COOK MEDICAL
1025 ACUFF ROAD, P.O. BOX 4195
BLOOMINGTON, IN 47402-4195 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

05/23/2023

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
In collaboration with the FDA, 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.

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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	All unexpired 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 via fax (812.339.7316) or email (FieldActionsNA@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 Cook Medical Customer Relations by phone at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30am and 5:00pm (Eastern Time), or by email to: CustomerRelationsNA@CookMedical.com.

Other Information

This action is being taken with the knowledge of the Food and Drug Administration.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA:

- Visit http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm.
- Call the FDA at 800.FDA.1088.

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 Cook Medical Customer Relations at 800.457.4500 or 812.339.2235 or your local Cook representative. We look forward to your response.

Sincerely,

Blair Younts

BLAIR YOUNTS
Team Lead, Regulatory Reporting & Field Actions
Cook Medical