YOUR GUIDE TO

Gelsoft™ Plus
Vascular Prosthesis

Patient Information Leaflet

Gelsoft™ Plus

TERUMO Aortic

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Device Manufacturer:

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

Device Name and Models:

Gelsoft™ Plus Vascular Prosthesis

Models:

- Gelsoft Plus Straight
- Gelsoft Plus Bifurcate
- Gelsoft Plus Double Bifurcate
- Gelsoft Plus Thin Wall
- Gelsoft Plus Extra Length

Extra Anatomical:

Extra Anatomical devices join the artery at the shoulder to the arteries at the top of the legs.

- Gelsoft Plus Ax-Fem
- Gelsoft Plus Ax-Bifem

Externally Reinforced (ERS) Extra Anatomical:

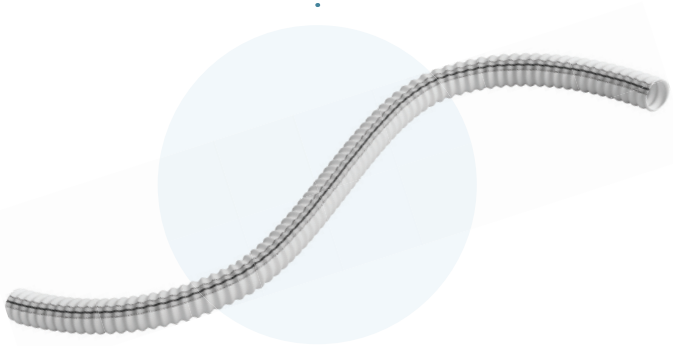
ERS devices are reinforced on the outside with a polypropylene support.

- Gelsoft Plus ERS Ax-Fem
- Gelsoft Plus ERS Fem-Fem
- Gelsoft Plus ERS Ax-Bifem

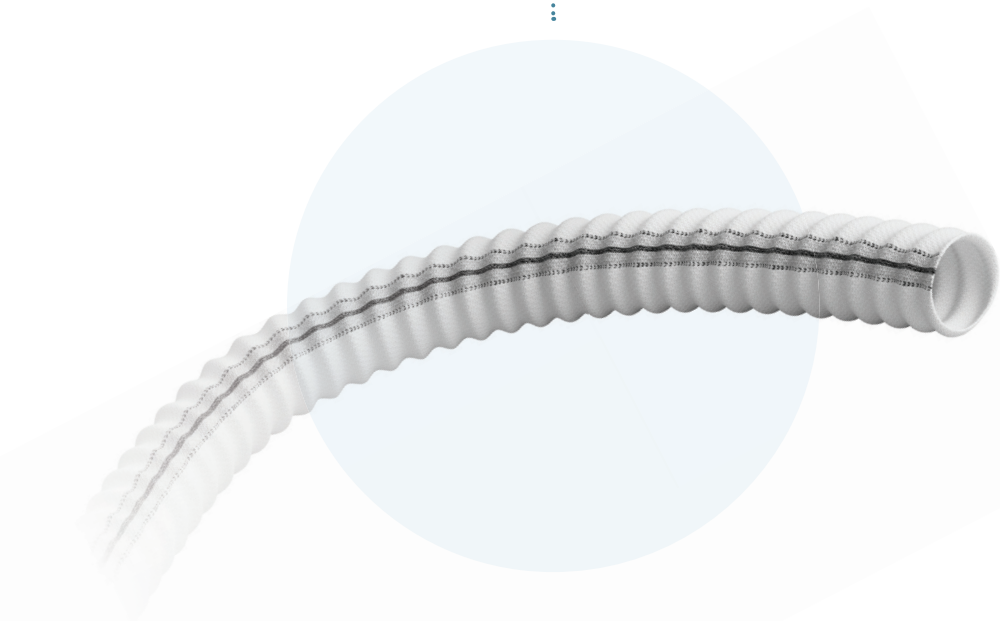
Device Description:

Gelsoft Plus devices are a range of fabric tubes, known as grafts. They are made from knitted polyester fabric coated with gelatin. These devices are designed for repairing diseased parts of the blood vessels within the vascular system.

Gelsoft Plus Straight Grafts
(Extra anatomical and extra length)



