



FSN & FSCA Ref: 2020FA0009

Date: 04.Jan.2021

Urgent Field Safety Notice
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.
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.



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Urgent Field Safety Notice (FSN) **Hemospray Endoscopic Hemostat**

1. 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 customers purchasing Hemospray Endoscopic Hemostat in Germany in the past three (3) years.

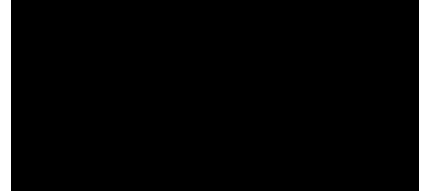
2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem There is no product problem with the Hemospray Endoscopic Hemostat (HEMO). The HEMO Instructions for Use (IFU) have been clarified to assist the user in avoiding catheter occlusion. The updates are highlighted in the attached sample Instructions for Use. In addition, an educational video is now available for German users at the following link: https://bcove.video/2VZhJek
2.	2. Hazard giving rise to the FSCA There are no new hazards nor new potential adverse effects to the patient as a result of this IFU update. These clarifications are anticipated to assist in the reduction of the overall occurrence of the “unable to spray Hemospray powder” malfunction; however, they are not intended to reduce the risk of death or serious deterioration in the state of health. This FSN is being distributed to customers at the request of Federal Institute for Drugs and Medical Devices (BfArM).
2.	3. Background on Issue This FSN which outlines the IFU clarifications and introduces the educational video is being conducted for the German market specifically at the request of BfArM.



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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"/> Take note of amendment/reinforcement of Instructions for Use (IFU)</p> <p><input checked="" type="checkbox"/> Other</p> <p>Please complete the enclosed Customer Reply Form and include contact details.</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 35%;">2. By when should the action be completed?</td> <td>Immediately notify all users of Hemospray about the update to the IFU, instruct users to watch the educational video, and then return the Customer Reply Form. Satisfactory customer response rate from German customers is required by BfArM to reintroduce Hemospray devices back into the German market.</td> </tr> </table>	2. By when should the action be completed?	Immediately notify all users of Hemospray about the update to the IFU, instruct users to watch the educational video, and then return the Customer Reply Form. Satisfactory customer response rate from German customers is required by BfArM to reintroduce Hemospray devices back into the German market.
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3.	<p>4. Action Being Taken by the Manufacturer</p> <p><input checked="" type="checkbox"/> IFU or labelling change</p> <p>Please see the updated Instructions for Use attached to this Field Safety Notice. The updated portions are highlighted for ease of identification.</p>		
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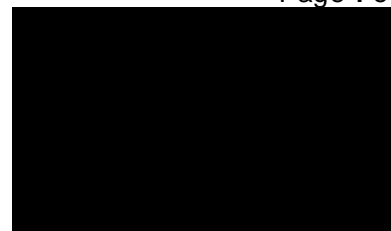
4. General Information				
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4.	<p>3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 45%;">a. Company Name</td> <td rowspan="2" style="background-color: black;"></td> </tr> <tr> <td>b. Address</td> </tr> </table>	a. Company Name		b. Address
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4.	4. The Competent (Regulatory) Authority of your country, Federal Institute for Drugs and Medical Devices (BfArM) has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	A copy of revised Instructions for Use with revisions highlighted.
4.	6. Name/Signature	

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>



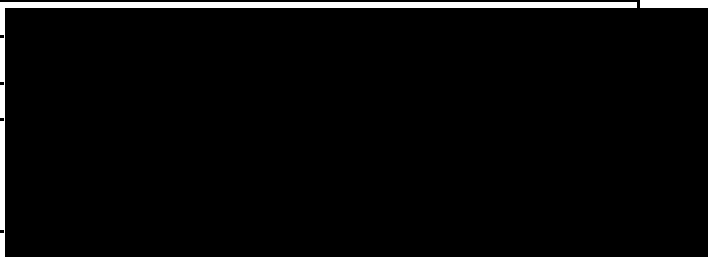
Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2020FA0009
FSN Date	04.Jan.2021
Product/ Device name	Hemospray Endoscopic Hemostat
Product Code(s)	HEMO-7-EU & HEMO-10-EU

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	
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.
<input type="checkbox"/>	I performed all actions requested by the FSN.
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.
Print Name	
Signature	
Date	

4. Return acknowledgement to sender	
Email	
Fax	
Deadline for returning the customer reply form	



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.