

Gelsoft™

USA

Gelsoft Plus™

Gelsoft™ ERS

Gelsoft Plus™ ERS

Gelseal™

Gelweave™

Gelweave Valsalva™

Vascular Prostheses

Instructions for Use

**Vascutek Ltd**  
**Gelatin Sealed Polyester Vascular Prosthesis**  
**Instructions for Use**

**Caution:- Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.**

**Description**

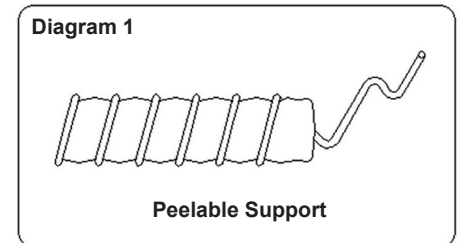
Gelsoft™, Gelsoft™ ERS, Gelsoft Plus™, Gelsoft Plus™ ERS and Gelseal™ are warp knitted polyester prostheses, the Gelsoft™ and Gelsoft Plus™ ERS version is externally reinforced. Gelweave™ is a woven polyester prosthesis. Branched Gelweave™ is available to accommodate reconstruction of the major aortic branch vessels or intra-operative attachment of a perfusion cannula during cardio-pulmonary bypass where antegrade perfusion techniques are employed (Ante-Flo).

Gelweave™ branched vascular grafts, including Siena™ grafts can also be used for debranching i.e. reconstruction of the aortic vessels and associated Hybrid procedures<sup>7,8</sup>. Hybrid procedures are defined as a treatment combination employing open surgical debranching with endovascular aortic repair. These grafts are also available with radiopaque markers to aid *in vivo* visualization.

The Gelweave™ Valsalva configuration mimics the geometry of the sinuses of Valsalva™. Post-operative increase in graft diameter (dilatation) is known to be associated with knitted vascular prostheses<sup>1,2</sup>. Testing has shown that the structure of Gelsoft Plus™ may be more resistant to dilatation than currently available knitted vascular prostheses<sup>3,4</sup>.

All these prostheses have been impregnated with an absorbable protein. The aim of the impregnation is to provide a polyester vascular prosthesis, which does not require preclotting. The protein is a modified mammalian gelatin, which has been cross-linked to a set level to control its rate of removal. It serves in place of fibrin, which seals the polyester prosthesis during normal preclotting. The gelatin is hydrolyzed within approximately 14 days<sup>5</sup> and is replaced by normal tissue incorporation. Gelatin has been chosen, as it is a non-antigenic and non-toxic protein, a fact, which is reflected by its extensive use as a safe plasma expander.

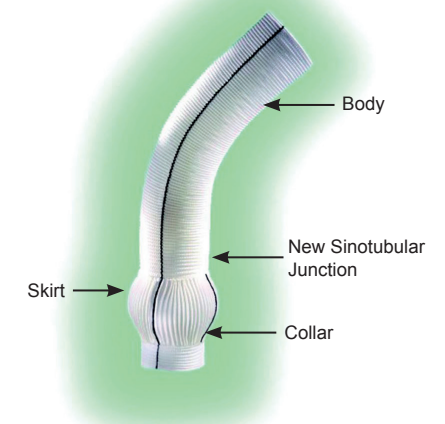
The Gelsoft™ and Gelsoft Plus™ ERS has an external polypropylene support to provide kink resistance and a smooth flow surface. The polypropylene support may be peeled where it extends to the ends of the prosthesis, in order to facilitate the fashioning of the anastomosis (Diagram 1).



**Gelweave™ Valsalva**

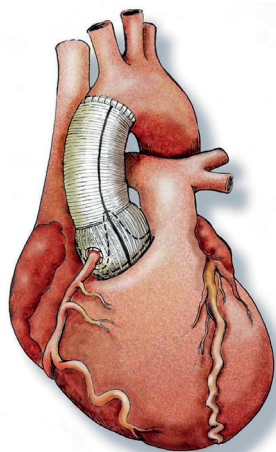
Gelweave™ Valsalva mimics the geometry of the sinuses of Valsalva™ (Diagram 2). The Gelweave™ Valsalva graft features a "skirt" and "collar" at its proximal end.

