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21st October 2013

URGENT FIELD SAFETY NOTICE

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Anaconda™ ONE-LOK Bifurcate Body; Anaconda™ Bifurcate Body
TYPE OF ACTION:	FIELD SAFETY CORRECTIVE ACTION
VASCUTEK REFERENCE:	FSN_17Oct2013
PRODUCT CATALOGUE NUMBERS:	Reference Attachment 1
BATCH NUMBERS:	All Batch Numbers

Dear Customer,

1. Description of the problem:

Vascutek Ltd has received 3 complaints (with an occurrence rate of 0.1%) where the release wire of an Anaconda™ Body delivery system has fractured following stent deployment. Two of these three incidents resulted in conversion to open repair.

Vascutek Ltd is initiating a Voluntary Recall of all Anaconda Bodies pending identification of root cause and implementation of corrective actions.

This Voluntary Recall addresses potential patient risks associated with the wire fracturing and the possibility of conversion to open repair.

Please Note:

- This is a potential failure mode of the delivery system and does not affect the safety or efficacy of the implantable stent. Previously implanted stents are not affected by this Voluntary Recall.
- There is no suggestion that patients already implanted with Anaconda™ ONE-LOK Bifurcate Body or Anaconda™ Bifurcate Body are exposed to any raised level of risk.
- This notice applies only to Anaconda™ ONE-LOK Bifurcate Bodies and Anaconda™ Bifurcate Bodies and does not apply to Anaconda™ Straight Legs, Tapered Legs, Flared Legs or Aortic Extension Cuffs.

This action by Vascutek Ltd. 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 all countries where this product is sold.

Registered Office: Newmains Avenue, Inchinnan, Renfrewshire PA4 9RR. Registered in Scotland No. 79773

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 numbers within the scope of this field action.

2. Users should cease use of 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

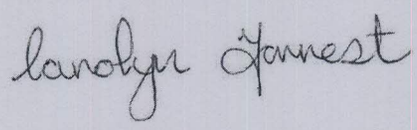
Or

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
Vice President Quality Assurance and Regulatory Affairs

Attachment 1 – List of affected products
Attachment 2 – Acknowledgement Form

APPENDIX 1 **LIST OF AFFECTED PRODUCTS**

Description	Catalogue Number	Item Number
Anaconda™ ONE-LOK Bifurcate Body	OLB21 OLB23 OLB25 OLB28 OLB30 OLB32 OLB34	OLB21 OLB23 OLB25 OLB28 OLB30 OLB32 OLB34
Anaconda™ Bifurcate Body	B19 B21 B23 B25 B28 B30 B32 B34	B19*01, B19*02 B21*01, B21*02 B23*01, B23*02 B25*01, B25*02 B28*01, B28*02 B30*01, B30*02 B32*01, B32*02 B34*01, B34*02