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21st October 2013

URGENT FIELD SAFETY NOTICE

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Anaconda™ ONE-LOK Bifurcate Body; Anaconda™ Bifurcate Body
TYPE OF ACTION:	FIELD SAFETY CORRECTIVE ACTION
VASCUTEK REFERENCE:	FSN_17Oct2013
PRODUCT CATALOGUE NUMBERS:	Reference Attachment 1
BATCH NUMBERS:	All Batch Numbers

Dear Customer,

1. Description of the problem:

Vascutek Ltd has received 3 complaints (with an occurrence rate of 0.1%) where the release wire of an Anaconda™ Body delivery system has fractured following stent deployment. Two of these three incidents resulted in conversion to open repair.

Vascutek Ltd is initiating a Voluntary Recall of all Anaconda Bodies pending identification of root cause and implementation of corrective actions.

This Voluntary Recall addresses potential patient risks associated with the wire fracturing and the possibility of conversion to open repair.

Please Note:

- This is a potential failure mode of the delivery system and does not affect the safety or efficacy of the implantable stent. Previously implanted stents are not affected by this Voluntary Recall.
- There is no suggestion that patients already implanted with Anaconda™ ONE-LOK Bifurcate Body or Anaconda™ Bifurcate Body are exposed to any raised level of risk.
- This notice applies only to Anaconda™ ONE-LOK Bifurcate Bodies and Anaconda™ Bifurcate Bodies and does not apply to Anaconda™ Straight Legs, Tapered Legs, Flared Legs or Aortic Extension Cuffs.

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 this product is sold.

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