



COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
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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. <u>Please include contact details on the Reply Form.</u> 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	 Blair Younts Team Lead, Regulatory Reporting & Field Actions

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.

1. Field Safety Notice (FSN) information	
FSN Reference number	2024FA0007
FSN Date	30 October 2024
Product/ Device name	Hemospray Endoscopic Hemostat; HEMO-7-EU, HEMO-7, HEMO-10
Batch/Serial Number (s)	See Affected Lots List

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Contact Name	
Title or Function	
Telephone number	
Email	

☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	The information and required actions have been brought to the attention of all relevant users.	
☐	I have affected devices to return - enter Lot number and quantities in table below.	
☐	No affected devices are available for return	
Print Name	Customer print name here	
Signature	Customer sign here	
Date		

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

[illegible]



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Product Part Number(s)	Product Lot Number(s)	Quantity

4. Return acknowledgement to sender

Email	European.FieldAction@CookMedical.com
Customer Helpline	See Country Contacts List
Fax	+ 353 61 239294
Deadline for returning the customer reply form*	Within five (5) days of receipt

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

2024FA0007 Affected Lot Number List

Lot Number	RPN	GPN	Lot Number	RPN	GPN	Lot Number	RPN	GPN
W4843112	HEMO-10	G21049	W4859528	HEMO-10	G21049	W4845125	HEMO-7	G56572
W4843113	HEMO-10	G21049	W4859890	HEMO-10	G21049	W4845538	HEMO-7	G56572
W4843519	HEMO-10	G21049	W4843115	HEMO-7	G56572	W4845539	HEMO-7	G56572
W4843864	HEMO-10	G21049	W4843116	HEMO-7	G56572	W4845540	HEMO-7	G56572
W4843866	HEMO-10	G21049	W4843117	HEMO-7	G56572	W4845541	HEMO-7	G56572
W4844250	HEMO-10	G21049	W4843118	HEMO-7	G56572	W4845543	HEMO-7	G56572
W4844645	HEMO-10	G21049	W4843119	HEMO-7	G56572	W4845546	HEMO-7	G56572
W4845117	HEMO-10	G21049	W4843511	HEMO-7	G56572	W4845542	HEMO-7	G56572
W4845537	HEMO-10	G21049	W4843512	HEMO-7	G56572	W4845545	HEMO-7	G56572
W4845544	HEMO-10	G21049	W4843513	HEMO-7	G56572	W4845880	HEMO-7	G56572
W4845885	HEMO-10	G21049	W4843514	HEMO-7	G56572	W4845881	HEMO-7	G56572
W4845888	HEMO-10	G21049	W4843515	HEMO-7	G56572	W4845882	HEMO-7	G56572
W4847502	HEMO-10	G21049	W4843516	HEMO-7	G56572	W4845883	HEMO-7	G56572
W4847503	HEMO-10	G21049	W4843517	HEMO-7	G56572	W4845884	HEMO-7	G56572
