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

December 21, 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 products listed below were manufactured with longer than specified sheaths. Therefore, Cook Medical is initiating a voluntary recall of this specific product lot.

A potential adverse event that may occur if an affected product is used is a minor delay of the procedure due to the need for device replacement.

Details about the affected products

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Check-Flo Performer® Introducer	RCFW-5.0-25-45-RB-CHB	G11571	8858425

Intended use for the affected products

PRODUCT BRAND NAME	INTENDED USE
Check-Flo Performer® Introducer	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).

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

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

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

URGENT: PROMPT RESPONSE REQUIRED

Acknowledgement and Receipt Form

You are required to fill out and return this form. Please return it within 5 business days of receipt, even if you do not have any of the affected product(s).

Please complete the following information regarding the recall on the Check-Flo Performer® Introducer.

Your customer information

Customer Account Number:	Customer Name:	
Street Address:	City:	
State, Zip Code:	Department:	Phone:
Form Completed By (Printed Name, Signature):		Date:

Actions you have taken

1. I have received the letter titled "URGENT: MEDICAL DEVICE RECALL" regarding the Check-Flo Performer® Introducer, and I understand the instructions in the letter. ☐Yes ☐No

Affected product information

Please list the quantity of affected product at your facility to be returned, or write "none" if the affected product is no longer in your inventory or is no longer with your customers.

QUANTITY	PART NUMBER	LOT NUMBER/SERIAL NUMBER

Returning this form and affected product(s)

Upon completion of this form, please return it to the Cook Medical Customer Relations department via fax or email. Fax: 812.339.7316 Email: FieldActionsNA@CookMedical.com

For information regarding the recall, medical questions, or to report adverse events, contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235.

Return affected product(s) and send this form to this address:

Cook Medical
ATTN: Return Good/Recall # FAIP-2018-010
400 Daniels Way
Bloomington, IN 47404