COOK MEDICAL EUROPE LTD.
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FSN Ref: 2023FA0006

Date: 23MAY2023

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
Communication of Risks Related to
Powder Adherence to the Endoscope or Endoscope to Tissue

1. **Information on Affected Devices**	
1.	1. Device Type(s)
	Hemospray Endoscopic Hemostat is intended to be used for hemostasis of nonvariceal upper gastrointestinal bleeding.
1.	2. Commercial name(s)
	Hemospray Endoscopic Hemostat
1.	3. Primary clinical purpose of device(s)
	Used for hemostasis of nonvariceal upper gastrointestinal bleeding.
1.	4. Device Model/Catalogue/part number(s)
	HEMO-7-EU, HEMO-7, HEMO-10-EU, HEMO-10
1.	5. Affected serial or lot number range
	This communication is being sent to customers who have purchased Hemospray devices that are not expired; however, this communication is not specific to lot number.

2 **Reason for Field Safety Corrective Action (FSCA)**	
2.	1. Description of the product problem
	No new product problems have been identified with Hemospray. The intended use for Hemospray is for haemostasis of nonvariceal upper gastrointestinal bleeds. This FSCA has been initiated and the FSN will be issued to users to bring heightened awareness of the potential risks of Hemospray powder adhering to the distal end of the endoscope, which can result in difficulty or inability to manoeuvre/remove the endoscope, or adhesion of the endoscope to tissue.
2.	2. Hazard giving rise to the FSCA*
	During use, the Hemospray powder may adhere to the distal end of the endoscope. The majority of the time this can occur without incident; however, through complaints reported from the field, powder adhesion to the endoscope or adhesion of the endoscope to the GI tissue, especially in the esophagus or stomach, can result in difficulty or inability to maneuver or to remove the endoscope at the time of the initial hemostasis procedure. In some, but not all known instances, this occurred when the powder was sprayed while the endoscope was in a retroflexed position. Adhesion of the powder to the endoscope or endoscope to the tissue can result in delay in treatment, mucosal tear, perforation, pain, distress, aggravation of an existing bleed, hemorrhage, cardiac arrest, or death. Providers should be prepared to take immediate steps to manage events of adhesion. The specific measures should be guided by facility resources and clinical circumstances.

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2.	3. Probability of problem arising
	Over the lifetime of Hemospray, the global rate of occurrence of difficulty or inability to manoeuvre or remove the endoscope or adhesion of the endoscope to tissue is 0.014%. The global occurrence rate of patient harm when this situation occurs is 0.004%. There have been no reports of aggravation of existing bleeds, delays in haemostasis treatment, nor death.
2.	4. Predicted risk to patient/users
	The current individual risk of harm to the patient is negligible.
2.	5. Background on Issue
	The current Hemospray Instructions for Use states, "Potential Complications: When spraying in the retroflexed position, Hemospray powder may adhere to the outside of the endoscope. This may result in difficulty repositioning/removing the endoscope, particularly if passing through a strictured area. Cook Endoscopy, as a United States-based manufacturer, in collaboration with the US Food and Drug Administration, is bringing heightened awareness to Hemospray users of the potential risks of Hemospray powder adhering to the distal end of the endoscope (which can result in difficulty or inability to manoeuvre/remove the endoscope), or adhesion of the endoscope to tissue. Cook is extending this communication to users in the EU per Article 87 of the EU MDR 2017/745. This includes users in the United Kingdom and Switzerland.

	3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Other Read the information in this FSN and distribute this information to the user level.		
3.	2. By when should the action be completed?	Within five (5) business days of receipt.	
3.	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)		Yes
3.	**4. Action Being Taken by the Manufacturer** ☒ Other Cook is providing this FSN as a communication tool to bring heightened awareness to potential risks as described in Section 2.		
3	5. By when should the action be completed?	Within five (5) business days of receipt.	

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3.	6. Is the FSN required to be communicated to the patient /lay user?	No

	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	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:	Please find attached a Country Contacts List.
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. Please transfer this notice to other organisations on which this action has an impact. 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.