

Update: 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
4400604S*	82144604*
4400604S*	82144617*
4400804S*	82144499*

September 06, 2018, Updated August 23, 2019

Dear Valued Customer,

Previously, Cordis had notified you of a Field Safety Notice (Removal) in September 2018 regarding five (5) lots of Cordis® POWERFLEX® PRO Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter product (reference number Cordis20180906-OUS). The removal of these five lots from the impacted markets has been completed.

Cordis was recently informed that three (3) additional lots (see lot numbers marked with an asterisk "*" in tables above and below) are also affected by this action.

Recall Overview:	<p>Cordis has determined that eight total 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).</p> <p>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.</p> <p>There is no safety concern for patients that are treated successfully using product from these lots.</p> <p>Cordis has not received any complaints related to POWERFLEX® PRO that are related to shaft burst or leakage.</p>
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Details on Affected Devices, to assist in identification of the product involved:	Product involved			
	• Eight (8) 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
4400604S*	82144604*	6mm	4cm	

4400604S*	82144617*	6mm	4cm
4400804S*	82144499*	8mm	4cm

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.

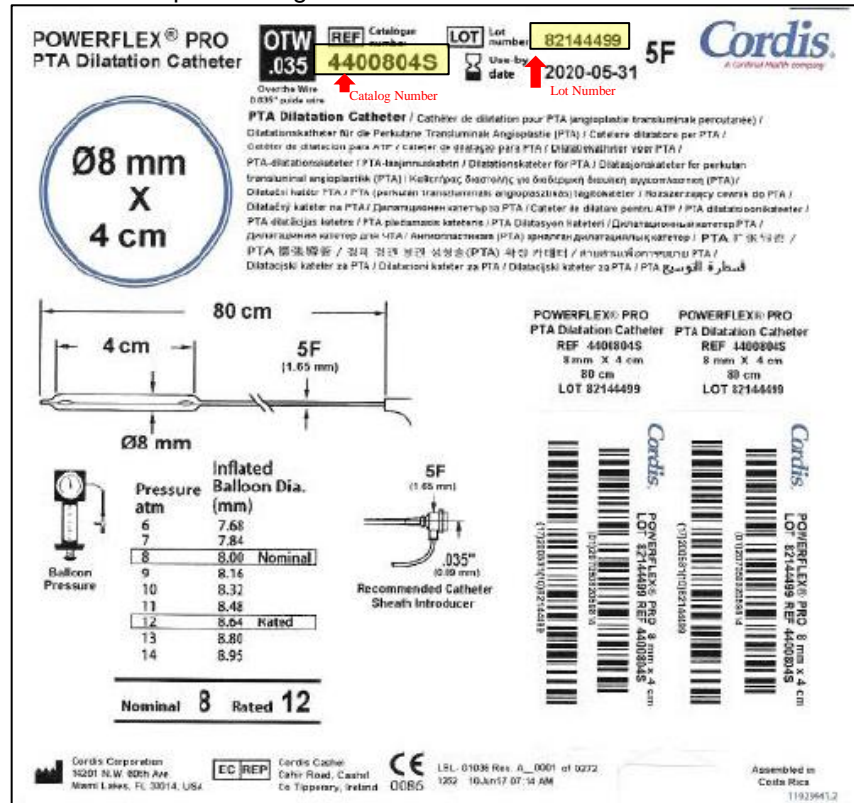
Identification

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):

Identification (Continued)

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.

	<p>5) Share this letter with others in your facility who need to be made aware of this recall.</p> <p>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.</p> <p>7) Maintain awareness of this notice until all affected product has been returned to Cordis.</p> <p>8) Keep a copy of this notice with the affected product.</p>
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Description of the problem:	<p><u>What is the issue?</u> Cordis became aware from the manufacturer that three additional lots of product may not meet the shaft subassembly burst strength specification. The lots were previously not identified by the manufacturer and were discovered by follow-up investigation.</p> <p><u>Why are we recalling this product?</u> 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.</p> <p>There is no safety concern for patients that are treated successfully using product from these lots.</p> <p><u>What other actions is Cordis taking?</u> 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 eight (8) lots.</p>
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Available Assistance:	If you have any questions regarding this recall, please contact your local sales representative or local sales office.
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Additional Information:	<p><u>Regulatory Notification</u></p> <p>The applicable regulatory agencies and notified body are being notified that Cordis is voluntarily taking this action.</p>
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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,



