COOK MEDICAL EUROPE LTD.
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WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2020FA0005

Date: 11Aug2020

Urgent Field Safety Notice

Zenith Alpha® Abdominal Endovascular Graft

For Attention of: Chief Executive / Risk Management / Purchasing

Contact details of local representative (name, e-mail. telephone. address etc.)

Cook Medical Europe Ltd.
O'Halloran Road
National Technology Park
Limerick, lreland
E-mail: European.FieldAction@CookMedical.com
Phone: Please refer to the attached Country Contacts List

For any further information or support concerning the information within this FSN please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.

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Urgent Field Safety Notice (FSN)

Zenith Alpha® Abdominal Endovascular Graft

Risk addressed by FSN

Information on Affected Devices	
1.	1. Device Type(s)
	The Zenith Alpha® Abdominal Endovascular Graft (21MB) is part of a modular system consisting of the following components: a bifurcated main body component (21MB) and two iliac legs (ZISL). The graft modules are constructed of woven polyester fabric sewn to self-expanding nitinol stents with braided polyester and monofilament polypropylene suture, providing a conduit that is intended to exclude the aneurysm from bloed flow.
1.	2. Commercial name(s)
	Zenith Alpha® Abdominal Endovascular Graft
1.	3. Primary clinical purpose of device(s)
	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.
	4. Device Cataloque number(s) specific affected lot numbers
	Refer to attached list of affected lot numbers
Reason for Field Safety Corrective Action (FSCA)	
2.	1. Des cription of the productproblem
	Cook Medical has identified that specific lots of the Zenith Alpha® Abdominal Endovascular Graft (21MB main body) may contain excess glue within the handle of the delivery system, resulting in an inability to fully deploy the graft via the standard method or troubleshooting deployment method provided in the IFU. Cook has received two complaints for this issue. The procedures were able to be completed successfully without any serieus adverse effects to the patient.
2.	2. Hazard giving rise to the FSCA
	Potential adverse events that may occur if an affected product is used include a prolonged procedure and/or open surgical repair. Devices already implanted are not affected by this recall. The Reply Form is still required to be returned forthese devices.
2.	3. Background on Issue
	Based on two customer complaints, Cook Medica! has identified that specific lot numbers of these devices may contain excess glue within the handle of the delivery system.

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Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** 181 Identify Devices 181 Quarantine Devices l&I Return Devices 181 Other Please complete the enclosed Reply Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Reply Form. Returned Product should be addressed to: Cook Medical EUDC Robert-Koch-Stra e. 2 52499 Baesweiler GERMANY Credit will be provided for the returned affected products where applicable.	
3.	2. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Devices already implanted are not affected by this recall. The Reply Form is still required to be returned for these devices.	
3.	3. Is customer Reply Required? Form is attached specifying deadline for return	Yes

General Information		
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSNJ	
	a. Company Name	William Cook Europe
	b. Address	Sandet6 4632 Bjaeverskov Denmark
4.	4. The Competent (Regulatory} Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	List of affected lots Reply form Country Contacts List

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FSN & **FSCA Ref:** 2020FA0005

4.	6. Name/Signature	▪ ▪ ▪ ▪ ▪ ▪ ▪ ▪ ……

Transmission of this Field Safety Notice	
	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. (As appropriate) Please transfer this notice to ether organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if approoriate, as this orovides important feedback.