W4848136	HEMO-10	G21049	W4843518	HEMO-7	G56572	W4845886	HEMO-7	G56572
W4848708	HEMO-10	G21049	W4843520	HEMO-7	G56572	W4845887	HEMO-7	G56572
W4849066	HEMO-10	G21049	W4843860	HEMO-7	G56572	W4845889	HEMO-7	G56572
W4849069	HEMO-10	G21049	W4843861	HEMO-7	G56572	W4846299	HEMO-7	G56572
W4859893	HEMO-10	G21049	W4843862	HEMO-7	G56572	W4846301	HEMO-7	G56572
W4860295	HEMO-10	G21049	W4843863	HEMO-7	G56572	W4846303	HEMO-7	G56572
W4860304	HEMO-10	G21049	W4843865	HEMO-7	G56572	W4847081	HEMO-7	G56572
W4849592	HEMO-10	G21049	W4843867	HEMO-7	G56572	W4847085	HEMO-7	G56572
W4849598	HEMO-10	G21049	W4843868	HEMO-7	G56572	W4847495	HEMO-7	G56572
W4851258	HEMO-10	G21049	W4843869	HEMO-7	G56572	W4847496	HEMO-7	G56572
W4851593	HEMO-10	G21049	W4844246	HEMO-7	G56572	W4847497	HEMO-7	G56572
W4851588	HEMO-10	G21049	W4844247	HEMO-7	G56572	W4847498	HEMO-7	G56572
W4851873	HEMO-10	G21049	W4844248	HEMO-7	G56572	W4847499	HEMO-7	G56572
W4852282	HEMO-10	G21049	W4844249	HEMO-7	G56572	W4847500	HEMO-7	G56572
W4853467	HEMO-10	G21049	W4844251	HEMO-7	G56572	W4847504	HEMO-7	G56572
W4853103	HEMO-10	G21049	W4844252	HEMO-7	G56572	W4847892	HEMO-7	G56572
W4853945	HEMO-10	G21049	W4844253	HEMO-7	G56572	W4847893	HEMO-7	G56572
W4854701	HEMO-10	G21049	W4844254	HEMO-7	G56572	W4847894	HEMO-7	G56572
W4855273	HEMO-10	G21049	W4844643	HEMO-7	G56572	W4847896	HEMO-7	G56572
W4855274	HEMO-10	G21049	W4844644	HEMO-7	G56572	W4848132	HEMO-7	G56572
W4855699	HEMO-10	G21049	W4844646	HEMO-7	G56572	W4848709	HEMO-7	G56572
W4855700	HEMO-10	G21049	W4844647	HEMO-7	G56572	W4848710	HEMO-7	G56572
W4856897	HEMO-10	G21049	W4844649	HEMO-7	G56572	W4848711	HEMO-7	G56572
W4856898	HEMO-10	G21049	W4844651	HEMO-7	G56572	W4848712	HEMO-7	G56572
W4857717	HEMO-10	G21049	W4845120	HEMO-7	G56572	W4848713	HEMO-7	G56572
W4858447	HEMO-10	G21049	W4845121	HEMO-7	G56572	W4848714	HEMO-7	G56572
W4858448	HEMO-10	G21049	W4845122	HEMO-7	G56572	W4848715	HEMO-7	G56572
W4858868	HEMO-10	G21049	W4845123	HEMO-7	G56572	W4848716	HEMO-7	G56572
W4859527	HEMO-10	G21049	W4845124	HEMO-7	G56572	W4848717	HEMO-7	G56572
W4849067	HEMO-7	G56572	W4851878	HEMO-7	G56572	W4855271	HEMO-7	G56572
W4849068	HEMO-7	G56572	W4851879	HEMO-7	G56572	W4855269	HEMO-7	G56572
W4859892	HEMO-7	G56572	W4851880	HEMO-7	G56572	W4855272	HEMO-7	G56572
W4859894	HEMO-7	G56572	W4852625	HEMO-7	G56572	W4855694	HEMO-7	G56572
W4859895	HEMO-7	G56572	W4852626	HEMO-7	G56572	W4855695	HEMO-7	G56572
W4859896	HEMO-7	G56572	W4852627	HEMO-7	G56572	W4855696	HEMO-7	G56572
W4859897	HEMO-7	G56572	W4852628	HEMO-7	G56572	W4855697	HEMO-7	G56572
W4859898	HEMO-7	G56572	W4853098	HEMO-7	G56572	W4855698	HEMO-7	G56572
W4859899	HEMO-7	G56572	W4853099	HEMO-7	G56572	W4855701	HEMO-7	G56572
