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15th November 2017

To: Vascular Surgeons

CC: Chairman of Medical Board and all relevant Head(s) of Department

**Urgent Field Safety Notice Important Medical Device Information**

<b>Product Description:</b>	Anaconda™ Longer Leg Iliac Stent Graft System (including Straight, Flared and Tapered configurations)
<b>Catalogue Numbers</b>	L12X160, L12X180, FL1213X150, FL1213X170, FL1215X150, FL1215X170, FL1217X150, FL1217X170, FL1219X150, FL1219X170, FL1221X150, FL1221X170, FL1223X150, FL1223X170, TL1210X150, TL1210X170
<b>Lot/Serial Number</b>	All Lots

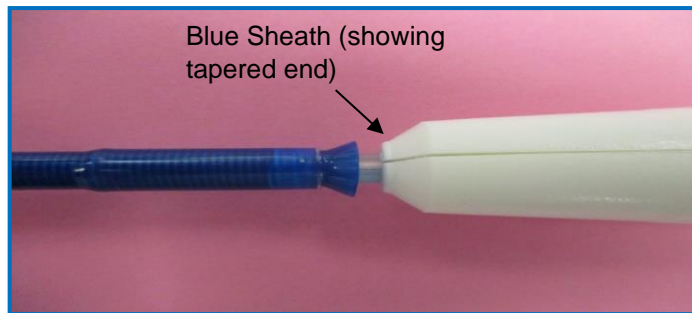
Dear Healthcare Professional,

Terumo Singapore Pte. Ltd., in consultation with Healthcare Sciences Authority (HSA), is issuing the letter to inform you about important information concerning the Anaconda™ Longer Leg Iliac Stent Graft System, including straight, flared and tapered configurations.

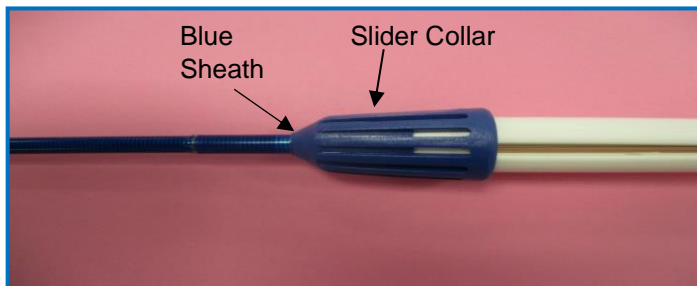
Vascutek Ltd. have received 2 complaints whereby the delivery system sheath became detached from the collar during the deployment of the Anaconda™ Longer Leg Iliac Leg Stent device from the Delivery System. Deployment of the stent graft was not affected. The root cause of this issue has been identified and rectified.

In both instances, a small section of the tapered end of the blue sheath became detached from the slider collar when the device was retracted (Figures 1a, 1b and 1c). The appropriate bailout procedure outlined in the Instructions for Use (IFU) was utilised and the legs were deployed without incident or injury to the patient.





**Figure 1a:** Anaconda Longer Leg Delivery System (intact sheath prior to application of slider collar)



**Figure 1b:** Anaconda Longer Leg Delivery System (intact; showing position of blue sheath and slider collar)



**Figure 1c:** Small section of the tapered end of the blue sheath detached from the slider collar following retraction of device

The purpose of this notice is to increase clinician awareness regarding this potential issue when using Anaconda™ Longer Leg Iliac Stent Graft Systems, and to remind users to refer to the IFU for details of the steps that should be taken should this issue occur.

Vascutek Ltd. will not be taking any action with respect to product in the field as the severity of this risk is assessed as negligible. This is a mechanical failure of the device and poses no physical risk to the patient. The event rate associated with this issue is 0.1%.

## User Information

Vascutek Ltd. advises that should this event occur during deployment of an Anaconda™ Longer Leg Iliac Stent Graft device, you should refer to the Anaconda™ Stent Graft System IFU for details of the bailout procedure.

The appropriate bailout procedure is also presented below;

**Visualise via fluoroscopy if the stent has been partially unsheathed. If no unsheathing has occurred remove the delivery system and introduce a new delivery system.**

**If the graft has been partially unsheathed the following stages will fully unsheath the graft:**

1. **Retract the sheath slider until its blue tip is fully docked with the delivery system handle**
2. **Carefully cut a central line through the outer sheath from the handle approximately 10 cm long**
3. **Attach one set of forceps to each side of the sheath, ensuring the delivery system handle is stabilised.**
4. **Retract the outer sheath carefully under fluoroscopy ensuring the sheath is split apart well away from the vessel, and that the sheath is split outside the arteriotomy to prevent any damage to the native vessel**
5. **The sheath should be retracted until its distal end is in line with the blue tip of the fully retracted sheath slider. This will ensure that the graft is fully unsheathed.**

## Action to be Taken

**Please complete the User Return Confirmation Slip provided in Appendix 1.**

Distributors and UK Hospitals should return this to [FSN@vascutek.com](mailto:FSN@vascutek.com). Non-UK Hospitals should return this to their local Sales Representative, Clinical Specialist, or Distributor.

## 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, Clinicians, Vascular Surgeons, Radiologists, Risk Managers, Supply Chain/Distribution centres, Procurement, Surgical Directors, Chief Executives of Hospital Trusts, etc. in the circulation of this notice.

If you require a copy of the Anaconda Stent Graft System IFU, please contact Vascutek Ltd. at [FSN@vascutek.com](mailto:FSN@vascutek.com) or go to <http://www.vascutek.com/site/301-179.pdf>.



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

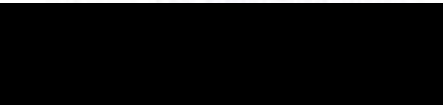
Vascutek Ltd. is also informing the Competent Authorities in all countries where these products are sold.

### 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@vascutek.com](mailto:FSN@vascutek.com).

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

For and on behalf of Vascutek Ltd.



**Carolyn Forrest**  
**Vice President of Quality**

### Appendix 1: User Return Confirmation



## Appendix 1

### User Return Confirmation

#### Return Completed Form Immediately To:

Distributors and UK Hospitals: By e-mail to [FSN@vascutek.com](mailto:FSN@vascutek.com)

Non-UK Hospitals: By e-mail to local Sales Representative, Clinical Specialist,  
or Distributor.

#### REFERENCE:

Type of Action: Urgent Field Safety Notice (AN17-002)

In signing below, I confirm the following:

I acknowledge receipt of this Field Safety Notice and confirm that I understand the contents and the instructions and acknowledge that all users and responsible personnel have been made aware of the information provided within.

Institution Name (Hospital, Health Care Organisation) / Distributor Name:

.....

Person Responding (please print name) .....

E-mail Address .....

Position .....

Signature ..... Date .....

