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
PHONE: +603 7669 3889, FAX: +603 7669 3898
WWW.COOKMEDICAL.COM

24 May 2023

Cook Malaysia Field Action Reference Number: FCA-23-001-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 the letter is to bring heightened awareness to all Hemospray users of the potential risks of the Hemospray powder adhering to the distal end of the endoscope, which can result in adhesion of the endoscope to tissue and consequent difficulty or inability to maneuver/remove the endoscope. This communication extends to the user level.

Hemospray Endoscopic Hemostat is intended to be used for hemostasis of nonvariceal gastrointestinal bleeding.

Reason for Voluntary Correction
Cook Medical is initiating this voluntary correction to bring awareness to potential risks to patient health as described in the following **Risk to Health** section of this letter.

Currently, the 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.” The **Risk to Health** section of this letter provides additional information that is not currently in the Hemospray Instructions for Use. Cook Medical will make available updated Instructions for Use reflecting information in this Urgent Medical Device Correction Notice and will notify customers when the updated Instructions for Use is available.

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, 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.

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
PHONE: +603 7669 3889, FAX: +603 7669 3898
WWW.COOKMEDICAL.COM

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	All unexpired lot numbers	00827002565722 00827002210493 00827002246638 00827002213463

Note: Above is the complete global list of affected lots identified by product owner. If you have any questions or concerns on the affected product list, please contact MLY-QA@cookmedical.com.

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 via email 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 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. We look forward to your response.

Sincerely,

Jasmpr Jason Poh
24 May 2023

Jason Poh
QA Manager
Cook Asia (Malaysia) Sdn Bhd