YOUR GUIDE TO

Gelweave™ Vascular Prosthesis

Patient Information Leaflet

Gelweave™

TERUMO Aortic

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Device Manufacturer:

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

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Gelweave™ Vascular Prosthesis

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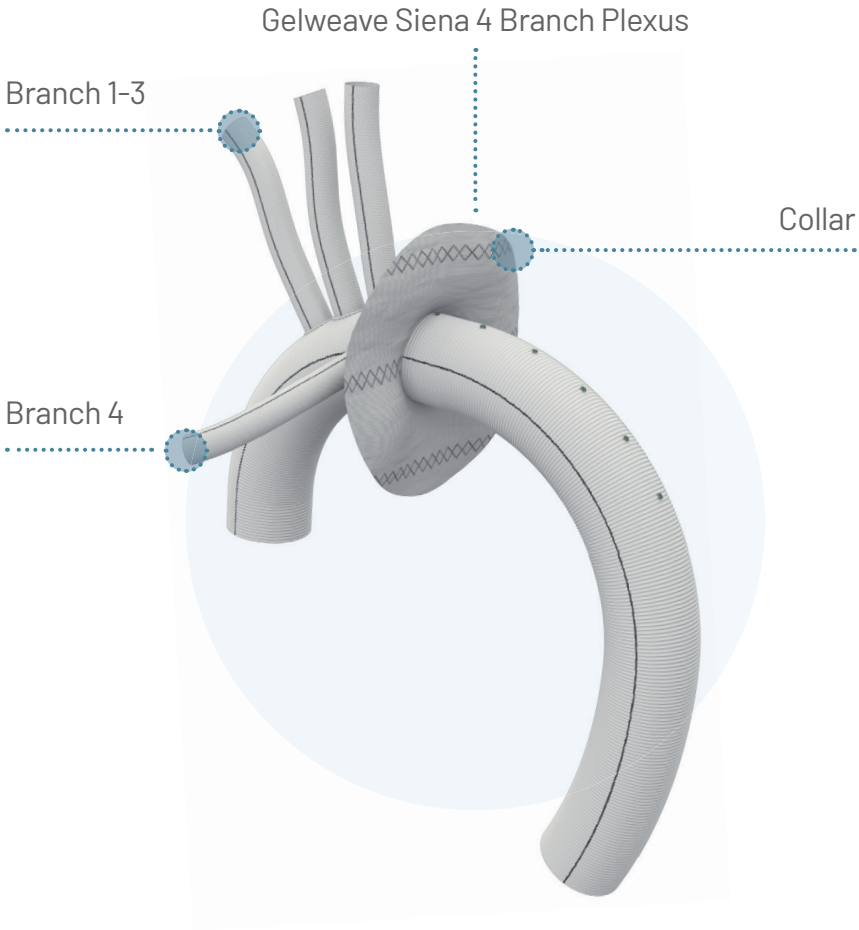
- Gelweave Ante-Flo Offset Side Branch

Device Description:

Gelweave devices are a range of fabric tubes, known as grafts. They are made from woven polyester fabric coated with gelatin. These devices are designed to repair diseased parts of the blood vessels within the vascular system.

