

28 September 2017

To: Vascular Surgeons, Radiologists, Risk Managers, Procurement, Medical / Surgical Directors and Chief Executives of Hospital Trusts

**Field Safety Notice
 Important Medical Device Information**

Type of Action: Updates to Anaconda Instructions for Use

Product Description:	<ul style="list-style-type: none"> • 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 Medical Staff

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

All product in your hospital will require to be identified and re-packed with the new IFU.



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Advice on Action To Be Taken By Medical Staff:

1. Please complete the User Return Form in Appendix 2. In the UK only, please return this form immediately to the email address provided in Appendix 2. For all other countries, please return immediately to your local Sales Representative, Clinical Specialist, or Distributor.
2. Please complete Appendix 3 for all products in your hospital, or indicate that you hold no stock.
In the UK only, please return this form immediately to the email address provided in Appendix 3. For all other countries, please return immediately to your local Sales Representative, Clinical Specialist, or Distributor.
Please Note: as this FSN applies to all lots, any stock you hold of the products listed in this FSN will be affected.
3. If you do not have stock of the products subject to this Field Safety Notice, please mark the corresponding check box on the Stock Check Confirmation Form in Appendix 3. Please return this form immediately to the email address provided in Appendix 3. For all other countries, please return immediately to your local Sales Representative, Clinical Specialist or Distributor.

Following receipt of this information, either Vascutek Ltd, your local Sales Representative, Clinical Specialist, or Distributor will contact you to make arrangements for the re-packing of these devices with the updated IFU.

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 are transferred or distributed. Please consider end users, Vascular Surgeons, Radiologists, Risk Managers, Supply Chain/Distribution centres, Procurement, 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 the contact email address below, or go to <http://www.vascutek.com/site/301-179.pdf>.

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



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

Alternatively, please feel free to contact your local Sales Representative or Distributor or Vascutek Ltd Clinical Risk personnel.

For and on behalf of Vascutek Ltd

A handwritten signature in black ink that reads "Carolyn Forrest".

Carolyn Forrest

Vice President Quality Assurance and Regulatory Affairs

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	<ol style="list-style-type: none"> 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).



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3.1 Anaconda™ Bifurcate Body, Aortic Cuff and Iliac Leg Delivery System Deployment Issues		
Issue	Potential Problem	Process
		<p>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.</p> <p>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.</p> <p>6. Evaluate any other potential reasons for difficulty in removing the delivery system e.g. catheters, wires, balloons or anatomical obstructions.</p> <p>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</p>



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3.1 Anaconda™ Bifurcate Body, Aortic Cuff and Iliac Leg Delivery System Deployment Issues		
Issue	Potential Problem	Process
		<p>sheath and carefully remove from the patient.</p> <p>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.</p>



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**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.



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Appendix 2

User Return Confirmation

Return Completed Form Immediately To:

E-mail: FSN@Vascutek.com (UK only)

Or to your Distributor

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.

Institution Name (Hospital, Health Care Organisation)

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Person Responding (please print name)

E-mail Address

Position

Signature Date



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Appendix 3 Stock Check Confirmation

REFERENCE:

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

<input type="checkbox"/> Mark box with a 'X' Our inventory DOES include products affected by this Field Safety Notice and details have been provided below.	<input type="checkbox"/> Mark box with a 'X' Our inventory does NOT include products affected by this Field Safety Notice.
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Product Name	Catalogue Number	Serial Number

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

Institution Name (Hospital, Health Care Organisation):

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Institution Address (Hospital, Health Care Organisation):

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Person Responding (please print name)

E-mail Address

Position

Signature Date



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