Urgent FIELD SAFETY NOTICE (REMOVAL)

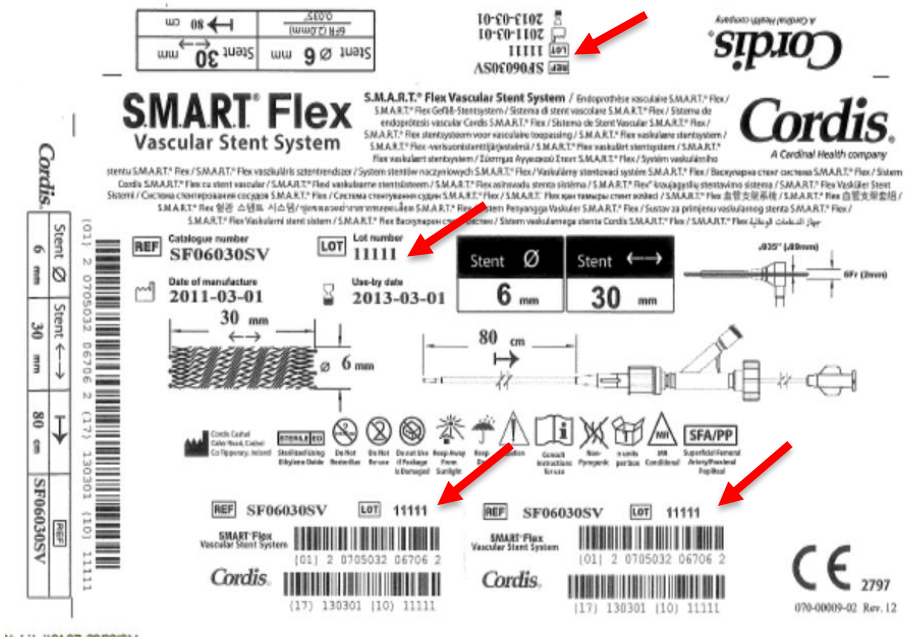
Cordis S.M.A.R.T.™ Flex Vascular Stent System
Specific Lots – See Listing in Table 1 at end of letter

October 01, 2021

Dear Valued Customer,

The purpose of this communication is to inform you Cordis is recalling (removing) specific lots of Cordis S.M.A.R.T.™ Flex Vascular Stent System.

Recall Overview:	Cordis has identified that for the lots listed in Table 1 below, there is a potential for distal tip dislodgement / separation due to inadequate adhesive application. The potential impacts of distal tip separation include an intra-procedural delay as the device is exchanged for another, unplanned percutaneous or surgical intervention, and peripheral ischemia or necrosis.

Details on Affected Device, to assist in identification of the product involved:	**Product involved** This letter applies to: • Specific lots of S.M.A.R.T.™ Flex Vascular Stent System. (See Table 1 below). **Intended Use:** The S.M.A.R.T.™ Flex Stent 5-8mm stent diameters is intended as a treatment for atherosclerotic superficial femoral artery lesions and proximal popliteal lesions. The S.M.A.R.T.™ Flex Stent 9 and 10mm stent diameters is intended for use in the common and external iliac arteries to improve luminal diameters in patients with symptomatic vascular stenotic and/or occlusive diseases. **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 S.M.A.R.T.™ Flex Vascular 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 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 **please contact** any other facility that may have been sent the affected units of S.M.A.R.T.™ Flex Vascular 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. 6. **Keep** a copy of this notice with the affected product.

Description of the problem:	What is the issue? Cordis has identified that the lots listed in Table 1 below may have had inadequate adhesive applied which could result in distal tip dislodgement / separation. This issue was identified internally by our supplier and no adverse events have been reported. Why are we recalling this product? The potential impacts of distal tip separation include an intra-procedural delay as the device is exchanged for another, unplanned percutaneous or surgical intervention, and peripheral ischemia or necrosis. Is there any concern with the product already used successfully in procedures? No. The recall is for distal tip separation and does not affect S.M.A.R.T.™ Flex Vascular Stent Systems 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 CordisCashelQRA@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)

Catalog Code	Lot Number
SF05080MV	254997
SF05080MV	258274
SF05080SV	266285
SF05150MV	255004
SF05150MV	258277
SF05150MV	258278
SF06030MV	254200
SF06040MV	255005
SF06040SV	266359
SF06040SV	266361
SF06060MV	256302
SF06100MV	256310
SF06100MV	260092
SF06100SV	266395
SF06120MV	254201
SF06120MV	256315
SF06120MV	258279
SF06150MV	253338
SF06150MV	253339
SF06150MV	256320
SF06150MV	256321
SF06150MV	256322
SF06150MV	256323
SF07040MV	266460
SF07060MV	254202
SF07080MV	266467
SF07100MV	254203
SF07120MV	254204
SF07200MV	254205
SF07200MV	259764
SF08100MV	253342
SF08120MV	253343
SF08200MV	253345
SF08200MV	253346
SF09020MV	254208
SF09100MV	253350
SF10060SV	253353
SF10080SV	253354

CUSTOMER ACKNOWLEDGEMENT FORM
URGENT FIELD SAFETY NOTICE (Removal)
Cordis20211001-EMEA
Cordis S.M.A.R.T.™ Flex Vascular Stent System

Cordis is recalling (removing) specific lots of S.M.A.R.T.™ Flex Vascular Stent System due to a potential for distal tip dislodgement / separation due to inadequate adhesive application.
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 CordisCashelQRA@cardinalhealth.com