

**VASCUTEK Ltd**  
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[www.vascutek.com](http://www.vascutek.com)

30<sup>th</sup> November 2017

**To: Cardiothoracic / Cardiovascular / Vascular Surgeons**

**CC: Chairman of Medical Board and all relevant Head(s) of Department**

**Field Safety Notice  
 Important Medical Device Information**

**Type of Action: Updates to Instructions for Use**

<b>Product Catalogue Reference:</b>	<ul style="list-style-type: none"> <li>• All Gelsoft™, Gelsoft™ ERS, Gelsoft™ Plus, Gelsoft™ Plus ERS, Gelseal™, Gelseal™ ERT, Gelweave™, K-Thin, K-Thin ERS, and Gelseal™ Plus Vascular Prostheses</li> <li>• All Fluoropassiv™, Fluoropassiv™ ER, Thin Wall Fluoropassiv and Thin Wall Fluoropassiv ER Vascular Prostheses</li> <li>• All Cardiovascular Fabric Patches</li> <li>• All SealPTFE™ and Taperflo™ Vascular Prostheses</li> </ul>
<b>Lot/Serial Number</b>	All Lots

Dear Customer,

This notice is to inform you about important information concerning updates to the Instructions for Use (IFU) for the above products.

Vascutek Ltd has taken the opportunity to conduct a full review of the IFU contents to ensure consistency across all product families and to ensure that the Instructions for Use provide state of the art instruction and content to users. As a result of these updates, further clarity will be provided to Clinicians regarding immersion of grafts in saline solution, and to enhance knowledge on the use of formaldehyde in the manufacturing process. Further details are provided overleaf.

**The purpose of this notice is to provide supplementary information only.**



## Description of the IFU Updates

### Update 1: Immersion of graft/patch in saline solution

In the current IFUs for all gelatin sealed vascular prostheses and cardiovascular patches, Vascutek Ltd. recommend immersing the prostheses / patches in sterile saline prior to implantation. Vascutek's post market surveillance and customer feedback processes confirm that even with the recommendation in the IFU, not all customers are soaking the grafts prior to use and the length of soaking time varies from seconds to up to 1 hour.

Vascutek Ltd are therefore updating the IFUs to make the recommendation for soaking the graft prior to use into a mandated requirement and to mandate a soaking time of 5 minutes. This mandated 5 minute soaking time provides optimum graft performance because the gelatin is fully rehydrated prior to implant. This will aid haemostasis after implant.

### Update 2: Formaldehyde residuals

Details relating to the presence of formaldehyde in the prostheses / patch manufacturing processes and information relating to formaldehyde residuals on finished product have been included in the updated IFU.

There has been no change to the manufacturing processes. This new information has been added with the sole aim of enhancing the knowledge of the end user on the current manufacturing process for Vascutek Ltd. gelatin sealed prostheses and patches.

## Transmission of this Field Safety Notice

This notice needs to be passed on to all persons who need to be aware within your organisation or to any organisation where the devices are transferred or distributed. Please consider end users, Clinicians, Cardiothoracic / Cardiovascular / Vascular Surgeons, Risk Managers, Supply Chain / Distribution Centres, Procurement, Surgical Directors, Chief Executives of Hospital Trusts, etc. in the circulation of this notice.

Please maintain awareness of this Field Safety Notice until these products are provided with the updated IFU. In the meantime, if you require a copy of the updated IFUs, please contact Vascutek Ltd. at [FSNSP17-001@vascutek.com](mailto:FSNSP17-001@vascutek.com), or go to [www.vascutek.com](http://www.vascutek.com).

**Please complete the User Return Confirmation Slip in Appendix 1. Distributors and UK Hospitals should return this to [FSNSP17-001@vascutek.com](mailto:FSNSP17-001@vascutek.com).**

**Non-UK Hospitals should return this to your local Sales Representative, Clinical Specialist, or Distributor.**



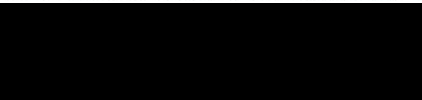
Vascutek Ltd. is informing the Competent Authorities in all countries where these products are sold, including the National Competent Authority – Medicines and Healthcare Products Regulatory Agency (MHRA), of this action.

**Contact reference person:**

Vascutek Ltd. is committed to providing high quality, safe and effective products. If you have any further questions or comments, please do not hesitate to contact us at [FSNSP17-001@vascetek.com](mailto:FSNSP17-001@vascetek.com).

Alternatively, please feel free to contact your local Sales Representative or Distributor or Vascutek Ltd. Customer Service personnel.

For and on behalf of Vascutek Ltd.



**Carolyn Forrest**

**Vice President Quality Assurance**

***Appendix 1: User Return Confirmation***





Company Reg. No.: 201201787G  
TERUMO SINGAPORE PTE LTD  
300 Beach Road #33-06 The Concourse Singapore 199555  
Tel: (65) 6291 3603 Fax: (65) 6291 2696

### **Field Safety Notice and Corrective Action Form**

**Devices:**

DE0008495 Vascutek Gelsoft™ Plus ERS Gelatin impregnated Vascular Prosthesis  
DE0008496 Vascutek GELSOFT™ PLUS Gelatin impregnated Vascular Prosthesis  
DE0012931 Vascutek Gelweave™ Gelatin Impregnated Woven Vascular Prosthesis (Branched)  
DE0012933 Vascutek Gelweave™ Gelatin Impregnated Woven Vascular Prosthesis (Straight)  
DE0006378 Vascutek Fluoropassiv™ Thin Wall Carotid Patch  
DE0006455 Vascutek Gelatin Sealed ePTFE Vascular Prosthesis  
MDSAHL1201601467 Vascutek Gelweave Valsalva Graft

**Reference:** HSA 600:41/01-028/18/01\_48

**Please complete, sign and fax this back to:** 6291 2696, TERUMO SINGAPORE PTE LTD

<b>Hospital Name</b>	
<b>Country</b>	Singapore

**List of Affected Units:**

Serial Number	In Use	NO

**Corrective Actions:**

Inform and disseminate FSN to local consignees.

***By completion and return of this form, I confirmed that I have received and read the above stated safety notice and corrective action was done on the affected units listed above.***

<b>Person Responding</b>	
<b>Title</b>	
<b>Phone Number</b>	
<b>Signature</b>	
<b>Date</b>	