Gelsoft™

USA

Gelsoft™ Plus

Gelseal™

Gelweave™

Gelsoft™ Plus ERS

Vascular Prostheses

Instructions for Use

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English

Vascutek Ltd. Gelsoft™, Gelsoft™ Plus, Gelseal™, Gelweave™ & Gelsoft™ Plus ERS Vascular Prostheses

Instructions for Use

CONTENTS

SECTION 1 INSTRUCTIONS FOR USE

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

SECTION 1.1 DESCRIPTION

Gelsoft™, Gelsoft™ Plus & Gelseal™ vascular prostheses are gelatin sealed warp knitted polyester prostheses, designed for vascular repair.

Gelsoft Plus™ ERS vascular prostheses are gelatin sealed Köper knitted polyester prostheses, designed for extra anatomical vascular repair.

Gelsoft Plus™ ERS are externally reinforced with an external polypropylene support to provide kink resistance and a smooth flow surface. The polypropylene support may be peeled where it extends to the ends of the prosthesis, in order to facilitate the fashioning of the anastomosis.

Gelweave™ vascular prostheses are gelatin sealed woven polyester prostheses, designed for vascular repair.

Branched versions of the **Gelseal™ and Gelweave™** vascular prostheses accommodate reconstruction of the associated side vessels and allow intra-operative attachment to cardiopulmonary bypass. The presence of radiopaque markers (**Gelweave™** prostheses only) aids *in vivo* visualization.

SECTION 1.2 INDICATIONS FOR USE

Knitted Vascular Prostheses

<table>
<tr><th></th><th>INDICATIONS FOR USE (FDA Cleared)</th></tr>
<tr><td>Gelseal™ Vascular Prostheses</td><td rowspan="2">Indicated for replacement or bypass of abdominal arteries afflicated with aneurysmal or occlusive disease.</td></tr>
<tr><td>Gelseal™ Ante-Flo™ Vascular Prostheses</td></tr>
<tr><td>Gelsoft™ Vascular Prostheses</td><td>Indicated for abdominal & peripheral vascular repair, i.e. replacement
or bypass in aneurysmal & occlusive disease of arteries.</td></tr>
<tr><td>Gelsoft™ Plus Vascular Prostheses</td><td>Indicated exclusively for vascular repair of damaged and diseased vessels of the abdomen, i.e. replacement or bypass in aneurysmal & occlusive disease of abdominal arteries.</td></tr>
</table>

Gelsoft™ Plus ERS AX -FEM Vascular Prostheses	Indicated for vascular repair i.e. primarily for axillo-femoral bypass procedures & femoro- popliteal reconstruction in aneurysmal & occlusive disease of the arteries
Gelsoft™ Plus ERS FEM- FEM Vascular Prostheses	Indicated for vascular repair i.e. primarily for femoro-femoral bypass procedures in aneurysmal & occlusive disease of the arteries
Gelsoft™ Plus ERS AX-BIFEM Vascular Prostheses	Indicated for vascular repair i.e. primarily for axillo-bi-femoral bypass procedures in aneurysmal & occlusive disease of the arteries.

Woven Vascular Prostheses

	INDICATIONS FOR USE (FDA Cleared)
Gelweave™ Straight Vascular Prostheses	Indicated for thoracic reconstruction procedures for replacement of diseased segments of the thoracic aorta in cases of aneurysm, dissection or coarctation.
Gelweave™ Ante-Flo™ Vascular Prostheses	
Gelweave™ Bifurcate Vascular Prostheses	Indicated for repair or replacement of damaged & diseased vessels of the abdomen in cases of aneurysmal or occlusive disease.
Gelweave™ Branched Vascular Prostheses with or without radiopaque markers	Indicated for repair or replacement of damaged & diseased vessels of the abdomen and thoracic aorta in cases of aneurysm, dissection or coarctation.

Gelweave™ Collared Ante-Flo™& Plexus Vascular Prostheses (with & without radiopaque markers)	Repair or replacement of damaged & diseased vessels of the thoracic aorta in cases of aneurysm, dissection or coarctation.
Gelweave™ Valsalva Vascular Prostheses	Indicated for the repair or replacement of damaged & diseased thoracic aorta in cases of aneurysm, dissection or coarctation.
Gelweave™ Branched Vascular Prostheses, including Siena Vascular Prostheses	Gelweave™ branched vascular prostheses, including Siena vascular prostheses can also be used for debranching, i.e. reconstruction of the aortic vessels & associated Hybrid procedures. (Hybrid procedures are defined as a treatment combination employing open surgical debranching with endovascular aortic repair).

