URGENT: MEDICAL DEVICE RECALL
PROMPT RESPONSE REQUIRED

ATTENTION:
Risk Management and Recall Administration
Our records indicate that you have received some of the affected products listed below.

Description of the problem
Cook Medical is initiating a voluntary recall of the products listed below. 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.

Details about the affected products

<table>
<thead>
<tr>
<th>PRODUCT BRAND NAME</th>
<th>REFERENCE PART NUMBER (RPN)</th>
<th>ORDER NUMBER</th>
<th>LOT NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft-Trans Embryo Transfer Catheter</td>
<td>K-SOFT-5000</td>
<td>G20195</td>
<td>7957338; 7974435; 8004947; 8007578; 7777932; 7777933; 7777934; 7727424; 7727426; 7727431; 7732361; 7797490; 7808886; 7829304; 7829305; 7861623; 7861621; 7861622; 7916922; 7921104; 7921105</td>
</tr>
<tr>
<td>Soft-Trans Embryo Transfer Catheter</td>
<td>K-SOFT-5000-TC</td>
<td>G26662</td>
<td>7877866; 7885350; 7885356; 7889531; 7939958; 7875754; 7861619; 7737392; 7737401; 7889530; 7925760; 7936640; 7943117; NS7943119; 7931407</td>
</tr>
<tr>
<td>Soft-Trans Embryo Transfer Catheter</td>
<td>K-SOFT-5000-MO</td>
<td>G26669</td>
<td>7939954; 8043185; 7787738; 782069</td>
</tr>
<tr>
<td>Soft-Trans Embryo Transfer Catheter</td>
<td>K-SOFT-5020</td>
<td>G26151</td>
<td>NS8039947; NS7808887; 7875752</td>
</tr>
<tr>
<td>Soft-Trans Embryo Transfer Catheter</td>
<td>K-SOFT-5100</td>
<td>G20197</td>
<td>NS8039951; NS7855975; NS7875755</td>
</tr>
</tbody>
</table>

Intended use for the affected products

<table>
<thead>
<tr>
<th>PRODUCT FAMILY</th>
<th>INTENDED USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft-Trans Embryo Transfer Catheter</td>
<td>Used to place in vitro fertilized (IVF) embryos into the uterine cavity. Intended for one-time use.</td>
</tr>
</tbody>
</table>
Action to take

1. Examine your inventory immediately to determine if you have affected product(s), and quarantine affected product(s). Immediately cease all distribution and use of the above lots.

2. Return the affected product(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit.
   
   Note: Unaffected products that are returned will not be credited.

3. Please complete the Acknowledgement and Receipt Form within 5 business days of receiving this letter. Even if you do not have affected product(s) on hand, you must still complete the Acknowledgement and Receipt Form and return it via fax (812.339.7316) or email (FieldActionsNA@CookMedical.com).

4. Immediately report adverse events to Cook Medical Customer Relations by phone at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30 am and 5:00 pm (Eastern Time) or by email to CustomerRelationsNA@CookMedical.com.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA.

- Visit [http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) to obtain a form to fax or mail.
- Call the FDA at 800.FDA.1088.

Transmission of this notice

This notice must be shared with appropriate personnel, including down to the user level, within your organization or with any organization where the potentially affected devices have been transferred.

We recognize that this situation is a potential disruption to your normal operations, and we sincerely apologize. Thank you for your immediate assistance in this matter. If you have any questions or concerns, please contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235. We look forward to your response.
**FIELD ACTION CUSTOMER RESPONSE FORM**

Field Action reference no.: 2018FA0005

**Affected devices:**

<table>
<thead>
<tr>
<th>Product Brand Name</th>
<th>Reference Part Number</th>
<th>Global Part Number</th>
<th>Lot Number</th>
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**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:

<table>
<thead>
<tr>
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<th>Product Lot Number</th>
<th>Quantity</th>
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Please return the completed Customer Response Form to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 334441.