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28 September 2017

To: Distributors

Field Safety Notice
Important Medical Device Information

Type of Action: Updates to Anaconda Instructions for Use

Product Description:	• Anaconda™ ONE-LOK™ AAA Stent Graft System • Anaconda™ Iliac Stent Graft System • Anaconda™ AAA Stent Graft System Aortic Cuff
Lot/Serial Number	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.

We are taking the opportunity to provide further clarity for Clinicians regarding the use of the above products in several different areas to reflect current clinical practice. In addition, we have combined the three current IFUs / IFU supplements for the above products into one main IFU that now covers all these product ranges.

A description of the key updates is provided in Appendix 1.

Action To Be Taken by Distributors

The updated IFU will be provided with all products sold from 28th September 2017.

All product in stock / inventory and on hospital consignment will require to be identified and re-packed with the new IFU.

Instruction For Distributors Of Affected Products

1. Please communicate the Field Safety Notice to your Competent Authority, unless it has been confirmed that Vascutek will be responsible for the communication.

2. Please provide the attached Field Safety Notice to all of your customers who have received product in the scope of the Field Safety Notice within the past 5 years.

3. Please ensure that all customers complete Appendix 3 for all products in their possession or to indicate that they hold no stock. All completed forms are to be returned immediately by you to the e-mail address referenced in Appendix 3.

4. Distributors, please check your stock and complete the appropriate parts of Appendix 3 for all products in your possession, or indicate that you hold no stock.
   Please return all completed forms immediately to the e-mail address referenced in Appendix 3.
   Please Note: as this FSN applies to all lots, any stock you hold of the products listed in this FSN will be affected.

5. Customers are to complete Appendix 2 and send back to you. All completed forms are to be returned immediately by you to the e-mail address referenced in Appendix 2.

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

7. Upon completion of your actions, please complete the Distributor Return Confirmation in Appendix 2 and return to the e-mail address referenced.

Transmission of the Field Safety Notice

The notice needs to be passed on to all persons who need to be aware within your organisation or to Hospitals where the devices are transferred or distributed. Please consider end users, Vascular Surgeons, Radiologists, Risk Managers, Supply Chain/Distribution centres, Procurement / Sales Personnel, Medical / 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. A copy of the new bailout procedure is included within this FSN (Appendix 1). However, if you have any concerns and require an electronic copy please contact Vascutek Ltd at FSN@vascutek.com , or go to http://www.vascutek.com/site/301-179.pdf

Your Vascutek Ud Clinical Specialist will discuss and provide training on the key changes detailed within this notice to enable you to comply with the revised IFU. lf there is no Clinical Specialist in your country, please contact the Clinical Risk Department at Vascutek Ud to arrange this support.

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 these products are sold.

Contact Reference Person:

Vascutek Ltd. is committed to providing high quality, safe and effective products. lf you have any further questions or comments, please do not hesitate to contact us at FSN@vascutek.com.

For and on behalf of Vascutek Ltd.

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Appendix 1: Description of the Key IFU Updates

Appendix 2: User Return Confirmation

Appendix 3: Stock Check Confirmation

Appendix 1: Description of the Key IFU Updates

Update 1: New Bailout Procedure (Section 3, Bailout Procedures)

Following receipt of a complaint related to a snapped release wire, Vascutek Ltd. have implemented a new bailout procedure into the Anaconda™ Stent Graft System IFU.

Investigation into the complaint determined the root cause to be procedural error. It was identified that a bailout procedure for this type of issue is currently provided in the IFU supplement provided with Custom Made Anaconda™ AAA Stent Graft Systems, but not in the standard Anaconda™ AAA Stent Graft System IFU. As this issue could also arise with the standard Anaconda™ AAA Stent Graft System, Vascutek Ltd. are including this bailout procedure in the Anaconda™ AAA Stent Graft System IFU.