SECTION 1.3 CONTRAINDICATIONS

Gelsoft™, Gelsoft™ Plus, Gelsoft™ Plus ERS, **Gelseal™ & Gelweave™** prostheses should not be implanted in patients with active infection or who exhibit sensitivity to polyester, tantalum (applicable to **Gelweave™** prostheses containing tantalum radiopaque markers only), or materials of bovine origin.

Gelseal™ prostheses are contraindicated for use in patients who require repair of an infected prosthesis, patients who will require anticoagulant therapy for longer than 2 months, patients whose red cell count is greater than $7.5x10^6$ per mm^3 and patients whose platelet count is greater than $1x10^6$ per mm^3.

Gelsoft™, Gelsoft™ Plus, Gelseal™ Gelweave™ & Gelsoft™ Plus ERS prostheses are contraindicated for coronary vascular repair, blood access fistula (e.g. haemodialysis) and pulmonary shunting.

Gelsoft™, Gelsoft™ Plus & Gelsoft™ Plus ERS prostheses are contraindicated for thoracic use.

Gelsoft™, Gelsoft™ Plus, **Gelseal™ & Gelweave™** prostheses are contraindicated for use in the extra-anatomic (**EXCEPT for Gelsoft™ Plus ERS)** pulmonary positions, use in arteriovenous shunting or cardiovascular patching.

SECTION 1.4 WARNINGS & PRECAUTIONS

1. The **Gelweave™** vascular prosthesis material is based on a woven structure and therefore must be cut with a cautery to minimise fraying. **NOTE: IMMERSION OF THE PROSTHESIS IN A STERILE SALINE SOLUTION IMMEDIATELY PRIOR TO USE WILL PREVENT FOCAL BURNING WHICH MAY RESULT DURING CAUTERISATION.** The prosthesis must be immersed in a sterile saline solution for 5 minutes. Failure to rinse for 5 minutes could lead to the graft being more susceptible to leakage when implanted. Vascutek do not recommend that the device is soaked for longer than 5 minutes as the onset of gelatin hydrolysis may start to

occur which may have an impact on clinical performance. The prosthesis must not be allowed to dry out after soaking.

2. ADDITIONAL CAUTION FOR ALL KNITTED PRODUCTS. USE OF A CAUTERY FOR ANY SEALED POLYESTER PROSTHESES CAN CAUSE BURNING. THIS CAN BE PREVENTED BY SOAKING IN STERILE SALINE. The prosthesis must be immersed in a sterile saline solution for 5 minutes. Failure to rinse for 5 minutes could lead to the graft being more susceptible to leakage when implanted. Vascutek do not recommend that the device is soaked for longer than 5 minutes as the onset of gelatin hydrolysis may start to occur which may have an impact on clinical performance. The prosthesis must not be allowed to dry out after soaking.

3. DO NOT PRECLOT. These prostheses contain a gelatin sealant and must not be pre-clotted.

4. DO NOT USE BEYOND THE INDICATED EXPIRATION DATE. The gelatin impregnation may not meet the design specification after the expiration date.

5. DO NOT RESTERILIZE. FOR SINGLE USE ONLY. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the prosthesis and/or lead to prosthesis failure which, in turn, may result in deterioration of health or death of patients. Reuse, reprocessing or resterilization may also create a risk of contamination of the prosthesis and/or cause patient infection or cross infection, including but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the prosthesis may lead to injury, illness or death of the patient end-user.

6. The prosthesis must be implanted within one month after removal from the foil pouch. Please refer to Section 2.3 Packaging.

7. Clamping may damage the prosthesis. Atraumatic clamps, ideally with soft shod jaws, should be used with a minimum application of force and for **Gelsoft™ Plus ERS** prostheses should be used on the section with no external polypropylene support. Excessive force should be avoided as it will damage the polyester fibres and the gelatin impregnation.

8. Excessive tension on the prosthesis should be avoided.

9. Round body taper point needles should be used when implanting the prosthesis to minimise fibre damage.

10. If de-airing is required, then the smallest needle possible should be used. A 19-gauge needle is normally sufficient. Hypodermic needles have a cutting point which may result in blood leakage and require repair by suturing.

11. Caution should be exercised when performing the Elephant Trunk procedure. Although there has been success with this procedure, there have been a few reports of bleeding from the implanted prosthesis during the second stage. Variability of the patient's healing response may account for the difference.

12. Additional caution for Gelweave™ Valsalva. For Valve sparing techniques ensure that the top of the commissures are sutured to the new sinotubular junction (join of the prosthesis body to the skirt).

