COOK ASIA (MALAYSIA) SDN. BHD.
CO. REG. NO. 199001015417
UNIT 1602, LEVEL 16, UPTOWN 1,
NO. 1, JALAN SS21/58, DAMANSARA UTAMA,
47400 PETALING JAYA, SELANGOR, MALAYSIA
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WWW.COOKMEDICAL.COM

24 August 2026

Cook Asia (Malaysia) Sdn. Bhd. Field Action Reference Number: FCA-26-001-MY

URGENT: MEDICAL DEVICE CORRECTION
Hemospray Endoscopic Hemostat
PROMPT RESPONSE REQUIRED

ATTENTION:
Endoscopy Staff/Risk Management/Recall Administration
Our records indicate that you have received affected products.

Cook Medical considers the safety and satisfaction of our customers a top priority. We appreciate your time and attention in reading this important notice.

Purpose of this Letter

The purpose of this letter is to inform all Hemospray Endoscopic Hemostat users about the upcoming updates to the Hemospray Instructions for Use (IFU) to address two Hemospray potential issues: endoscope adhesion and inability to spray powder. This is not a removal of devices from the field.

This communication extends to the user level.

Hemospray Endoscopic Hemostat (HEMO-7 & HEMO-10) are intended to be used for hemostasis of nonvariceal gastrointestinal bleeding; Hemospray Endoscopic Hemostat with HEMO-7-EU & HEMO-10-EU part numbers are intended to be used for hemostasis of nonvariceal upper gastrointestinal bleeding.

Reason for the Correction and Update to Instructions for Use

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. Cook is aware of 53 complaints in relation to this issue since Hemospray became available to the market. Of these, 21 resulted in adverse events requiring medical intervention, including delay in treatment, mucosal tear, pain, distress, hemorrhage, and cardiac arrest. The most severe event reported was cardiac arrest in a patient with chronic heart disease. No deaths were directly attributed to endoscope adhesion.
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. Cook is aware of 777 complaints in relation to this issue since Hemospray became available to the market. Of these, 52 have resulted in adverse events including use of medical intervention such as an alternative treatment method to achieve hemostasis, and/or hospitalization and surgical intervention to achieve hemostasis. The most severe event reported was surgical intervention to achieve hemostasis. No deaths were directly attributed to unable to spray.

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:

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- "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 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.

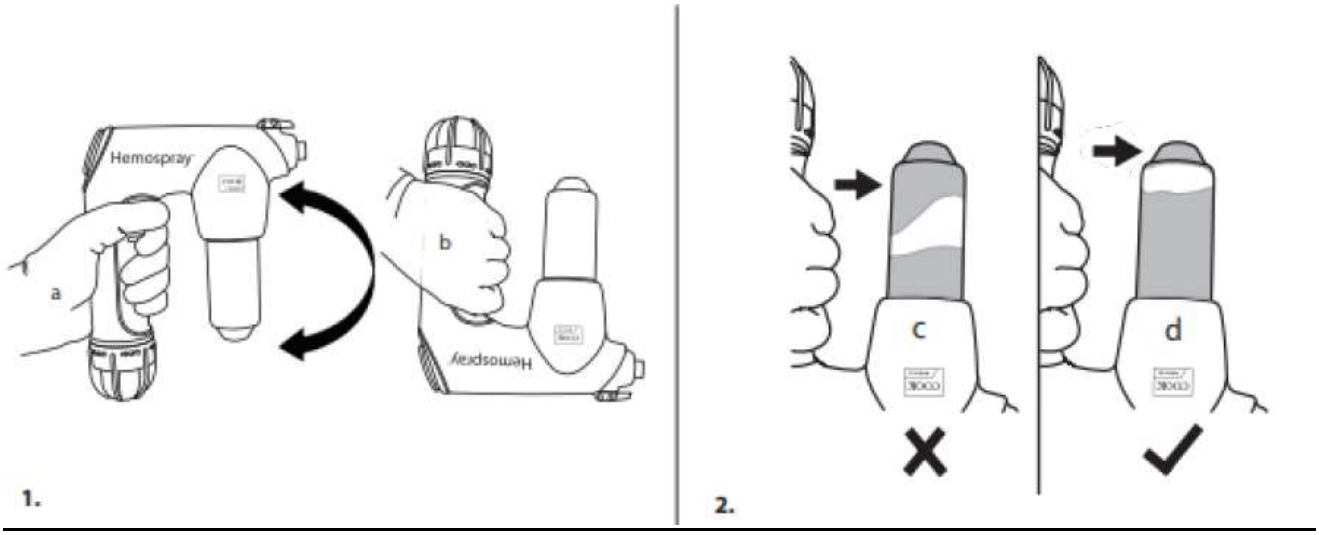
  Do not perform endoscope maneuvers (rotating, pushing, or pulling) if difficulty repositioning/removing the endoscope is encountered. **Use saline irrigation targeted at the endoscope shaft to hydrate and loosen the powder prior to attempting endoscope maneuvers, if needed, and removal.** Saline has 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. Alternatively, follow this link:
https://players.brightcove.net/309212793001/default_default/index.html?videoId=6399387869112

