URGENT FIELD SAFETY NOTICE

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Date: **17th February 2012**

Name of product affected: ... **Anaconda and Anaconda ONE-LOK™ Stent Graft Systems**

FSCA identifier: CAPA 162

Type of Action: ...**Additional instructions to enable the bifurcate body delivery system to be safely withdrawn after being fully deployed.**

Catalogue Nos:

B19, B21, B23, B25, B28, B30, B32 and B34;

(including B19*01, B21*01, B23*01, B25*01, B28*01, B30*01, B32*01 to B34*01.

B19*02, B21*02, B23*02, B25*02, B28*02, B30*02, B32*02 to B34*02)

OLB21, OLB23, OLB25, OLB28, OLB30, OLB32 and OLB34 (ONE-LOK™)

Batch No:/Sterile Lot No: .....All batches..... Serial No: All serial numbers.

Reason for Urgent Field Safety Notice:

Vascutek is issuing this Field Safety Notice to increase clinician awareness. As this Field Safety Notice does not pertain to, or relate to an implanted device, patient notification is not necessary.

No product recall is required.

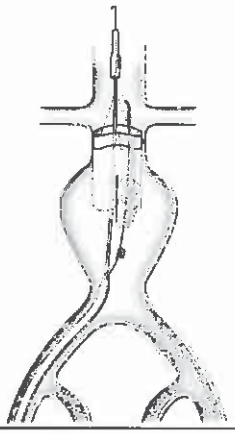
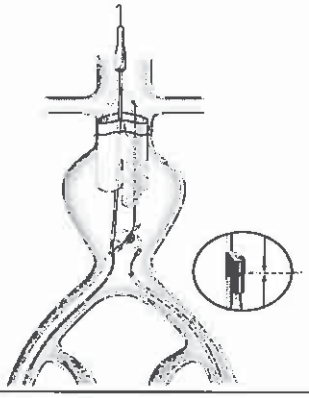
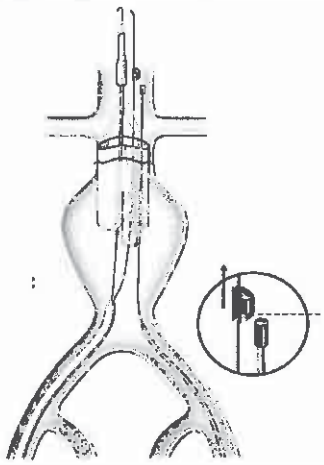
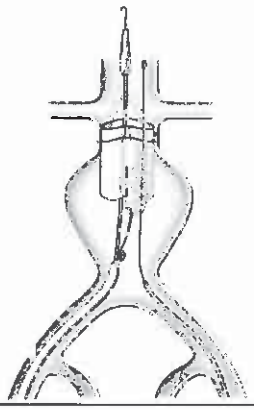
This Field Safety Notice relates to the Anaconda™ and Anaconda ONE-LOK™ Stent Graft Systems, which are intended for Endovascular Abdominal Aortic Aneurysm (AAA) repair, the intended deployment site being the infra-renal abdominal aorta.

It has been identified from a small number of field reports (less than 0.05% of the total number of devices distributed) that under exceptional circumstances an additional procedure may be required to remove the bifurcate body delivery system

Description of the problem:

The normal deployment procedure is outlined throughout Schematic 1 given on the next page:

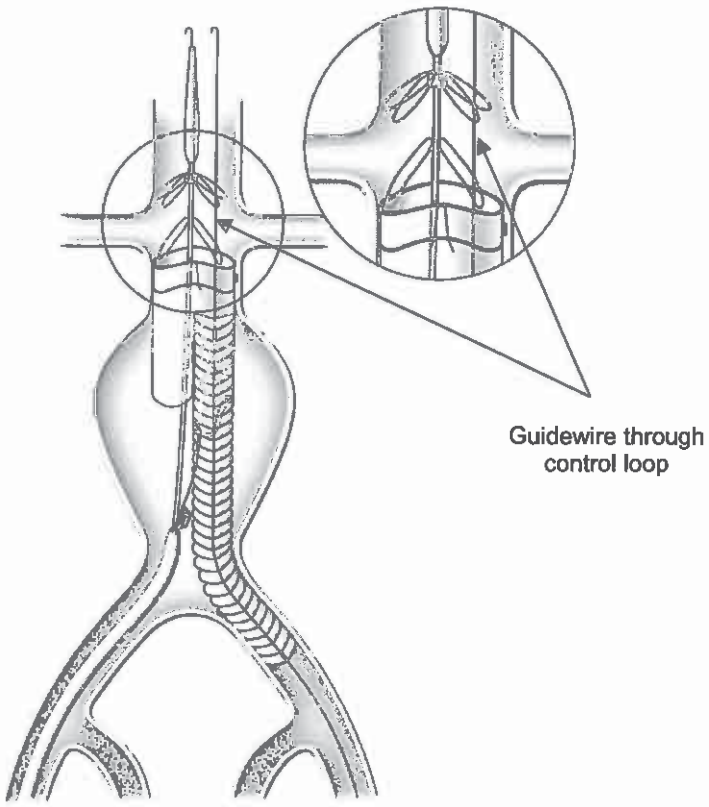
Schematic 1: Standard Procedure Deployment Images: from current product Instructions for Use

