

**URGENT FIELD SAFETY NOTICE**

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**Date: 17<sup>th</sup> 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 Additional instructions to enable the bifurcate body delivery system to be safely withdrawn after being fully deployed.**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:**

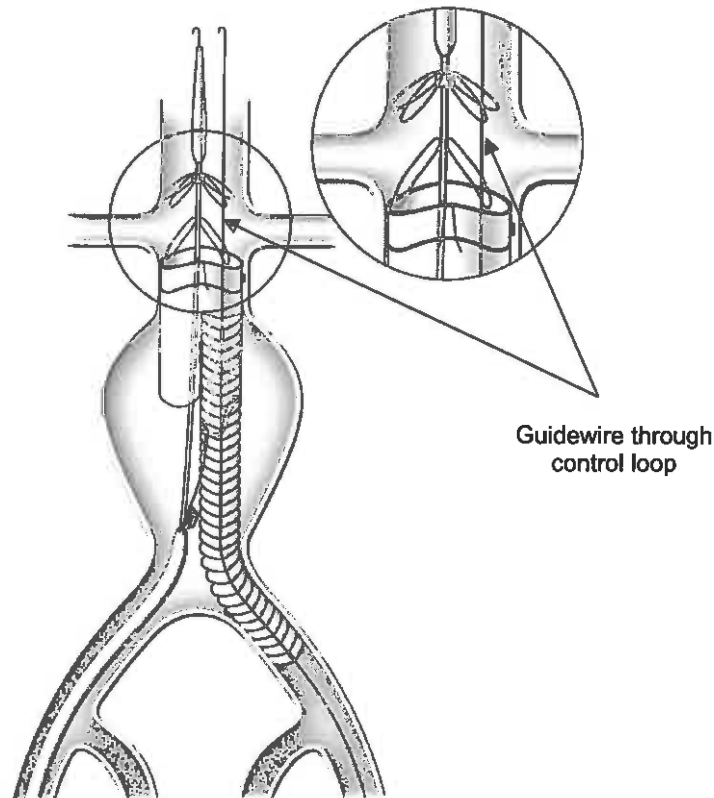
**Schematic 1: Standard Procedure Deployment Images: from current product Instructions for Use**

	<p align="center"><b>Instructions for Use Reference</b></p> <p align="center"><b>Figure 9:</b> Stage 1 Procedure 9</p> <p align="center"><i>"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."</i></p>
	<p align="center"><b>Instructions for Use Reference</b></p> <p align="center"><b>Figure 10:</b> Stage 2 Procedure 6</p> <p align="center"><i>"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."</i></p>
	<p align="center"><b>Figure 11:</b> Stage 2 Procedure 7</p> <p align="center"><i>"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."</i></p> <p align="center"><b>Figure 11:</b> Stage 2 Procedure 8</p> <p align="center"><i>"To detach the magnets, fix the Contralateral Magnet Guide Wire and advance the Intrinsic Magnet Wire the final 20mm."</i></p>
	<p align="center"><b>Figure 12:</b> Stage 2 Procedure 9</p> <p align="center"><i>"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."</i></p>

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.**

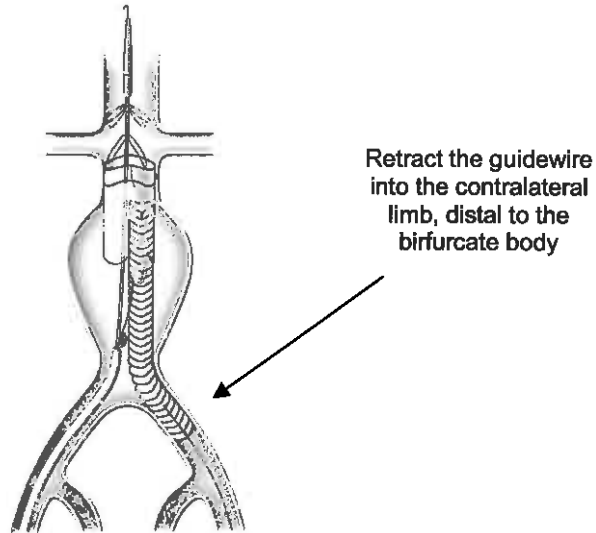


**Advice on action to be taken by the user:**

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:

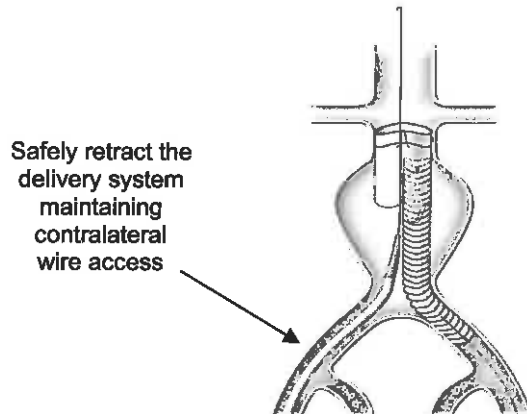
Carefully retract any contralateral guidewire, catheter and/or balloon until their tips are within the iliac leg stent graft but distal to the contralateral stump of the bifurcate body as illustrated in Schematic 3.

**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:

Date:

6.2.12

Position

QA Manager, Vascutek