Urgent Field Safety Notice (Removal)

Cordis SELUTION SLR™ 018 PTA 3.0mm X 100mm Balloon Catheters
For specific lots - See listing in Table below:

Item/Product Number	Lot Number
SE18030100	L92505
SE18030100	L92835
SE18030100	L93029
SE18030100	L93495

October 29, 2024

Dear Valued Customer,

The purpose of this communication is to inform you that, Cordis is voluntarily removing specific lots of SELUTION SLR™ 018 PTA 3.0mm X 100mm Balloon Catheters. You are receiving this letter because our records indicate that you have purchased and have in your possession one or more of the impacted lots of the subject product: SELUTION SLR™ 018 PTA 3.0mm X 100mm Balloon Catheters.

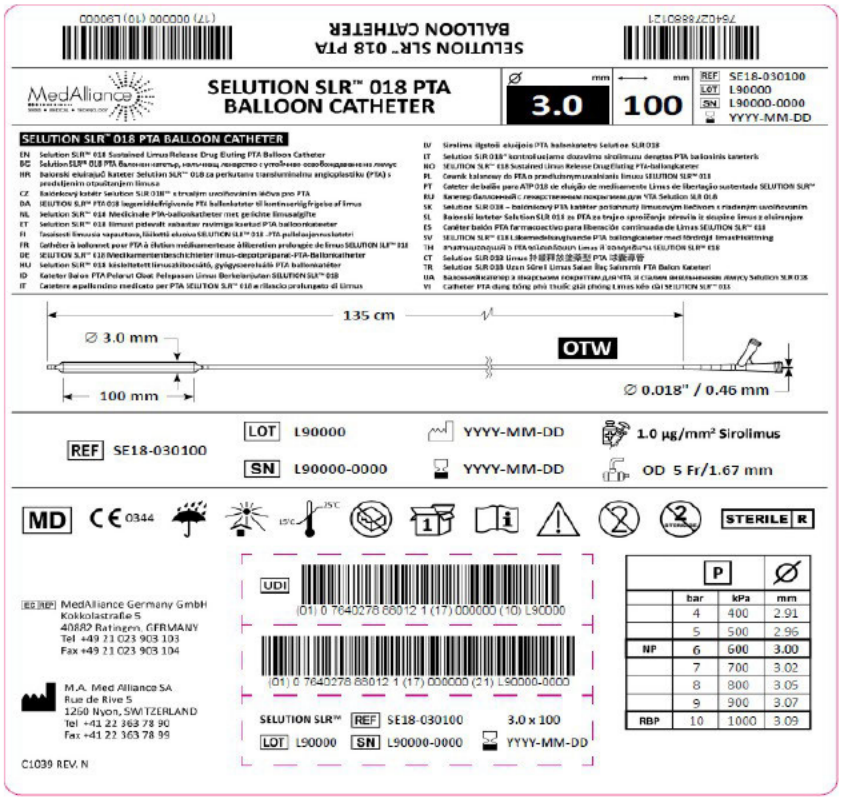
Field Safety Notice (Removal) Overview:	Cordis has identified a potential for "slow deflation" to occur during use of certain lots of SELUTION SLR™ 018 PTA 3.0mm X 100mm. A total of three complaints have been received by Cordis. The potential impacts include but are not limited to situations of patient discomfort, increased procedure time, additional intervention, vessel occlusion and vessel injury.

Details on Affected Device, to assist in identification of the product involved:

Product involved:
This letter applies to:

Item/Product Number	Lot Number
SE18030100	L92505
SE18030100	L92835
SE18030100	L93029
SE18030100	L93495

Intended for Use:
The SELUTION SLR™ PTA DEB is intended for use as a Percutaneous Transluminal Angioplasty (PTA) balloon catheter to dilate de nova or restenotic vascular lesions, for the purpose of improving limb perfusion and decreasing the incidence of restenosis.

Identification:	Provided below is a sample of the box label for the affected product. This will help you identify the affected unit (s). 
Actions requested on your part:	1) Read this **Urgent Field Safety Notice (Removal) letter.** 2) Immediately check your inventory to confirm that you do not 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 directly to Cordis at the fax number on the form or email to: GMB-CordisFieldAction@cordis.com 4) Return any affected product to the address listed on the form, with reference to your Customer Number which is listed on the form. 5) Share this letter with others in your facility who need to be made aware of this removal 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. 6) Maintain awareness of this notice until all affected product has been returned to Cordis and keep a copy of this notice with the affected product.

