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

March 26, 2018

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 has identified that the specific product lots listed below were manufactured outside of specification because the radiopaque marker band was placed at an incorrect distance from the distal end of the sheath. Therefore, Cook Medical is initiating a voluntary recall of these specific product lots.

Potential adverse events that may occur if an affected product is used in a procedure include a delayed or prolonged procedure due to the need for sheath replacement, vessel damage, or medical intervention to remove a stent that is partially deployed inside a sheath.

Details about the affected products

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Flexor® Shuttle - SL Introducer with Tuohy-Borst Side-Arm	KSAW-6.0-38-80-RB-SHTL-HC	G13539	8185792
	KSAW-7.0-38-90-RB-SHTL	G31124	8189202

Intended use for the affected products

PRODUCT BRAND NAME	INTENDED USE
Flexor® Shuttle - SL Introducer with Tuohy-Borst Side-Arm	Introducers are intended for introduction of balloons, closed and non-tapered end catheters or other diagnostic and interventional devices.

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. 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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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.

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]

Director, Post Market
Cook Incorporated