



COOK ASIA (MALAYSIA) SDN. BHD.
CO. REG. NO. 199001015417
UNIT 1602, LEVEL 16, UPTOWN 1,
NO. 1, JALAN SS21/58, DAMANSARA UTAMA,
47400 PETALING JAYA, SELANGOR, MALAYSIA
PHONE: +603 7669 3889, FAX: +603 7669 3898
WWW.COOKMEDICAL.COM

01 Nov 2024

Cook Malaysia Field Action Reference Number: RC-24-001-MY

**URGENT: MEDICAL DEVICE RECALL EXTENSION
HEMOSPRAY ENDOSCOPIC HEMOSTAT
PROMPT RESPONSE REQUIRED**

ATTENTION:

Risk Management/Recall Administration

Our records indicate that you have received affected devices.

Purpose of this Letter

You are receiving this letter because Cook Medical is extending the voluntary recall from 29 August 2024 to include additional lot numbers of Hemospray Endoscopic Hemostat devices due to the receipt of additional complaints and adverse events since the recall was originally initiated. Twenty (20) complaints on twenty-five (25) devices have been received, resulting in seven (7) reports of minor harm and thirteen (13) malfunctions.

This recall extends to the user level.

Attached is a list of the affected lot numbers. Please review the attached list to ensure that affected devices are quarantined and returned to Cook.

The HEMO-7 & HEMO-10 devices are used for hemostasis of nonvariceal gastrointestinal bleeding. The HEMO-7-EU device is used for hemostasis of nonvariceal upper gastrointestinal bleeding.

Reason for Voluntary Recall

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.

Risk to Health

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.

Product Identification and Device Information

The devices being recalled are listed in the attached Affected Lots List. Please see the table below to assist with identification of affected devices.



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DEVICE BRAND NAME	REFERENCE PART NUMBER (RPN)	MODEL NUMBER	UNIVERSAL DEVICE IDENTIFIER
Hemospray Endoscopic Hemostat	HEMO-7	G56572	00827002565722
	HEMO-10	G21049	00827002210493
	HEMO-7-EU	G24663	00827002246638

Actions to be Taken by the Customer

1. Examine inventory immediately to determine if you have affected device(s) and quarantine affected device(s). Immediately cease all use of the affected devices.
2. Return the affected device(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a credit.
3. Please complete the Acknowledgement and Receipt Form within **5 business** days of receiving this letter. **Even if you do not have affected device(s) on hand**, you must still complete the Acknowledgement and Receipt Form and return via email (MLY-QA@cookmedical.com).
4. 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.
5. Immediately report adverse events to your local Cook Representative or email to MLY-QA@cookmedical.com.

Actions to be Taken by the Distributor

1. Examine inventory immediately to determine if you have affected device(s) and quarantine affected device(s). Immediately cease all distribution of the affected devices.
2. Return the affected device(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a credit.
3. Please complete the Acknowledgement and Receipt Form within **5 business** days of receiving this letter. **Even if you do not have affected device(s) on hand**, you must still complete the Acknowledgement and Receipt Form and return email (MLY-QA@cookmedical.com).
4. This notice must be shared with appropriate personnel, including down to the user level, within your organization and with any organization where the affected devices have been distributed.
6. Immediately report adverse events to your local Cook Representative or email to MLY-QA@cookmedical.com.

Additional Action being Taken by Cook Medical

Cook Medical has initiated an investigation and will determine the appropriate corrective action(s) to prevent recurrence of this similar issue.


We recognize that this situation is a potential disruption to your normal operations, and we sincerely apologize. If you have any questions or concerns, please contact MLY-QA@cookmedical.com. We look forward to your response.

Patient safety and customer satisfaction are Cook Medical's highest priorities. We appreciate your time and attention in reading this important notice. Thank you for your immediate assistance in this matter.



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Sincerely,

 30 Oct 2024

Emerald Seah
QA Team Lead
Cook South East Asia Pte Ltd



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HEMO Recall Expansion Affected Lots List