Description of the problem:	<u>What is the issue?</u> Cordis has identified that there is potential for deflation difficulty or *"slow deflation"* of 4 lots of SELUTION SLR™ 018 PTA 3.0mm X 100mm balloon catheters. <u>Why are we removing this product?</u> The potential impact of deflation difficulty or *"slow deflation"* includes increased procedure time, additional intervention, vessel occlusion and vessel injury. <u>Is there any concern with the product already used successfully in procedures?</u> There is no concern with product that has been successfully used. <u>What other actions is Cordis taking?</u> Cordis has identified the root cause and will take appropriate corrective actions. Only these devices from the four specific lots are impacted by the issue.

Available Assistance:	If you have any questions regarding this field safety notice, please contact your local sales representative or local sales office, or Cordis at: GMB-CordisFieldAction@cordis.com

Additional Information:	**<u>Regulatory Notification</u>** The applicable regulatory agencies and notified body are being notified that Cordis is voluntarily taking this action.

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]

Joseph Duffy

Vice President, Quality & Design Assurance
Cordis
cc: Materials Director; Field Action Contact or Risk Manager

Urgent Field Safety Notice (Removal) Customer Acknowledgement
Cordis SELUTION SLRTM 018 PTA 3.0mm X 100mm Balloon Catheters
Cordis Selution – Field Action Reference: Cordis20241024

Cordis is recalling (removing) L92505, L92835, L93029, L93495 lots of SE18030100 catalog code of SELUTION SLR™ 018 PTA 3.0mm X 100mm Balloon Catheter due to a potential for "slow deflation" to occur during use of certain lots of SELUTION SLR™ 018 PTA 3.0mm X 100mm. The potential impacts include but are not limited to situations of patient discomfort, increased procedure time, additional intervention, vessel occlusion and vessel injury.

This Field Safety Notice applies to:

Item/Product Number	Lot Number
SE18030100	L92505
SE18030100	L92835
SE18030100	L93029
SE18030100	L93495

Contact Person:	
Department:	
Customer Name:	
Postcode:	
Street:	
City:	
Country:	
Contact Email:	
Contact Phone:	

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

Part 1: FIELD SAFETY NOTICE (Removal) ACKNOWLEDGEMENT
We (customer) are aware of the notification of the above recall.

Is there remaining product with affected batch units to be returned from our facility or from other facility to which we shipped affected product? (Please ensure to check stocks before replying)

Yes ☐ No ☐

If Yes, please set aside all remaining units to prevent continued use of the product and provide details in Table 1 below.

Appendix D (Page 2 of 3)

OR,

I (Cordis Representative), confirm that the customer has been made aware of the notification of the above recall. Does the customer have remaining product with affected batch units to be returned from its facility or from other facility that have received affected batch units from the customer facility? (Please ensure to check stocks before replying) Yes ☐ 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.

TABLE 1 (Complete this table if you have unused stock impacted by this recall)

Product Code	Lot Number	Quantity	Individual Units or Full Boxes	Original Invoice / PO

Select one of the 2 below options to receive credit:

☐ **Return product to Cordis (complete Part B and D)**
☐ **Destroy product and provide to Cordis with confirmation of destruction (complete Part C and D)**

PART B: RETURN PRODUCT TO CORDIS (Credit will be issue at product return)

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)	

Appendix D (Page 3 of 3)

PART C – CUSTOMER TO DESTROY PRODUCT (Credit will be issued once receipt of signed confirmation of destruction is received)

This is to certify that the products listed in Table 1 above have been made un-usable and will not be returned to Cordis. Destroyed products have been or will be disposed of in accordance with corporate, local and worldwide environmental policies during the next approved destruction cycle.

PART D - SIGNATURES

_____ _____

Customer Name/Signature Customer Position

_____

Customer Contact Phone Number

OR

_____ _____

Cordis Representative Name/Signature Position

_____ _____

Cordis Representative Contact Phone Number Date

Please return this completed form to your local Cordis sales representative or by email to GMB-Cordis-Cashel-QRA@cordis.com