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 products: Soft-Trans Embryo Transfer Catheter

Manufacturer: Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2018FA0005
Type of action: Field Safety Corrective Action (FSCA)

Date: 09 Apr 2018

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Reference Part Number	Global Part Number	Lot Number
Soft-Trans Embryo Transfer Catheter	K-SOFT-5000	G20195	7727431; 7861622; 7921104; 7777932; 7829304; 7829305; 7727424; 7777933; 7797490; 7916922; 8004947; 7861621; 7727426; 8007578; 7777934; 7974435; 7861623; 7732361; 7921105; 7957338
Soft-Trans Embryo Transfer Catheter	K-SOFT-5000-TC	G26662	7861619; 7885356; 7925760; 7877866; 7737392; 7737401; 7889530; 7936640; 7939958; 7943117; 7931407; 7875754; 7885350; 7889531
Soft-Trans Embryo Transfer Catheter	K-SOFT-5000-MO	G26669	7787738; 7882069; 7939954; 8043185
Soft-Trans Embryo Transfer Catheter	K-SOFT-5020	G26151	7875752; NS7808887; NS8039947
Soft-Trans Embryo Transfer Catheter	K-SOFT-5100	G20197	NS7855975; NS7875755; NS8039951

Description of the problem:

Cook Medical is initiating a voluntary recall of the products listed above. We have identified that three cannula lots used in the manufacture of these products may have been inadequately cleaned by the supplier. A potential adverse event that may occur is embryo loss.

This notice is directed to you because our records indicate that you have received product from the affected lot numbers.

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 61 334441). 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 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:

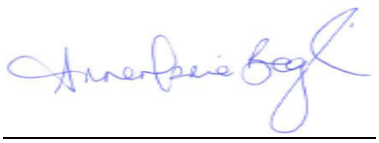
Michael Galvin
Regulatory Affairs Manager
COOK Ireland
O'Halloran Road, National Technology Park, Limerick, IRELAND

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

COOK®

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

FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2018FA0005

Affected devices:

Product Brand Name	Reference Part Number	Global Part Number	Lot Number
Soft-Trans Embryo Transfer Catheter	K-SOFT-5000	G20195	7727431; 7861622; 7921104; 7777932; 7829304; 7829305; 7727424; 7777933; 7797490; 7916922; 8004947; 7861621; 7727426; 8007578; 7777934; 7974435; 7861623; 7732361; 7921105; 7957338
Soft-Trans Embryo Transfer Catheter	K-SOFT-5000-TC	G26662	7861619; 7885356; 7925760; 7877866; 7737392; 7737401; 7889530; 7936640; 7939958; 7943117; 7931407; 7875754; 7885350; 7889531
Soft-Trans Embryo Transfer Catheter	K-SOFT-5000-MO	G26669	7787738; 7882069; 7939954; 8043185
Soft-Trans Embryo Transfer Catheter	K-SOFT-5020	G26151	7875752; NS7808887; NS8039947
Soft-Trans Embryo Transfer Catheter	K-SOFT-5100	G20197	NS7855975; NS7875755; NS8039951

Please indicate the following:

Customer Number: _____

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 for credit

***Proforma Invoice Required for Return of Product(s):* ☐ Yes ☐ No

Pick-up / Collection details for return of products:

Contact Name for Pick-up: _____

Address details for Pick-up: _____

Phone number / Email address for pick-up _____

Total number of boxes for pick-up _____
(Please Print)

**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

Please return the completed Customer Response Form to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 334441.