Urgent FIELD SAFETY NOTICE (REMOVAL)

Cordis SABER™ PTA Dilatation Catheter

Catalog	Lot
48004010X	82219442

July 26, 2021

Dear Valued Customer,

The purpose of this communication is to inform you Cordis is recalling one (1) lot of Cordis SABER™ PTA Dilatation Catheter.

Recall Overview:	Cordis was notified by its supplier that for the lot listed above, the balloon protective sheath may potentially be contaminated with a foreign material left over from the manufacturing process. The contaminant may transfer over from the sheath to the balloon. The potential impacts of contamination are Hypersensitivity and Anaphylaxis reactions.

Details on Affected Device, to assist in identification of the product involved:	**Product involved** This letter applies to: • Catalog 48004010X, Lot 82219442 of SABER™ PTA Dilatation Catheter. The lot was recently distributed, with only eight (8) units distributed globally. No complaints or incidents have been reported. **Intended Use:** The SABER™ PTA Dilatation 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 post-dilation of balloon-expandable and self-expanding stents in the peripheral vasculature. **Identification** The example of the box labeling below is provided to help you identify the affected units. 

Why you are being contacted:	You are receiving this letter because our records indicate that you have purchased one or more units of this impacted Cordis SABER™ PTA Dilatation Catheter lot.

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 Cordis distribution center. Please contact your local sales representative to facilitate return of the affected product, if necessary. 5. **Share** this letter with others in your facility who need to be made aware of this recall and **please contact** any other facility that may have been sent the affected units of SABER™ PTA Dilatation Catheter 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. 6. **Maintain** awareness of this notice until all affected product has been returned to Cordis and **keep** a copy of this notice with the affected product.

Description of the problem:	What is the issue? Cordis was notified by its supplier that for the lot listed above the balloon protective sheath may potentially be contaminated with a foreign material left over from the manufacturing process. The contaminant may transfer over from the sheath to the balloon. Why are we recalling this product? The potential impact of SABER™ PTA Dilatation Catheter with potentially contaminated protective sheaths are Hypersensitivity and Anaphylaxis reaction. What other actions is Cordis taking? Cordis is working with our supplier to determine the root cause and will take appropriate corrective action.

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.

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 Affairs
Cordis Corporation