 Cordis Corporation

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:	<p>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).</p> <p>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.</p> <p>There is no safety concern for patients that are treated successfully using product from these lots.</p> <p>Cordis has not received any complaints related to POWERFLEX® PRO that are related to shaft burst or leakage.</p>
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Details on Affected Devices, to assist in identification of the product involved:	<p><u>Product involved</u></p> <ul style="list-style-type: none"> Five (5) lots are affected: <table border="1"> <thead> <tr> <th>Catalog Number</th> <th>Lot Number</th> <th>Balloon Diameter</th> <th>Balloon Length</th> </tr> </thead> <tbody> <tr> <td>4400322X</td> <td>82144115</td> <td>3mm</td> <td>22cm</td> </tr> <tr> <td>4400602S</td> <td>82144141</td> <td>6mm</td> <td>2cm</td> </tr> <tr> <td>4400515X</td> <td>82144947</td> <td>5mm</td> <td>15cm</td> </tr> <tr> <td>4400308S</td> <td>82148810</td> <td>3mm</td> <td>8cm</td> </tr> <tr> <td>4400508S</td> <td>82148811</td> <td>5mm</td> <td>8cm</td> </tr> </tbody> </table> <p><u>Usage</u> 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 postdilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.</p> <p><u>Identification</u> The example labeling below is provided to help you identify the affected units.</p>	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
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Details on Affected Devices, to assist in identification of the product involved (Continued):

Identification (Continued)

Example labeling:

POWERFLEX® PRO PTA Dilatation Catheter

OTW REF Catalogue number LOT Lot number Use-by date
 .035 4400308S 82148810 5F
 2020-11-30

Over the Wire 0.035" guide wire
 Catalog Number Lot Number

PTA Dilatation Catheter / Cathéter de dilatation pour PTA (angioplastie transluminale percutanée) / Dilatationskatheter für die Perkutane Transluminale Angioplastie (PTA) / Cateter dilatatore per PTA / Cateter de dilatación para ATP / Cateter de dilatación para PTA / Dilatatiekatheter voor PTA / PTA-dilatationskatheter / PTA-lasjennuskatetri / Dilatationskatheter für PTA / Dilatationskatheter for perkutan transluminale angioplastie (PTA) / Катетер для перкутанной транслюминальной ангиопластики (ПТА) / Dilatační katetr PTA / PTA (perkutane transluminale angioplastie) legítelőtű / Rozszerzájcső csomók do PTA / Dilatačný katetr na PTA / Dilatacionen kateter za PTA / Cateter de dilatare pentru ATP / PTA dilatatsioonikateeter / PTA dilatacijske katetre / PTA riepilasmis kateteris / PTA Dilatacijski Kateteri / Дилатационный катетер PTA / Дилатационный катетер для ПТА / Ангиопластичног (PTA) артериалк дилатационный катетер / PTA 扩张导管 / PTA 擴張導管 / 경피 경관 혈관 성형술 (PTA) 확장 카테터 / 血管成形術用 PTA / Dilatacijski kateter za PTA / Dilatacion kateter za PTA / Dilatacijski kateter za PTA / قطر التوسيع

Ø3 mm X 8 cm

80 cm
 8 cm 5F (1.65 mm)

Ø3 mm 5F (1.65 mm) 0.035" (0.89 mm)

Recommended Catheter Sheath Introducer

Pressure atm	Inflated Balloon Dia. (mm)
8	2.90
9	2.95
10	3.00 Nominal
11	3.05
12	3.10
13	3.14
14	3.19
15	3.24
16	3.29
17	3.33
18	3.38 Rated
19	3.43
20	3.48

Nominal 10 Rated 18

POWERFLEX® PRO PTA Dilatation Catheter REF 4400308S 3 mm X 8 cm 80 cm LOT 82148810

POWERFLEX® PRO PTA Dilatation Catheter REF 4400308S 3 mm X 8 cm 80 cm LOT 82148810

Cordis Corporation 14201 N.W. 50th Ave. Miami Lakes, FL 33014, USA

EC REP Cordis Cashel Cashel Road, Cashel Co Tipperary, Ireland 0086

CE LBL- 01036 Rev. A_0066 of 0312 1879 05Dec17 05:03 PM

Assembled Costa Rica 119

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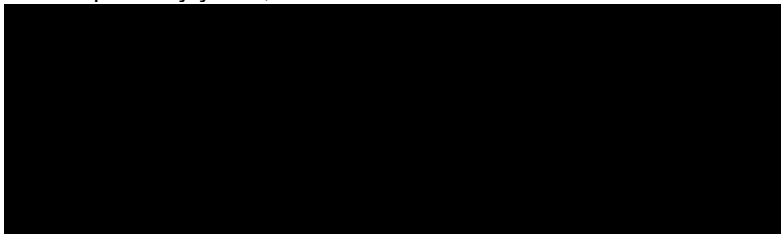
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