COOK®

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product: Advance® Enforcer™ 35 Focal-Force PTA Balloon Catheter
Manufacturer: Cook Incorporated
Cook Reference Number: 2019FA0006
Type of action: Field Safety Corrective Action (FSCA) – Recall of Specific Lots

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Date: 24 May 2019

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

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

Description of the problem:
Cook Medical has received multiple 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 Advance Enforcer 35 Focal Force PTA Balloon Catheter lots listed in the table above.

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.

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.

Advise on action to be taken by the user:

1. Immediately collect all remaining affected products as per the specified lot listing from your inventory.

2. Please complete the enclosed Customer Response Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Response form.

   Product should be addressed to:
   Cook Medical EUDC
   Robert-Koch-Straße, 2
   52499 Baesweiler
   GERMANY

   Credit will be provided for the returned affected products where applicable.

3. Send the Customer Response Form via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61239294). Do not enclose the response form with the returned product.

4. Please report any adverse events to Cook Medical by contacting our Customer Support Department.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

[redacted]

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause. If you need any further information or support concerning this information, please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd. (e-mail: European.FieldAction@CookMedical.com, phone +353 61 334440).

[redacted]

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FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2019FA0006
Affected device: Advance® Enforcer™ 35 Focal-Force PTA Balloon Catheter

Please indicate the following:

Customer Number (As Indicated on the attached product list): _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____

(Please Print)

Please indicate which of the following applies to your facility:

☐ None of the affected product remains in our inventory

☐ We are returning our remaining inventory, please see details listed below

If you are a distributor, have your customers been notified of this Field Safety Corrective Action?

☐ Yes ☐ No

If you are returning any affected product, please indicate the part number, lot number and quantity:

Product Part Number	Product Lot Number	Quantity

Signed: _____ Date: _____

Please return the completed Customer Response Form to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 239294.