**Diagram 2**



This allows the creation of an anatomical configuration similar to the natural aortic root on removal of the latter (Diagram 3). An Ante-flo version i.e. with side branch is also available.

Diagram 3

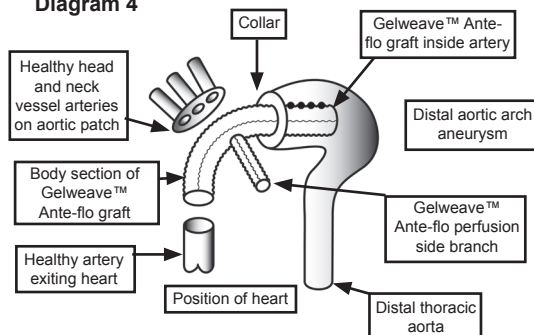


#### Gelweave™ Ante-Flo with Collar and Gelweave™ 4 Branch Plexus with Collar

Gelweave™ single (Ante-Flo) and 4 branch (Plexus) grafts are also available with a distal sewing collar attached (Diagram 4). These grafts are also available with radiopaque markers to aid *in vivo* visualization. These grafts are called Gelweave™ Siena Collared Grafts with Radiopaque Markers.

In the presence of large aneurysms, without a definite neck beyond the left subclavian artery, there is an increased risk of rupture at the level of the distal anastomosis due to the delicate nature of the tissue and diameter mismatch between the distal portion of the graft and native tissue. The collared graft allows the “Elephant Trunk” technique<sup>6</sup>, a two-stage technique, to be more easily conducted. This technique overcomes the difficulties and risks inherent to a large aneurysmal neck e.g. excessive tension on the anastomosis that may lead to bleeding and/or rupture of the distal portion of the aneurysm prior to the second stage of the repair. Gelweave™ branched vascular grafts, including Siena™ grafts can also be used for debranching i.e. reconstruction of the aortic vessels and associated Hybrid procedures<sup>7,8</sup>.

Diagram 4



As for the standard branched grafts, the branches are used to accommodate reconstruction of the aortic branch vessels and intra-operative attachment to a perfusion cannula during cardiopulmonary bypass, especially where antegrade as opposed to retrograde perfusion techniques may be preferred. Gelweave™ branched vascular grafts, including Siena™ grafts can also be used for debranching i.e. reconstruction of the aortic vessels and associated Hybrid procedures<sup>7,8</sup>.

#### Origin of the gelatin

Vascutek Ltd. uses gelatin manufactured from animals native to and exclusively raised in the Australia. Australia is one of only a few countries recognised as free from TSE infected animals, including BSE and Scrapie. The EU Scientific Steering Committee has conducted Geographical BSE Risk Assessment (GBR) and concluded that Australia has the most favourable level 1 rating in relation to BSE risk.

#### Indications

##### Gelsoft™

Indicated for abdominal and peripheral vascular repair i.e. replacement or bypass in aneurysmal and occlusive disease of arteries.

##### Gelsoft Plus™

Indicated exclusively for vascular repair of damaged and diseased vessels of the abdomen i.e. replacement or bypass in aneurysmal and occlusive disease of abdominal arteries.

##### Gelsoft™ ERS and Gelsoft Plus™ ERS

Indicated for extra-anatomical vascular repair, primarily axillo-femoral/bifemoral bypass and femoro-popliteal reconstruction.

#### Gelseal™

Indicated exclusively for vascular repair of diseased vessels of the abdomen i.e. replacement or bypass in aneurysmal and occlusive disease of abdominal arteries.

#### Gelweave™ and Gelweave™ Valsalva

Indicated for repair or replacement of damaged and diseased vessels of the abdomen and thoracic aorta in cases of aneurysm, dissection or coarctation.

