Urgent FIELD SAFETY NOTICE (REMOVAL)

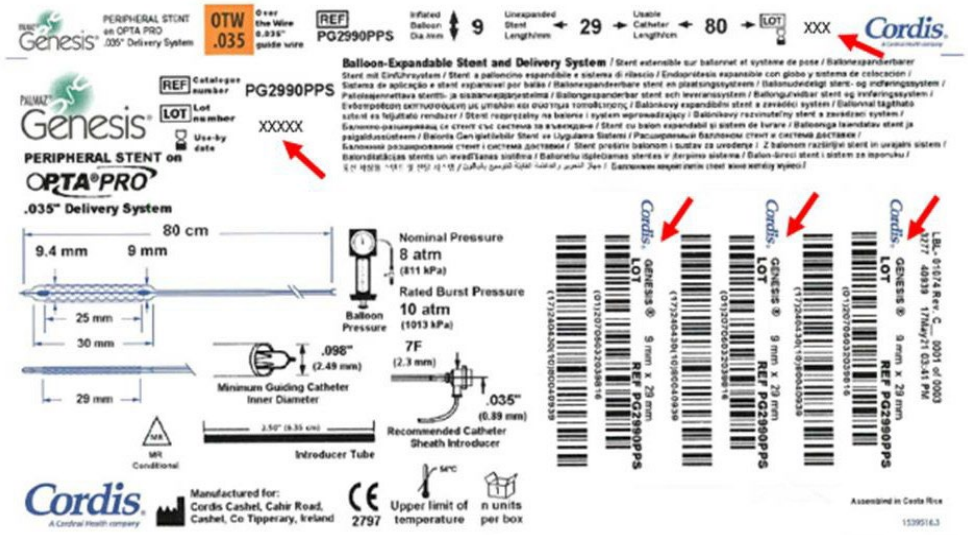
PALMAZ GENESIS™ Peripheral Stent on OPTA™ PRO .035" Delivery System. Catalog Numbers PG2990PPS, PG2990PPX, PG3990PPS, PG3990PPX – Specific Lots

20 May 2022

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis is voluntarily recalling (removing) specific lots of the 9x29 and 9x39 Cordis PALMAZ GENESIS™ Peripheral Stent on OPTA™ PRO .035" Delivery System.

Recall Overview:	Cordis has identified that, for the catalogs listed above, there is a potential for stent dislodgement related to these two specific sizes of the PALMAZ GENESIS™ Peripheral Stent on OPTA™ PRO .035" Delivery System. The potential impacts of stent dislodgement include an intra-procedural delay as the device is exchanged for another or may result in complications such as: unplanned percutaneous or surgical intervention, GI tract trauma or perforation.

Details on Affected Device, to assist in identification of the product involved:	**Product involved** This letter applies specific lots of PALMAZ GENESIS™ Peripheral Stent on OPTA™ PRO .035" Delivery System, catalogs PG2990PPS, PG2990PPX, PG3990PPS, PG3990PPX (see Table 1) **Intended Use:** The PALMAZ GENESIS™ Peripheral Stent on OPTA™ PRO .035" Delivery System is intended for use in the treatment of atherosclerotic disease of peripheral arteries below the aortic arch and for palliation of malignant neoplasms in the biliary tree. **Identification** An 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 PALMAZ GENESIS™ Peripheral Stent on OPTA™ PRO .035" Delivery System catalogs/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 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:	What is the issue? Cordis has become aware of an increased trend for stent dislodgement related to two specific sizes of the PALMAZ GENESIS™ Peripheral Stent on OPTA™ PRO .035" Delivery System that were produced during a particular timeframe. Why are we recalling this product? The potential impacts of stent dislodgement include an intra-procedural delay as the device is exchanged for another or may result in complications such as: unplanned percutaneous or surgical intervention, GI tract trauma or perforation. Is there any concern with the product already used successfully in procedures? No. The recall is being undertaken due to stent dislodgement prior to or during placement and does not affect PALMAZ GENESIS™ stents that have been successfully deployed. What other actions is Cordis taking? Cordis has an active investigation underway, is working with our manufacturer to determine the root cause and will take appropriate corrective action. 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,

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Vice President, Global Quality and Regulatory Affairs
Cordis Corporation

Table 1 (List of Impacted Lots)

Product Code	Lot Number
PG2990PPS	82184215
	82218087
PG2990PPX	82178943
	82191727
	82211305
PG3990PPS	82178944
	82182764
	82193097
	82208537
	82212821
PG3990PPX	82195965
	82212989
	82218097