COOK MEDICAL EUROPE LTD.
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WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2020FA0001

Date: 14Jan2020

Urgent Field Safety Notice

Zenith Alpha™ Spiral-Z® Endovascular Leg

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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Urgent Field Safety Notice (FSN)

Zenith Alpha™ Spiral-Z® Endovascular Leg

Risk addressed by FSN

Information on Affected Devices	
1.	1. Device Type(s)
	The Zenith Alpha™ Spiral-Z® Endovascular Leg is part of a modular system consisting of multiple components, most typically a bifurcated main body and two iliac legs. The iliac legs are constructed of woven polyester fabric sewn to five self-expanding nitinol Cook-Z® stents and a continuous nitinol spiral stent with braided polyester and monofilament polypropylene suture.
1.	2. Commercial name(s)
	Zenith Alpha™ Spiral-Z® Endovascular Leg
1.	3. Primary clinical purpose of device(s)
	Indicated for use with the Zenith Alpha Abdominal Endovascular Graft, Zenith Low Profile AAA/Zenith Alpha Abdominal Ancillary Components, Zenith Flex AAA Endovascular Graft, Zenith Renu AAA Ancillary Graft, Zenith Flex AUI Endovascular Graft, Zenith Fenestrated AAA Endovascular Graft, Zenith Branch Endovascular Graft-Iliac Bifurcation, and Zenith AAA Ancillary Components, during either a primary or a secondary procedure in patients who have adequate iliac/femoral access compatible with the required introduction systems. The graft is used in combination with these products for the endovascular treatment of abdominal aortic and aorto-iliac aneurysms.
1.	4. Device Model/Catalogue/part number(s)

Reference Part Number (RPN)	Order Number	Reference Part Number (RPN)	Order Number	Reference Part Number (RPN)	Order Number
ZISL-9-42	G35955	ZISL-9-59	G35956	ZISL-9-77	G35957
ZISL-9-93	G34508	ZISL-9-110	G35959	ZISL-9-125	G35960
ZISL-11-42	G35961	ZISL-11-59	G35962	ZISL-11-77	G35963
ZISL-11-93	G35964	ZISL-11-110	G35965	ZISL-11-125	G35966
ZISL-13-42	G35967	ZISL-13-59	G35968	ZISL-13-77	G35969
ZISL-13-93	G35970	ZISL-13-110	G34409	ZISL-13-125	G34410
ZISL-16-42	G35971	ZISL-16-59	G35972	ZISL-16-77	G35973
ZISL-16-93	G35975	ZISL-20-42	G35977	ZISL-20-59	G35976
ZISL-20-77	G35980	ZISL-20-93	G35981	ZISL-24-42	G35982
ZISL-24-59	G35983	ZISL-24-77	G35984	ZISL-24-93	G35985

1.	5. Affected serial or lot number range
	All lot numbers

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Reason for Field Safety Corrective Action (FSCA)

2. 1. Description of the product problem

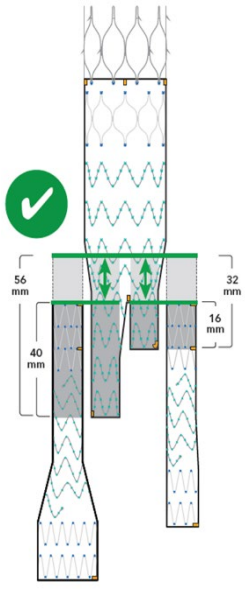
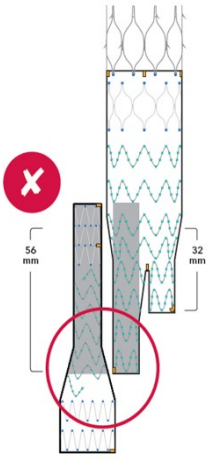
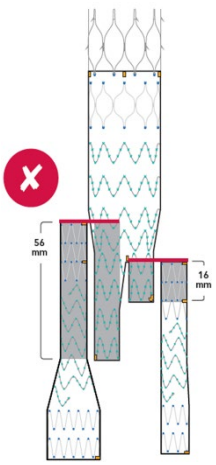
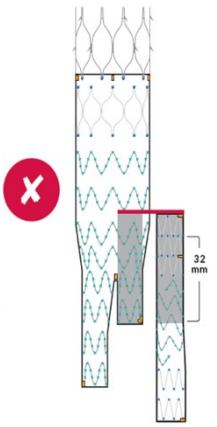
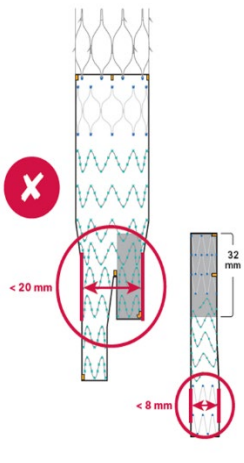
None

