FSN Ref: 2026FA0004

Date: 04 August 2026

Urgent Field Safety Notice
HEMOSPRAY ENDOSCOPIC HEMOSTAT

For Attention of: Endoscopy Staff / Risk Management

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 Updates to Instructions for Use

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 (HEMO-7-EU & HEMO-10-EU); or, hemostasis of nonvariceal gastrointestinal bleeding (HEMO-7 & HEMO-10).
1.	2. Commercial name(s)
	Hemospray Endoscopic Hemostat
1.	3. Primary clinical purpose of device(s)
	HEMO-7-EU & HEMO-10-EU: Used for hemostasis of nonvariceal upper gastrointestinal bleeding. HEMO -7 & HEMO-10: Used for hemostasis of nonvariceal 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. This communication is not specific to lot number.

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	The purpose of this FSN is to bring heightened awareness to all Hemospray Endoscopic Hemostat users about upcoming updates to the Hemospray Endoscopic Hemostat Instructions for Use (IFU). This FSCA is not a removal of devices; devices do not need to be returned. The updated Hemospray Instructions for Use (IFU) will include new guidance to address two key clinical considerations: 1. **Endoscope adherence:** Instructions will be added to mitigate the occurrence of powder adhering to the distal end of the endoscope. This condition can cause the endoscope to adhere to tissue, potentially resulting in difficulty maneuvering or removing the endoscope. 2. **Inability to spray powder:** Additional instructions will be included for device preparation to reduce situations in which the Hemospray device is unable to dispense powder as intended. **Regarding Endoscope Adherence:** The Potential Complications section of the Hemospray IFU will be updated to state the following regarding powder adherence to the distal end of the endoscope: “Hemospray powder may adhere to the outside of the endoscope, which may result in difficulty repositioning/removing the endoscope. The likelihood of this occurrence increases when using a water-based lubricant, spraying in endoscope retroflexion, or removing the endoscope

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through narrowed anatomy. Potential complications associated with difficulty repositioning/removing the endoscope may include: delay in treatment • mucosal tear • pain • distress • aggravation of an existing bleed • perforation • hemorrhage • cardiac arrest • or death.

NOTES

Clinicians have reported that continuously moving the endoscope during and after powder application may reduce the occurrence of difficulty repositioning/removing the endoscope.

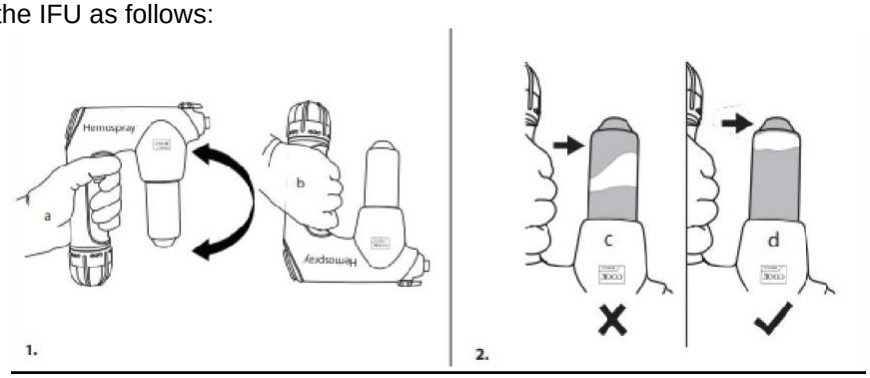
Do not perform endoscope maneuvers (rotating, pushing, or pulling) if difficulty repositioning/removing the endoscope is encountered. **Use saline irrigation targeted at the endoscope shaft to hydrate and loosen the powder prior to attempting endoscope maneuvers, if needed, and removal.** Saline has been shown to more effectively loosen the powder than sterile water.

To minimize the likelihood of rebleeding, care should be taken to limit disturbance of the treatment site when possible."

Scan this QR code to access the video showing recommended mitigation techniques for endoscope adherence.

Regarding Inability to Spray Hemospray Powder:

New illustrations will be added to the IFU as well as new instructions to the Device Preparation section of the IFU as follows:



DEVICE PREPARATION

1. Remove device from package.

NOTE

The powder may become compacted within the handle's powder chamber during shipping or storage. To facilitate powder delivery, the powder must be agitated to remove powder compaction.

2. To agitate powder, the device handle must be flipped upside down and returned to its upright position (See Fig. 1). The powder chamber may also be tapped, flicked, and/or gently shaken when in the upside-down position (See Fig. 1b) to further loosen compacted powder.

NOTE

Do not tap, flick, or shake the powder chamber when the handle is in the upright position (See Fig. 1a) as this may further compact the powder.

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	3. Continue agitating the powder until powder compaction is resolved. Powder compaction has been successfully resolved when the powder freely moves within the powder chamber as the handle is flipped. Fig. 2c illustrates a device that requires further agitation; the arrow highlights the powder that remains compacted in the powder chamber when the device is upside down. Fig. 2d illustrates a device with powder compaction adequately resolved; the arrow highlights the small amount of powder that may remain in the tip of the powder chamber." Scan this QR code to access the Instructions for Use video showing appropriate steps for Hemospray use.
2.	2. Hazard giving rise to the FSCA*
	Endoscope Adherence: 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 can result in difficulty or inability to maneuver or remove the endoscope. The likelihood of this occurrence is increased when using a water-based lubricant, spraying in endoscope retroflexion, or removing the endoscope through narrowed anatomy. Adhesion of the powder to the endoscope can result in delay in treatment, mucosal tear, perforation, pain, distress, aggravation of an existing bleed, hemorrhage, cardiac arrest, or death. est hazard to the patient/end user that the advice/action is intended to mitigate. Inability to Spray Powder: The Hemospray powder may become compacted within the powder chamber during shipping or storage, resulting in the device being unable to dispense powder as intended. Failure to deliver powder during an active bleeding event can result in failure to achieve hemostasis, potentially requiring additional intervention or resulting in continued hemorrhage, serious injury, or death.
2.	3. Probability of problem arising
	Endoscope Adherence: The global rate of occurrence of difficulty or inability to manoeuvre or remove the endoscope is 0.0184%. The global occurrence rate of patient harm when this situation occurs is 0.0072%. Inability to Spray Powder: The global rate of occurrence of inability to dispense powder related to powder compaction is 0.1693%. The global occurrence rate of patient harm when this situation occurs is 0.0200%.

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	3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User*** ☒ Take note of upcoming updates of Instructions For Use (IFU) by reviewing the FSN and viewing the videos at the QR codes provided.		
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** ☒ IFU or labelling change		
3.	5. 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	[redacted]
	b. Address	[redacted]
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	[redacted]

	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.