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

<Reference: 92946782-FA> 3 October 2022

Urgent Field Safety Notice – Urgent Medical Device Recall
EMBLEM™ S-ICD Subcutaneous Implantable Defibrillators (S-ICDs) (Model A209 and A219)

SUBJECT: Field Safety Notice – Incorrect manufacturing date/timestamp for a subset of Model A209 and A219 EMBLEM™ S-ICDs. (Boston Scientific Field Action Reference: 92946782-FA).

Dear «Users_Name»;

Boston Scientific is retrieving approximately 150 Model A209 and A219 EMBLEM™ Subcutaneous Implantable Defibrillators (S-ICDs) worldwide because of an incorrect manufacturing date/timestamp within the software, which causes an inaccurate display of battery capacity. Our records indicate that your institution has affected inventory.

Description

- The device's manufacturing date/timestamp is used by the programmer and LATITUDE™ Patient Management system to calculate and display the battery capacity. The battery capacity value is intended to decrement in a linear manner over the device's implant life. For devices with an incorrect manufacturing date/timestamp, the initial battery capacity displayed after exiting storage mode is approximately 10%. The instructions for use (IFU) directs a user to check the device prior to implantation.
- If a low battery capacity value is not detected and implantation/setup is completed, the battery capacity displayed will be an expected value. Over the device's implant life, the displayed battery capacity value will decrement non-linearly and will be inaccurate. Because battery status indicators (e.g., elective replacement indicated-ERI and end of life-EOL) and battery alerts (e.g., Battery Depletion-BD alert) do not use the manufacturing date/timestamp, they are accurately displayed over the life of the device and unaffected by the incorrect manufacturing date/timestamp within the software. This displayed battery capacity behavior does not affect the device's performance (i.e., ability to detect/treat arrythmias) or the actual battery longevity.
- For those few patients who are implanted with an affected device, Boston Scientific will contact customers individually to provide follow-up recommendations.

Our records indicate that your facility has received some of the concerned product. **The table below (Attachment A) provides a list of all affected products**, including Material Number (UPN) and 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.

Retrieval Action
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.Immediately segregate all affected product (Appendix A) to ensure that it will not be used

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 **10 October 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 health 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.

Further Information
Boston Scientific strives to ensure the highest quality product for our patients and physicians. If you have any questions about this retrieval, please contact your local Boston Scientific representative.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance

Attachment: Verification Form

Appendix A - Affected EMBLEM S-ICDs to be retrieved for incorrect manufacturing date/timestamp

UPN	MODEL	SERIAL
00802526548406	A209	169276
00802526548406	A209	169297
00802526548406	A209	169509
00802526548406	A209	169645
00802526548406	A209	169671
00802526548406	A209	169774
00802526548406	A209	169876
00802526581519	A219	168979
00802526581519	A219	169203
00802526581519	A219	169206
00802526581519	A219	169267
00802526581519	A219	169271
00802526581519	A219	169307
00802526581519	A219	169312
00802526581519	A219	169314
00802526581519	A219	169340
00802526581519	A219	169342
00802526581519	A219	169350
00802526581519	A219	169351
00802526581519	A219	169353
00802526581519	A219	169356
00802526581519	A219	169371
00802526581519	A219	169373
00802526581519	A219	169384
00802526581519	A219	169396
00802526581519	A219	169402
00802526581519	A219	169404
00802526581519	A219	169407
00802526581519	A219	169409
00802526581519	A219	169413
00802526581519	A219	169421
00802526581519	A219	169428
00802526581519	A219	169435
00802526581519	A219	169441
00802526581519	A219	169442

UPN	MODEL	SERIAL
00802526581519	A219	169446
00802526581519	A219	169447
00802526581519	A219	169448
00802526581519	A219	169450
00802526581519	A219	169455
00802526581519	A219	169468
00802526581519	A219	169469
00802526581519	A219	169470
00802526581519	A219	169471
00802526581519	A219	169474
00802526581519	A219	169475
00802526581519	A219	169477
00802526581519	A219	169491
00802526581519	A219	169493
00802526581519	A219	169495
00802526581519	A219	169496
00802526581519	A219	169502
00802526581519	A219	169505
00802526581519	A219	169510
00802526581519	A219	169521
00802526581519	A219	169539
00802526581519	A219	169545
00802526581519	A219	169551
00802526581519	A219	169561
00802526581519	A219	169589
00802526581519	A219	169595
00802526581519	A219	169596
00802526581519	A219	169600
00802526581519	A219	169603
00802526581519	A219	169605
00802526581519	A219	169635
00802526581519	A219	169653
00802526581519	A219	169654
00802526581519	A219	169674
00802526581519	A219	169731

«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
EMBLEM™ S-ICD Subcutaneous Implantable Defibrillators (S-ICDs) (Model A209 & A219)
92946782-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 3 October 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

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

4. **TICK ONE OF THESE STATEMENTS*, SIGN THIS FORM**

- ❑ 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.***

5- When completed, please return the Verification Form to your local Boston Scientific office for the attention of «Customer_Service_Fax_Number» on or before **10 October 2022**.

TO RETURN PRODUCTS:
1. Contact «Customer_Service_Tel» of your Local Office to arrange return of any affected product
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/y