13. Additional caution for Gelweave™ Siena collared prostheses. Prosthesis sealant reabsorption will be complete within approximately 14 days of the stage 1 open procedure. If a second stage conventional open repair technique is used, careful handling and clamping of the distal portion of the arch prosthesis should be observed in order to minimize bleeding through this section of the prosthesis wall.

14. Additional caution for Hybrid procedure. Vascutek Ltd. only recommends the use of the 8mm and 10mm side branch for the debranching and associated hybrid procedures. Ensure that the prosthesis side branch has a suitable inside diameter to accommodate the endovascular system chosen, i.e. a 20F or 22F catheter should be used for an 8mm side branch and a 20F, 22F 24F or 26F catheter should be used for a 10mm side branch.

15. Additional caution for Gelsoft™ Plus, Gelseal™ & Gelweave™ prostheses. Safety and effectiveness in the peripheral positions has not been established.

16. The manufacturing process for gelatin sealed vascular grafts uses the cross-linking agent formaldehyde to achieve the graft performance. All gelatin sealed grafts are thoroughly rinsed with RO (reverse osmosis) water to reduce residual formaldehyde, however residual amounts

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. The risks of these potential harms from the product have not been established clinically.

17. Although these prostheses are gelatin sealed, intraoperative leakage at the branch seams might occasionally be observed.

18. Due to potential blood loss, it is not recommended to use these prostheses as a conduit/ cannula between a patient and Extracorporeal Membrane Oxygenation (ECMO) equipment.

SECTION 1.5 PATIENT COUNSELLING AND ADVERSE EVENTS

PATIENT COUNSELLING

The clinician should review all associated risks and benefits when counselling the patient about this vascular prosthesis and all associated procedures.

Vascutek Ltd. recommends that the clinician inform the patient of all associated risks and benefits, in written form. These include but are not limited to:

- **patient age and life expectancy**
- **risks and benefits related to procedure**
- **risks related to non-interventional treatment or medical management**
- **long term monitoring requirements**

Details regarding risks occurring during or after implantation of the device are provided in the Potential Adverse Events section.

Please instruct the patient as to proper postoperative care, including limiting movement of the affected area during the convalescent period.

POTENTIAL ADVERSE EVENTS

Adverse events that may occur and/or require intervention include, but are not limited to:

Arterial or venous thrombosis	Fever & localised inflammation
Arteriovenous fistula	Allergic reaction to polyester / gelatin
Stenosis	Oedema
Vascular spasm or vascular trauma	Multi organ failure
Vessel damage	Death
Aneurysm infection	Neointimal Hyperplasia
Prosthesis occlusion	Prosthesis dilatation
Seroma	Hepatic failure
Infection of the prosthesis / wound site	Lymphatic complications e.g. lymph fistula
Aortic damage, including perforation, dissection, bleeding, rupture & death	Renal complications e.g. renal dysfunction, artery occlusion, failure, infarction

Bleeding, blood loss, haematoma, coagulopathy, re-opening	Bowel complications e.g. ileus, perforation, transient ischaemia, infarction, necrosis
Aneurysm enlargement, rupture, death	Wound complications e.g. dehiscence, infection, haematoma, seroma, cellulitis, pain
Genitourinary complications e.g. ischaemia, erosion, fistula, incontinence, haematuria, infection, impotence	Cardiac complications e.g. arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension
Respiratory complications e.g. pneumonia, respiratory failure, prolonged intubation, pulmonary oedema	Neurological local or systematic complications e.g. confusion, stroke, transient ischaemia attack, paraplegia, paraparesis, paralysis
Pseudoaneurysm	Kinking/compression

DEVICE RELATED ADVERSE EVENT REPORTING

Any adverse event involving a **Gelsoft™, Gelsoft™ Plus, Gelsoft™ Plus ERS, Gelseal™, or Gelweave™** prosthesis should be immediately reported to Vascutek Ltd. using either the email address complaintsuk@terumoaortic.com or via your local distributor.

SECTION 1.6 ADDITIONAL INSTRUCTIONS

Gelsoft™, Gelsoft™ Plus, Gelsoft™ Plus ERS, Gelseal™ & Gelweave™ prostheses should be immersed completely in a sterile saline solution for 5 minutes. The prosthesis must not be allowed to dry out after soaking.

Additional Instructions for the Plexus and Ante-Flo™ Prostheses
Initiation of Antegrade Perfusion: The bypass catheter should be placed in the side arm of the Ante-Flo™ and 4-Branch Plexus and securely attached.

Completion of Antegrade Perfusion: Once bypass is complete, the cannula side arm of the Ante-Flo™ and 4-Branch Plexus should be cut off and the remaining stump over-sewn using standard surgical technique.