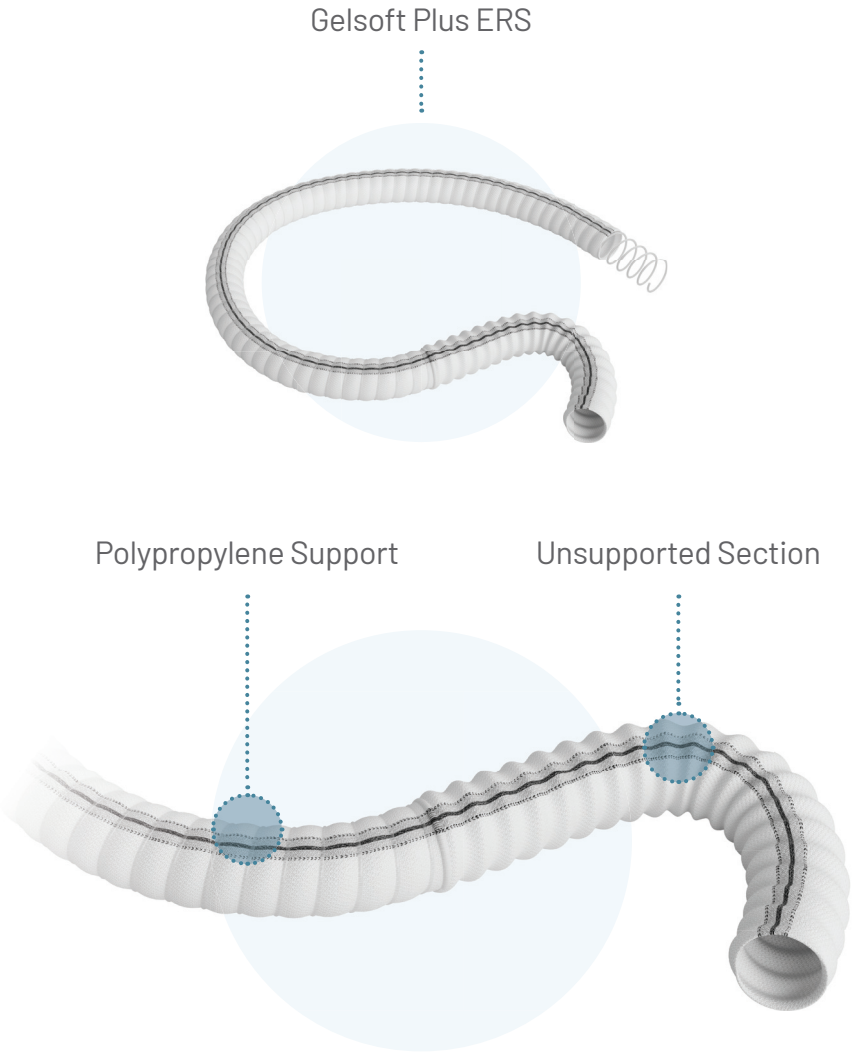
Knitted polyester fabric coated with gelatin



Device Description Continued:

Gelsoft Plus ERS devices are reinforced on the outside of the graft with a plastic polypropylene support. This helps to provide kink resistance and a smooth surface for blood to pass through.

Clinicians implant these devices into a patient by open surgery to replace a diseased or damaged blood vessel and allow blood to be transported in the body through the graft.



Intended Purpose of the Device

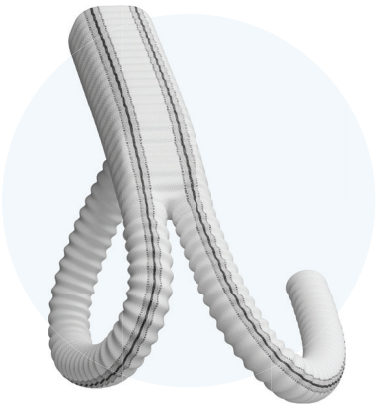
(and the kind of patient on whom the device is intended to be used):

Gelsoft Plus grafts are intended to repair or replace diseased or damaged arteries in a patient and allow blood to flow through the device instead of the diseased or damaged part of the vessel.

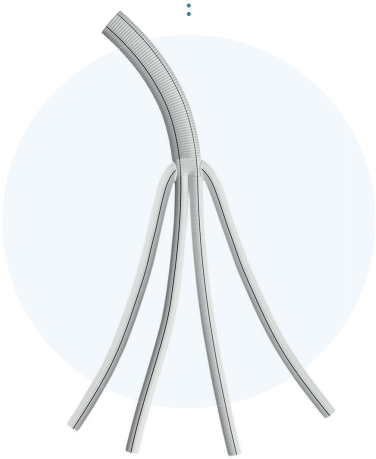
Gelsoft Plus ERS is also designed for repair of the blood vessels, primarily for axillo-femoral/axillo-bi- femoral bypass procedures (joining of the axillary artery at the shoulder to one or both femoral arteries in the groin) & femoral- popliteal reconstruction (where part of the vessel is bypassed, and the femoral artery is connected to the popliteal artery in the leg with the Gelsoft Plus device.)

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

Gelsoft Plus Bifurcate



Gelsoft Plus Double Bifurcate



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.

Gelsoft Plus devices should not be implanted in patients with active infection or who are sensitive to polyester or products from cows such as gelatin.

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

Intended Performance:

Gelsoft Plus devices are used to replace vessels with aneurysm (swelling) or dissection (tearing) to allow blood to flow and reduce the chance of the vessel rupturing (bursting) which in many cases will be fatal.

When the Gelsoft Plus devices are used to replace or bypass lower extremity arterial vessels (such as the femoral artery in the leg) that have been blocked due to a build-up of plaque (atherosclerosis) they can reduce the risk of disease or medical conditions such as a stroke and death.

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.

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 Gelsoft Plus 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 Gelsoft Plus 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 Gelsoft Plus 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

Gelsoft Plus devices 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.

Clinicians should refer to the Instructions for Use for further details and information on MRI safety information with the Gelsoft Plus 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. Gelsoft Plus 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.

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 Gelsoft Plus implantable device.
Your medical practitioner will be able to answer any specific questions you may have on your condition.

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Product availability subject to local regulatory approval.

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

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