COOK MEDICAL EUROPE LTD.
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NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2024FA0007

Date: 30 October 2024

Urgent Field Safety Notice
Product Removal
Hemospray Endoscopic Hemostat

For Attention of: Chief Executive / Risk Management / Purchasing/ Recall Coordinator

Contact details of local representative (name, e-mail, telephone, address etc.)
Cook Medical Europe Ltd. O'Halloran Road National Technology Park Limerick, Ireland E-mail: European.FieldAction@CookMedical.com Phone: Please refer to the attached Country Contacts List For any further information or support concerning the information within this FSN, please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.

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Urgent Field Safety Notice (FSN)
Hemospray Endoscopic Hemostat
Risk Addressed by FSN

	Information on Affected Devices
1.	1. Device Type(s)
	Hemospray Endoscopic Hemostat is a gastrointestinal haemostasis device supplied sterile.
1.	2. Commercial name(s)
	Hemospray Endoscopic Hemostat
1.	3. Primary clinical purpose of device(s)
	The HEMO-7 & HEMO-10 devices are used for haemostasis of nonvariceal gastrointestinal bleeding. The HEMO-7-EU device is used for haemostasis of nonvariceal upper gastrointestinal bleeding.
1.	4. Device Model/Catalogue/part number(s)
	HEMO-7, HEMO-7-EU, HEMO-10
1.	5. Affected serial or lot number range
	Please see the attached Affected Lots List.

	Reason for Field Safety Corrective Action (FSCA)
2.	1. Description of the product problem
	Cook Medical has identified that a limited number of nonconforming raw materials were manufactured into certain lot numbers of Hemospray devices and distributed into the field. Use of the devices with these nonconforming raw materials may result in the red activation knob cracking or breaking at the activation knob internal threading while the device is activated, prior to and during use, or after the procedure is complete. This can lead to the activation knob and carbon dioxide cartridge exiting the handle with force.
2.	2. Hazard giving rise to the FSCA
	Potential adverse effects to the user or patient that may occur if they are exposed to a sharp object or projectile include superficial laceration, laceration, infection secondary to laceration, pain, or permanent impairment of a body structure, or may occur without incident and the potential for injury is unlikely. Potential adverse effects to the patient that may occur if there is a significant delay in the hemostasis procedure are additional interventions or medications needed to stabilize the patient, bleeding requiring additional hemostasis, surgical intervention, or death. Additionally, the device failure could be recognizable prior to use and the device would be replaced with an insignificant delay in procedure and the potential for injury is unlikely.
2.	3. Probability of problem arising
	The probability of this incident occurring is 0.3551%.
2.	4. Predicted risk to patient/users
	The predicted individual risk of harm to the user is negligible.

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2.	5. Background on Issue There are several lots of nonconforming Hemospray Endoscopic Hemostat devices in the field where use or preparation may result in the activation knob cracking or breaking at the internal threading which may lead to the activation knob and carbon dioxide cartridge exiting the device with force.	
Type of Action to mitigate the risk		
3.	1. Action To Be Taken by the User ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☒ Other Please complete the enclosed Reply Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Reply Form. Returned Product should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler Germany Credit will be provided for the returned affected products where applicable.	
3.	2. By when should the action be completed?	Within five (5) business days of receipt.
3.	3. Is customer Reply Required? *	Yes, within five (5) business days of receipt.
3.	4. Action Being Taken by the Manufacturer ☒ Product Removal Affected lot numbers of Hemospray devices are being removed from the market and should be returned to Cook per the attached directions on the Field Action Reply Form.	
3	5. By when should the action be completed?	Within five (5) business days of receipt.
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

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General Information		
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Cook Endoscopy/Wilson-Cook Medical, Inc.
	b. Address	4900 Bethania Station Road, Winston-Salem, NC USA
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	

	Transmission of this Field Safety Notice
	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. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.