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

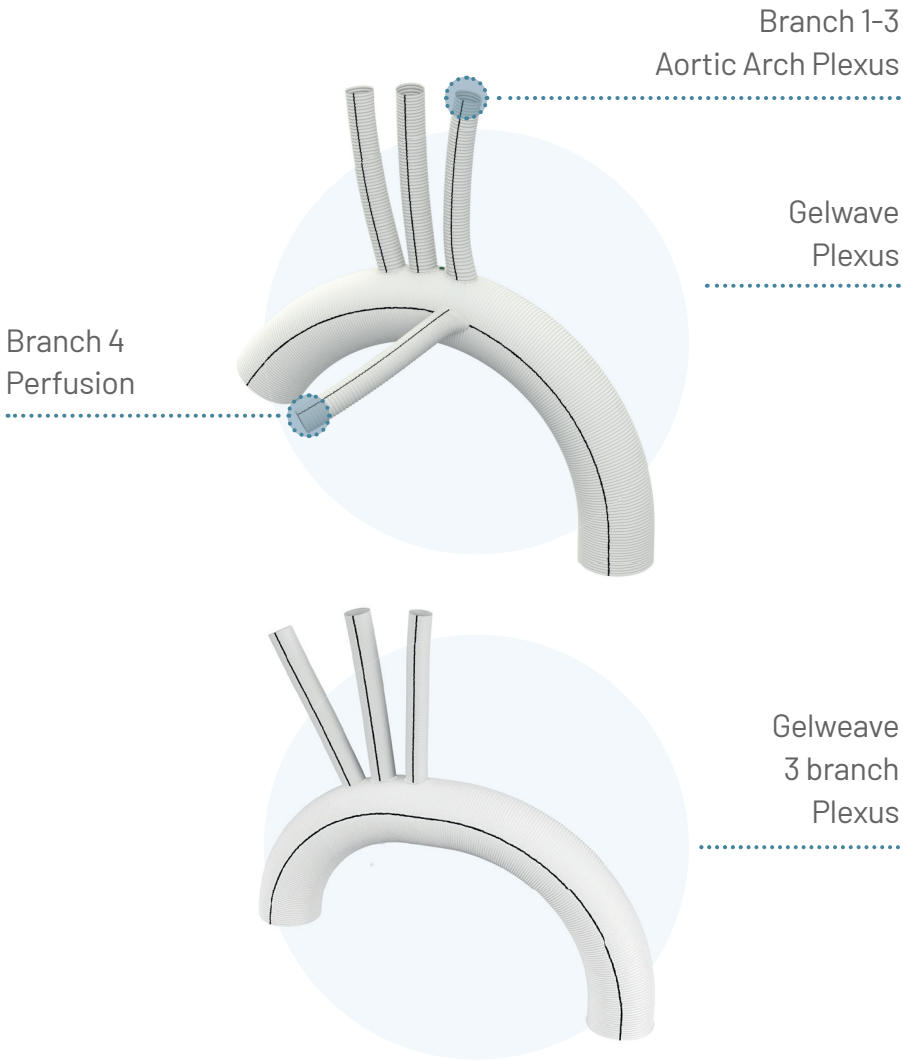
The Gelweave devices with branches, including the Gelweave Siena grafts, can also be used for reconstruction of the side vessels of the aorta during the repair of the aorta itself.



Device Description Continued:

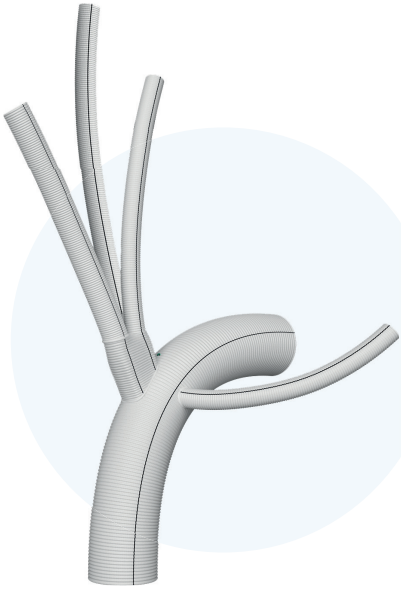
'Plexus' devices are used to replace the curved arch of the aorta and the main vessels that come away from the arch: the part of the blood vessel nearest the heart.

Gelweave Ante-Flo and Valsalva are used to replace the thoracic aorta (the part of the blood vessel in the upper part of the chest.)



Some Gelweave devices contain radiopaque markers. These are made of tantalum metal and can be seen under x-ray and other types of imaging. These markers are used by the clinician to make sure the device is in the correct position.

Clinicians implant these devices during open surgery into a patient to replace the vessel and allow blood to be transported in the body.



