COOK®

Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441

Urgent Field Safety Notice

Commercial name of the affected product: Hemospray Endoscopic Hemostat
Manufacturer: Cook Endoscopy/Wilson-Cook Medical, Inc.
Cook Reference Number: 2019FA0007
Type of action: Field Safety Corrective Action

Date: 24/July/2019

Attention: Healthcare Provider, Chief Executive, Risk Manager, and Purchasing

Details on affected devices:

PRODUCT BRAND NAME	Catalog Identifier	Lot Number
Hemospray Endoscopic Hemostat	HEMO-10-EU HEMO-7-EU	W4180860, W4181071, W4189223, and W4189224

Description of the problem:
The product is being recalled because Cook has received eight (8) complaints of the Hemospray device being unable to spray powder due to misassembly of devices. This has been reported to have led to an inability to achieve haemostasis, so the patient was transferred to surgery. There is also a potential risk of death if haemostasis is unable to be achieved in emergent cases.

As stated above, the devices may not spray powder resulting in an inability to achieve haemostasis. In these cases, additional haemostasis may be required, haemostasis may be delayed, and/or the patient may need to be transferred to surgery. Ultimately, if haemostasis cannot be achieved in a timely manner in emergent cases, this may result in death.

Advise on action to be taken by the user:

1. Please review the impacted Catalogue and Lot numbers to identify and quarantine any affected product that remains in your stock.

2. Please complete and return the enclosed Customer Response Form by 31/July/2019. Where product is indicated as being returned, our Customer Services department will contact you to organise the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Response form.

3. Please return only the impacted Catalogue Numbers and Lot Numbers that are affected by this Field Safety Corrective Action.

   Send the removed devices to:

   Cook Medical EUDC
   Robert-Koch-Straße, 2
   52499 Baesweiler
   GERMANY

   Credit will be provided for the returned devices where applicable.

4. Where devices have already been used in a patient, there is no risk to the patient and no need for any further action.

5. Complete and return via email or facsimile the attached **Field Action Customer Response Form** by e-mail to European.FieldAction@CookMedical.com or by fax to + 353 61239294.

Transmission of this Field Safety Notice: (if appropriate)

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.

Contact reference person:

Scottie Fariole
Regulatory Reporting Manager
Cook Endoscopy/Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105 USA

Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@CookMedical.com, phone +353 61 334441).

We regret the inconvenience this may cause you. Thank you again for your immediate assistance in this matter. We look forward to receiving your response.

We confirm that this notice has been notified to the appropriate Regulatory Agency.

Scottie Fariole
Regulatory Reporting Manager

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FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2019FA0007
Affected device: Hemospray Endoscopic Hemostat

Please indicate the following:

Customer Number (As Indicated on the attached product list): _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____

(Please Print)

Please indicate which of the following applies to your facility:

☐ None of the affected product remains in our inventory

☐ We are returning our remaining inventory, please see details listed below

**If you are a distributor, have your customers been notified of this Field Safety Corrective Action?

☐ Yes ☐ No

If you are returning any affected product, please indicate the part number, lot number and quantity:

Product Part Number	Product Lot Number	Quantity

Signed: _____ Date: _____

Please return the completed Customer Response Form to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 239294.

COOK ENDOSCOPY
4900 BETHANIA STATION ROAD
WINSTON-SALEM, NC 27105 U.S.A.
PHONE: 336.744.0157 TOLL FREE: 800.245.4707
WWW.COOKMEDICAL.COM

July 25th, 2019

URGENT: MEDICAL DEVICE RECALL
PROMPT RESPONSE REQUIRED

ATTENTION:
Risk Management and Recall Administration
Our records indicate that you have received some of the affected products listed below.

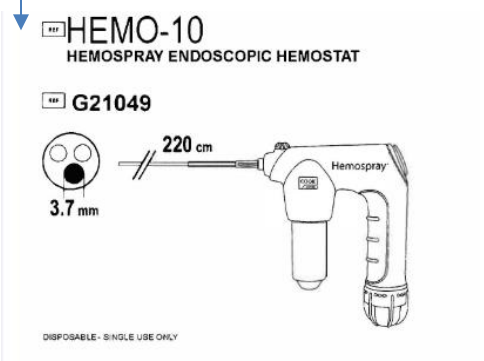
Hemospray Endoscopic Hemostat devices are used for hemostasis of nonvariceal gastrointestinal bleeding. **Serious injuries and/or deaths could occur due to the failure of this product. We have a report of one (1) of serious injury at this time.**

Reason for the Voluntary Recall:
The product is being recalled because Cook has received eight (8) complaints of the Hemospray device being unable to spray powder due to misassembly of devices. This has been reported to have led to an inability to achieve hemostasis, so the patient was transferred to surgery. There is also a potential risk of death if hemostasis is unable to be achieved in emergent cases.

