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«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country_name»

<Reference: 92850920-FA> 4 April 2022

Urgent Field Safety Notice - Urgent Medical Device Recall
Promus ELITE™ Monorail Everolimus-Eluting Platinum Chromium Coronary Stent System

Dear «Users_Name»,

Boston Scientific Corporation is conducting a removal of one (1) batch (139 devices) of Promus ELITE™ Monorail Everolimus-Eluting Platinum Chromium Coronary Stent Systems as detailed in the table below. Through internal investigation, Boston Scientific has determined that this batch was not subject to all required inspection steps during the manufacturing process. While the investigation has not concluded that devices in this batch were manufactured incorrectly, it is possible that balloon and/or stent defects may exist due to the missing inspection steps. Examples of possible defects that may exist include stent strut and/or balloon damage, which may not be visible to the user. No other batches are impacted.

The most serious health consequence that could occur from use of a Promus ELITE Stent System that was not subject to all inspection steps during the manufacturing process is use of a device with a defect that could cause vessel trauma or stent thrombosis, either of which could be fatal. The most common health consequence expected to occur as a result of this device not undergoing all inspection steps is use of a device with a defect that prolongs the procedure to exchange the device due to an inability to cross the lesion. To date, no complaints related to this issue have been reported. There is no evidence of an increased safety risk for patients who have been previously treated with Promus ELITE.

Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all affected products, including Product Description, Material Number (UPN), GTIN, Lot/Batch number and expiry date**. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice**.
Further distribution or use of any remaining product affected by this action should cease immediately.

Product Description	UPN #	GTIN	Lot/Batch #	Expiration Date
Promus ELITE™ Monorail Everolimus-Eluting Platinum Chromium Coronary Stent System 3.0 x 20 mm	H7493941320300	08714729972181	28541541	2 December 2023

INSTRUCTIONS:

1- **Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

2- **Please complete the attached Verification Form** even if you do not have any product to return.

3- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **20 April 2022**.

4- **If you have products to return,** please package them in an appropriate shipping box. **After receipt of the Verification Form, Boston Scientific will contact you to arrange return.**

5- Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (if appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

Boston Scientific is committed to offering products that meet the highest quality standards and to the continuous improvement in the interest of patient benefit, where patient safety remains our priority. We regret any inconvenience that this action may cause, but believe transparent communication will ensure you have timely, relevant information for managing your patients.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Please Complete the form even if you do not have any affected product & send it to your Local Office:
«Customer_Service_Fax_Number»

Verification Form – Urgent Medical Device Recall
Promus ELITE™ Monorail Everolimus-Eluting Platinum Chromium Coronary Stent System
92850920-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 4 April 2022.

2. **Boston Scientific records indicate you have received the following affected product** *(additionally please check inventory against complete list of affected product provided)*

Material N° (UPN)	Lot / Batch N° / Serial N°	Customer PO	Qty Sent	Qty to return (Units)

3. We confirm that all areas where affected product could be located have been checked.

4. **TICK ONE OF THESE STATEMENTS***, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»

- ❑ We do not have any affected product.
- ❑ We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please **add the UPN, Lot/Batch/Serial number and the quantity to return.***

TO RETURN PRODUCTS:
1. After receipt of the Verification Form, Boston Scientific will contact you to arrange return.
2. Prepare the package
3. Follow the instructions given by your Local Office about collection of the package

NAME* _____ Title _____

Telephone _____ Email _____

Customer' **SIGNATURE*** _____ **DATE*** _____
* Required field dd/mm/yyyy