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

19Mar2018

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

Cook Medical is initiating a voluntary recall of the products listed below. We have identified that devices in the specific lots listed below may have been manufactured with equipment that was out of calibration. Our preliminary investigation into this matter has identified that this could result in the cap-adapter assembly of the device not being adequately tightened. Potential adverse events that may occur are fluid leakage from the connecting tube or air aspiration into the connecting tube.

Details about the affected products

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Connecting Tube – Female to Male Luer Lock	HPCT8.8-60-M-FM	G00066	7853883, 7871665, 7940332
Connecting Tube – Female to Male Luer Lock	HPCT8.8-60-M-FM-BNS	G31762	NS7881928, NS7898133
Connecting Tube – Female to Male Luer Lock	HPCT8.8-30-M-FM	G00063	7828771, 7846437, 7863752, 7881930, 7886974, 7886975
Connecting Tube – Female to Male Luer Lock	HPCT8.8-80-M-FM	G00068	7844043, 7898128, 7940347, NS7904210
Connecting Tube – Female to Male Luer Lock	HPCT8.8-100-M-FM	G00058	NS7835000, NS7835001, NS7846433, NS7853877, NS7853880, NS7866660, NS7875342, NS7898129, NS7898130, NS7898131, NS7928009, NS7928014, NS7940349
Connecting Tube – Female to Male Luer Lock	HPCT8.8-120-M-FM	G00060	7797164, 7844038, 7844039, 7844040, 7844041, 7844042, 7846434, 7846435, 7853869, 7853870, 7853871, 7853872, 7853873, 7853874, 7857491, 7857492, 7857493, 7857494, 7857495, 7857496, 7857497, 7857498, 7857499, 7857500, 7863742, 7863744, 7863745, 7863747, 7863748, 7863749, 7863750, 7863751, 7871644, 7871645, 7871646, 7871647, 7881937, 7881938, 7881939,

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			7881940, 7881941, 7881942, 7888498, 7888505, 7888506, 7888507, 7917423, 7917424, 7917425, 7917426, 7917434, 7925136, 7925137, 7925138, 7925139, 7925140, 7940326, 7940327, 7940328, 7940345, 7940346, 7949048, NS7835002, NS7875343, NS7881929, NS7888468, NS7928016, NS7940350

Intended use for the affected products

PRODUCT BRAND NAME	INTENDED USE
Connecting Tube – Female to Male Luer Lock	Connecting Tube

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 connecting tube 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.

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

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