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

December 27, 2019

URGENT: MEDICAL DEVICE RECALL
Dawson-Mueller Drainage Catheter

ATTENTION:
Risk Management/Recall Administration
Our records indicate that you have received affected products.

Cook Medical considers the safety and satisfaction of our customers a top priority. We appreciate your time and attention in reading this important notice.

Purpose of this Letter

The purpose of this letter is to advise you that Cook Medical is voluntarily recalling specific lots of the Dawson-Mueller Drainage Catheter. Refer to the Product Information section below for a list of affected products.

The Dawson-Mueller Drainage Catheter is intended for percutaneous drainage in a variety of drainage applications (e.g., nephrostomy, biliary and abscess), either direct stick or Seldinger access technique.

Reason for Voluntary Recall

Cook Medical has identified that specific lots of the Dawson-Mueller Drainage Catheter were not manufactured to specification, which could lead to leakage from the Mac-Loc hub assembly.

Risk to Health

Potential adverse events that may occur if an affected product is used include increased procedural time to obtain a replacement device if leakage is detected during placement and additional intervention to remove and replace a device if leakage is detected after the initial procedure.

If an affected product is used to treat pneumothorax, loss of vacuum may occur preventing evacuation of air from the pleural space. There is also the potential for more air to enter the pleural space, worsening the patient's condition.

Product Information

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBERS
Dawson-Mueller Drainage Catheter	ULT6.3-35-15-P-5S-CLDM-HC	G51594	9799196, 9909433, 9909435, NS9915808
	ULT6.3-35-25-P-5S-CLDM-HC	G51595	9796032, 9797075, 9803175, 9806067, 9903048, 9904465, 9904469, 9908750, 9912303, 9916724
	ULT7.0-35-25-P-5S-CLDM-HC	G11020	9785599, 9785601, 9791159, 9796027, 9813313, 9824161, 9825417, 9828101, 9828889, 9830401, 9830764, 9833563, 9836323, 9839119, 9844952, 9846005, 9846008, 9913052, 9915805, 9791163X, 9792493X, NS9813314, NS9828892, NS9834712

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Actions to be Taken by the Customer

1. Examine inventory immediately to determine if you have affected product(s) and quarantine any affected product that remains unused. Immediately cease all distribution and use of this product.
2. Return the affected product(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit. Refer to the Acknowledgement and Receipt Form for return instructions.

   Note: Unaffected products that are returned will not be credited.
3. Please complete the Acknowledgement and Receipt Form within **5 business** days of receiving this letter. **Even if you do not have affected product(s) on hand**, you must still complete the Acknowledgement and Receipt Form and return via fax (812.339.7316) or email (FieldActionsNA@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 Cook Medical Customer Relations by phone at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30am and 5:00pm (Eastern Time), or by email to: CustomerRelationsNA@CookMedical.com.

Action being Taken by Cook Medical

Cook Medical is removing impacted devices from the market. Corrective actions have been implemented to reduce the occurrence of leakage.

Other Information

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

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

- Visit http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm to obtain a form to fax or mail.
- Call the FDA at 800.FDA.1088.

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.

[redacted]

Larry D. Pool
Director, Post Market
Cook Incorporated