COOK®

Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441

Urgent Field Safety Notice

Commercial name of the affected product: Fuhrman Pleural/Pneumopericardial Drainage Set

Manufacturer: Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2017FA0018
Type of action: Field Safety Corrective Action

Date: 27 Nov 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Reference Part Number	Global Part Number	Lot Number
Fuhrman Pleural/Pneumopericardial Drainage Set	C-PPD-1020-WCE-IMH	G55716	7564490

Description of the problem:

Cook Medical is initiating a voluntary field action of lot 7564490 for C-PPD-1020-WCE-IMH. Cook Medical has received complaints that the pigtail catheter, three-way stopcock, and multipurpose tubing adapter were missing.

Potential adverse events if the nonconforming products are used include delay in the procedure to retrieve a replacement device, or a more invasive surgical procedure is performed if a replacement is not immediately available.

The Fuhrman Pleural/Pneumopericardial Drainage Set and Tray is intended for evacuation of air from the pericardial sac or to drain air or fluid from the pleural space.

This notice is directed to you because our records indicate that you have received lot 7564490 of the C-PPD-1020-WCE-IMH.

Advise on action to be taken by the user:

1. Immediately collect all remaining affected products as per the specified lot listing from your inventory.

2. Please complete the enclosed Customer Response 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 Response form.

   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.

 © COPYRIGHT DOCUMENT

3. Send the Customer Response Form 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). Do not enclose the response form with the returned product.

4. Please report any adverse event to Cook Medical 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 of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

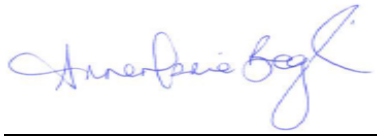
Thomas Kirk
Team Lead, Regulatory Reporting
Regulatory Affairs
William Cook Europe ApS
Sandet 6, DK-4632 Bjaeverskov, Denmark

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.



Annemarie Beglin
Quality Systems Manager

© COPYRIGHT DOCUMENT