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

April 16, 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
We appreciate your time and attention in reading this important notice.

Cook Medical has identified that the specific product lots listed below were inadvertently switched during the packaging process. The product packages labeled as a 6mm x 2cm balloon contain a 4mm x 4cm balloon, and vice versa. 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 balloon catheter replacement. In addition, if a larger balloon size is inadvertently used in a smaller vessel, it could potentially result in vessel damage and/or hemorrhage.

Details about the affected products

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Advance® 35LP Low-Profile PTA Balloon Dilatation Catheter	PTA5-35-135-6-2.0	G52264	8429883
	PTA5-35-135-4-4.0	G52252	8426883

Intended use for the affected products

PRODUCT BRAND NAME	INTENDED USE
Advance® 35LP Low-Profile PTA Balloon Dilatation Catheter	Indicated for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including iliac, renal, popliteal, infrapopliteal, femoral and iliofemoral as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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.

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

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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 Advance® 35LP Low-Profile PTA Balloon Dilatation Catheter.

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 Advance® 35LP Low-Profile PTA Balloon Dilatation Catheter, 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

Additional actions for distributors

Share the letter "URGENT: MEDICAL DEVICE RECALL" with appropriate personnel within your organization or with any organization where the potentially affected product(s) have been transferred.
Please confirm the following:

1. I have notified my customers of the recall. ☐Yes ☐No

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-2018-007
400 Daniels Way
Bloomington, IN 47404