Cordis
A Cardinal Health company

Urgent Field Safety Notice (Removal)

Cordis® POWERFLEX® PRO PTA Dilatation Catheter

Catalog Number	Lot Number
4400322X	**82144115**
4400602S	**82144141**
4400515X	**82144947**
4400308S	**82148810**
4400508S	**82148811**

September 06, 2018

Dear Valued Customer,

The purpose of this communication is to inform you Cordis is recalling (removing) five (5) lots of Cordis® POWERFLEX® PRO Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter product.

Recall Overview:	Cordis has determined that five lots of POWERFLEX® PRO PTA Dilatation Catheters have not met an internal manufacturing specification for shaft burst strength, though it meets the label claim (18 ATM). A shaft leakage/burst that occurs during balloon inflation would likely create an inability to inflate or maintain pressure of the balloon component. The user may experience inflation difficulty/deflation difficulty of the balloon component. The most likely occurrence would result in a procedural delay, however damage to healthy intima, vessel spasm, ischemia, or additional intervention could result, but only occasionally and/or under unusual circumstances. There is no safety concern for patients that are treated successfully using product from these lots. Cordis has not received any complaints related to POWERFLEX® PRO that are related to shaft burst or leakage.

Details on Affected Devices, to assist in identification of the product involved:

Product involved

- Five (5) lots are affected:

Catalog Number	Lot Number	Balloon Diameter	Balloon Length
4400322X	**82144115**	3mm	22cm
4400602S	**82144141**	6mm	2cm
4400515X	**82144947**	5mm	15cm
4400308S	**82148810**	3mm	8cm
4400508S	**82148811**	5mm	8cm

Usage

The POWERFLEX® PRO PTA Catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for postdilation of balloon-expandable and self-expanding stents in the peripheral vasculature.

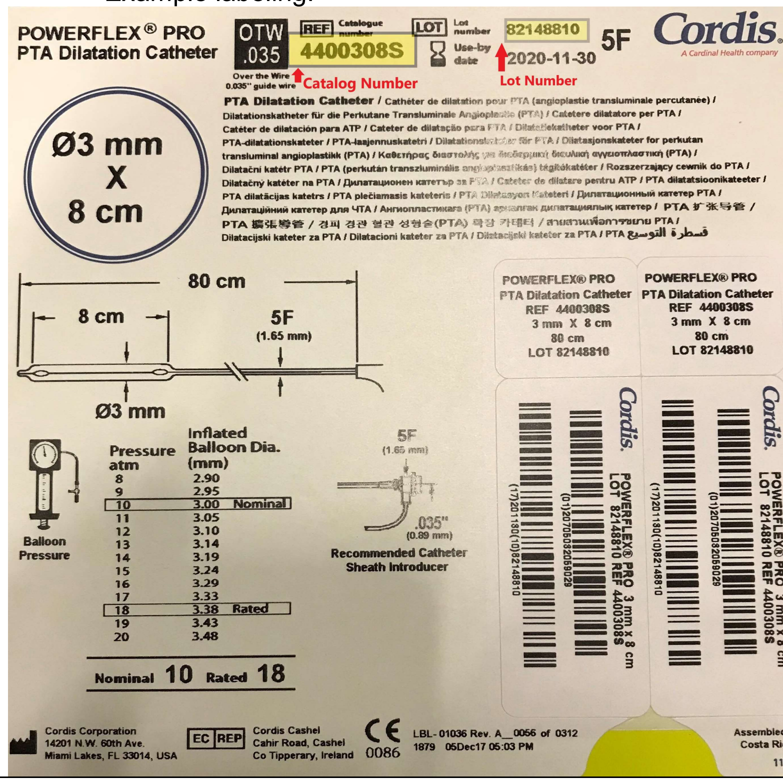
Identification

The example labeling below is provided to help you identify the affected units.

Details on Affected Devices, to assist in identification of the product involved (Continued):

<u>Identification (Continued)</u>

Example labeling:



Why you are being contacted:

You are receiving this letter because our records indicate that you have purchased the POWERFLEX® PRO lot numbers indicated in this letter.

Actions requested on your part:

1) Read this Field Safety Notice (Removal) letter.

2) Immediately check your inventory to confirm whether you have any units from the affected lots in your possession. Identify and set aside any units from the affected lots in a manner that ensures the affected product will not be used. Check all storage and usage locations.

3) Review, complete, sign and return the enclosed Acknowledgement Form in accordance with the directions on the form.

4) Return all affected product to the Cardinal Health distribution center. Please contact your local sales representative to facilitate return of the affected product, if necessary. Your sales representative will inform you of the product replacement or credit options.

5) Share this letter with others in your facility who need to be made aware of this recall.

6) Please contact any other facility who may have received the affected units of POWERFLEX® PRO product from your facility. If any units of the affected lots are found to be at the other facility, please arrange the return of the units.

7) Maintain awareness of this notice until all affected product has been returned to Cordis.

8) Keep a copy of this notice with the affected product.

Description of the problem:	What is the issue? Cordis became aware that the product may not meet the shaft subassembly burst strength specification. Why are we recalling this product? A shaft leakage/burst that occurs during balloon inflation would likely create an inability to inflate or maintain pressure of the balloon component. Additionally, the user may experience inflation difficulty/deflation difficulty of the balloon component. The most likely occurrence would result in a procedural delay, however damage to healthy intima, vessel spasm, ischemia, or additional intervention could result, but only occasionally and/or under unusual circumstances. There is no safety concern for patients that are treated successfully using product from these lots. What other actions is Cordis taking? Cordis has performed a root cause investigation and taken immediate corrective action. Cordis has not identified any other lots that may be affected. In keeping with our commitment to provide customers with quality products, Cordis has voluntarily decided to recall these five (5) lots.

Available Assistance:	If you have any questions regarding this recall, please contact your local sales representative or local sales office.

Additional Information:	**Regulatory Notification** The applicable regulatory agencies and notified body are being notified that Cordis is voluntarily taking this action.

We apologize for any inconvenience this communication may cause. We know that you place high value in our products and we appreciate your cooperation in this matter. Cordis is committed to maintaining your confidence in the safety and quality of the products that Cordis supplies.

Respectfully yours,

Miguel Ávila
Vice President, Global Quality and Regulatory Compliance
Cordis Corporation