GCN001

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8 July 2014

## Urgent Field Safety Notice
## Important Medical Device Information

**Type of Action: Field Safety Corrective Action/Correction**

- **Removal of Cautery from Gelweave™,Thoraflex™ Hybrid, BioValsalva™ Stentless Biplex™, Stented BioValsalva™ Biplex™ and RVOT elan™ Biplex™ products**
- **Associated Updates to Instructions for Use (IFU)**

| | |
|---|---|
| **Product Catalogue Reference:** | • All Gelsoft™, Gelsoft Plus™, K-Thin, Gelsoft Plus™ ERS, K-Thin ERS, Gelseal™, Gelseal Plus™, Gelseal™ ERT and Gelweave™ Vascular Prostheses<br>• All Thoraflex™ Hybrid Devices<br>• All BioValsalva™ Stentless Biplex™ Conduits<br>• All Stented BioValsalva™ Biplex™ Conduits<br>• All RVOT elan™ Biplex™ Conduits |
| **Lot/Serial Number** | • All Lots |

Dear Customer,

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

Currently Vascutek provides a high temperature cautery with each Gelweave™ and Thoraflex Hybrid product and a low temperature cautery with each BioValsalva™ Stentless Biplex™, Stented BioValsalva™ Biplex™ and RVOT elan™ Biplex™ conduit. These cauteries are used to cut and trim the graft. We have decided to stop supplying the cautery with these product packs due to the cautery battery having a shorter shelf life than the Vascutek graft product. Vascutek will update the IFU, removing reference to the inclusion of a cautery with these products.

Vascutek Ltd will not be recalling any product as there is negligible risk to users and patients.

**User Instructions:**

A. Vascutek advises that you ensure suitable equipment is available prior to implantation to trim the graft if required.

B. For product received with a cautery in the interim, Vascutek request that you check the shelf life of each product before every operation. If you find that the cautery is out of date, please contact your local representative who will organise reimbursement. If you require an appropriate cautery supplied as a separate item, please contact your local Vascutek representative.

C. Vascutek are taking this opportunity to reinforce the cautions from the Gelsoft™, Gelsoft Plus™, K-Thin, Gelsoft Plus™ ERS, K-Thin ERS, Gelseal™ , Gelseal Plus™, Gelseal™ ERT and Gelweave™ Vascular Prostheses IFU regarding soaking of the graft in saline to prevent

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focal burning if a cautery is to be used. This statement is already included in the IFU and now appears in bold, red font to ensure appropriate awareness.

**"7: Immersion of the Gelweave™ prosthesis in saline immediately prior to use will prevent focal burning, which may result during cauterisation. 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, Rifampicin and/or Heparin."**

Please ensure this action is followed when a cautery is used to trim these products.

**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 have been transferred or distributed.

Please maintain awareness of this Field Safety Notice while all actions are taken in your organisation and until these products are provided without the cautery.

**Please return the User Return Slip by e-mail or fax to the Distributor's address given on page 3.**

This action by Vascutek Ltd. is being taken with the knowledge of the National Competent Authority - Medicines and Healthcare Products Regulatory Agency (MHRA).

If you have any further questions or comments, please do not hesitate to contact us at FSN@vascutek.com.

If required, your Vascutek Ltd. representative can discuss and provide more information on the use of cautery with Vascutek products.

For and on behalf of Vascutek Ltd.

Carolyn Forrest

**Carolyn Forrest**
**Vice President Quality Assurance and Regulatory Affairs**

**Enclosed: User Return Confirmation**

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# User Return Confirmation

## For Onward Transmission to User or to Customer by Distributor

## Return Completed Form Immediately To:

## E-mail: FSN@Vascutek.com or Fax: +44 – 141 – 812 - 4204

**REFERENCE:**

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**In signing below, I confirm the following:**

**I acknowledge receipt of this Field Safety Notice and confirm that I completely understand the contents and the instructions. I acknowledge that all users and responsible personnel have been made aware of required actions.**

Institution Name (Hospital, Health Care Organisation)/Distributor Name:

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Person Responding (please print name) .....

e-mail address .....

Position: .....

Signature ..... Date .....

 