Gelweave Lupiae

Gelweave Thoracoabdominal Graft

Gelweave Coselli

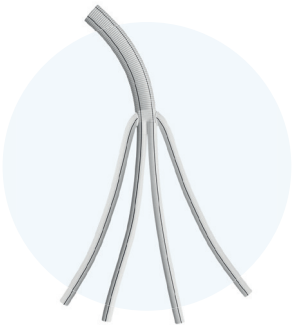
Gelweave Straight

Gelweave Precurved Branch

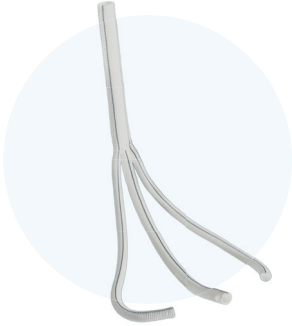
Gelweave Precurved

Gelweave Bifurcate

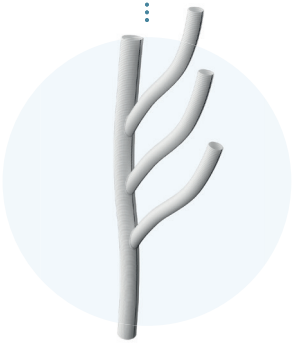
Gelweave Double Bifurcate



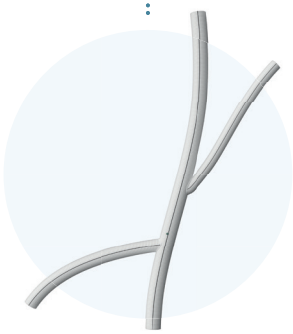
Gelweave Trifurcate



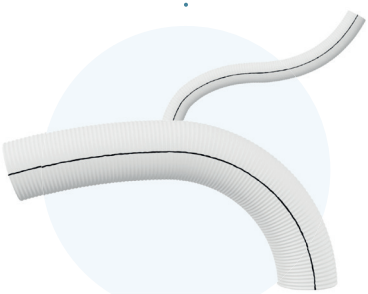
Gelweave Aortic Arch Graft



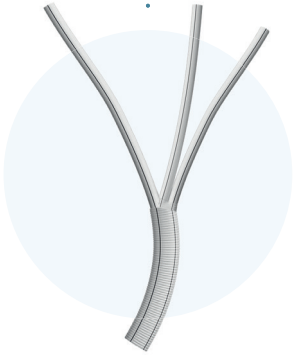
Gelweave Thoracic Arch Graft with Radiopque Markers



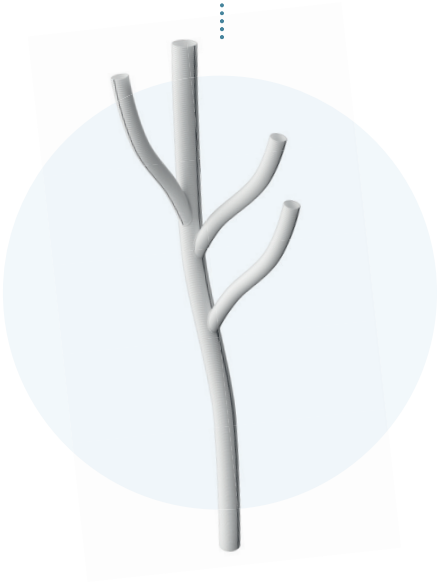
Gelweave Ante-Flo



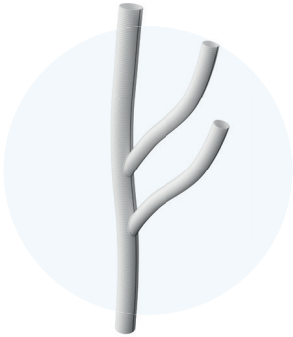
Gelweave Trifurcate Side Branch



Gelweave Trifurcate Arch Graft with Side Branch



Gelweave Trifurcate Arch Graft



This image is also representative of Gelweave Trifurcate and Gelweave Trifurcate Arch Grafts

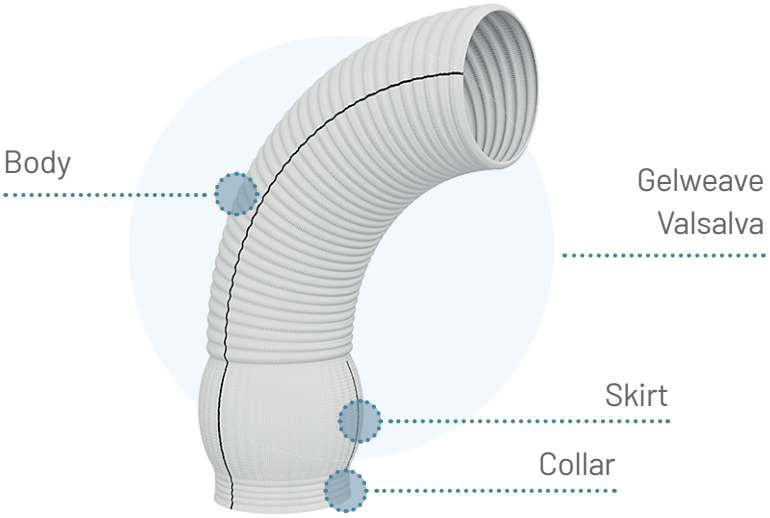
Intended Purpose of the Device

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

Gelweave grafts are intended to repair or replace diseased or damaged blood vessels in a patient and allow blood to flow through the device instead of the diseased or damaged vessel.

The intended purpose of the Gelweave Valsalva device is to repair or replace a portion of the aorta in patients with an aneurysm (swelling), dissection (tear) or narrowing of the vessel.

Your clinician will decide whether a Gelweave device is right for you.

