COOK MEDICAL EUROPE LTD.
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WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2023FA0007

Date: 14 July 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.)* |
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| Cook Medical Europe Ltd.<br>O'Halloran Road<br>National Technology Park<br>Limerick, Ireland<br>E-mail: European.FieldAction@CookMedical.com<br>Phone: Please refer to the attached Country Contacts List<br><br>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. | 1. Device Type(s) |
| | Fusion Lithotripsy Extraction Basket is a sterile device used for endoscopic removal of biliary stones and foreign bodies. |
| 1. | 2. Commercial name(s) |
| | Fusion Lithotripsy Extraction Basket |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | 10827002482774, 10827002482781 |
| 1. | 4. Primary clinical purpose of device(s) |
| | The intended use for Fusion Lithotripsy Extraction Basket is for endoscopic removal of biliary stones and foreign bodies. |
| 1. | 5. Device Model/Catalogue/part number(s) |
| | FS-LXB-2X4, FS-LXB-3X6 |
| 1. | 6. Affected serial or lot number range |
| | See Attached Affected Lots List |

| 2 **Reason for Field Safety Corrective Action (FSCA)** | |
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| 2. | 1. Description of the product problem |
| | 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. |
| 2. | 2. Hazard giving rise to the FSCA |
| | 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. |
| 2. | 3. Probability of problem arising |
| | 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. |
| 2. | 4. Predicted risk to patient/users |
| | The worst-case scenario is non-endoscopic retrieval of an impacted object. |
| 2. | 5. Background on Issue |
| | 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 |

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|---|---|
| | wrench was immediately removed from the production line and operators were retrained on the torquing process.<br>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. |

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| | **3. Type of Action to mitigate the risk** | | |
| **3.** | **1. Action To Be Taken by the User**<br><br>☒ Identify Device ☒ Quarantine Device ☒ Return Device<br><br>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.**<br><br>Returned Devices should be addressed to:<br>Cook Medical EUDC<br>Robert-Koch-Straße, 2<br>52499 Baesweiler<br>Germany<br><br>Credit will be provided for the returned affected devices where applicable. | | |
| 3. | 2. By when should the action be completed? | Within five (5) business days of receipt. | |
| 3. | 3. Is customer Reply Required?<br>(If yes, form attached specifying deadline for return) | | Yes, within five (5) business days of receipt. |
| **3.** | **4. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal | | |
| 3 | 5. By when should the action be completed? | Within five (5) business days of receipt. | |
| 3. | 6. Is the FSN required to be communicated to the patient /lay user? | | No |

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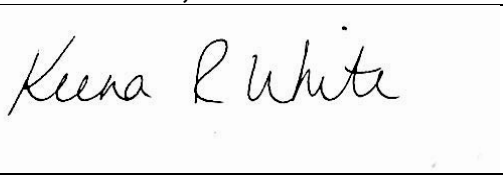
|---|---|---|
| | **4. General Information** | |
| 4. | 1. FSN Type | New |
| 4. | 2. Further advice or information already expected in follow-up FSN? | No |
| 4. | 3. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Cook 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 |  <br>Keena White<br>Regulatory Reporting Specialist |

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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)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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. |