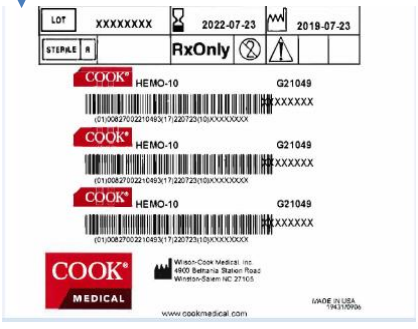
Risk to Health:
As stated above, the devices may not spray powder resulting in an inability to achieve hemostasis. Potential adverse events that may occur if impacted product is used include delayed hemostasis, the need for additional hemostasis, and/or the patient may need to be transferred to surgery. If hemostasis cannot be achieved in a timely manner in emergent cases, this may result in death.

The devices may be identified by inspection of the device label. **The devices impacted by the recall are labeled as Hemospray Endoscopic Hemostat, reference part number HEMO-10, Lot Numbers W4179646, W4180858, W4180861, and W4181073.** The issue cannot be detected by visual examination of the device, so the Lot Number on the device label must be reviewed to identify impacted product.

Reference part number information may be found in this section of the product labeling.



Lot number information may be found in this section of the product labeling.



Product and Distribution Information:

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Hemospray Endoscopic Hemostat	HEMO-10	G21049	W4179646
			W4180858
			W4180861
			W4181073

Actions to be taken by the Customer/User:

1. Please immediately review the labels of impacted product shipped to your account and quarantine any affected product that remains unused. If you are a distributor and the products have been distributed, contact your customer(s) and direct them to quarantine any affected product.
2. Return the impacted product(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit.
   NOTE: Unimpacted products that are returned will not be credited.
3. Please complete the attached Acknowledgement and Receipt Form within 5 business days of receiving this letter. Even if you do not have impacted product(s) on hand, you must still complete the Acknowledgement and Receipt Form and return it via fax (812.339.7316) or email FieldActionsNA@CookMedical.com.
4. Immediately report adverse events to Cook Medical Customer Relations by phone at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30 am and 5:00 pm (Eastern Time) or by email to CustomerRelationsNA@CookMedical.com.

Type of Action by the Company:
Cook Medical will remove these devices from the market while we fully investigate the root cause of this recall. Once the root cause is determined, corrective actions to prevent future recurrence will be implemented.

Contact Information: Please contact the Customer Relations Department at Cook Medical for more information or if you have questions. Please use FieldActionsNA@CookMedical.com, or call us **toll free – 1-800-457-4500,** press 4, then enter extension 15-2146, Monday through Friday, 8:00AM to 4:30PM, Eastern Time.

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

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA 1-800-FDA-1088

Transmission of this notice

This notice must be shared with appropriate personnel, including down to the user level, within your organization or with any organization where the potentially affected devices have been transferred.

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

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. We look forward to your response.

Sincerely,

Scottie Fariole
Manager, Regulatory Reporting
Cook Medical

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

URGENT: PROMPT RESPONSE REQUIRED

Acknowledgement and Receipt Form

July 25th, 2019

<Customer Number>
<Customer Name>
<ATTN Line>
<Customer Address>
<2nd Address Line>
<City, State, Postal Code>

You are required to fill out and return this form. Please return it within 5 business days of receipt, even if you do not have any of the affected product(s).

Please complete the following information regarding the recall on Hemospray Endoscopic Hemostat, HEMO-10.

Actions you have taken

1. I have received the letter titled "URGENT: MEDICAL DEVICE Recall" regarding Hemospray Endoscopic Hemostat, HEMO-10, and I understand the instructions in the letter.
   ☐ Yes ☐ No

Affected product information

Please list the quantity of affected product at your facility to be returned, or write "none" if the affected product is no longer in your inventory or is no longer with your customers.

QUANTITY	PART NUMBER	LOT NUMBER

Additional actions for distributors

Share the letter "URGENT: MEDICAL DEVICE RECALL" with appropriate personnel within your organization or with any organization where the potentially affected product(s) have been transferred.

Please confirm the following:

1. I have notified my customers of the recall.
   ☐ Yes ☐ No

Form Completed By (Printed Name, Signature):	Date:
Email address (Please print clearly for product return information):	

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Template Revision: 001

D00204553
Rev: 002

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

Returning this form and affected product(s)

Upon completion of this form, please return it to the Cook Medical Customer Relations department via fax or email. Fax: 812.339.7316 Email: FieldActionsNA@CookMedical.com

Should you have any questions regarding the recall, please contact the Customer Relations Department at Cook Medical. Please use FieldActionsNA@CookMedical.com, or call us toll free – 800.457.4500, press 5, then enter extension 151090. Monday through Friday, 8:00AM to 4:30PM, Eastern Time.

Before returning affected product to Cook Medical, please obtain an RGA#.

Please ensure your email address is clear and complete. The RGA#, return address and instructions will be emailed to the address provided.

You may also contact 800.457.4500 press option 5 and enter extension 151090 to obtain an RGA# and return address.

To report adverse events, contact Cook Medical Customer Relations at 800.457.4500 extension 152146 or 812.339.2235 extension 152146

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Rev: 002