COOK MEDICAL
1025 ACUFF ROAD, P.O. BOX 4195
BLOOMINGTON, IN 47402-4195 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

February 01, 2019

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 considers the safety and satisfaction of our customers a top priority. We appreciate your time and attention in reading this important notice.

Cook Medical has identified the products listed below were manufactured without a back bevel on the needle tip. This could cause damage to the inside of the introducer during needle insertion. Therefore, Cook Medical is initiating a voluntary recall of this specific product lot.

Potential adverse events that may occur if an affected product is used include a delay in the procedure, a prolonged procedure, or introducer particulate entering the bloodstream.

Details about the affected products

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Transseptal Needle	TSNC-18-71.0	G02364	8833687

Intended use for the affected products

PRODUCT BRAND NAME	INTENDED USE
Transseptal Needle	The Transseptal Needle is intended for transseptal left heart access in both diagnostic and interventional procedures.

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 these products.
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. 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.
5. 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.

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

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.

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.

[redacted]

Larry D. Pool
Director, Post Market
Cook Incorporated