



December 18, 2017

**URGENT: MEDICAL DEVICE RECALL**

**ATTENTION:**

Risk Management/Recall Administration

*Our records indicate that you have received some of the affected products listed below.*

**Description of the Problem:**

Cook Medical has identified that the specific product lots listed below were distributed without Limulus Amebocyte Lysate (LAL) and Mouse Embryo Assay (MEA) testing. While we have no evidence that these specific product lots pose any risk, the oversight in testing does not conform to Cook Medical’s level of quality assurance. Consequently, Cook Medical is initiating a voluntary recall of these specific product lots.

Potential adverse events that may occur if an embryotoxic product is used in a procedure include nonviable gametes and/or nonviable embryos.

**Details of Affected Products:**

PRODUCT BRAND NAME	CATALOG IDENTIFIER	GLOBAL PART NUMBER	LOT NUMBERS
Norm-Ject Tuberkulin Syringe	K-ATS-1000	G19871	5667080 NS6127577
Echosight® Jansen-Anderson Intratubal Transfer Set	K-J-JITS-572900	G17946	7131328
Marrs Laparoscopic GIFT Catheters	K-J-MLC-503000	G18022	5571684
SMS Embryo Transfer Set	K-J-SMS-571800	G19182	6802704
Guardia™ Access Nano Embryo Transfer Catheter	K-JETS-551910-L	G24215	NS6360603
Sydney IVF® Embryo Transfer Set	K-JETS-7019-SIVF	G18740	6503675

**Intended Use For Affected Products:**

PRODUCT BRAND NAME	INTENDED USE
Norm-Ject Tuberkulin Syringe	Used for hand injection of contrast or other media.
Echosight® Jansen-Anderson Intratubal Transfer Set	Used to inject either sperm, gametes, or embryos into the uterine ostium of the fallopian tube via ultrasound guidance. Intended for one-time use.
Marrs Laparoscopic GIFT Catheters	Used to transfer gametes directly into the fallopian tube under laparoscopic guidance. Intended for one-time use.
SMS Embryo Transfer Set	Used to place in vitro fertilized (IVF) embryos into the uterine cavity. Intended for one-time use.
Guardia™ Access Nano Embryo Transfer Catheter	Used to place in vitro fertilized (IVF) embryos into the uterine cavity. Intended for one-time use.
Sydney IVF® Embryo Transfer Set	Used to place in vitro fertilized (IVF) embryos into the uterine cavity. Intended for one-time use.



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

### Action to be Taken:

1. Examine inventory immediately to determine if you have affected product and quarantine affected product(s).
2. Return the affected products 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 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](mailto:FieldActionsNA@CookMedical.com)).
4. 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](mailto:CustomerRelationsNA@CookMedical.com).

Adverse events or quality problems experienced by using this product may also be reported to the FDA:

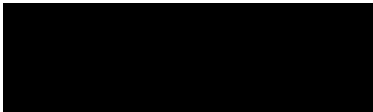
- Online at: <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail)
- Call the FDA at: 1.800.FDA.1088

### 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.

This action is being taken with the knowledge of the Food and Drug Administration.

We recognize this situation is a potential 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