The branched versions of Gelweave™ are available to accommodate reconstruction of the aortic branch vessels and intra-operative attachment of a perfusion cannula during cardio-pulmonary bypass, especially where antegrade as opposed to retrograde perfusion techniques may be preferred (Ante-Flo). Gelweave™ branched vascular grafts, including Siena™ grafts can also be used for debranching i.e. reconstruction of the aortic vessels and associated Hybrid procedures<sup>7,8</sup>.

#### Contraindications

##### Gelsoft™, Gelsoft™ ERS, Gelsoft Plus™ and Gelsoft Plus™ ERS

Coronary vascular repair Thoracic position.

##### Gelseal™

Coronary vascular repair. Use of systemic heparin should be avoided for dialysis.

##### Gelweave™ and Gelweave™ Valsalva

Coronary vascular repair.

#### GENERAL CONTRAINDICATIONS

##### – Applicable to all prostheses

These prostheses should not be implanted in patients who exhibit sensitivity to polyester or materials of bovine origin.

#### Precautions

##### Gelsoft™

Safety and effectiveness in the extra-anatomic, pulmonary positions or use in arteriovenous shunting have not been established.

##### Gelsoft Plus™

Safety and effectiveness in the extra-anatomic, peripheral, pulmonary positions, use in arteriovenous shunting or cardiovascular patching have not been established.

#### Gelsoft™ ERS and Gelsoft Plus™ ERS

Safety and effectiveness in the pulmonary position or use in arteriovenous shunting have not been established.

#### Gelseal™

1. Safety and effectiveness in the thoracic, extra-anatomic, peripheral, A-V access and pulmonary positions have not been established.
2. Safety and effectiveness have also not been established 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  $7.5 \times 10^6$  per  $\text{mm}^3$  and patients whose platelet count is greater than  $1 \times 10^6$  per  $\text{mm}^3$ . Please refer to Contraindication regarding systemic heparinization.

#### Gelweave™

Safety and effectiveness in the extra-anatomic, peripheral, pulmonary positions, use in arteriovenous shunting or cardiovascular patching have not been established.

#### Gelweave™ Branched Grafts with Radiopaque Markers and Gelweave™ Siena Collared Grafts with Radiopaque Markers.

MRI Compatibility

#### MAGNETIC RESONANCE IMAGING INFORMATION

Vascular grafts with radiopaque markers were determined to be **MR-conditional**.

Non-clinical testing demonstrated that vascular grafts with radiopaque markers were determined to be MR conditional. A patient with this device can be scanned safely, immediately after placement 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

#### MRI-Related Heating

In non-clinical testing, the vascular grafts with radiopaque markers produced the following temperature rises during MRI performed for 15 minutes of scanning (i.e., 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 relatively close to the position of the vascular graft with radiopaque markers. Therefore, optimization 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 10-mm relative to the size and shape of this implant.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	15, 818 mm <sup>2</sup>	1, 424 mm <sup>2</sup>	19, 077 mm <sup>2</sup>	2, 012 mm <sup>2</sup>
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

This information is based on the latest 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.

#### Cautions

- DO NOT PRECLOT.** These prostheses are sealed grafts and must not be preclotted.
- DO NOT USE BEYOND THE INDICATED EXPIRATION DATE.** The gelatin impregnation may not meet the design specification after the expiration date because of hydrolytic action.
- DO NOT RESTERILIZE.** These prostheses must not be resterilized.
- FOR SINGLE USE ONLY.**
- Store in clean, dry area at room temperature.
- Prostheses must be implanted within one month after removal from the foil pouch.
- Additional caution for Gelweave™ only.** Gelweave™ is based on a woven structure and therefore should be cut with a cautery to minimize fraying. **NOTE: IMMERSION OF THE GELWEAVE™ PROSTHESIS IN SALINE IMMEDIATELY PRIOR TO USE WILL PREVENT FOCAL BURNING, WHICH MAY RESULT DURING CAUTERIZATION. THE PROSTHESES SHOULD BE IMMERSED IN SALINE FOR 5 MINUTES AND SHALL NOT BE ALLOWED TO DRY OUT AFTER SOAKING. 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.**

