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: Pericardiocentesis Catheter Set, Thoracentesis Set
Manufacturer: Cook Incorporated
Cook Reference Number: 2019FA0003
Type of action: Field Safety Corrective Action (FSCA)

Date: 04 Apr 2019

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Pericardiocentesis Catheter Set	C-PCS-850	G03282	7703324, NS7703501, NS7703502, NS7703503, NS7704718
Thoracentesis Set	C-THS-850	G03286	NS7662071

Description of the problem:
Cook Medical is initiating a voluntary recall of the lots listed above. The catheters are designed to be used with a 0.038" wire guide and Cook Medical has identified that the affected products may have been manufactured with the catheter distal end hole too small.

Potential adverse events that may occur if an affected product is used include a delay in the procedure, prolonged procedure, and additional intervention. It is possible that organ or vessel injury could occur during manipulation of the catheter and/or wire guide when attempting to remove the wire guide from the catheter.

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.

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 61239294). Do not enclose the response form with the returned product.

4. Please report any adverse events to Cook Medical by contacting our Customer Support Department.

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. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (If appropriate)

Contact reference person:
Larry Pool
Post Market Director
Cook Incorporated
750 Daniels Way, PO Box 489, Bloomington, IN 47402, United States

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

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

Larry Pool
Post Market Director
Cook Incorporated

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FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2019FA0003
Affected device: Pericardiocentesis Catheter Set, Thoracentesis Set

Please indicate the following:

Customer Number (As Indicated on the attached product list): _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____

(Please Print)

Please indicate which of the following applies to your facility:

☐ None of the affected product remains in our inventory

☐ We are returning our remaining inventory, please see details listed below

If you are a distributor, have your customers been notified of this Field Safety Corrective Action?

☐ Yes ☐ No

If you are returning any affected product, please indicate the part number, lot number and quantity:

Product Part Number	Product Lot Number	Quantity

Signed: _____ Date: _____

Please return the completed Customer Response Form to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 239294.