Urgent FIELD SAFETY NOTICE (REMOVAL)

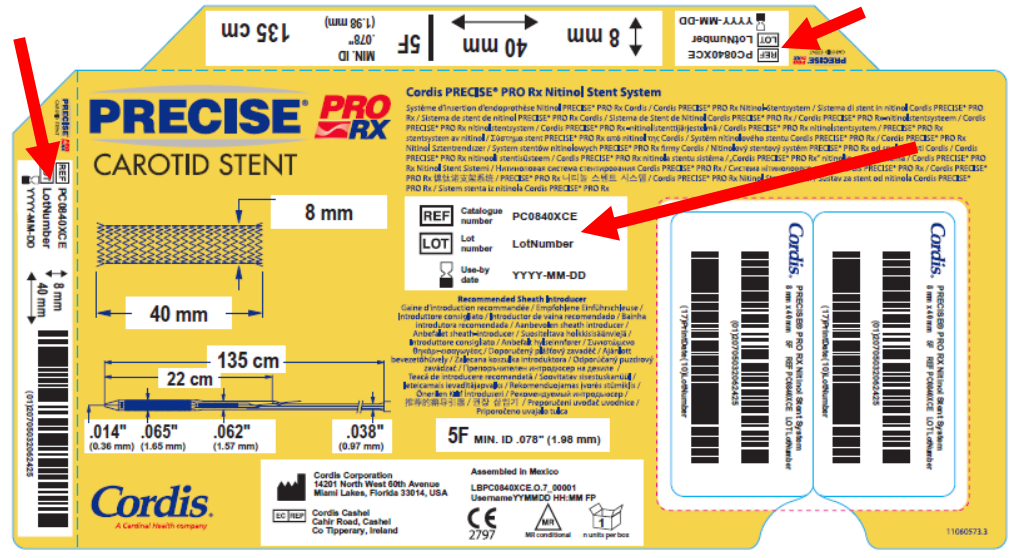
Cordis PRECISE PRO RX™ Carotid Stent System
Specific Lots – See Listing in Table 1 at end of letter

February 16, 2021

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis is recalling (removing) specific lots of Cordis PRECISE PRO RX™ Carotid Stent System.

Recall Overview:	Cordis has identified a potential for the distal tip to become separated from the wire lumen on certain lots of the PRECISE PRO RX™ Carotid Stent System. The potential impacts of distal tip separation include an intra-procedural delay while a replacement device is prepared; unplanned percutaneous or surgical intervention; or stroke, among others.

Details on Affected Device, to assist in identification of the product involved:	**Product involved** This letter applies to: • Specific lots of PRECISE PRO RX™ Carotid Stent System. See Table 1. **Intended Use:** The PRECISE PRO RX™ Carotid Stent System is indicated for use in patients with stenotic lesions of the carotid artery(ies). **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 of the impacted Cordis PRECISE PRO RX™ Carotid Stent System lots.

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 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. 5) **Share** this letter with others in your facility who need to be made aware of this recall and please **contact** any other facility who may have been sent the affected units of PRECISE PRO RX™ Carotid Stent System 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. **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 recently confirmed complaints for distal tip separation from the wire lumen that may be the result of inadequate joint adhesion. We have isolated the issue to particular lots of product made between October 2019 and August 2020. Product currently being manufactured and supplied are not affected. To date, there have been no reports of strokes, deaths or other long-term patient sequalae related to the distal tip separation. Why are we recalling this product? The potential impacts of distal tip separation include an intra-procedural delay while a replacement device is prepared; unplanned percutaneous or surgical intervention; or stroke, among others. Is there any concern with the product already used successfully in procedures? No. The recall is for distal tip separation and does not affect PRECISE PRO RX™ stents that have been successfully deployed. What other actions is Cordis taking? Cordis has an active investigation underway and has determined that the scope of the problem is limited to the lots listed in this letter. In keeping with our commitment to provide customers with quality products, Cordis has voluntarily decided to recall the affected lots listed in this letter.

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

Table 1 (List of Impacted Lots)

Product Code	Lot No.
PC0520XCE	17917083
PC0540XCE	17936916
	17941872
PC0620XCE	17912280
PC0630XCE	17910549
	17915159
	17915160
	17919722
	17923714
	17926319
	17938803
PC0640XCE	17910550
	17912282
	17913482
	17922172
	17928283
	17931759
	17933385
	17936917
	17937806
	17946962
	17950687
	17955965
	17958865
	17961561
PC0720XCE	17953165
PC0730XCE	17909815
	17910551
	17912283
	17915161
	17922173
	17927596
	17928284
	17932847
	17936919
	17940239
	17942801
	17954157
	17961224

Product Code	Lot No.
PC0740XCE	17905296
	17909816
	17911880
	17913483
	17916480
	17921808
	17925700
	17927597
	17929125
	17931760
	17931761
	17936921
	17940241
	17942802
	17943405
	17948770
	17948771
	17954158
	17955966
	17960314
	17961225
	17962540
PC0830XCE	17903566
	17910554
	17910555
	17914197
	17915163
	17922175
	17932848
	17938804
	17941420
	17945492
	17949019
	17949963

Product Code	Lot No.
PC0840XCE	17903568
	17905298
	17905299
	17907247
	17907248
	17909817
	17910557
	17912286
	17912287
	17918981
	17924452
	17926322
	17927598
	17929772
	17931764
	17933388
	17934631
	17935171
	17935172
	17936924
	17937808
	17941423
	17941878
	17941879
	17943063
	17948773
	17949347
	17950557
	17952940
	17954159
	17954607
	17955666
	17955667
	17956889
	17962541
	17963485
PC0930XCE	17912288
	17926323
	17932849
	17936246
	17947079
	17949966

Product Code	Lot No.
PC0940XCE	17905300
	17912291
	17912292
	17925701
	17928288
	17929127
	17935174
	17935175
	17939533
	17945245
	17955669
	17960315
PC1030XCE	17919726
PC1040XCE	17916483
	17925702
	17953166
	17960316