URGENT FIELD SAFETY NOTICE

Vascutek Ltd.
Newmains Avenue
Inchinnan Industrial Estate
Renfrewshire
PA4 9RR
Scotland
United Kingdom

For additional information contact: Mr Ian Hall QA Manager, Vascutek Ltd.

Telephone: 0141 812 5555
Fax: 0141 812 4204

Date: December 2012

Name of product affected: Biplex vascular grafts and Biplex Biovalsalva Conduits (stentless and stented)

FSCA identifier: CAPA 167

Type of Action: This action is being undertaken to increase clinician awareness regarding bleeding, experienced by some customers when using Biplex vascular grafts and Biplex BioValsalva Conduits.

Catalogue Numbers:

Biplex straight vascular grafts
BL6006, BL6007,BL6008, BL6009, BL6010, BL6011, BL6012, BL6014, BL6016, BL4006, BL4008, BL3006, BL3007, BL3008, BL3009, BL3010, BL3011, BL3012, BL3014, BL3016, BL1506, BL1507, BL1508, BL1509, BL1510, BL1511, BL1512, BL1514, BL1516, BL5016, BL5018, BL5020, BL5022, BL5024, BL5026, BL5028, BL5030, BL5032, BL5034, BL5036, BL5038, BL0526, BL0528, BL2518, BL2520, BL2522, BL2524, BL2526, BL2528, BL1218, BL1220, BL1222, BL1224, BL1226, BL1228, BL3018, BL3020, BL3022, BL3024, BL3026, BL3028, BL3030, BL3032, BL3034, BL3036, BL3038, BL1030, BL1032, BL1034, BL1036, BL2030, BL2032, BL2034, BL2036, BL2038, BL4030, BL4032, BL4034, BL4036, BL4038, BL6018, BL6020, BL6022, BL6024, BL6026, BL6028, BL6030, BL6032, BL6034, BL6036, BL6038

Biplex Valsalva vascular grafts
BL0022ADP, BL0024ADP, BL0026ADP, BL0028ADP, BL0030ADP, BL0032ADP, BL0034ADP

Biplex Biovalsalva Conduit (stentless)
EHVC21, EHVC23, EHVC25, EHVC27

Stented Biovalsalva Conduit (Biplex stented)
AHVC25, AHVC27, AHVC29

Batch No:/Sterile Lot No: All batches **Serial No:** All serial numbers

Reason for Urgent Field Safety Notice:

Vascutek is issuing this Field Safety Notice to increase clinician awareness of the additional implantation instructions and cautions being added to its Instructions For Use.

Description of the problem:

In recent months, Vascutek has received a number of events involving graft bleeding including anastomotic bleeding and suture hole bleeding, either during or shortly after surgery. Some have required re-intervention.

Vascutek has investigated all the events, carried out in-vitro studies and a customer survey.

The results of the investigation studies and survey could not identify a single root cause. They did however identify 3 issues which either singly or in combination could cause the problems. The issues are:

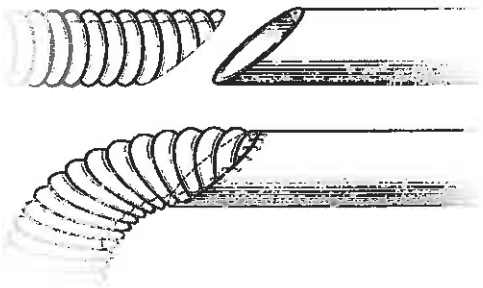
i) Difficulty in suturing because of the thickness of the graft.
ii) Oversizing of the graft relative to the native vessel
iii) Excessive tension at the distal anastomosis due to the graft being cut too short.

Advise on action to be taken by the user:

To reduce the risk of bleeding, Vascutek advise that clinicians are aware of an additional 5 cautions relating to sizing and insertion instructions:

1. It is essential that the sutures are tightened each time they are passed through the material.
2. In order to achieve a smooth suture line and good haemostasis, it is important that the graft diameter selected must not be oversized relative to the distal anastomotic site.
3. Care should be taken not to apply excessive tension at the distal anastomosis by ensuring the graft is cut to the correct length.
4. The use of haemostatic agents/ accelerants and/or felt/ pledgets may reduce the incidence of suture line bleeding and resternotomy.
5. The use of an oblique/ bevel graft to vessel anastomosis is recommended. This technique will minimise any blood leakage arising from the oversizing of the graft relative to the native vessel (see Diagram 1)

Diagram 1



Oblique/Bevel graft to vessel anastomotic technique

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have to be transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate).

Potential Risk:

No product recall is required and the issue does not impact other product lines/families.

Reports have been restricted to bleeding occurring during or shortly after surgery requiring re-intervention to correct bleeding.

Transmission of this Field Safety Notice:
The undersigned confirms that this notice has been submitted to the appropriate Regulatory Authority.

Signed: J Hall. Date: 11 December 2012.

Position: QA Manager, Vascutek Ltd.