Urgent FIELD SAFETY NOTICE (REMOVAL)
EXPANSION

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

July 22, 2022

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.
Please note that this action is an expansion of a previous recall conducted by Cordis in October 2021. You may have already received notification of the original recall in October 2021 and may have already returned products from the originally identified lots. **However, you have additionally been identified as having purchased products from the lots listed in Table 1 below, which are now included in the recall action.**

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:

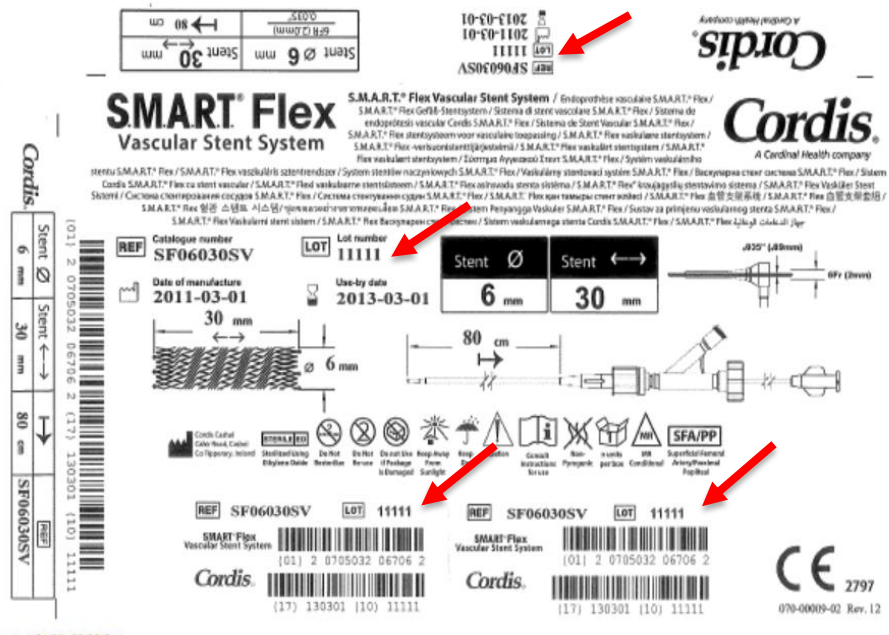
Product involved
This letter applies to:

- 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? Originally, Cordis (through our supplier) identified that certain S.M.A.R.T.™ Flex Vascular Stent System lots may have had inadequate adhesive applied which could result in distal tip dislodgement / separation. Through continued investigation, Cordis discovered that a sorting process used on several other lots may not have been 100% effective and has therefore decided to recall the additional lots identified in Table 1 below. 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 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,

Miguel Ávila
Vice President, Global Quality and Regulatory Affairs
Cordis Corporation

Table 1
Additional Lots – July 2022

Catalog Code	Lot Number
SF05040MV	266254
SF05060MV	254994
SF05100MV	266294
SF05100MV	266295
SF05150MV	258938
SF06040MV	256298
SF06100MV	266389
SF06120MV	266410
SF06150MV	259378
SF06150MV	266435
SF08060MV	257081
SF08060MV	266521
SF10040MV	253351
SF10060MV	253352

CUSTOMER ACKNOWLEDGEMENT FORM

Cordis S.M.A.R.T.™ Flex Vascular Stent System

FIELD SAFETY NOTICE (Removal)

Cordis20211001-EMEA - EXPANSION July 2022

Cordis is recalling (removing) specific lots of Cordis 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 GMB-Cordis-Cashel-QRA@cordis.com