**8. ADDITIONAL CAUTION FOR ALL KNITTED PRODUCTS. USE OF A CAUTERY FOR ANY SEALED POLYESTER GRAFT CAN CAUSE BURNING. THIS CAN BE PREVENTED BY SOAKING IN SALINE 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.**

- Clamping may damage any vascular prosthesis. Atraumatic clamps, ideally with soft shod jaws, should be used with a minimum application of force and for Gelsoft™ ERS and Gelsoft Plus™ ERS, should be used on the unsupported section only. Excessive force should be avoided, as it will damage the polyester fibers and the gelatin impregnation.
- Excessive tension on the prosthesis should be avoided.
- Round body taper point needles should

be used when implanting these prostheses to minimize fiber damage.

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

**13.** 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 graft during the second stage. Variability of the patients healing response may account for this difference.

Gelweave™ branched vascular grafts, including Siena™ grafts can also be used for debranching i.e. reconstruction of the aortic vessels and associated Hybrid procedures<sup>7,8</sup>. In relation to these procedures, no long term clinical data is available in relation to graft/stent performance<sup>7,8</sup>.

**14. Additional caution for Gelweave™ Valsalva only.** For valve sparing techniques ensure that the top of the commissures are sutured to the new sinotubular junction (join of graft body to the skirt).

**15.** 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 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.

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

#### 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 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<sup>1,2</sup> 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.

##### Peripheral Vascular Repair

A prospective trial was conducted to compare graft patency between Gelsoft™ and ePTFE grafts for femoro-popliteal 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 post-operatively 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.

##### Gelsoft™ ERS

##### Extra-Anatomical Repair

A prospective randomized study was performed in 14 vascular surgery centers in the United Kingdom and Ireland, to evaluate the safety and effectiveness of the Gelsoft™ ERS graft in patients requiring an extra-anatomic bypass and to examine the incidence of prosthetic graft infection. A total of 279 patients were randomized into two main groups of Gelsoft™ ERS with Rifampicin bonding\* (133 patients) or Gelsoft™ ERS without Rifampicin bonding (141 patients). As part of the broader nature of this study, some patients were randomized to



receive either a Gelseal™ ERT\*\* with Rifampicin bonding\* (1 patient) or the Gelseal™ ERT without Rifampicin bonding (4 patients). The study population consisted of 194 men and 85 women with a median age of 66. Pre-operative risk factors were well matched between the two main groups, as well as indications for surgery and distribution of the type of surgical procedure required. Patients were followed by physical examination for two years post-operatively. At two years, the patency rates for the bonded and unbonded grafts were well within the patency rate of 78.8% recorded for historical data. No significant differences were observed between the two groups and no side effects from Rifampicin\* were noted. The total rate of graft infection was found to be very low at one out of 279 patients (0.4%) and the rate of infective complications was similar in both groups. No significant differences between the bonded and unbonded groups were noted in terms of median hospital stay (approximately 10 days for both bonded and unbonded groups) and the need for post-operative antibiotics (15% and 22% respectively).

**\*This application of bonding has not been approved by the FDA for use in the USA.**

**\*\*Gelseal™ ERT has not been approved by the FDA for use in the USA.**

#### **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 asensate 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 (Gelweave™ and 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.

#### **Adverse Reactions**

Adverse reactions associated with all types of vascular grafts include bleeding, distal embolism, graft infection, aneurysm, false aneurysm, excessive blood loss through the graft wall and secondary fistula formation or bowel erosion.

#### **Preparation for Implant**

These prostheses may be briefly immersed in saline prior to implantation to improve their handling qualities. Prostheses should be immersed for 5 minutes.

#### **Additional Instructions for 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 oversewn using standard surgical technique.

