COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

11Apr2018

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

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Soft-Trans Embryo Transfer Catheter	K-SOFT-5000	G20195	7957338; 7974435; 8004947; 8007578; 7777932; 7777933; 7777934; 7727424; 7727426; 7727431; 7732361; 7797490; 7808886; 7829304; 7829305; 7861623; 7861621; 7861622; 7916922; 7921104; 7921105
Soft-Trans Embryo Transfer Catheter	K-SOFT-5000-TC	G26662	7877866; 7885350; 7885356; 7889531; 7939958; 7875754; 7861619; 7737392; 7737401; 7889530; 7925760; 7936640; 7943117; NS7943119; 7931407
Soft-Trans Embryo Transfer Catheter	K-SOFT-5000-MO	G26669	7939954; 8043185; 7787738; 7882069
Soft-Trans Embryo Transfer Catheter	K-SOFT-5020	G26151	NS8039947; NS7808887; 7875752
Soft-Trans Embryo Transfer Catheter	K-SOFT-5100	G20197	NS8039951; NS7855975; NS7875755

Intended use for the affected products

PRODUCT FAMILY	INTENDED USE
Soft-Trans Embryo Transfer Catheter	Used to place in vitro fertilized (IVF) embryos into the uterine cavity. Intended for one-time use.

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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 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.

Larry D. Pool
Director, Post Market
Cook Incorporated