Urgent Field Safety Notice (Removal)

Cordis® POWERFLEX® P3 PTA Dilatation Catheter

Catalog Number	Lot Number
4206020S	**82155955**

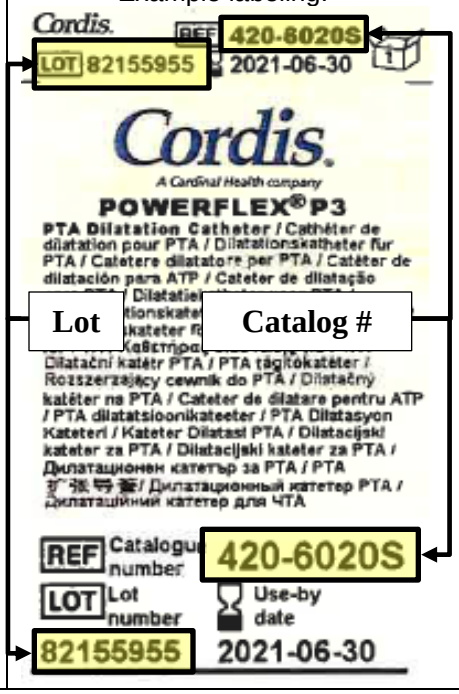
January 09, 2020

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis is recalling one (1) lot of Cordis POWERFLEX® P3 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter product.

Recall Overview:	Cordis is recalling one (1) lot of POWERFLEX® P3 PTA Dilatation Catheter due to the potential for body/shaft voids in the proximal seal area. The presence of body/shaft voids may lead to a weakened wall of the body/shaft, which could result in rupture at the site as pressure is applied for balloon inflation. A shaft leakage/burst that occurs during balloon inflation would likely create an inability to inflate or maintain pressure of the balloon component. This could result in an intra-procedural delay. If the inflation lumen becomes occluded due to the rupture, the user may experience deflation difficulty and withdrawal difficulty of the balloon component. Additionally, with an outer wall rupture of the device, a sudden jet of contrast may occur and damage the vessel wall. There is no safety concern for patients that are treated successfully using product from this lot. Cordis has not received any complaints related to POWERFLEX® P3 that are related to shaft burst or leakage.

Details on Affected Devices, to assist in identification of the product involved:	**Product involved** • One (1) lot is affected: Catalog Number | Lot Number | Balloon Diameter | Balloon Length **4206020S** | **82155955** | 6 mm | 20 mm **Usage** The POWERFLEX® P3 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. **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® P3 lot number 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 lot in your possession. Identify and set aside any units from the affected lot 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® P3 product from your facility. If any units of the affected lot 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 of one (1) unit that had body/shaft voids in the proximal seal area. Although the investigation into the issue did not indicate other affected units, Cordis is recalling the entire lot in an abundance of caution.

	Why are we recalling this product? A void in the body/shaft in the proximal seal area would likely create an inability to inflate or maintain pressure of the balloon component. The most likely occurrence would result in a procedural delay. If the inflation lumen becomes occluded due to the rupture, the user may experience deflation difficulty and withdrawal difficulty of the balloon component. Additionally, with an outer wall rupture of the device, a sudden jet of contrast may occur and damage the vessel wall. There is no safety concern for patients that are treated successfully using product from this lot. 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 this one (1) lot.

Available Assistance:	If you have any questions regarding this recall, please contact your local sales representative or local sales office, or Cordis at CordisCorp-FA-SS@cardinalhealth.com or +353-62-70062.

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