COOK MEDICAL EUROPE LTD.
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NATIONAL TECHNOLOGY PARK
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WWW.COOKMEDICAL.EU

FSN Ref: 2023FA0004 / QCR-2023-04 FSCA Ref: 2023FA0004 / QCR-2023-04

21 March 2023

Urgent Field Safety Notice
Zenith® Branch Endovascular Graft – Iliac Bifurcation (ZBIS)
Bifurcated Iliac Sidebranch Endovascular Graft (Custom Made Device)

For Attention of: Chief Executive Officer, Director of Nursing and Purchasing Officers/Stores Manager

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

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1. Information on Affected Devices

1. 1. Device Type(s)

The Zenith® Branch Endovascular Graft – Iliac Bifurcation (ZBIS) and Bifurcated Iliac Sidebranch Endovascular Graft (Custom Made Device) are bifurcated branch vessels grafts with openings to connect the common iliac, internal iliac side branch, and external iliac segments.
The devices are supplied sterile.

1. 2. Commercial name(s)

The Zenith® Branch Endovascular Graft – Iliac Bifurcation

Bifurcated Iliac Sidebranch Endovascular Graft (Custom Made Device)

1. 3. Primary clinical purpose of device(s)

These devices are indicated for the endovascular treatment of patients with an aortoiliac or iliac aneurysm, an insufficient distal sealing site within the common iliac artery and having morphology suitable for endovascular repair.

1. 4. Device Model/Catalogue/part number(s)

Zenith® Branch Endovascular Graft – Iliac Bifurcation (ZBIS):

Reference Part Number (RPN)	Order Number (GPN)
ZBIS-10-45-41	G38612
ZBIS-10-45-58	G38613
ZBIS-10-61-41	G38614
ZBIS-10-61-58	G38615
ZBIS-12-45-41	G38616
ZBIS-12-45-58	G38617
ZBIS-12-61-41	G38618
ZBIS-12-61-58	G38344

Bifurcated Iliac Sidebranch Endovascular Graft (Custom Made Device)

Reference Part Number (RPN)	Order Number (GPN)
REINFORCED-ILIAC-SIDE-BRANCH	G38048

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

William A. Cook Australia have received reports that the tip of the catheter, which is an indwelling component of the Zenith® Branch Endovascular Graft – Iliac Bifurcation (ZBIS) and Bifurcated Iliac Sidebranch Endovascular Graft (Custom Made Device) is splitting / breaking during device preparation or during the endovascular procedure.

2. 2. Hazard giving rise to the FSCA

The hazard is failure of the catheter tip leading to splitting or breaking of the tip during device preparation or during the endovascular procedure.

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	The potential adverse events that may occur depend on when the catheter tip breaks and whether it can be retrieved. The potential adverse events include an increased procedural time (to obtain a replacement device), medical intervention (to retrieve or isolate the catheter tip) or permanent impairment of body structure or function (if the catheter tip is left inside the iliac arteries causing occlusion).
2.	3. Probability of problem arising
	Globally, the occurrence rate for the issue is 0.91% (between 01 Jan 2020 and 31 Dec 2022).
2.	4. Predicted risk to patient/users
	There is a remote probability that the issue can cause minor to significant adverse health consequence, transient harm, medically reversible harm. To date, Cook Medical has not received reports of irreversible outcomes to patients. The catheter tip is radiopaque and visible under fluoroscopy which enables medical intervention by endovascular methods or open access in situations where the tip breaks during the procedure.

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device On receipt of this FSN, review your stock. To determine if a device is affected, refer to the attached list of affected lots. If you have an affected lot number in stock, quarantine the device(s). Please complete the enclosed Field Action Customer Reply Form. Since devices are to be returned, our Customer Services department will contact you to organize the return and issue you the relevant Returns Authorization number. **Please include contact details on the Field Action Customer Reply Form so that they can contact you.** Returned Devices should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler Germany Credit will be provided for the returned affected devices where applicable	
3.	**2. By when should the action be completed?**	Immediately
3.	**3. Is customer Reply Required?** (If yes, form attached specifying deadline for return)	Yes

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3.	**4. Action Being Taken by the Manufacturer**
	☒ Product Removal Replacement stock will be available for re-order

	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 A Cook Australia Pty Ltd
	b. Address	95 Brandl Street Brisbane Technology Park Eight Mile Plains QLD 4113 Australia
	c. Website address	www.cookmedical.com.au
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 lot numbers Country Contact List Customer Reply Form
4.	6. Name/Signature	Alana Davey QA Regulatory Reporting Team Leader William A Cook Australia

	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	2023FA0004
FSN Date	
Product/Device name	Zenith® Branch Endovascular Graft- Iliac Bifurcation (ZBIS) Bifurcated Iliac Sidebranch Endovascular Graft (Custom Made Device)
Product Code(s)	As per attached list.
Batch/Serial Number (s)	As per attached list.

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/ destruction	
Print Name		
Signature		
Date		

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