Additional Instructions for the Gelweave™ Valsalva prosthesis. The coronary arteries should be anastomosed to the skirted section of the Gelweave™ Valsalva™ prosthesis. The proximal collar can be used for prosthetic valve attachment or trimmed/inverted in valve sparing procedures according to the surgeon's preference of surgical technique.

Please also consider the need for intraoperative and postoperative patient anticoagulation therapy.

SECTION 1.7 MAGNETIC RESONANCE IMAGING (MRI) SAFETY

Gelsoft™, Gelsoft™ Plus, Gelsoft™ Plus ERS, Gelseal™ & Gelweave™ Vascular Prostheses without radiopaque markers do not contain any magnetic or metallic components and are therefore considered **Magnetic Resonance (MR) Safe**, although no formal testing has been carried out on these prostheses.

Gelweave™ vascular prostheses with radiopaque markers were determined to be **Magnetic Resonance (MR) conditional**. Non-clinical testing determined that prostheses with radiopaque markers were MR conditional. A patient with this prosthesis can be scanned safely, immediately after placement of the prosthesis 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.

MAGNETIC RESONANCE IMAGING (MRI) RELATED HEATING

In non-clinical testing, prostheses with radiopaque markers produced the following temperature rises during Magnetic Resonance Imaging performed for 15 minutes of scanning (per pulse sequence) in 1.5 Tesla/64 MHz (Magnetom, Siemens Medical Solutions, Malvern PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems:

	1.5 Tesla	**3 Tesla**
MR system reported, whole body averaged SAR .	2.9 W/kg	2.9 W/kg
Calorimetry measured values, whole body averaged SAR	2.1 W/kg	2.7 W/kg
Highest temperature change	+1.7°C	+2.0°C

These temperature changes will not pose a hazard to a human subject under the conditions indicated above.

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 prosthesis with radiopaque markers. Therefore, optimisation of MR imaging parameters to compensate for the presence of this prosthesis 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

This information is based on information from the Food and Drug Administration and the American Society for Testing and Materials (ASTM) International, Designation: F2503-08. Standard Practice for Marketing Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

SECTION 2 ADDITIONAL INFORMATION

SECTION 2.1 ORIGIN OF GELATIN

Vascutek uses gelatin manufactured from animals native to, and exclusively raised in the United States of America. The United States of America is classified as a negligible BSE risk country according to the OIE categorisation (adopted by the European Union with the Regulation (EC) N°722/2007). The gelatin is hydrolysed within approximately 14 days and is replaced by normal tissue incorporation.

SECTION 2.2 STERILIZATION

These prostheses have been sterilized using Ethylene Oxide and are supplied sterile. The Tyvek® seal on both intermediate and inner trays must be intact. Any damage to the trays renders the prosthesis non-sterile. **Note**: In the event of damage to the primary packaging, the prosthesis must not be used and should be returned immediately to the supplier.

CAUTION: PROSTHESES MUST NOT BE RE-STERILIZED.

SECTION 2.3 PACKAGING

Trays are enclosed in a foil pouch that serves as a vapour barrier and preserves optimal prosthesis characteristics. A sachet containing a desiccant is included to aid this purpose. **Note**: The foil pouch and outer tray are not sterile. Only the innermost tray can be introduced to the sterile field.

SECTION 2.4 STORAGE CONDITIONS

Store in clean, dry area at room temperature.

SECTION 2.5 ADDITIONAL LABELS

Additional labels are attached for use on patient records.

SECTION 2.6 RETURNING A PROSTHESIS

All explanted prostheses should be returned to Vascutek for analysis as soon as possible. In the event of a used prosthesis needing to be returned to Vascutek, it is a requirement to have the prosthesis, and any other items used in the procedure to be returned in an explants box which can be obtained from Vascutek's Quality Assurance Department. If required, explant kits can be requested at complaintsuk@terumoaortic.com or through your local distributor and will be provided for the retrieval and preservation of the explanted prosthesis or other components for transit to Vascutek.

SECTION 2.7 DISPOSAL OF PROSTHESES

Ensure that local and national regulatory requirements for the disposal of contaminated clinical waste products are adhered to.

SECTION 3 CLINICAL EXPERIENCE AND REFERENCES

CLINICAL EXPERIENCE

Gelsoft™

Abdominal Vascular Repair

A prospective clinical trial was conducted to evaluate the safety and effectiveness of the Gelsoft™ vascular graft in the treatment of aneurysmal and occlusive disease, by replacement or repair of the abdominal aorta. The clinical study involved 65 patients at two centers in the United States and 100 patients implanted at the Glasgow Royal Infirmary Glasgow in Scotland, United Kingdom. Study patients ranged in age from 35 to 83 years and the female: male ratio of 1:4 was typical of patients that undergo this type of surgery.

