COOK®

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product:
Single Lumen Central Venous Catheter Sets
Femoral Artery Pressure Monitoring Catheter Sets
Radial Artery Pressure Monitoring Catheter Sets

Manufacturer: Cook Incorporated
Cook Reference Number: 2016FA0001
Type of action: Field Safety Corrective Action

Date: January 06, 2016

Attention: Risk Management/Recall Administration

Details on affected devices:

Product Name:

Brand Name	Catalog Number	Lot Number
Single Lumen Central Venous Catheter Set	C-PMS-301J-PED	NS6042799
	C-PUM-301J	5945120
Femoral Artery Pressure Monitoring Catheter Set	C-NPMS-501J-15	6078670
	C-PMS-300-FA	NS5892108, NS6075555
	C-PMS-300J-FA	NS6028553, NS6090274, NS6100601
	C-PMS-301-FA	5860387
Radial Artery Pressure Monitoring Catheter Set	C-PMS-300-RA	5800313, 5911486, 6148790
	C-PMS-301-RA	5994817, 6081723

Description of the problem:

Cook Medical is initiating a field action of specific lot numbers of the Central Venous Catheter and Arterial Pressure Monitoring sets. These catheters are intended for use in venous or arterial pressure monitoring, blood sampling, and administration of drugs and fluids. Cook Medical has internally identified an issue with a manufacturing process that could result in the potential for catheter tip fracture and or separation.
Potential adverse events that may occur as a result of catheter tip fracture and or separation may include loss of device function, medical intervention to retrieve a separated segment, or complications resulting from a separated tip occluding blood flow to end organs. There have been no reports of illness or injury associated with this issue. If the product was already used and there were no issues with the catheter tip, there are no additional patient risks.

Our records indicate that your facility has received devices that are subject to this field action.

Advise on action to be taken by the user:

1. Please review the attached list of affected products and lot numbers that were shipped to your account, and quarantine any affected product that remains unused.

2. Immediately collect and return all unused affected products to Cook Medical as soon as possible for credit. Please contact our Customer Services Department to arrange pick up.

   Send the removed products to:
   Cook Medical EUDC
   Robert-Koch-Straße, 2
   52499 Baesweiler
   GERMANY

   Credit will be provided for the returned devices where applicable.

3. Please complete the enclosed Customer Response Form and send via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61 334441).

4. Please report any adverse event to Cook Medical Customer Relations by contacting our Customer Services Department.

Transmission of this Field Safety Notice:

This notice needs to be passed on to 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.

Contact reference person:

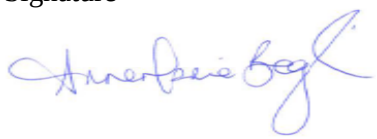
Marianne Høy
Manager, Support, Regulatory Affairs
William Cook Europe
Bjaeverskov, DENMARK

Or
Annemarie Beglin
Quality Systems Manager
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@CookMedical.com, phone +353 61 334440).

We confirm that this notice has been notified to the appropriate Regulatory Agency.

Signature



Annemarie Beglin
Quality Systems Manager