



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

December 07, 2017

**URGENT: MEDICAL DEVICE RECALL**

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

**Details of Affected Products:**

PRODUCT BRAND NAME	CATALOG IDENTIFIER	GLOBAL PART NUMBER	LOT NUMBER
Transseptal Needle	TSNC-18-71.0	G02364	8181945

**Description of the Problem:**

Cook Medical has become aware that the Transseptal Needle from TSNC-18-71.0 lot 8181945 may be the incorrect length. Cook Medical is initiating a voluntary recall of this lot number.

Potential adverse events may occur by using the nonconforming products, including being unable to perform the transseptal puncture. This could necessitate replacing the device or rescheduling the procedure. In addition, use of the nonconforming products could make the puncture less controlled, which could potentially lead to injury of the heart.

**Intended Use For Affected Products:**

PRODUCT BRAND NAME	INTENDED USE
Transseptal Needle	<p>The Transseptal Needle is intended for transseptal left heart access in both diagnostic and interventional procedures.</p> <p>The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters, and wire guides should be employed.</p>

**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

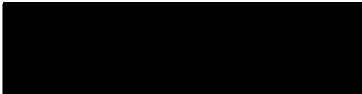


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**Transmission of this Notice:**

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