W4860112	HEMO-7	G56572	W4853102	HEMO-7	G56572	W4856108	HEMO-7	G56572
Lot Number	RPN	GPN	Lot Number	RPN	GPN	Lot Number	RPN	GPN
W4849070	HEMO-7	G56572	W4853949	HEMO-7	G56572	W4853462	HEMO-7	G56572
W4849071	HEMO-7	G56572	W4853950	HEMO-7	G56572	W4853463	HEMO-7	G56572
W4849072	HEMO-7	G56572	W4853952	HEMO-7	G56572	W4853464	HEMO-7	G56572
W4849073	HEMO-7	G56572	W4853953	HEMO-7	G56572	W4853465	HEMO-7	G56572
W4849074	HEMO-7	G56572	W4853954	HEMO-7	G56572	W4853948	HEMO-7	G56572
W4849075	HEMO-7	G56572	W4854699	HEMO-7	G56572	W4859529	HEMO-7	G56572
W4849593	HEMO-7	G56572	W4854700	HEMO-7	G56572	W4859530	HEMO-7	G56572
W4849594	HEMO-7	G56572	W4854702	HEMO-7	G56572	W4859531	HEMO-7	G56572
W4849595	HEMO-7	G56572	W4854703	HEMO-7	G56572	W4859532	HEMO-7	G56572
W4849596	HEMO-7	G56572	W4854704	HEMO-7	G56572	W4859533	HEMO-7	G56572
W4849597	HEMO-7	G56572	W4854705	HEMO-7	G56572	W4859534	HEMO-7	G56572
W4849599	HEMO-7	G56572	W4854706	HEMO-7	G56572	W4859536	HEMO-7	G56572
W4851251	HEMO-7	G56572	W4855265	HEMO-7	G56572	W4844245	HEMO-7-EU	G24663
W4851252	HEMO-7	G56572	W4855266	HEMO-7	G56572	W4847501	HEMO-7-EU	G24663
W4851253	HEMO-7	G56572	W4855267	HEMO-7	G56572	W4851589	HEMO-7-EU	G24663
W4851254	HEMO-7	G56572	W4855268	HEMO-7	G56572			
W4851255	HEMO-7	G56572	W4855270	HEMO-7	G56572			
W4851256	HEMO-7	G56572	W4856109	HEMO-7	G56572			
W4851257	HEMO-7	G56572	W4856471	HEMO-7	G56572			
W4851259	HEMO-7	G56572	W4856889	HEMO-7	G56572			
W4851591	HEMO-7	G56572	W4856891	HEMO-7	G56572			
W4851592	HEMO-7	G56572	W4856892	HEMO-7	G56572			
W4851594	HEMO-7	G56572	W4856893	HEMO-7	G56572			
W4851595	HEMO-7	G56572	W4856894	HEMO-7	G56572			
W4851596	HEMO-7	G56572	W4856895	HEMO-7	G56572			
W4851660	HEMO-7	G56572	W4856896	HEMO-7	G56572			
W4851590	HEMO-7	G56572	W4857004	HEMO-7	G56572			
W4851871	HEMO-7	G56572	W4857326	HEMO-7	G56572			
W4851872	HEMO-7	G56572	W4857327	HEMO-7	G56572			
W4851874	HEMO-7	G56572	W4857716	HEMO-7	G56572			
W4851875	HEMO-7	G56572	W4857719	HEMO-7	G56572			
W4851876	HEMO-7	G56572	W4857718	HEMO-7	G56572			
W4851877	HEMO-7	G56572	W4858445	HEMO-7	G56572			
W4859891	HEMO-7	G56572	W4858446	HEMO-7	G56572			
W4853104	HEMO-7	G56572	W4858449	HEMO-7	G56572			
W4853105	HEMO-7	G56572	W4858450	HEMO-7	G56572			
W4853466	HEMO-7	G56572	W4858451	HEMO-7	G56572			
W4853468	HEMO-7	G56572	W4858452	HEMO-7	G56572			
W4853469	HEMO-7	G56572	W4858453	HEMO-7	G56572			
W4853470	HEMO-7	G56572	W4858454	HEMO-7	G56572			
W4853471	HEMO-7	G56572	W4858869	HEMO-7	G56572			
W4853096	HEMO-7	G56572	W4859147	HEMO-7	G56572			
W4853097	HEMO-7	G56572	W4859152	HEMO-7	G56572			
W4853100	HEMO-7	G56572	W4853101	HEMO-7	G56572			