Updated

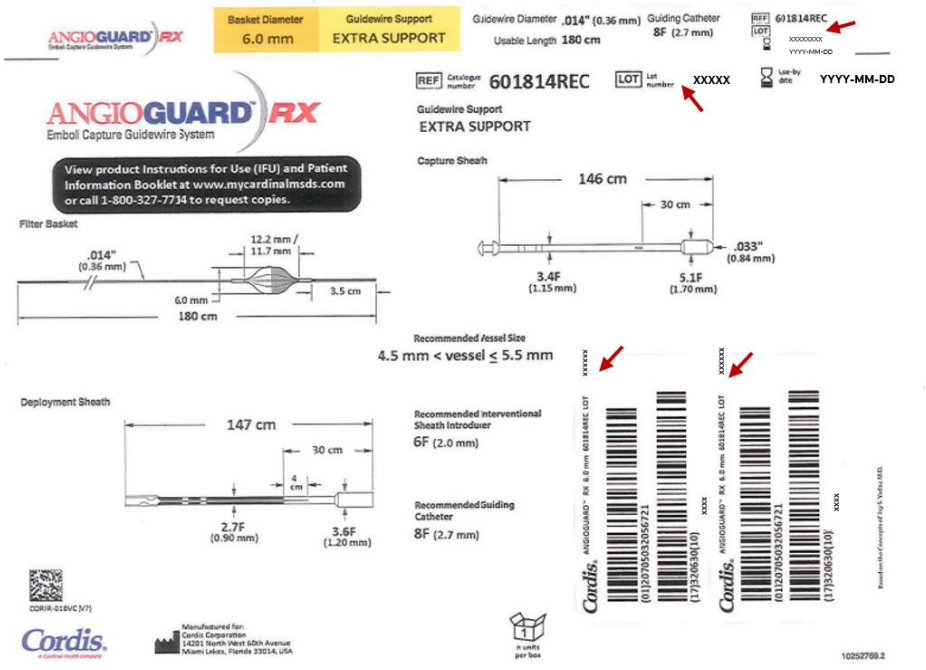
Urgent Field Safety Notice (Removal)
ANGIOGUARD™ RX / XP Emboli Capture Guidewire System
For specific lots - See listing in Table 1 at the end of this letter

April 20, 2023

Dear Valued Customer,

The purpose of this communication is to inform you Cordis is voluntarily recalling (removing) specific lots of ANGIOGUARD™ RX / XP Emboli Capture Guidewire System. You are receiving this letter because our records indicate that you have purchased one or more of the impacted Cordis ANGIOGUARD™ RX / XP Emboli Capture Guidewire System lots.

Recall Overview:	Cordis has identified that there is a potential for the inability to safely deploy and capture the filter basket of the ANGIOGUARD™ RX / XP delivery system due to deployment sheath peeling difficulty and/or separation, capture sheath separation and difficulty exiting the guidewire RX port. A total of 106 global complaints have been received by Cordis. The potential impacts include but are not limited to situations of an intra-procedural delay; unplanned percutaneous or surgical intervention; or stroke.

Details on Affected Device, to assist in identification of the product involved:	**Product involved:** This letter applies to certain lots of ANGIOGUARD™ RX/XP Emboli Capture Guidewire System (see Table 1) **Intended Use:** The ANGIOGUARD™ RX/XP Emboli Capture Guidewire System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3 mm to 7.5 mm. **Identification:** The example of the box labeling below is provided to help you identify the affected units. 

Actions requested on your part:	1) Read this Urgent Field Safety Notice (Removal) letter. 2) Immediately check your inventory to confirm if you have any units from the affected lots in your possession. Identify and set aside any units from the identified 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 any affected product to the Cordis distribution center or destroy locally and provide a certificate of destruction, as applicable. Your local sales representative will inform and support you on local return or destruction options. 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 or destruction of the units. 6) Maintain awareness of this notice until all affected product has been returned to Cordis or destroyed locally, as applicable. Keep a copy of this notice with the affected product.

Description of the problem:	What is the issue? Cordis has identified that there is a potential for the inability to safely deploy and capture the filter basket of the ANGIOGUARD™ RX / XP delivery system due to deployment sheath peeling difficulty and/or separation, capture sheath separation and difficulty exiting the guidewire RX port on product that were produced after a particular date. Why are we recalling this product? The potential impacts of separation, peeling difficulty, and difficulty exiting the guidewire RX port include an intra-procedural delay; 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 being undertaken due to potential separation, peeling difficulty, and difficulty exiting the guidewire RX port during use of the device and does not affect product that has been successfully used. What other actions is Cordis taking? Cordis is working to investigate and determine the root cause and will take appropriate corrective actions.

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 issue may cause. We know that you place high trust 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,

[redacted]

TABLE 1
- LIST OF AFFECTED LOTS –

ITEM_NUMBER	LOT_NUMBER
401814RM	35265339
	35265670
401814RMC	35262517
	35263334
	35264204
	35264222
	35265345
501814RE	**35264205****
	35264210**
	35264214**
	35264217
	35264226
	35265330
	35265340**
	35265341**
	35265344
	35265381
	35265394**
	35265641
	35265643**
	35265652
	35265655

ITEM_NUMBER	LOT_NUMBER
501814REC	35264223
501814RM	**35265644****
501814RMC	35264208
	35264212
	35265329
	35265649
	35265654
	35265667
601814RE	**35264206****
	35264218
	35264224
	35264806
	35265342
	35265343
	35265382
	35265383
	35265645**
	35265646
	35265653**
	35265656
601814RM	**35264211****
	35264225**
	35265647**
	35265658

ITEM_NUMBER	LOT_NUMBER
601814RMC	35263328
	35264207
	35264213
	35264216
	35265393
	35265648
	35265659
603014MC	35265492
701814RE	35264219
	35265391
	35265392
	35265399
	35265660**
	35265668
701814RMC	35265661
801814RE	**35267611****
801814RMC	35264202
	35265335

**Denotes additional lots added to scope of recall.

Note: 4 lots initially included have been removed from the scope.

ITEM_NUMBER	LOT_NUMBER
401814RMC	35265669
501814RE	35265639
	35265662
	35265664