



COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
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, Ireland

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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Zenith Alpha® Abdominal Endovascular Graft

Risk addressed by FSN

Information on Affected Devices	
1.	<p>1. Device Type(s)</p> <p>The Zenith Alpha® Abdominal Endovascular Graft (ZIMB) is part of a modular system consisting of the following components: a bifurcated main body component (ZIMB) 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 blood flow.</p>
1.	<p>2. Commercial name(s)</p> <p>Zenith Alpha® Abdominal Endovascular Graft</p>
1.	<p>3. Primary clinical purpose of device(s)</p> <p>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.</p>
	<p>4. Device Catalogue number(s) specific affected lot numbers</p> <p>Refer to attached list of affected lot numbers</p>
Reason for Field Safety Corrective Action (FSCA)	
2.	<p>1. Description of the product problem</p> <p>Cook Medical has identified that specific lots of the Zenith Alpha® Abdominal Endovascular Graft (ZIMB 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.</p> <p>Cook has received two complaints for this issue. The procedures were able to be completed successfully without any serious adverse effects to the patient.</p>
2.	<p>2. Hazard giving rise to the FSCA</p> <p>Potential adverse events that may occur if an affected product is used include a prolonged procedure and/or open surgical repair.</p> <p>Devices already implanted are not affected by this recall. The Reply Form is still required to be returned for these devices.</p>
2.	<p>3. Background on Issue</p> <p>Based on two customer complaints, Cook Medical has identified that specific lot numbers of these devices may contain excess glue within the handle of the delivery system.</p>

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Type of Action to mitigate the risk			
3.	<p>1. Action To Be Taken by the User</p> <p> <input checked="" type="checkbox"/> Identify Devices <input checked="" type="checkbox"/> Quarantine Devices <input checked="" type="checkbox"/> Return Devices <input checked="" type="checkbox"/> Other </p> <p>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:</p> <p>Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY</p> <p>Credit will be provided for the returned affected products where applicable.</p>		
3.	<p>2. Particular considerations for: Implantable device</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p> <p>Devices already implanted are not affected by this recall. The Reply Form is still required to be returned for these devices.</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">3. Is customer Reply Required? Form is attached specifying deadline for return</td> <td style="text-align: center;">Yes</td> </tr> </table>	3. Is customer Reply Required? Form is attached specifying deadline for return	Yes
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General Information					
4.	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">1. FSN Type</td> <td style="text-align: center;">New</td> </tr> <tr> <td>2. Further advice or information already expected in follow-up FSN?</td> <td style="text-align: center;">No</td> </tr> </table>	1. FSN Type	New	2. Further advice or information already expected in follow-up FSN?	No
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2. Further advice or information already expected in follow-up FSN?	No				
4.	<p>3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">a. Company Name</td> <td>William Cook Europe</td> </tr> <tr> <td>b. Address</td> <td>Sandet 6 4632 Bjaeverskov Denmark</td> </tr> </table>	a. Company Name	William Cook Europe	b. Address	Sandet 6 4632 Bjaeverskov Denmark
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b. Address	Sandet 6 4632 Bjaeverskov Denmark				
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.				
4.	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">5. List of attachments/appendices:</td> <td>List of affected lots Reply form Country Contacts List</td> </tr> </table>	5. List of attachments/appendices:	List of affected lots Reply form Country Contacts List		
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4.	6. Name/Signature	 Thomas Hessner Kirk Manager, Regulatory Reporting, Quality Assurance William Cook Europe
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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 other 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 appropriate, as this provides important feedback.

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