Lot Number	RPN	GPN	Lot Number	RPN	GPN	Lot Number	RPN	GPN
W4843112	HEMO-10	G21049	W4843512	HEMO-7	G56572	W4845546	HEMO-7	G56572
W4843113	HEMO-10	G21049	W4843513	HEMO-7	G56572	W4845880	HEMO-7	G56572
W4843519	HEMO-10	G21049	W4843514	HEMO-7	G56572	W4845881	HEMO-7	G56572
W4843864	HEMO-10	G21049	W4843515	HEMO-7	G56572	W4845882	HEMO-7	G56572
W4843866	HEMO-10	G21049	W4843516	HEMO-7	G56572	W4845883	HEMO-7	G56572
W4844250	HEMO-10	G21049	W4843517	HEMO-7	G56572	W4845884	HEMO-7	G56572
W4844645	HEMO-10	G21049	W4843518	HEMO-7	G56572	W4845886	HEMO-7	G56572
W4845117	HEMO-10	G21049	W4843520	HEMO-7	G56572	W4845889	HEMO-7	G56572
W4845537	HEMO-10	G21049	W4843860	HEMO-7	G56572	W4846299	HEMO-7	G56572
W4845544	HEMO-10	G21049	W4843861	HEMO-7	G56572	W4846301	HEMO-7	G56572
W4845885	HEMO-10	G21049	W4843862	HEMO-7	G56572	W4846303	HEMO-7	G56572
W4845888	HEMO-10	G21049	W4843863	HEMO-7	G56572	W4847081	HEMO-7	G56572
W4847502	HEMO-10	G21049	W4843865	HEMO-7	G56572	W4847085	HEMO-7	G56572
W4847503	HEMO-10	G21049	W4843867	HEMO-7	G56572	W4847495	HEMO-7	G56572
W4848136	HEMO-10	G21049	W4843868	HEMO-7	G56572	W4847496	HEMO-7	G56572
W4848708	HEMO-10	G21049	W4843869	HEMO-7	G56572	W4847497	HEMO-7	G56572
W4849066	HEMO-10	G21049	W4844246	HEMO-7	G56572	W4847498	HEMO-7	G56572
W4849069	HEMO-10	G21049	W4844247	HEMO-7	G56572	W4847499	HEMO-7	G56572
W4849592	HEMO-10	G21049	W4844248	HEMO-7	G56572	W4847500	HEMO-7	G56572
W4849598	HEMO-10	G21049	W4844249	HEMO-7	G56572	W4847504	HEMO-7	G56572
W4851258	HEMO-10	G21049	W4844251	HEMO-7	G56572	W4847892	HEMO-7	G56572
W4851593	HEMO-10	G21049	W4844252	HEMO-7	G56572	W4847893	HEMO-7	G56572
W4851873	HEMO-10	G21049	W4844253	HEMO-7	G56572	W4847894	HEMO-7	G56572
W4852282	HEMO-10	G21049	W4844254	HEMO-7	G56572	W4847896	HEMO-7	G56572
W4853103	HEMO-10	G21049	W4844643	HEMO-7	G56572	W4848132	HEMO-7	G56572
W4853467	HEMO-10	G21049	W4844644	HEMO-7	G56572	W4848709	HEMO-7	G56572
W4853945	HEMO-10	G21049	W4844646	HEMO-7	G56572	W4848710	HEMO-7	G56572
W4854701	HEMO-10	G21049	W4844647	HEMO-7	G56572	W4848711	HEMO-7	G56572
W4855273	HEMO-10	G21049	W4844649	HEMO-7	G56572	W4848712	HEMO-7	G56572
W4855699	HEMO-10	G21049	W4844651	HEMO-7	G56572	W4848713	HEMO-7	G56572
W4858447	HEMO-10	G21049	W4845120	HEMO-7	G56572	W4848714	HEMO-7	G56572
W4858868	HEMO-10	G21049	W4845121	HEMO-7	G56572	W4848715	HEMO-7	G56572
W4859528	HEMO-10	G21049	W4845122	HEMO-7	G56572	W4848716	HEMO-7	G56572
W4859890	HEMO-10	G21049	W4845124	HEMO-7	G56572	W4848717	HEMO-7	G56572
W4859893	HEMO-10	G21049	W4845125	HEMO-7	G56572	W4849067	HEMO-7	G56572
W4860295	HEMO-10	G21049	W4845538	HEMO-7	G56572	W4849068	HEMO-7	G56572



