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18th March 2014

URGENT FIELD SAFETY NOTICE

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Aspire Aortic Valve (A44-xx) Aspire Mitral Valve (M55-xx)
TYPE OF ACTION:	FIELD SAFETY CORRECTIVE ACTION
VASCUTEK REFERENCE:	FSN_18Mar2014
PRODUCT CATALOGUE NUMBERS:	Reference Attachment 1
BATCH NUMBERS:	Reference Attachment 1

Dear Customer,

1. Description of the problem:

Vascutek Ltd, Leeds has become aware of a labelling issue with a limited quantity of Aspire Aortic Valves and Aspire Mitral Valves.

A report was received from a customer indicating receipt of a box labelled as an Aspire Aortic Valve (A44-25), that actually contained an Aspire Mitral Valve (M55-27). The valve was returned unused by the customer.

Upon opening the packaging, it would be immediately obvious to the cardiothoracic surgeon or scrub nurse if the pot contained the correct valve or not. There is therefore a very remote risk that an incorrect valve would be implanted.

Vascutek Ltd, Leeds is initiating a Voluntary Recall of a discrete quantity of valves that were processed through the same sterilization run and into finished goods at the same time. The valves were manufactured and distributed between 2012 and 2013 and the likely mix-up has occurred because of serial number similarities between an Aspire Aortic Valve and an Aspire Mitral Valve.

Vascutek's distribution records indicate that a discrete quantity of 3 units of M55-27 valves was shipped to a distributor in Russia. All other valve products within the sterilization run have either been implanted without incident or remain within Vascutek's control.

This Voluntary Recall addresses the risk of the correct valve not being available for a procedure to continue, versus the risk of incorrect use of the valve.

Please Note:

- This is a limited label mix-up and does not affect the safety or efficacy of previously implanted valves.
- There is no suggestion that patients already implanted with Aspire Aortic Valves or Aspire Mitral Valves are exposed to any raised level of risk. An aortic valve and a mitral valve are immediately recognisable as different valves.

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

Vascutek Ltd. is also informing the Competent Authorities in the affected countries where the affected product was sold.

2. Field Safety Corrective Action Instructions:

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF:

1. Please review the list of affected products in Appendix 1 and quarantine any catalogue/serial numbers within the scope of this field action.

2. Users should cease use of affected stock immediately.

3. If you have stock listed in Appendix 1, please mark the corresponding checkbox on the Acknowledgement Form (Appendix 2).

4. **Complete Appendix 2 for all products in your possession and under your control.** Please return this form immediately to your local Sales Representative or Distributor and they will coordinate the retrieval of the affected products.

5. If you do not have stock listed in Appendix 1, please mark the checkbox on the Acknowledgement Form (Appendix 2) and return the form immediately to your local Sales Representative or Distributor.

6. Vascutek Ltd or your local Distributor will provide credit upon receipt of the returned devices.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCTS

1. If you are a Distributor, please provide this Field Safety Notice to all of your customers who have received product in the scope of this Field Safety Corrective Action.

2. **Please ensure that all customers complete Appendix 2 for all products in their possession and under their control.**

3. **Please ensure that you complete Appendix 2 for all products in your possession and under your control. All completed forms to be returned immediately to the fax number or e-mail address referenced.**

4. The remaining unused products should be returned as soon as possible to Vascutek Ltd. Please contact Vascutek Customer Services to obtain a Returned Goods Authorisation (RGA) number for the return shipment. Please reference the RGA number in the appropriate field on the Acknowledgement Form.

5. Please reference the RGA number issued by Customer Services clearly on the outside of the shipping carton when returning product to Vascutek Ltd.

6. As a Distributor, you are required to confirm to Vascutek Ltd, that you have completed the field action outlined above.

7. Upon completion of your actions, please forward the completed Acknowledgement Form to the fax number or e-mail address referenced.

3. Transmission of this Field Safety Notice

This notice needs to be passed on to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, Clinicians, Risk Managers, Supply Chain/Distribution centres etc. in the circulation of this notice.

Please maintain awareness of this Field Safety Notice until all required actions have been completed in your organization.

4. Contact reference person:

Carolyn Forrest
Vice President Quality Assurance and Regulatory Affairs
Vascutek Ltd
Newmains Road
Inchinnan, Renfrewshire PA4 9RR
Scotland
UK

Or

Customer Service Department
+44 – (0)141 – 812 - 5656

Vascutek Ltd is committed to providing high quality, safe and effective products. We sincerely apologise for any inconvenience this action may cause your operations.

If you have any questions, 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

Carolyn Forrest
Vice President Quality Assurance and Regulatory Affairs

Appendix 1 – List of Affected Products

Appendix 2 – Acknowledgement Form

APPENDIX 1 LIST OF AFFECTED PRODUCTS

Description	Catalogue Number	Serial Number
Aspire Mitral Valves	M55-27	0025182 0025074 0025174

APPENDIX 2

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

VOLUNTARY RECALL BY VASCUTEK LTD, LEEDS
IMMEDIATE ACTION REQUIRED

RETURN COMPLETED FORM IMMEDIATELY TO:
FAX: +44 - 141 - 812 - 4204 **E-mail: FSN@Vascutek.com**

☐ Mark box with a 'X'	☐ Mark box with a 'X'
Our inventory does NOT include products affected by this Field Action.	**Our inventory DOES include products affected by this Field Action.** **The use and further distribution of these affected products has stopped.** **All products are On Hold and the items listed below will be returned.** **Returned Goods Authorisation Number (RGA)** --- • Include a copy of the **Acknowledgement Form** in the returned goods package • Please ensure **RGA** number is clearly visible on returns package.

PLEASE PRINT PRODUCT CATALOGUE AND QUANTITY NUMBERS CLEARLY

COMMERCIAL NAME OF AFFECTED PRODUCTS:	ASPIRE MITRAL VALVE	
CATALOGUE NUMBER	QUANTITY	SERIAL NUMBER
M55-27		

Complete this Acknowledgement Form and return to Vascutek Ltd immediately by using the fax number or e-mail address above.

INSTITUTION NAME (EG. NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	
FORM COMPLETED BY:	**TITLE/ROLE:**
DATE:	