COOK®

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product: Zenith Alpha Abdominal Endovascular Graft
Manufacturer : William Cook Europe
Cook Reference Number: 2019FA0005
Type of action: Field Safety Corrective Action (FSCA) – Recall of specific lots

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Date: 25 April 2019

Attention: Health Care Provider / Chief Executive / Risk Management / Purchasing

Details on affected devices:

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN) PREFIX	ORDER NUMBER	LOT NUMBER
Zenith Alpha Abdominal Endovascular Graft	ZIMB	See Attachment 1	See Attachment 1

Description of the problem:
Cook Medical has identified that specific lots of the Zenith Alpha Abdominal Endovascular Graft may contain a damaged grey safety lock knob, which could potentially result in difficulty or an inability to fully deploy the graft via the standard or troubleshooting method provided in the Instruction for Use. Therefore, Cook Medical has determined to initiate a voluntary recall of the lots listed in Attachment 1.

Potential adverse events that may occur if an affected product is used include a prolonged procedure and open surgical intervention.

Devices already implanted are not affected by this recall.

Intended use for the affected products:
The Zenith Alpha Abdominal Endovascular Graft is indicated for the endovascular treatment of patients with abdominal aortic or aorto-iliac aneurysms having morphology suitable for endovascular repair.

Advise on action to be taken by the user:

1. Examine your inventory immediately to determine if you have affected product(s), and quarantine affected product(s). Immediately cease all distribution and use of these products.
2. Return the affected product(s) to Cook Medical with a copy of the Customer Response Form to receive a product credit.
   NOTE: Unaffected products that are returned will not be credited.
3. Please complete the attached Customer Response Form within 5 business days of receiving this Field Safety Notice and return it to Cook Medical as directed on the form.

Transmission of this Field Safety Notice:
This notice must be shared with appropriate personnel, including down to the user level, within your organization or with any organization where the potentially affected devices have been transferred.

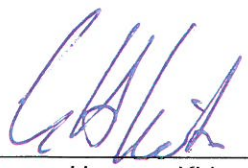
We apologize for any inconvenience this may cause. If you need any further information or support concerning this information, please contact your local Cook Medical Sales Representative.

Contact reference person:

Thomas Hessner Kirk
Team Lead, Regulatory Reporting
Regulatory Affairs
William Cook Europe
Bjaeverskov, DENMARK

We recognize this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@cookmedical.com, phone +353 61 334440).

We confirm that this notice has been notified to the appropriate Regulatory Agency.



Thomas Hessner Kirk
Team Lead