	**Instructions for Use Reference** **Figure 9:** Stage 1 Procedure 9 *"To confirm the position of the ring stent in relation to the renal arteries, release the control collar to fully open the top ring stent."*
	**Instructions for Use Reference** **Figure 10:** Stage 2 Procedure 6 *"The Intrinsic Magnet Wire and Contralateral Magnet Guide Wire are manipulated until the two magnets attach. Ensure the ipsilateral guide wire is not accidentally withdrawn from the bifurcate body during guide wire manipulation."*
	**Figure 11:** Stage 2 Procedure 7 *"When the magnets attach, carefully advance both magnet guide wires simultaneously until the magnets are visualized in the supra-renal position. Ensure 20mm of the Ipsilateral Magnet Wire remains distal to the delivery handle."* **Figure 11:** Stage 2 Procedure 8 *"To detach the magnets, fix the Contralateral Magnet Guide Wire and advance the Intrinsic Magnet Wire the final 20mm."*
	**Figure 12:** Stage 2 Procedure 9 *"Withdraw the Intrinsic Magnet Wire until the floppy tip of the wire is across the contralateral cannulation flare. There will be some resistance as the mould slides along the wire.* ***This procedure must be visualised under fluoroscopic guidance."***

As detailed, it has been identified from a small number of field reports that under exceptional circumstances an additional procedure may be required to remove the bifurcate body delivery system.

Upon advancement of the guidewires the Intrinsic magnet wire may pass through one of the control loops. As a result, when the Intrinsic magnet wire is withdrawn, the remaining contralateral guidewire, catheter and/or balloon will also have passed through the same loop of the body delivery system, as indicated in Schematic 2. On attempting to remove the bifurcate body delivery system from the ipsilateral lumen, it will be found it cannot be withdrawn. The loops which are tied to the body delivery system are being held by the contralateral guidewire, catheter and/or balloon in the contralateral lumen, above the bifurcate flow splitter.

Schematic 2: Guidewire passing through control loop.

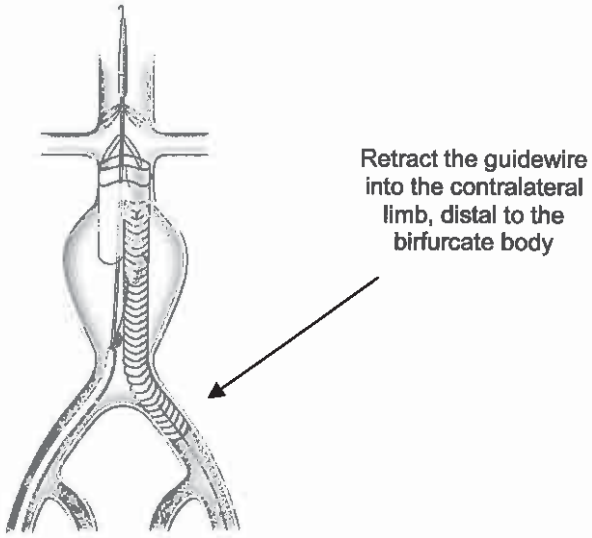


Advice on action to be taken by the user:

To help prevent further occurrences, if difficulty is experienced in removing the bifurcate body delivery system, the following action as presented in Schematics 3 and 4 is recommended:

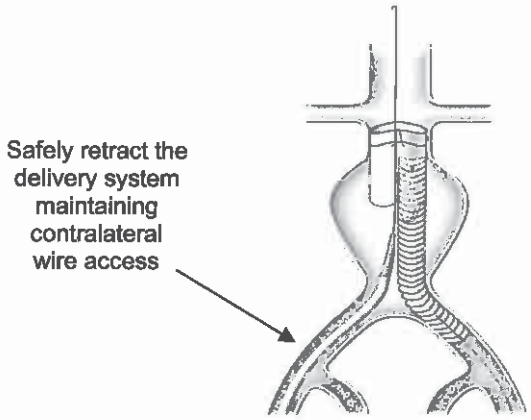
Carefully retract any contralateral guidewire, catheter and/or balloon until their tips are within the iliac leg stent graft but distal to the contralateral stump of the bifurcate body as illustrated in Schematic 3.

Schematic 3: Retracting guidewire.



Following this adjunctive procedure, it should now be possible to remove the bifurcate body delivery system as shown in Schematic 4.
Ensure fluoroscopic visualization is maintained throughout this procedure, to allow for observation of any movement of the bifurcate body stent graft.
Ipsilateral guidewire access must be maintained throughout to allow for introduction and deployment of the Ipsilateral leg.

Schematic 4: Removing body delivery system.



Potential Risk

If difficulty is experienced in removing the bifurcate body delivery system, and the recommended action as described in Schematics 3 and 4 is not undertaken, it is likely a conversion to open surgery would be required.

Transmission of this Field Safety Notice:

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Signed: [redacted] Date: 6.2.12

Position QA Manager, Vascutek

User Return Slip
For Onward Transmission to User/ Customer by Distributor

REFERENCE:

Vascutek has issued a Field Safety Notice relating to the Anaconda™ and Anaconda ONE-LOK™ Stent Graft Systems.

Please Follow the Instructions for Transmission of this Field Safety Notice:

1. **This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.**

2. **Please return the FORM 2 User Return Slip within 3 working days either by mail, e-mail, fax to the Distributor's address given on page 2.**

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

FORM 2 User Return Slip For Onward Transmission to User/Customer by Distributor

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RETURN SLIP: Please complete and return to address given below within 3 working days.

This is to acknowledge receipt of Anaconda™ and Anaconda ONE-LOK™ Stent Graft Systems Field Safety Notice and that the information has been prominently displayed for a minimum time to allow all user's to become aware of the information.

Distributor……

Address……

……

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E-mail address……

Telephone……

Fax……

I Acknowledge Receipt of this Field Safety Notice.
I understand the Instructions as given in this Field Safety Notice.
I Acknowledge that all user's have been made aware of the Field safety Notice and understand its content.

User ……

Person Responding (please print) ……

e-mail address ……

Position ……

Signature …… Date ……