The new bailout procedure is detailed below:

3.1 Anaconda™ Bifurcate Body, Aortic Cuff and Iliac Leg Delivery System Deployment Issues		
Issue	**Potential Problem**	**Process**
6. Resistance is experienced on removal of the white (valley) release clip/wire and/or blue (peak) release clip/wire:	Release wire has become damaged/ snapped and still through control loops	1. Perform a high resolution single shot x-ray over the proximal section of the delivery system, to visualise all release wires. Review the imaging for potential obstruction that may prevent resheathing and removal of the delivery system. 2. If no obstruction is identified, then the clinician should proceed to remove the release wires following the standard deployment sequence. If the clinician still encounters resistance, repeat step 1. 3. On removal of the release wires from the delivery system, check both release wires are intact and are similar lengths (~130 cm).

3.1 Anaconda™ Bifurcate Body, Aortic Cuff and Iliac Leg Delivery System Deployment Issues		
Issue	**Potential Problem**	**Process**
		4. Perform a final high resolution single shot x-ray before removal of the delivery system ensuring no remaining parts of the release wire are still attached to the delivery system. 5. Under continuous fluoroscopic visualisation carefully remove the delivery system observing for any movement of the stent graft. If movement is noted; stop and perform further imaging to assess the proximal section of the stent graft. 6. Evaluate any other potential reasons for difficulty in removing the delivery system e.g. catheters, wires, balloons or anatomical obstructions. 7. If the remaining portion of release wire is attached to the peak eyelets of the proximal ring stent, it may be possible to remove the remaining portion using an antegrade approach. Obtain access from an antegrade approach using an introducer sheath. Using a catheter, catch the loop of the release wire. Advance a guidewire through the catheter to facilitate snaring and removal of release wire. Snare the free end of the guidewire to secure the release wire. Close and retract the snare, guidewire and catheter into the

3.1 Anaconda™ Bifurcate Body, Aortic Cuff and Iliac Leg Delivery System Deployment Issues		
Issue	**Potential Problem**	**Process**
		sheath and carefully remove from the patient. 8. If the release wires are similar lengths, proceed to remove the delivery system. If the release wires are not similar lengths, perform a final high resolution single shot x-ray to ensure that no section of release wire remains. If no sections of release wire are observed, then proceed to re-sheath the delivery system and remove from the patient.

Update 2: New Caution for Anaconda™ AAA Stent Graft System Aortic Cuff (Section 2.3, Deployment Procedure for Anaconda™ AAA Stent Graft System Aortic Cuff)

A new caution has been added to the deployment instructions for the Anaconda™ AAA Stent Graft System Aortic Cuff, as shown below (new caution in red text):

If the leg markers are above the docking markers, the distal marker of the Aortic Cuff can be positioned in line with the proximal iliac leg marker to give maximum cuff to body docking overlap.

CAUTION: Ensure that the distal marker is not below the level of the docking zone before deployment.

This new caution has been implemented based on clinical feedback. If the cuff is deployed too low in the main body, i.e. the distal marker below the docking zone, the distal portion of the cuff may not open fully and will potentially be constrained within the bifurcation of the body. As the cuff is non-repositionable, should this occur, the deployment of the cuff in this position could potentially cause occlusion to the opposite side of the graft and the only bailout available to the clinician would be open conversion.

Appendix 2

Distributor Return Confirmation

Return Completed Form Immediately To:

E-mail: FSN@Vascutek.com

REFERENCE:

Type of Action: Field Safety Notice – Updates to Anaconda Instructions for Use

In signing below, I confirm the following:

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

Distributor Name:

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Person Responding (please print name) ……

E-mail Address ……

Position ……

Signature …….. Date …….

Appendix 3

Distributor Stock Check Confirmation

REFERENCE:

Type of Action: Field Safety Notice – Updates to Anaconda Instructions for Use

☐ **Mark box with a 'X'**	☐ **Mark box with a 'X'**
Our inventory **DOES** include products affected by this Field Safety Notice and details have been provided below.	Our inventory does **NOT** include products affected by this Field Safety Notice.

Product Name	Catalogue Number	Serial Number

**If additional lines, please use the supplementary table on page 11.*

Distributor Name:

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Distributor Address:

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Person Responding (please print name) ……

E-mail Address ……

Position ……

Signature …….. Date ……

Supplement to Appendix 3

Product Name	Catalogue Number	Serial Number