#### **Additional Instructions for Gelweave™ Valsalva**

The coronary arteries should be anastomosed to the skirted section of the Gelweave™ Valsalva graft. 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. Cutting of the graft, whether for adjusting its length or for creating coronary ostia, should be performed by using a sterile cautery. **USE OF A CAUTERY FOR ANY SEALED POLYESTER GRAFT CAN CAUSE BURNING. THIS CAN BE PREVENTED BY SOAKING IN SALINE.**

#### **Sterilization**

These prostheses are sterilized by ethylene oxide, are supplied sterile and must not be resterilized. The Tyvek seal on both intermediate and inner trays must be intact. Any damage to the trays renders the prosthesis non-sterile. In the event of damage to the primary packaging, the product must not be used and should be returned immediately to the supplier.

#### **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 may be introduced to the sterile field.

#### **Additional labels**

Additional labels are attached for use on patient records.

#### **References**

1. Blumenberg, R., Gelfand, M., Barton, E., Bowers, C., and Gittleman, D. Clinical Significance of Aortic Graft Dilatation. *J. Vasc. Surg.* 1990. Vol. 12 pp. 291-297.
2. Nunn et al. Post-operative Dilation of Knitted Dacron Aortic Bifurcation Grafts. *Journal of Vascular Surgery.* 1990. Vol 12 pp. 291 – 297.
3. Walker et al. Novel Structure for a Polyester Vascular Prosthesis with Improved Mechanical Properties. 21st Annual Meeting of the Society of Biomaterials. 1995. p. 84.
4. Goéau-Brissonnière O. et al. Can Knitting Structure Affect Dilatation of Polyester Vascular Prostheses? A Randomized Study with the use of Computed Tomographic Scanning. *Journal of*

*Vascular Surgery.* 2000. Vol.31. pp 157-163.

5. Cavallaro, A., Sciacca, V., Cisternino, S., Di Marzo, L., Mingoli, A., Abrize, C., Gallo, P., Pollock, J.G. and Maini, R. Pretreatment with Gelatin of Dacron Grafts. *Experimental Research. Policlinico Saz Chir.* 1986. Vol 93. pp275-283.













6. Neri, E., Massetti, M. and Sani, G. (2004). The "elephant trunk" technique made easier. *The Annals of Thoracic Surgery.* Vol 78. pp e17-18.

7. Chiesa, R., Melissano, G., Tshomba, Y., Civilini, E., Marone, E.M., Bertoglio, L., Calliari, F.M. and Bernardo, B. (2008). Aortic Arch Aneurysms. *J. Vasc. Bras.* Vol. 7, 2; pp. 90-8.

8. Lumsden, A.B., Peden, E.K., Walkes, J.C., Ramchandani, M., Tripathy, U. and Reardon, M.J. (2007). Hybrid Interventions for Complex Aortic Pathology. *Endovascular Today.* November. pp. 80 - 85.

Tyvek® is a Du Pont Registered Trade Mark.

**EXPLANATION OF SYMBOLS ON PRODUCT LABELLING**

	<p><b>EN</b> Latex-free</p>
	<p><b>EN</b> Temperature limit to which the medical device can be safely exposed</p>
	<p><b>EN</b> Serial Number</p>
	<p><b>EN</b> Catalogue Number</p>
	<p><b>EN</b> Date of Manufacture</p>
	<p><b>EN</b> Usable Length</p>
	<p><b>EN</b> Do not re-use, single use only</p>
	<p><b>EN</b> Read Instructions before Use</p>
	<p><b>EN</b> Batch Code</p>
	<p><b>EN</b> Use-by Date</p>
	<p><b>EN</b> Sterilized using Ethylene Oxide</p>
	<p><b>EN</b> Diameter</p>

For ordering in the USA only, please contact:



**Terumo CardioVascular Systems Corp**  
6200 Jackson Road,  
Ann Arbor, MI 48103-9300  
Toll Free: 888 758 8000

Manufactured By:



**VASCUTEK Ltd**  
Newmains Avenue, Inchinnan  
Renfrewshire PA4 9RR, Scotland, UK  
Tel: +44 (0) 141 812 5555

Part No: 301-181