COOK MEDICAL EUROPE LTD.
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FSN & FSCA Ref: 2019FA0011

Date: 02 January 2020

Urgent Field Safety Notice

Dawson-Mueller Drainage Catheter

For Attention of: Chief Executive / Risk Management / Purchasing

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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Risk Addressed by FSN

Information on Affected Devices		
1.	**1. Device Type(s)**	
	The Dawson-Mueller Drainage Catheter is a sterile, single-use device constructed from Ultrathane®. These catheters come in a range of French sizes, lengths, and sideport quantities, and contain a Mac-Loc® locking loop mechanism.	
1.	**2. Commercial name(s)**	
	Dawson-Mueller Drainage Catheter	
1.	**3. Primary clinical purpose of device(s)**	
	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.	
1.	**4. Device Model/Catalogue/Part Number(s)**	**5. Affected serial or lot number range**
	ULT6.3-35-25-P-5S-CLDM-HC (G51595)	9803175, 9903048
	ULT7.0-35-25-P-5S-CLDM-HC (G11020)	9791159, 9828889

Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	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.
2.	**2. Hazard giving rise to the FSCA**
	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.

Type of Action to Mitigate the Risk	
3.	**1. Action To Be Taken by the User** ☒ Identify Devices ☒ Quarantine Devices ☒ Return Devices ☒ Other Please complete the enclosed Customer 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 Customer 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.

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Type of Action to Mitigate the Risk		
3.	**2. Is Customer Reply Required?** Form is attached specifying deadline for return.	Yes
3.	**3. Action Being Taken by the Manufacturer** ☒ Product Removal	

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 Incorporated
	b. Address	750 Daniels Way Bloomington, IN 47402, United States
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
	5. Name/Signature	[redacted] Cook Incorporated

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.