sew the device in place.

The stented section of the graft has stents (metal rings) made of nitinol. These stents keep the device open and in place when implanted. The stents are attached to the graft with polyester sutures (stitches). The stented section also has metal markers made from tantalum. These markers allow the device to be seen under x-ray.

The delivery system is used to insert the device into the body. Once the stented section is inserted in the correct position the delivery system is removed.



Intended Purpose of the Device

(and the kind of patient on whom the device is intended to be used):

The aorta is a blood vessel that carries blood from the heart to the rest of the body. It travels from the heart to the groin.

The part that travels from the heart and through the chest is the "thoracic aorta". This has three parts. The part that comes up and out of the heart is the "ascending aorta". The next part is the "aortic arch" which curves down towards the toes. Finally, the "descending aorta" travels down the body through the chest.

Thoraflex Hybrid treats people who have damage in this part of their body. Once in place, blood flows through the device instead of the diseased part of the aorta. This can prevent the disease from getting worse and the vessel bursting, which could be fatal.

There are two main types of diseases that can happen in this part of the body.

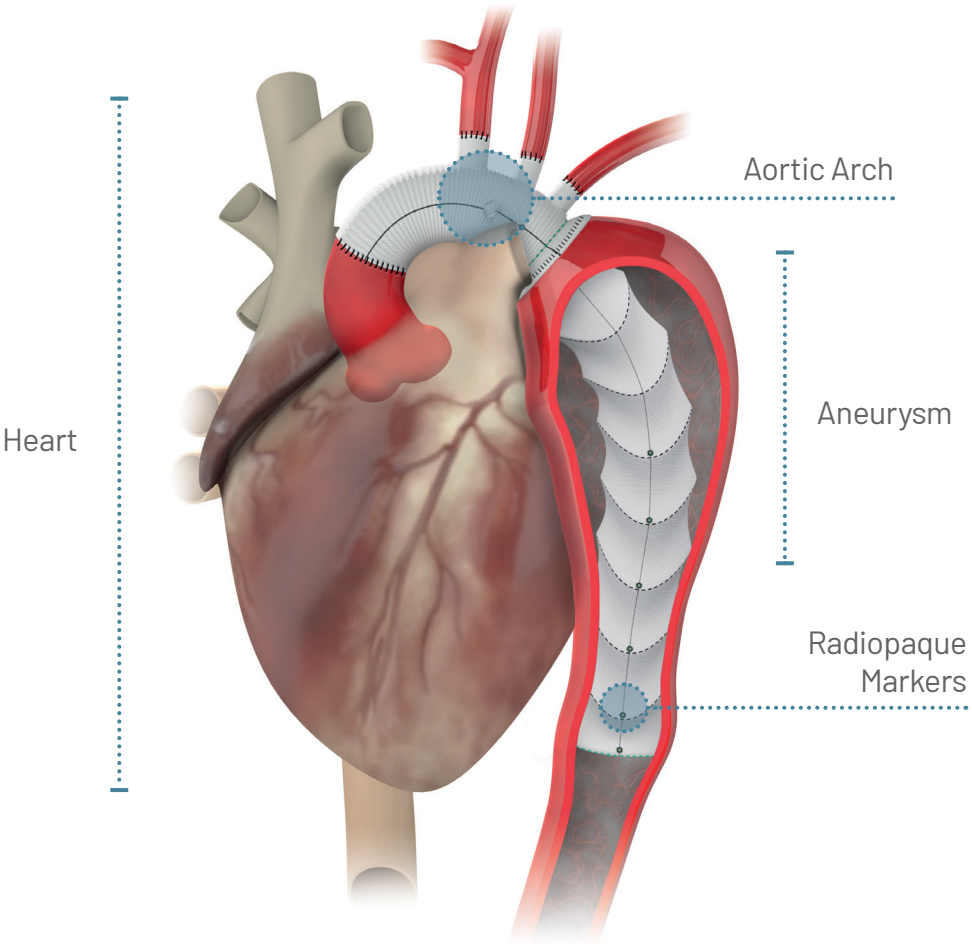
Aneurysms

This is when the aorta grows larger than its normal size. It is dangerous because the bigger an aneurysm gets, the more likely it is to burst, which can lead to death.

Dissections

This is when there is a tear in the wall of the aorta. When this happens, blood can then flow into the tear. This causes the layers in the wall of the aorta to separate (also known as "dissection"). This is a medical emergency and needs treatment straight away.

Your clinician will decide whether a Thoraflex Hybrid device is suitable for you.


Heart
Aortic Arch
Aneurysm
Radiopaque
Markers

Any Special Operating Instructions for Use of the Device:

Users of Thoraflex Hybrid should be properly trained. This includes training in vascular surgery and experience with procedures such as open arch surgery.

Thoraflex Hybrid can't be used to treat:

- People who are sensitive to polyester, nitinol, tantalum, or products from cows such as gelatin
- People who currently have an infection

Intended Performance of the Device and Any Undesirable Side Effects That Could Be Caused by Use of the Device:

Intended Performance:

Thoraflex Hybrid prevents a swollen or torn blood vessel from bursting. It works by making a different path for blood to flow through. This stops the swollen or torn part of the aorta from getting more damaged and bursting.

