



## 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.

<b>Field Safety Notice (Removal) Overview:</b>	<p>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.</p> <p>The potential impacts include but are not limited to situations of patient discomfort, increased procedure time, additional intervention, vessel occlusion and vessel injury.</p>
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<b>Details on Affected Device, to assist in identification of the product involved:</b>	<p><b>Product involved:</b> This letter applies to:</p> <table border="1" style="margin-left: auto; margin-right: auto;"><thead><tr><th>Item/Product Number</th><th>Lot Number</th></tr></thead><tbody><tr><td>SE18030100</td><td>L92505</td></tr><tr><td>SE18030100</td><td>L92835</td></tr><tr><td>SE18030100</td><td>L93029</td></tr><tr><td>SE18030100</td><td>L93495</td></tr></tbody></table> <p><b>Intended for Use:</b> 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.</p>	Item/Product Number	Lot Number	SE18030100	L92505	SE18030100	L92835	SE18030100	L93029	SE18030100	L93495
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SE18030100	L92505										
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SE18030100	L93495										

**Identification:**

Provided below is a sample of the box label for the affected product. This will help you identify the affected unit (s).

**SOLUTION SLR™ 018 PTA BALLOON CATHETER**

REF: SE18-030100  
 LOT: L90000  
 SN: L90000-0000  
 YYY-MM-DD

Ø 3.0 mm  
 100 mm

**SOLUTION SLR™ 018 PTA BALLOON CATHETER**

EN: Solution SLR™ 018 Sustained Release Drug Eluting PTA Balloon Catheter  
 BC: Solution SLR™ 018 PTA Balloon Catheter, sans-matériau rétracteur : un médicament contrôlé par le gouvernement fédéral  
 FR: Cathéter à ballonnet à libération prolongée de médicament à base de sirolimus (PTA) pour l'angioplastie percutanée transluminale  
 CZ: Balóncový katéter Solution SLR 018™ s trvanlivým uvolňováním léčiva pro PTA  
 DA: SOLUTION SLR™ 018 Sustained Release Drug Eluting PTA Balloon Catheter til ballonterapi af kransår  
 NL: Solution SLR™ 018 Medicinale PTA-balloonkatheter met geleidelijk vrijkomen van sirolimus  
 IT: Solution SLR™ 018 Sonda per dilatare arteriosclerotizzata con rilascio prolungato di sirolimus  
 H: Szívesszűrésre alkalmazható, szilikon alapú, megoldható PTA ballonkatéter  
 FR: Cathéter à ballonnet pour PTA à libération prolongée de médicament à base de sirolimus (PTA) SLR™ 018  
 DE: SOLUTION SLR™ 018 Hochdruckempfindliche, lösliche, erweiterbare PTA-Balloonkatheter  
 HU: Solution SLR™ 018 szilikon alapú, megoldható, gyógyszerelhető PTA ballonkatéter  
 ID: Kateter Balon PTA Prolonged Drug Release Limes Balloon Solution SOLUTION SLR™ 018  
 ET: Catheter a pallonecino ereditato per PTA SOLUTION SLR™ 018 a libeacco prolungata di sirolimus  
 SV: Sustained release drug eluting PTA ballooncatheter Solution SLR 018  
 IT: Solution SLR 018™ Sustained Release Drug Eluting PTA Balloon Catheter  
 PL: Catheter balonowy do PTA ereditowany z kontrolnym uwolnieniem sirolimu SOLUTION SLR™ 018  
 PT: Catheter de balão para PTA 018 de liberação prolongada de medicamento Limes de libertação sustentada SOLUTION SLR™  
 RU: Катетер баллонный с пролонгированным высвобождением препарата Лимес для баллонной ангиопластики SOLUTION SLR™ 018  
 SK: Balóncový katéter Solution SLR 018 s PTA s trvanlivým uvolňovaním sirolimu v zásobnej línii a s libeáciou  
 ES: Catheter balón PTA farmacoactivo para liberación controlada de Limes SOLUTION SLR™ 018  
 TH: SOLUTION SLR™ 018 ไลนัส รีลีส ยาละลายไขมัน PTA บอลลูนคัทเธอร์แบบถาวร  
 TR: Sustained Release Drug Eluting PTA Balloon Catheter SOLUTION SLR™ 018  
 CT: Solution SLR 018 Limes 持續釋放藥 PTA 球囊導管  
 TW: Solution SLR 018 Limes 持續釋放藥 PTA 球囊導管  
 VI: Catheter Balon PTA Prolonged Drug Release Limes Balloon Solution SOLUTION SLR 018  
 VN: Catheter PTA giải phóng thuốc giải phóng Limes kéo dài SOLUTION SLR™ 018

135 cm  
 100 mm  
 3.0 mm  
 OTW  
 Ø 0.018" / 0.46 mm

REF SE18-030100  
 LOT L90000  
 SN L90000-0000  
 YYY-MM-DD  
 1.0 µg/mm<sup>2</sup> Sirolimus  
 OD 5 Fr/1.67 mm

MD CE 0344

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C1039 REV. N

	bar	kPa	mm
P	4	400	2.91
	5	500	2.96
NP	6	600	3.00
	7	700	3.02
	8	800	3.05
	9	900	3.07
RBP	10	1000	3.09

**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](mailto: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.



<b>Description of the problem:</b>	<p><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.</p> <p><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.</p> <p><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.</p> <p><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.</p>
<b>Available Assistance:</b>	If you have any questions regarding this field safety notice, please contact your local sales representative or local sales office, or Cordis at: <a href="mailto:GMB-CordisFieldAction@cordis.com">GMB-CordisFieldAction@cordis.com</a>
<b>Additional Information:</b>	<p><u>Regulatory Notification</u> The applicable regulatory agencies and notified body are being notified that Cordis is voluntarily taking this action.</p>

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,

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 Solution – 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

<b>Contact Person:</b>	
<b>Department:</b>	
<b>Customer Name:</b>	
<b>Postcode:</b>	
<b>Street:</b>	
<b>City:</b>	
<b>Country:</b>	
<b>Contact Email:</b>	
<b>Contact Phone:</b>	

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.

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**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](mailto:GMB-Cordis-Cashel-QRA@cordis.com)