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:



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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.

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. Alternatively, follow this link:
https://players.brightcove.net/309212793001/default_default/index.html?videoId=6363265645112

Risk to Health

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, can result in difficulty or inability to maneuver or to remove the endoscope at the time of the initial hemostasis procedure. The likelihood of this occurrence increases when using a water-based lubricant, spraying in endoscope retroflexion, or removing the endoscope through narrowed anatomy. Endoscope maneuvers should not be performed when adhesion is encountered; use saline irrigation targeted at the endoscope shaft to hydrate and loosen the powder prior to attempting endoscope maneuvers. Adhesion of the powder to the endoscope or endoscope to the tissue can result in delay in treatment, mucosal tear, pain, distress, aggravation of an existing bleed, perforation, hemorrhage, cardiac arrest, or death.

During use, the Hemospray device may be unable to spray powder as intended due to powder compaction. The majority of the time this can occur without incident and the potential for injury is unlikely and the device is replaced with an insignificant delay in the procedure; however, it could also lead to inability to achieve hemostasis as a single or dual modality, or a significant delay in procedure. These situations could lead to patient harms such as death, required surgical intervention, medical intervention, or bleeding requiring additional hemostasis methods.

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Product Information

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER	Universal Device Identifier (UDI)
Hemospray Endoscopic Hemostat	HEMO-7 HEMO-10 HEMO-7-EU HEMO-10-EU	G56572 G21049 G24663 G21346	The information supplied in this letter applies to all Hemospray devices- regardless of lot numbers.	00827002565722 00827002210493 00827002246638 00827002213463

Actions to be Taken by the Customer

1. Please complete the Acknowledgement and Receipt Form within **5 business** days of receiving this letter. **Even if you do not have subject product(s) on hand**, you must still complete the Acknowledgement and Receipt Form and return to (MLY-QA@cookmedical.com).
2. This notice must be shared with appropriate personnel, down to the user level, within your organization or with any organization where the subject devices have been transferred.
3. Immediately report adverse events to your local Cook Representative or by email to: MLY-QA@cookmedical.com.

Actions to be Taken by the Distributor

1. This notice must be shared with appropriate personnel **with any organization where the affected devices have been distributed.**
2. Complete the Acknowledgement and Receipt Form within **5 business** days of receiving this letter and return to (MLY-QA@cookmedical.com).
3. Immediately report adverse events to your local Cook Representative or by email to: MLY-QA@cookmedical.com.

We recognize that this situation is a potential disruption to your normal operations, and we sincerely apologize. Thank you for your immediate assistance in this matter. If you have any questions or concerns, please contact MLY-QA@cookmedical.com or your local Cook representative. We look forward to your response.

Sincerely,

24 Aug 2026

Emerald Seah
QA Team Lead