COOK MEDICAL EUROPE LTD.
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FSN & FSCA Ref: 2021FA0003

Date: DD:MMM:YYYY.

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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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 since 13 May 2020.

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 following was added to the IFU: "NOTE: To limit fluid from entering the working channel of the catheter, temporarily occlude the catheter by placing a thumb over the red catheter hub, while advancing the catheter down the accessory channel (See Fig. 2)". An image was added to visually demonstrate this note. An additional note was also added, "Scope suction can be turned off or disconnected temporarily to avoid accidental aspiration of powder into the endoscope channel which may cause endoscope occlusion." Please see attached for a copy of the revised Instructions for Use.
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.

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	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Take note of amendment/reinforcement of Instructions for Use (IFU) ☒ Other Please complete the enclosed Customer Reply Form and include contact details.	
3.	2. By when should the action be completed?	Immediately notify all users of Hemospray about the update to the IFU and then return the Customer Reply Form.
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, immediately upon receipt and upon completion of above actions.
3.	**4. Action Being Taken by the Manufacturer** ☒ IFU or labelling change Please see the revised Instructions for Use attached to this Field Safety Notice.	
3	5. By when should the action be completed?	Immediately upon receipt.

	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	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:	A copy of revised Instructions for Use.

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4.	6. Name/Signature	 Blair Younts Team Lead, Regulatory Reporting & Field Actions

	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..*