To put the device inside the body, the surgeon starts by cutting open the chest and the aortic arch. Then, the surgeon inserts the delivery system into the descending aorta. Once it is in the right place, the surgeon removes the delivery system, releasing the device. The bottom (stented) part of the device expands inside the aorta to keep it in place. The surgeon then sews the rest of the device in place replacing the diseased part of the aorta.

Residual Risks and Undesirable Side Effects:

If you feel like you are getting side-effects related to the device or are concerned about risks, you should contact your healthcare professional. This document is not meant to replace a consultation with your healthcare professional, if needed.

The manufacturer reduces any possible risks of Thoraflex Hybrid through:

- Carefully designing and testing the device before supply.
- Continuously tracking how well the device performs by gathering complaints and feedback from surgeons.
- Providing users with an instruction manual, called 'instructions for use'. This makes sure surgeons use the device in the right way.

Risks and undesirable side effects associated with Thoraflex Hybrid are not common, but may include the following:

- **Aneurysm sac or dissection enlargement**
  When the diseased part of the aorta continues to worsen.
- **Rupture of the aorta**
  When the aorta bursts and blood leaks inside the body.
- **Consequences of exposure to radiation**
  The device should be monitored after implant to check for any problems. This can sometimes require small amounts of radiation exposure from medical imaging techniques which may lead to some side effects.
- **Endoleaks**
  When the device does not work as it should, leading to leaking of blood around the device inside the aorta.
- **Hypersensitivity**
  A reaction inside the body caused by an allergy to the materials that make up the device.
- **Infection due to device contamination**
  This is an illness caused by microorganisms growing inside the body. It causes problems like high temperature, pain, and itching.
- **Migration**
  When the device moves out of its correct position inside the aorta.
- **Patency issues (e.g., blockage from graft kinking)**
  When something stops or reduces blood flow through the device.
- **Requirement for extension of Thoraflex Hybrid and associated risks**
  The device may need to be extended if it's not long enough to fully cover the aneurysm or dissection. Also, if the device doesn't work properly a second procedure may be needed to fix it. This can be done by open or endovascular repair.
- **Spinal Cord Injury/paraparesis/paraplegia**
  When the blood supply to the spine gets cut off. This can lead to suddenly or gradually losing control of parts of the body.
- **Stent fracture**
  When a stent that holds the device open breaks.
- **Stent graft induced aortic wall injury**
  Damage to the aorta caused by the device.

Additionally, risks of extending a Thoraflex Hybrid with another device, such as a thoracic endovascular aortic repair (TEVAR) include:

- Aneurysm sac or false lumen diameter enlargement
- Endoleaks
- Risks related to access, delivery, deployment, and withdrawal of the TEVAR device
- Stent Fracture

Warnings and Precautions:

Anyone who has a device like Thoraflex Hybrid implanted should have regular follow up visits with their clinician to make sure it is working properly, and any problems can be identified and fixed quickly.

MRI Safety

Thoraflex Hybrid is Magnetic Resonance (MR) Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3.0 or 1.5 Tesla.
- Maximum magnetic field spatial gradient of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Artefact Information

MR image quality may be compromised if the area of interest is in the exact same area or close to the position of the device with radiopaque markers. Therefore, optimisation of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artefact size (i.e. as seen on the gradient echo pulse sequence) extends approximately 10mm relative to the size and shape of this implant.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	15,828mm^2	1,424mm^2	19,077mm^2	2,012mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Clinicians should refer to the Instructions for Use for further details and information on MRI safety information with the Thoraflex Hybrid devices.

Post-surgery Follow-Up, Monitoring, Examination and Maintenance:

The expected minimum lifetime of the implant is 10 years. Regular follow-up including imaging of the Thoraflex Hybrid should be performed in accordance with the standard of care of your hospital/clinician.

Additional endovascular or open repair should be considered for patients with malperfusion (an obstruction in the vessel that is preventing blood supply), an increase in aneurysm size of more than 5mm or evidence of sub-optimal fixation (the graft is not attached as well as it should be), distal or junction endoleak (tearing causing blood leakage at certain points of the graft), or unknown origin of peri-graft flow (when blood flows outside of the graft but remains inside the aneurysm).

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

Medicinal Substances and Manufacturing Residuals:

There are no medicinal substances in this device. Thoraflex Hybrid is comprised of polyester, nitinol, tantalum gelatin material.

The manufacturing process for gelatin sealed implants uses the cross-linking agent formaldehyde to achieve the graft performance. All gelatin sealed grafts are thoroughly rinsed with pure water to reduce the amount of residual formaldehyde. However, some residual formaldehyde may be present in the finished graft.

Formaldehyde is also found at low levels naturally in the body, some of which is derived from food. Formaldehyde is known to be mutagenic and carcinogenic.

Serious Incidents:

Any serious incidents that occur in relation to this device should be reported to the manufacturer (Vascutek Ltd) and to the Australian Therapeutic Goods Administration (https://www.tga.gov.au/)

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

This leaflet gives only general information for patients about the Thoraflex Hybrid implantable device. Your medical practitioner will be able to answer any specific questions you may have on your condition.

terumoaortic.com

Product availability subject to local regulatory approval.

Manufactured by: Vascutek Ltd, Newmains Avenue, Inchinnan, Renfrewshire, PA4 9RR, United Kingdom

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