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Lot Number	RPN	GPN	Lot Number	RPN	GPN	Lot Number	RPN	GPN
W4860304	HEMO-10	G21049	W4845539	HEMO-7	G56572	W4849070	HEMO-7	G56572
W4843115	HEMO-7	G56572	W4845540	HEMO-7	G56572	W4849071	HEMO-7	G56572
W4843116	HEMO-7	G56572	W4845541	HEMO-7	G56572	W4849072	HEMO-7	G56572
W4843117	HEMO-7	G56572	W4845542	HEMO-7	G56572	W4849074	HEMO-7	G56572
W4843118	HEMO-7	G56572	W4845543	HEMO-7	G56572	W4849075	HEMO-7	G56572
W4843119	HEMO-7	G56572	W4845545	HEMO-7	G56572	W4849593	HEMO-7	G56572
W4849594	HEMO-7	G56572	W4853470	HEMO-7	G56572	W4859532	HEMO-7	G56572
W4849595	HEMO-7	G56572	W4853471	HEMO-7	G56572	W4859533	HEMO-7	G56572
W4849596	HEMO-7	G56572	W4853948	HEMO-7	G56572	W4859891	HEMO-7	G56572
W4849597	HEMO-7	G56572	W4853949	HEMO-7	G56572	W4859892	HEMO-7	G56572
W4849599	HEMO-7	G56572	W4853950	HEMO-7	G56572	W4859894	HEMO-7	G56572
W4851251	HEMO-7	G56572	W4853952	HEMO-7	G56572	W4859895	HEMO-7	G56572
W4851252	HEMO-7	G56572	W4853954	HEMO-7	G56572	W4859896	HEMO-7	G56572
W4851253	HEMO-7	G56572	W4854699	HEMO-7	G56572	W4859897	HEMO-7	G56572
W4851254	HEMO-7	G56572	W4854700	HEMO-7	G56572	W4859898	HEMO-7	G56572
W4851255	HEMO-7	G56572	W4854702	HEMO-7	G56572	W4859899	HEMO-7	G56572
W4851256	HEMO-7	G56572	W4854703	HEMO-7	G56572	W4860112	HEMO-7	G56572
W4851257	HEMO-7	G56572	W4854704	HEMO-7	G56572	W4844245	HEMO-7-EU	G24663
W4851590	HEMO-7	G56572	W4854705	HEMO-7	G56572	W4847501	HEMO-7-EU	G24663
W4851591	HEMO-7	G56572	W4854706	HEMO-7	G56572	W4851589	HEMO-7-EU	G24663
W4851592	HEMO-7	G56572	W4855265	HEMO-7	G56572			
W4851596	HEMO-7	G56572	W4855266	HEMO-7	G56572			
W4851660	HEMO-7	G56572	W4855267	HEMO-7	G56572			
W4851871	HEMO-7	G56572	W4855269	HEMO-7	G56572			
W4851872	HEMO-7	G56572	W4855270	HEMO-7	G56572			
W4851874	HEMO-7	G56572	W4855271	HEMO-7	G56572			
W4851876	HEMO-7	G56572	W4855272	HEMO-7	G56572			
W4851877	HEMO-7	G56572	W4855696	HEMO-7	G56572			
W4851878	HEMO-7	G56572	W4855697	HEMO-7	G56572			
W4851879	HEMO-7	G56572	W4855701	HEMO-7	G56572			
W4851880	HEMO-7	G56572	W4856471	HEMO-7	G56572			
W4852627	HEMO-7	G56572	W4856889	HEMO-7	G56572			
W4852628	HEMO-7	G56572	W4856892	HEMO-7	G56572			
W4853096	HEMO-7	G56572	W4856893	HEMO-7	G56572			
W4853097	HEMO-7	G56572	W4856894	HEMO-7	G56572			
W4853098	HEMO-7	G56572	W4856895	HEMO-7	G56572			
W4853099	HEMO-7	G56572	W4857327	HEMO-7	G56572			



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W4853100	HEMO-7	G56572	W4857719	HEMO-7	G56572
W4853101	HEMO-7	G56572	W4858445	HEMO-7	G56572
W4853102	HEMO-7	G56572	W4858449	HEMO-7	G56572
W4853104	HEMO-7	G56572	W4858450	HEMO-7	G56572
W4853105	HEMO-7	G56572	W4858452	HEMO-7	G56572
W4853462	HEMO-7	G56572	W4858454	HEMO-7	G56572
W4853463	HEMO-7	G56572	W4858869	HEMO-7	G56572
W4853464	HEMO-7	G56572	W4859152	HEMO-7	G56572
W4853465	HEMO-7	G56572	W4859529	HEMO-7	G56572
W4853468	HEMO-7	G56572	W4859530	HEMO-7	G56572
W4853469	HEMO-7	G56572	W4859531	HEMO-7	G56572

Note: Above is the complete global list of affected lots identified by product owner. If you have any questions or concerns on the affected product list, please contact MLY-QA@cookmedical.com.