United States patients were followed by physical examination, for 12 months post-operatively and patients in the United Kingdom were followed 25 to 59 months after implant. The major endpoints of intra-operative bleeding through the graft and primary patency were comparable to the approved Vascutek Gelseal™ graft.

There were no adverse events attributed to a dysfunction of the graft and no graft related mortality. Post-operative increase in graft diameter was observed during the abdominal use clinical trial, however this phenomenon, is generally known to be associated with knitted vascular grafts[15,16] and was not shown to be clinically significant. The key adverse events recorded during the abdominal use clinical trial included bleeding and distal embolism. Gelsoft™ safety and performance data for abdominal use analysed by gender did not illustrate a difference in the safety and effectiveness of the Gelsoft™ graft in males and females.

No specific trials have been carried out on **Gelsoft™ Plus & Gelsoft™ Plus ERS** Vascular Prostheses.

Peripheral Vascular Repair

A prospective trial was conducted to compare graft patency between Gelsoft™ and ePTFE grafts for femoropopliteal bypass. The clinical study involved 108 patients at three centers in Australia. Distal anastomosis was performed above the knee in 75 patients and below the knee in 33 patients. Patients were followed postoperatively by physical examination for 1 to 53 months, with a mean of 19 months and a median of 18 months. There was no difference between treatment groups in terms of graft primary and secondary patency.

Gelseal™

Clinical safety and effectiveness data was collected from 180 abdominal applications in primary study patients, for aneurysmal and occlusive disease in the United States and United Kingdom. 53% of the patients had no post- surgical complications, while 47% had at least one complication.

None of the complications were deemed by the investigators to be graft related (including 61 events of ischemia distal to the graft, which were thought to be as a result of disease progression, poor cardiac output, or long ischemic times during surgery). Several complications were classified as “unknown cause”. These included complications such as fever with unknown origin, seroma, erythema, vomiting and diarrhoea without gastro- intestinal problems, shortness of breath without pulmonary problems, joint pain, renal failure and insensate limb.

There were a total of 15 deaths: none were graft related. One year actuarial (freedom from post-surgical complications) rates from the United States Gelseal™ patients, for patency, mortality, graft infection and thromboembolic events were 100%, 93.4%, 98.5% and 97.9% respectively. For the United Kingdom patients, rates were 97.9%, 95.8%, 100% and 97.9 % respectively.

Gelweave™

A prospective clinical trial was conducted to evaluate the safety and effectiveness of the Gelweave™ vascular graft for reconstruction of the thoracic aorta. The study was conducted at three centers in the United States and involved a total of 69 patients (37 Gelweave and 32 controls) that underwent 75 graft replacement procedures (40 Gelweave and 35 Controls)
Patients were followed for one year and evaluated by physical examination. The Gelweave™ study population was 43% female and 57% male and ranged in age from 37 to 83 years. Intra-operative blood loss through the graft was reported in 5% (2 of 40) of Gelweave™ grafts, compared to 67% (14 of 21) of non-sealed and 14% (2 of 14) of sealed control grafts. There were no reports of post-operative blood loss through the graft for any graft type. There were no morbid events (including graft infection, graft occlusion and false aneurysm) attributed to the Gelweave™ graft and no graft related mortality. Comparison of morbid events by gender illustrated that the Gelweave™ graft was equally safe in males and females.

REFERENCES

1. ***Post-Operative Dilation of Knitted Dacron Aortic Bifurcation Grafts.*** Nunn *et al*. Journal of Vascular Surgery 1990; Vol. 12 pp. 291-297
2. ***Long Term Dilatation of Polyester and Expanded Polytetrafluoroethylene Tube Grafts*** After Open Repair of Infrarenal Abdominal Aortic Aneurysms. Stollwerck *et al*. Journal of Vascular Surgery 53 2011; pp. 1506-1513

SECTION 4 EXPLANATION OF SYMBOLS ON PRODUCT LABELLING

	Use-by Date
	Batch Code
	Catalogue Number
	Serial Number
	Sterilized using Ethylene Oxide
	Date of Manufacture
	Do not re-use, single use only
	Read Instructions before Use
	Latex-free
	Diameter
	Usable Length

For ordering in the USA only, please contact:

Terumo Medical Corporation
TMC Customer Care
265 Davidson Avenue, Somerset NJ 08873
tmccustomer.admin@terumomedical.com
Tel #800-888-3786

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