COOK

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

Customer Communication

Commercial name of the affected product: Hemospray Endoscopic Hemostat
Manufacturer: Wilson-Cook Medical
Cook Reference Number: 2018FA0011

Date: 10 December 2018

Attention: Chief Executive/Risk Management/Purchasing

Details on affected devices:
Hemospray Endoscopic Hemostat

PRODUCT BRAND NAME	Catalog Identifier
Hemospray Endoscopic Hemostat	HEMO-7-EU
	HEMO-10-EU

Description of the problem:
Cook Medical has become aware that the Hemospray Endoscopic Hemostat has been used to treat patients with upper gastrointestinal bleeding that is accessed for treatment by using an endoscope in the retroflexed position. We have received reports of the Hemospray Endoscopic Hemostat powder adhering to the endoscope shaft after being sprayed in the retroflexed position, which led to difficulty or inability removing the endoscope from the patient.
Cook Medical has revised the Hemospray Endoscopic Hemostat Instructions for Use (IFU) to include a statement to bring awareness to the potential for this clinical situation that states "When spraying in 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." Please see Potential Complications section of the attached copy of the IFU for further information.

Advise on action to be taken by the user:
No devices need to be returned. Please do the following:

- Please share this notice with others in your organization who use this device so they are aware of this clinical situation.
- Maintain a copy of this notice for your records.
- Complete and return via email or facsimile the attached **Customer Response Form** by e-mail to European.FieldAction@cookmedical.com or by fax marked for the attention of European Customer Quality Assurance to + 353 61 239294.
- Please report any adverse events to Cook Medical by contacting our Customer Support Department. (e-mail SSCProduct.Complaints@CookMedical.com, phone +353 61 239252).
- Please contact your Cook Sales Representative if further information is desired.

Transmission of this Customer Communication: (if appropriate)

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.
Thank you for your immediate attention to this matter. Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@CookMedical.com, phone +353 61 334440).

Contact reference person:

[redacted]
Wilson-Cook Medical
4900 Bethania Station Road
Winston-Salem, NC 27105 USA
+1(336)740-0157