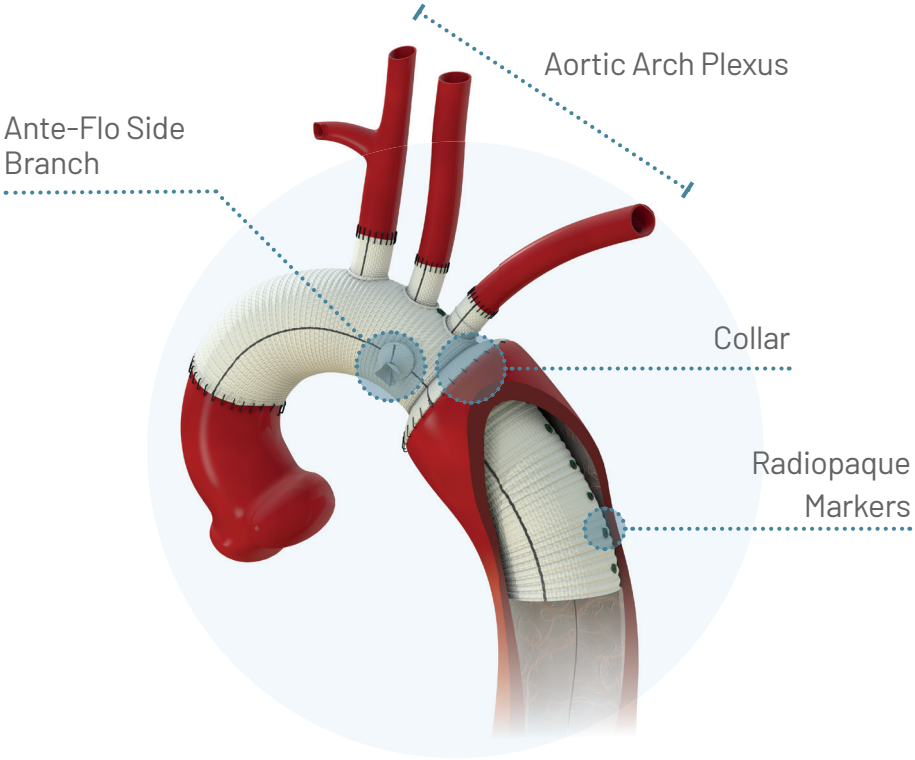


Any Special Operating Instructions for Use of the Device:

The intended users of these devices are clinicians and teams with experience and training in cardiovascular surgery.

Gelweave devices should not be used to treat:

- Patients who have an active infection.
- Patients who are sensitive to polyester, products from cows such as gelatin, or tantalum (only applicable to Gelweave devices with radiopaque markers.)


Aortic Arch Plexus
Ante-Flo Side Branch
Collar
Radiopaque Markers

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

Intended Performance:

Gelweave devices are used to replace or bypass diseased arteries to restore adequate blood flow in patients.

Restoring blood flow should reduce symptoms associated with restricted blood flow such as pain and/or cramping in the lower leg due to inadequate blood flow to the muscles, shortness of breath, fatigue and chest pain.

Patients with an aneurysm (swollen vessel) or dissection (tear in the vessel) often do not have symptoms. In these cases, the main aim is to replace the diseased portion of the vessel and reduce the risk of the artery rupturing (bursting), which in many cases will be fatal.

Branched models of the Gelweave devices can allow patients to be rewarmed earlier after implant which may shorten the operating time – a benefit for both the surgeon and the patient.

Residual Risks and Undesirable Side Effects:

If you feel like you are experiencing side-effects relating to the device or are concerned about risk, 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 Gelweave devices 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 Gelweave devices are not common, but may include the following:

- Formation of a blood clot in an artery, vein, or the device
- Narrowing or blocking of an artery, vein, or the device
- Formation of an abnormal connection between an artery and a vein
- Graft or wound infection
- Fever
- Vascular spasm or vascular trauma
- Vessel damage
- Infection
- Seroma (a pocket of clear fluid that sometimes develops in the body after surgery)
- Bleeding, blood loss, severe bruising of soft tissues called a haematoma, complications in blood clotting
- Growth or rupture (bursting) of aneurysm
- Pseudoaneurysm (Sometimes called a false aneurysm. This is when a blood vessel wall is injured and the leaking blood collects in the surrounding tissue.)
- Oedema (swelling caused by fluid leaking)
- Multi-organ failure
- Death
- Increase in graft size (dilation)
- Wound, kidney, lung, liver, bowel, genitourinary, lymphatic, neurological (e.g., confusion, stroke, paralysis) or heart complications

Warnings and Precautions:

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

MRI Safety

Gelweave devices without radiopaque markers do not contain any magnetic or metallic components and are therefore considered MRI compatible, although no formal testing has been carried out on these devices.

Gelweave devices with radiopaque markers are considered to be Magnetic Resonance (MR)-conditional. Non-clinical testing determined that devices with radiopaque markers were MR conditional. A patient with this device can be scanned safely, after placement of the device under the following conditions:

Static Magnetic Field

- Static magnetic field of 3 Tesla or less.
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less.

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 Gelweave 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 implant should be performed in accordance with the standard of care of your hospital/clinician.

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. Gelweave devices are made of polyester and 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.

Some Gelweave devices also contain radiopaque markers made of tantalum. These are located at points along the graft to help the clinician to see the graft during implant and during any follow-up procedures (if required.)

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 Gelweave 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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