

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>																																				
Details on Affected Devices, to assist in identification of the product involved:	<table><tr><th colspan="4"><u>Product involved</u></th></tr><tr><td colspan="4">● Eight (8) lots are affected:</td></tr><tr><th>Catalog Number</th><th>Lot Number</th><th>Balloon Diameter</th><th>Balloon Length</th></tr><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><tr><td>4400604S*</td><td>82144604*</td><td>6mm</td><td>4cm</td></tr></table>	<u>Product involved</u>				● 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
<u>Product involved</u>																																					
● 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																																		

	<table><tr><td>4400604S*</td><td>82144617*</td><td>6mm</td><td>4cm</td></tr><tr><td>4400804S*</td><td>82144499*</td><td>8mm</td><td>4cm</td></tr></table>	4400604S*	82144617*	6mm	4cm	4400804S*	82144499*	8mm	4cm												
4400604S*	82144617*	6mm	4cm																		
4400804S*	82144499*	8mm	4cm																		
	<p>Usage</p> <p>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.</p> <p>Identification</p> <p>The example labeling below is provided to help you identify the affected units.</p>																				
<p>Details on Affected Devices, to assist in identification of the product involved (Continued):</p>	<p>Identification (Continued)</p> <p>Example labeling:</p> <div><div><p>POWERFLEX® PRO PTA Dilatation Catheter</p><p>Ø8 mm X 4 cm</p></div><div><p>Over-the-Wire 0.035" outside wire</p><p>PTA Dilatation Catheter / Cathéter de dilatation pour PTA (angioplastie transcatéterale percutanée) / Dilatationskatheter für die Perkutane Transkathetäre Angioplastie (PTA) / Cateters dilatadores per PTA / Cateter de dilatación para PTA / catheter de dilatação para PTA / Dilatationskatheter voor PTA / PTA-dilatationskatheter / PTA-lazajmuskatheter / Dilatationskatheter für PTA / Dilatationskatheter for perkutan transkathetäre angioplastiek (PTA) / Катетер/посуд расширитель via баллончик/катетер, расширяющий стент/катушка (PTA) / Dilatationskatheter für die Perkutane Transkathetäre Angioplastie (PTA) / Dilatationskatheter / Rozszerzający cewnik do PTA / Dilatador kateter na PTA / Дилатационный катетер до PTA / Catheter de dilatare pentru ATP / PTA dilatationskatheter / PTA dilatācijas katetere / PTA pildamais katetērs do PTA / Dilatasyon kateteri / Дилатационный катетер PTA / Дилатационный катетер для PTA / Ангиопластика (PTA) катетер/дилатационный катетер / PTA 8 mm x 4 cm / PTA 擴張器 / 8mm 擴張 4cm 伸縮管 (PTA) 확장 카테터 / 8mmx4cmPOTENTIAL PTA / Dilatációs katéter za PTA / Dilatatori kateter za PTA / Dilatacijski kateter za PTA / PTA قطر التوسيع</p><p>Ø8 mm X 4 cm</p><p>80 cm</p><p>4 cm</p><p>5F (1.65 mm)</p><p>Ø8 mm</p><p>Balloon Pressure</p><table><tr><th>Pressure atm</th><th>Inflated Balloon Dia. (mm)</th></tr><tr><td>6</td><td>7.68</td></tr><tr><td>7</td><td>7.84</td></tr><tr><td>8</td><td>8.00 Nominal</td></tr><tr><td>9</td><td>8.16</td></tr><tr><td>10</td><td>8.32</td></tr><tr><td>11</td><td>8.48</td></tr><tr><td>12</td><td>8.64 Rated</td></tr><tr><td>13</td><td>8.80</td></tr><tr><td>14</td><td>8.95</td></tr></table><p>Nominal 8 Rated 12</p><p>5F (1.65 mm)</p><p>0.035" (0.89 mm)</p><p>Recommended Catheter Sheath Introducer</p><p>POWERFLEX® PRO PTA Dilatation Catheter REF 4400804S 8 mm X 4 cm 80 cm LOT 82144499</p><p>POWERFLEX® PRO PTA Dilatation Catheter REF 4400804S 8 mm X 4 cm 80 cm LOT 82144499</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><p>Cardinal LOT 82144499 REF 4400804S</p><</div></div>	Pressure atm	Inflated Balloon Dia. (mm)	6	7.68	7	7.84	8	8.00 Nominal	9	8.16	10	8.32	11	8.48	12	8.64 Rated	13	8.80	14	8.95
Pressure atm	Inflated Balloon Dia. (mm)																				
6	7.68																				
7	7.84																				
8	8.00 Nominal																				
9	8.16																				
10	8.32																				
11	8.48																				
12	8.64 Rated																				
13	8.80																				
14	8.95																				

	<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>
--	--

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>
------------------------------------	---

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

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>
--------------------------------	--

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 Affairs
Cordis Corporation