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

November 17, 2017

URGENT: MEDICAL DEVICE RECALL

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

Details of Affected Products:

PRODUCT BRAND NAME	DISTRIBUTED BY	CATALOG IDENTIFIER	GLOBAL PART NUMBER	LOT NUMBERS
Fallopian Tube Catheterization Set	Guangzhou Mokin Medical Instrument Co., Ltd.	FTC-550	G10991	5514352 7322651 7327355 7587849 7587853 7697724 7906950 7916277 7924173 7951718
		FTC-550-NT	G10992	5514349 5547638 5547647 5569133 5569142 5569163

Description of the Problem:

Cook Medical has identified an increase in reports of tip separation associated with Fallopian Tube Catheterization Sets that have been distributed through Guangzhou Mokin Medical Instrument Co., Ltd. in China. Therefore, Cook Medical is initiating a voluntary recall of the products and lot numbers listed above. The scope of the recall will be limited to Guangzhou Mokin Medical Instrument Co., Ltd. and the customers who have purchased affected products from Guangzhou Mokin Medical Instrument Co., Ltd.

Potential adverse events that may occur as a result of catheter tip separation include medical intervention to retrieve the separated segment or complications resulting from a separated segment that is left behind in a patient. If a separated segment is left behind in the uterus, it could cause discomfort and/or could disrupt the normal menstrual cycle. If a separated segment migrates into the salpinges (fallopian tubes), it could cause symptoms including discomfort, infections, and hydrosalpinx. In addition to, and as a possible result of the previously mentioned mechanisms, it would be possible to see unexplained infertility.

Intended Use For Affected Products:

PRODUCT BRAND NAME	INTENDED USE
Fallopian Tube Catheterization Set	Fallopian Tube Catheterization Sets are intended for selective catheterization of the proximal fallopian tube(s), injection of contrast medium, and evaluation of tubal patency.

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Action to be Taken:

1. Notify any organization where the affected products have been transferred of the recall.
2. Examine inventory immediately to determine if you have affected product and quarantine affected product(s).
3. Return the affected products to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit.
   NOTE: Un-affected products that are returned will not be credited.
4. Please complete the Acknowledgement and Receipt Form within **5 business days** of receipt of this letter. **Even if you do not have affected products on hand**, you must still complete the Acknowledgement and Receipt Form. Send the form via fax (812.339.7316) or email to (FieldActionsNA@CookMedical.com).
5. 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 via CustomerRelationsNA@CookMedical.com.

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

- Online at: http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail)
- Call the FDA at: 1.800.FDA.1088

Transmission of this Notice:

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

We recognize this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. Should 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