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

May 24, 2019

URGENT: MEDICAL DEVICE RECALL

Advance® Enforcer™ 35 Focal-Force PTA Balloon Catheter

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 Medical 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 received five (5) complaints for balloons bursting below the rated burst pressure on Advance Enforcer 35 Focal Force PTA Balloon Catheters manufactured with specific balloon material lots. Therefore, Cook Medical is initiating a voluntary recall of the 12 lots of Advance Enforcer 35 Focal Force PTA Balloon Catheter manufactured with the affected balloon material lots.

Potential adverse events that may occur if an affected product is used include a delay in the procedure, additional intervention, vessel injury, and balloon fragmentation in the patient.

Details about the Affected Products

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Advance® Enforcer™ 35 Focal Force PTA Balloon Catheter	ASB5-35-50-6-4	G35248	9234424, 9331618
	ASB5-35-80-6-4	G35252	9212015, 9243035, 9320430, 9386804
	ASB5-35-135-6-4	G35257	9338194, 9234423, 9278982, 9209468, 9248603, 9320429

Intended Use for the Affected Products

PRODUCT BRAND NAME	INTENDED USE
Advance® Enforcer™ 35 Focal Force PTA Balloon Catheter	The Advance Enforcer 35 Focal-Force PTA Balloon Catheter is intended 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. Not for use in the cerebral or coronary vasculature.

Actions to be Taken by the Customer

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.

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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 by email to FieldActionsNA@CookMedical.com.
4. 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.
5. 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.

Additional Actions being Taken by Cook Medical

Cook Medical has initiated an investigation and will determine the appropriate corrective action(s) to prevent reoccurrence of a similar issue.

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

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.

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