

#### **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.
- 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 <a href="mailto:European.FieldAction@CookMedical.com">European.FieldAction@CookMedical.com</a> 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

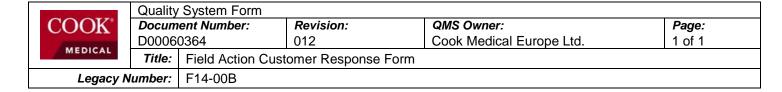
The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Should you have any questions, please feel free to contact us for more information (e-mail: <a href="mailto:European.FieldAction@CookMedical.com">European.FieldAction@CookMedical.com</a>, 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 Cathet	er Set, Thoracentesis Set			
Please indicate the following: Customer Number (As Indicated on the atta	ched 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				
	ease indicate the part number, lot number an			
Product Part Number	Product Lot Number	Quantity		
Signed:	Date:	_		
Please return the completed Customer Response + 353 61 239294.	e Form to by e-mail to European.FieldAction@coc	okmedical.com or by fax to		