2. 2. Hazard giving rise to the FSCA

This notice is to call customers attention to several aspects of the Instructions for Use (IFU) for the Zenith Alpha™ Spiral-Z® Endovascular Leg that are of key importance when selecting and implanting a device. This notice is for information purposes only. No devices need to be returned, and patients already treated with this device should be followed in accordance with the current IFU.

Investigation of thrombus formation and/or lumen occlusion reports for Zenith Alpha™ Spiral-Z® Endovascular Legs identified that the factors listed in the table below have contributed to these failures. Therefore, Cook Medical is submitting this notification to all customers to highlight key points of the IFU pertaining to prevention of the identified contributing factors. In addition, the Planning and Sizing Worksheet has been updated to include information associated with the identified points from the IFU. A copy of the updated Planning and Sizing Worksheet is attached to this notice.

2. 3. Probability of problem arising

IFU INDICATIONS	CONTRIBUTING FACTORS FOR THROMBUS FORMATION AND/OR LUMEN OCCLUSION			
	1. Compression of the flare on the ipsilateral leg within the main body gate	2. Misalignment of the ipsilateral and contralateral legs	3. Excessive overlap of the leg(s) above the main body graft bifurcation	4. Compression of the graft(s) within a narrowed / stenosed aortic bifurcation or iliac region
				

2. 4. Predicted risk to patient

If the instructions listed below are not followed, graft compression and fabric infolding can occur, increasing the risk of a thromboembolic event and/or total occlusion of the leg graft.

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2.	5. Further information to help characterise the problem
	Key Points from the IFU Pertinent to Complaint Reports • Leg Placement – When a 42mm or 59mm leg graft is used on the ipsilateral side, contralateral leg overlap into the contralateral main body limb should be limited to 16mm. Failure to do so may result in occlusion of the ipsilateral limb (Section 4.1). – Closely align the proximal edge of the ipsilateral leg graft with the proximal edge of the previously placed contralateral leg graft (Section 10.1.5.4). – Excessive overlap of 12mm above the main body graft bifurcation may increase the risk of limb thrombosis (Section 4.5). • Anatomical Measurements – Pre-existing regions of stenosis/narrowing (less than approximately 20mm ID in the aorta or 7mm to 8mm ID in the iliacs) have been shown to increase the risk of a thromboembolic event (e.g., graft limb occlusion). Dilation of these regions with a noncompliant balloon and/or stent placement may be necessary to help assure maintained graft patency and to reduce the risk of a thromboembolic event (Section 4.2).
2.	6. Background on Issue
	Investigation of thrombus formation and/or lumen occlusion reports for Zenith Alpha™ Spiral-Z® Endovascular Legs identified the factors above that contributed to these failures.

Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Take note of reinforcement of Instructions For Use (IFU)	
3.	2. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Patients already treated with this device should be followed in accordance with the current IFU.	
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 FSN)	
	a. Company Name	William Cook Europe
	b. Address	Sandet 6 4632 Bjaeverskov Denmark

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4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	Reply form Planning and Sizing work sheet Country Contacts List
4.	6. Name/Signature	 Thomas Hessner Kirk Manager, Regulatory Reporting, Quality Assurance William Cook Europe

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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Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2020FA0001
FSN Date	14 January 2020
Product/ Device name	Zenith Alpha™ Spiral-Z® Endovascular Leg
Product Code(s)	ZISL- (all RPNs)
Batch/Serial Number (s)	All lots

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation	
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content. If you have questions regarding the content within the letter, please contact your local sales representative.
☐	The information and required actions have been brought to the attention of all relevant users and executed.
Print Name	
Signature	
Date	

4. Return acknowledgement to sender	
Email	European.FieldAction@CookMedical.com
Fax	+ 353 61 239294
Deadline for returning the customer reply form	Please return this form within 5 business days of receipt
Customer Helpline	Please refer to the attached Country Contacts List

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.