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

<Reference: 97288477-FA> 12 September 2024

Urgent Field Safety Notice - Urgent Medical Device Recall Model L331 ACCOLADE™, L231 PROPONENT™, and L131 ESSENTIO™ DR EL pacemakers

Dear «Users_Name»,

Boston Scientific is retrieving specific Model L331 ACCOLADE™, L231 PROPONENT™, and L131 ESSENTIO™ DR EL pacemakers due to inadvertent re-use/duplication of certain model/serial number combinations. This duplication occurred during the manufacturing of devices built over the past month.

There are no performance concerns with these pacemakers, and they have passed all manufacturing tests. Additionally, there have been no reported adverse events or patient harms related to their use. However, Boston Scientific systems (i.e., business systems, medical records, complaint management, and the LATITUDE™ NXT Patient Management System) are dependent on unique pacemaker model/serial number combinations, so we are retrieving non-implanted inventory. Note, that if an affected device is implanted, there is a potential inability to enroll or activate an affected pacemaker on the LATITUDE NXT Remote Patient Management System.

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 and Serial numbers**. 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.

Material Description	Material #	GTIN	Serial #			
PG ESSENTIO MRI DR EL L131	60L131-209	00802526559013	700792	700879		
PG PROPONENT MRI DR EL L231	60L231-209	00802526559143	700771	700051	700102	700108
			700137	700138	700271	700986
PG PROPONENT MRI DR EL L231	60L231-707	00802526576423	700001	700259	700274	700286
			700293	700348	700492	700553
			700557	702113	702689	
PG ACCOLADE MRI DR EL L331	60L331-207	00802526559273	701120	701126		
PG ACCOLADE MRI DR EL L331	60L331-707	00802526576485	700039	700163	700200	700321
			700414	702939		

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- **If an affected product has been implanted, please notify your local Boston Scientific Sales Professional.**

3- Boston Scientific is not recommending routine prophylactic replacement of any affected device that may have been implanted.

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

5- **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.**

6- 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.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

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

Yours sincerely,

[redacted]

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
Model L331 ACCOLADE™, L231 PROPONENT™, and L131 ESSENTIO™ DR EL pacemakers
97288477-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 12 September 2024.

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°	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