



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: 2023FA0007

Date: xx:06:2023

Urgent Field Safety Notice
Product Removal: Fusion Lithotripsy Extraction Baskets

For Attention of: **Chief Executive / Risk Management / Purchasing / Recall Coordinator**

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.

Urgent Field Safety Notice (FSN)



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Fusion Lithotripsy Extraction Baskets Risk addressed by FSN

1. Information on Affected Devices	
1.	<p>1. Device Type(s)</p> <p>Fusion Lithotripsy Extraction Basket is a sterile device used for endoscopic removal of biliary stones and foreign bodies.</p>
1.	<p>2. Commercial name(s)</p> <p>Fusion Lithotripsy Extraction Basket</p>
1.	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>10827002482774, 10827002482781</p>
1.	<p>4. Primary clinical purpose of device(s)</p> <p>The intended use for Fusion Lithotripsy Extraction Basket is for endoscopic removal of biliary stones and foreign bodies.</p>
1.	<p>5. Device Model/Catalogue/part number(s)</p> <p>FS-LXB-2X4, FS-LXB-3X6</p>
1.	<p>6. Affected serial or lot number range</p> <p>See Attached Affected Lots List</p>
2 Reason for Field Safety Corrective Action (FSCA)	
2.	<p>1. Description of the product problem</p> <p>Cook conducted a complaint investigation that confirmed on 26 Apr 2023 that nonconforming Fusion Lithotripsy Extraction Baskets were manufactured and distributed. This manufacturing nonconformance can appear in the field as inability to advance or retract the basket, or the drive wire breaking or separating from handle (with or without mechanical lithotripsy). Cook has received five (5) complaints worldwide for this nonconformance.</p>
2.	<p>2. Hazard giving rise to the FSCA</p> <p>If the basket will not advance or retract, it is likely that the device could be replaced with an insignificant delay in procedure. In that situation, the potential for injury is unlikely. The worst-case scenario if the drive wire breaks or separates from the handle, if the basket wire or drive wire breaks during mechanical lithotripsy, or if the device becomes impacted, is non-endoscopic retrieval of the impacted object.</p>
2.	<p>3. Probability of problem arising</p> <p>There have been five (5) complaints received worldwide associated with the nonconforming devices and these associated failures. This is 0.5071% of the affected devices.</p>
2.	<p>4. Predicted risk to patient/users</p> <p>The worst-case scenario is non-endoscopic retrieval of an impacted object.</p>
2.	<p>5. Background on Issue</p> <p>Cook conducted a complaint investigation that confirmed nonconforming Fusion Lithotripsy Extraction Baskets were manufactured and distributed. The investigation found that the bit on the electric torque wrench had been stripped preventing the wrench from applying sufficient torque to the cannula to secure the drive wire. The faulty torque</p>



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<p>wrench was immediately removed from the production line and operators were retrained on the torquing process.</p> <p>This FSCA has been initiated and the FSN will be issued to users to remove nonconforming Fusion Lithotripsy Extraction Baskets. EU MDR 2017/745 defines a field safety corrective action as a corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident. This field action is a removal of devices to reduce the risk of a serious incident. Since the subject devices were distributed in the EU, this is considered an FSCA in the affected EU member states.</p>
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3. Type of Action to mitigate the risk	
3.	<p>1. Action To Be Taken by the User</p> <p><input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device</p> <p>Please complete the enclosed Customer Reply Form. Since devices are to be returned, our Customer Services department will contact you to organize the return and issue the relevant Returns Authorization number. Please include contact details on the Customer Reply Form so they can contact you.</p> <p>Returned Devices should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler Germany</p> <p>Credit will be provided for the returned affected devices where applicable.</p>
3.	<p>2. By when should the action be completed? Within five (5) business days of receipt.</p>
3.	<p>3. Is customer Reply Required? (If yes, form attached specifying deadline for return) Yes, within five (5) business days of receipt.</p>
3.	<p>4. Action Being Taken by the Manufacturer</p> <p><input checked="" type="checkbox"/> Product Removal</p>
3.	<p>5. By when should the action be completed? Within five (5) business days of receipt.</p>
3.	<p>6. Is the FSN required to be communicated to the patient /lay user? No</p>

4. General Information	
4.	<p>1. FSN Type New</p>



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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	Cook Endoscopy/Wilson-Cook Medical, Inc.
	b. Address	4900 Bethania Station Road, Winston-Salem, NC USA
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	Country Contact List, Affected Lot List
4.	6. Name/Signature	
		 Regulatory Reporting Specialist

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>



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Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2023FA0007
FSN Date	DATE
Product/ Device name	Fusion Lithotripsy Extraction Basket
Product Code(s)	FS-LXB-2X4 FS-LXB-3X6
Batch/Serial Number (s)	See attached Affected Lot Numbers 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		
Please mark boxes below to indicate actions have been completed. If action is not applicable, please enter N/A.		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
<input type="checkbox"/>	I have affected devices to return - enter Lot number and quantities in table below.	Customer to complete or enter N/A
<input type="checkbox"/>	No affected devices are available for return.	Customer to complete or enter N/A
Print Name		
Signature		
Date		

