COOK MEDICAL EUROPE LTD.
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NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2022FA0005

Date: 15Dec2022

Urgent Field Safety Notice
Zenith Low Profile AAA Endovascular Graft Main Body Extension (ZLBE)
Zenith Low Profile AAA Endovascular Graft Converter (ZLC)

For Attention of: Chief Executive Officer, Director of Nursing, Operating Theatres and Purchasing Officers/Stores Managers

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

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Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	The main body extensions and converters are constructed from woven polyester fabric, self-expanding nitinol stents and braided polyester and polypropylene suture, providing a conduit that is intended to exclude the aneurysm from blood flow. The aortic main body extensions can be used to provide additional length to the proximal portion of the endovascular graft. The converters can be used to convert a bifurcated graft into an aortouni-iliac graft, if necessary.
1.	2. Commercial name(s)
	Zenith Low Profile AAA Endovascular Graft Main Body Extension and Zenith Low Profile AAA Endovascular Graft Converter
1.	3. Primary clinical purpose of device(s)*
	The Zenith Low Profile AAA Main Body Extensions and Converters are indicated for use with the Zenith Low Profile AAA Graft/Zenith Alpha Abdominal Endovascular Graft during either a primary or a secondary procedure in patients who have adequate iliac/femoral access compatible with the required introduction systems. (Zenith Low Profile and Alpha Abdominal Endovascular Grafts are indicated for the endovascular treatment for patients with abdominal aortic or aorto-iliac aneurysms).
1.	4. Device Model/Catalogue/part number(s)*
	ZLBE- and ZLC- in various sizes as per attached list
1.	5. Affected serial or lot number range
	As per attached list.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	The label on the product box contains incorrect manufacture and expiry date. The products described by this FSN contain a primary and a secondary packaging. Each layer of packaging contains a label. The primary packaging is the tyvek pouch and the secondary packaging is the product box. It has been identified that the label on the secondary packaging (the product box label) for the impacted devices contains an incorrect manufacture and expiry date. The manufacture and expiry date on the primary packaging (the product label) are correct.
2.	2. Hazard giving rise to the FSCA*
	The label on the product box contains incorrect manufacture and expiry date.
2.	3. Predicted risk to patient/users
	No patient risk unless products are used after correct expiry date. First product to expire is in Dec2024. Devices already implanted are not affected by this recall.

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2.	4. Background on Issue
	On 05-Nov-2022, an upgrade to Cook's labelling system was performed. A bug developed in the label reprint program during this upgrade which led to errors when a label was reprinted. The devices listed within this FSN were impacted by this error.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☒ Return Device Devices already implanted are not affected by this recall. The Reply Form is still required to be returned for these devices 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-Straße, 2 52499 Baesweiler GERMANY Credit will be provided for the returned affected products where applicable.	
3.	2. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

	4. 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:	List of affected RPNs and lot numbers
4.	6. Name/Signature [redacted]	[redacted] **Manager, Regulatory Reporting, Quality Assurance**

	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	2022FA0005
FSN Date	15 December 2022
Product/ Device name	Zenith Low Profile AAA Endovascular Graft Main Body Extension and Zenith Low Profile AAA Endovascular Graft Converter
Product Code(s) and Lot number(s)	Please refer to the attached list of affected lot numbers

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Shipping address if different to above	
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.
☐	The information and required actions have been brought to the attention of all relevant users and executed.
☐	I have affected devices to return - enter Lot number and quantities in table below.
☐	No affected devices are available for return.
Print Name	
Signature	
Date	

4. Return acknowledgement to sender	
Email	European.FieldAction@CookMedical.com
Customer Helpline	Please refer to the attached Country Contacts List

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Fax	+ 353 61 239294
Deadline for returning the customer reply form	Please return this form within 5 business days of receipt

If you are returning any affected product, please indicate the part number, lot number and quantity:

Product Part Number	Product Lot Number	Quantity

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.