COOK MEDICAL EUROPE LTD.
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WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2020FA0002

Date: 17-Jan-2020

# Urgent Field Safety Notice
# Product Removal- Hemospray Endoscopic Hemostat

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.<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. |

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# Urgent Field Safety Notice (FSN)
# Hemospray Endoscopic Hemostat
# Risk addressed by FSN

| Information on Affected Devices | |
|---|---|
| 1. | 1. Device Type(s) |
| | Hemospray Endoscopic Hemostat is an upper-gastrointestinal haemostasis device supplied sterile. |
| 1. | 2. Commercial name(s) |
| | Hemospray Endoscopic Hemostat |
| 1. | 3. Primary clinical purpose of device(s) |
| | This device is used for haemostasis of nonvariceal upper gastrointestinal bleeding. |
| 1. | 4. Device Model/Catalogue/part number(s) |
| | HEMO-7-EU, HEMO-10-EU |
| 1. | 5. Affected serial or lot number range |
| | All lot numbers manufactured 16 January 2017 to 15 January 2020. |

| Reason for Field Safety Corrective Action (FSCA) | |
|---|---|
| 2. | 1. Description of the product problem |
| | Cook Medical has received complaints regarding Hemospray Endoscopic Hemostat devices for the handle and/or activation knob cracking or breaking while the device is activated, prior to and during use. This has led to the carbon dioxide cartridge exiting the handle. Most of these complaints reported that the carbon dioxide cartridge exited the handle with minimal force. However, there have been complaints that the carbon dioxide cartridge exited the handle with force. There has been one (1) complaint reported where the user sustained a laceration to the hand which required basic first aid. |
| 2. | 2. Hazard giving rise to the FSCA |
| | Potential adverse effects to the user that may occur if an affected product is used include superficial laceration, laceration, or permanent impairment of a body structure. Please note that there have been no reports of a serious deterioration to the state of health to the user due to the carbon dioxide cartridge exiting the handle. |
| 2. | 3. Probability of problem arising |
| | The probability of this incident occurring is 0.022%. |
| 2. | 4. Predicted risk to patient/users |
| | The individual risk of harm to the user is negligible. |
| 2. | 5. Background on Issue |
| | Cook Medical has received complaints regarding Hemospray Endoscopic Hemostat devices for the handle and/or activation knob cracking or breaking while the device is activated; some of which have led to the carbon dioxide cartridge exiting the device. There is no root cause for this issue at this time. |

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| 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>☒ Other<br><br>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.<br><br>Returned Product 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 products where applicable. | |
| 3. | 2. By when should the action be completed? | Within five (5) business days of receipt. |
| 3. | 3. Is customer Reply Required? * | Yes, within five (5) business days of receipt. |
| 3. | 4. Action Being Taken by the Manufacturer<br><br>☒ Product Removal<br><br>Hemospray devices are being removed from the market and should be returned to Cook per the attached directions on the Field Action Reply Form. | |
| 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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| 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. Name/Signature | … |
| | | ..... ……<br>…… |

| | 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.<br><br>Please transfer this notice to other organisations on which this action has an impact.<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. |