Urgent Field Safety Notice (Removal)

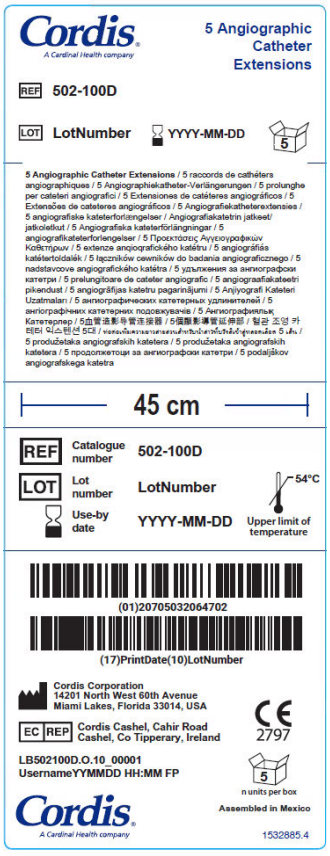
Cordis Angiographic Catheter Extensions
Specific Lots – See Listing in Table at end of letter

07 November 2022

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis is recalling (removing) specific lots of Cordis Angiographic Catheter Extensions.

Recall Overview:	Cordis has identified that, for the lots listed in the Table below, there is a potential for separation at the male connector. The potential impacts of a catheter extension tubing separation include an intra-procedural delay as the device is exchanged for another. Additionally, Cordis has identified potential complications resulting from the introduction of air into the tubing through the separated connection, such as ischemia, necrosis peripheral, unplanned percutaneous intervention, pulmonary embolism, cerebral stroke and myocardial infarction may occur but only occasionally or under unusual circumstances.

Details on Affected Device, to assist in identification of the product involved:	**Product involved** This letter applies to specific lots of Angiographic Catheter Extensions. (See Table below). **Intended Use** The Angiographic Catheter Extensions is indicated for use to transport fluid from the power injector to the catheter for injection into the patient. **Identification** An 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 Angiographic Catheter Extensions 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 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 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 with any other facility that may have been sent the affected units of 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. **Maintain** awareness of this notice until all affected product has been returned to Cordis. 6. **Keep** a copy of this notice with the affected product.

Description of the problem:	What is the issue? Cordis has identified that, for the lots listed below, there is a potential for separation at the male connector. Why are we recalling this product? The potential impacts of a catheter extension tubing separation include an intra-procedural delay as the device is exchanged for another. Additionally, Cordis has identified potential complications resulting from the introduction of air into the tubing through the separated connection, such as ischemia, necrosis peripheral, unplanned percutaneous intervention, pulmonary embolism, cerebral stroke and myocardial infarction may occur but only occasionally or under unusual circumstances. Is there any concern with the product already used successfully in procedures? There is no safety concern for patients that have already been treated successfully using product from these lots. What other actions is Cordis taking? Cordis has an active investigation underway related to this issue and is currently working to determine the root cause and will take appropriate corrective action. 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 GMB-Cordis-Cashel-QRA@cordis.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,

Table - List of impacted lots

Catalog code	Lot Number
502-100D	18068258
502-100D	18069744
502-100D	18101041
502-100D	18111609
502-101D	18062881
502-101D	18064731
502-101D	18066535
502-101D	18070824
502-101D	18077497
502-101D	18081307
502-101D	18086388
502-101D	18097369
502-101D	18102623
502-102D	18060997
502-102D	18062882
502-102D	18064732
502-102D	18072508
502-102D	18074058
502-102D	18076420
502-102D	18078225
502-102D	18079156
502-102D	18083133
502-102D	18084892
502-102D	18088193
502-102D	18090247
502-102D	18099118
502-102D	18104313
502-102D	18106093
502-102D	18108019
502-102D	18109512

CUSTOMER ACKNOWLEDGEMENT FORM
URGENT FIELD SAFETY NOTICE (Removal)
Cordis20221107-EMEA
Cordis Angiographic Catheter Extensions

Cordis is recalling (removing) specific lots of Angiographic Catheter Extensions due to a potential for separation at the male connector.

Refer to Table 1 in the field safety notice letter for the listing of impacted lots.

Contact Person:	
Department:	
Hospital Name	
Postcode:	
Street	
City	
Contact Email	
Contact Phone	

Our records indicate that your facility received product subject to the above product recall.

Part 1: Letter Acknowledgement (Customer)
We are aware of the notification of the above recall.

Is there remaining product to be returned at your facility or at any other facility that may have received affected batch units from your facility? (Please ensure to check stocks before replying)?
Yes? _____ or **No?** _____

If Yes, please set aside all remaining units to prevent continued use of the product and provide details in the Table below.

Cordis will contact you to arrange for product to be returned and will issue credit once returns are received and verified.

_____ _____
Name/Signature: (Customer) Position: (Customer)

_____ _____
Contact Phone Number: (Customer) Date:

OR

Part 2: Letter Acknowledgement (Cordis Representative)
I confirm that the customer has been made aware of the notification of the above recall.

Is there remaining product to be returned at the customer facility or at any other facility that may have received affected batch units from the customer facility? (Please ensure to check stocks before replying)?
Yes? _____ or **No?** _____

If Yes, please request the customer to set aside all remaining units to prevent continued use of the product and provide details in the Table below.

_____ _____
Name/Signature: Position:
(Cordis Representative)

_____ _____
Contact Phone Number: Date:
(Cordis Representative)

RETURN REQUEST FORM

Complete table below if you have affected stock to return.

Product Code	Lot Number	Quantity to be returned	Unit of Measure (Eaches, Cartons)	Original Invoice / PO

Opening Hours for parcel collections	
Number of Parcels **Weight**	
Additional instructions for courier collecting product?	
Sales Representative Name (if known)	
Sales Representative Contact Details (if known)	

Please return this completed form by email to your local sales representative or to insert local QRA email address.