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<References: 92400926D ; 92384167 & 92628736-FA> December 2020

Urgent Field Safety Notice - Cover letter for
EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Models A209 and A219)
EMBLEM™ S-ICD Subcutaneous Electrode (Model 3501)

Subject: **Important Medical Device Advisory** Update to August 2019 Advisory

Dear Healthcare Professional,

Please find below:
- Acknowledgement Form and,
- 3 Field Safety Notices being issued by Boston Scientific.

Instructions:
1. Please read carefully the 3 Field Safety Notices attached.
2. Then, complete and sign the enclosed Acknowledgement Form. Return the form to Boston Scientific at «Customer_Service_Fax_Number» by **24 December 2020.** It is mandatory for each customer to return this form to Boston Scientific.

Should you have any queries or require further assistance regarding this matter, please contact your local Sales Representative.
Yours sincerely,

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

December 2020

Dear Healthcare Professional,

More than a decade ago Boston Scientific introduced an entirely subcutaneous implantable cardioverter defibrillator (S-ICD) and since then nearly 90,000 patients worldwide have been recipients of this therapy. The S-ICD now has class I, IIa, and IIb recommendations for sudden cardiac death prevention in contemporary societal guidelines.[1,2] Its safety and efficacy in comparison to other transvenous defibrillation therapies has been rigorously studied.[3]

Boston Scientific is committed to vigilant monitoring of the performance of all our therapies, including the S-ICD. Our quality system allows us to maintain a clear picture of how our devices are performing, whether performance differs from expectation, and to identify opportunities for improvement. The system allows us to monitor multiple sources of information about our devices, including component suppliers, testing, manufacturing and field performance.

Product advisories (i.e., Field Safety Notices in some countries) are one way in which we communicate outcomes from our quality monitoring system. It is our practice to initiate product advisories (i.e., Field Safety Notices) whenever we can provide meaningful recommendations or guidance to improve patient outcomes or device performance, or when there is a material elevation in risk to patient safety with the potential for compromised lifesaving therapy. Beyond these criteria, Boston Scientific considers many perspectives in the decision to initiate a communication, including feedback from healthcare professionals like you. We also solicit guidance from an independent, external Patient Safety Advisory Board, a globally representative, safety-specific physician and patient panel with deep expertise in the management and patient experience of cardiac implantable electronic devices. Further, we believe timely communication of information that may reduce patient risk is critical.

Recently, three separate and unrelated EMBLEM™ S-ICD System behaviors have been identified in which our standards prompt us to communicate to you. There are recommendations and guidance associated with each of these that will increase safety in patients who could be affected.

Although not all your patients with a S-ICD will be affected by any or all of these behaviors, we believe that simultaneous communication (i.e., Field Safety Notices) of these will facilitate more efficient discussion and decision making on a patient-specific basis. This packet contains three separate letters (i.e., Field Safety Notices):

It is important to note that some patients may be impacted by more than one of these FSNs, therefore please read each one carefully in order to take the most appropriate clinical decisions and actions for your patients. A small number of patients may be exposed to the risks described by all three FSNs, and although the recommendations are similar, there are specific considerations for each behavior.

1. EMBLEM S-ICD Models A209 and A219 (subset) – Elevated likelihood for early replacement due to accelerated battery depletion.

[1] Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. *Heart Rhythm* 2017. doi: 10.1016/j.hrthm.2017.10.036.
[2] The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. *European Heart Journal* 2015;36, 2793–2867 doi:10.1093/eurheartj/ehv316.
[3] Knops RE, Olde Nordkamp LRA, et al. Subcutaneous of Transvenous Defibrillator Therapy. N Engl J Med 2020;383:526-36. doi: 10.1056/NEJMoa1915932

2. EMBLEM S-ICD Models A209 and A219 (subset) – Potential for electrical overstress during delivery of high voltage therapy.
3. EMBLEM S-ICD Subcutaneous Electrode Model 3501 – Potential for electrode body fracture at a location distal to the proximal sense ring.

The individual letters (i.e., Field Safety Notices) explain these topics in detail and provide specific recommendations that can reduce the potential for patient harm, allowing you to tailor management to individual patients.

The contemporary S-ICD devices described in these letters (i.e., Field Safety Notices) have been the subject of extensive clinical evaluation demonstrating high efficacy and safety[4] and clinical studies continue in the ongoing assessment of the long-term safety and efficacy of the S-ICD platform. It is important to note that the 3501 S-ICD lead continues to perform as intended and within the established risk levels. Consideration of the vulnerability for the 3501 S-ICD lead described in the associated FSN, should be a part of overall clinical decision-making for all S-ICD implantations, according to current guidelines.

Boston Scientific remains committed to the continual improvement of this important therapy in the interest of patient benefit, and patient safety remains our priority and our constant focus. Although we recognize the impact this information may have on both you and your patients, we believe transparent communication with physicians will ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or technical services.

Please continue to report all complaints related to these behaviours in accordance with all applicable local regulations and to Boston Scientific.

Alexandra Naughton Vice President, Quality Assurance	Kenneth Stein, MD, FACC, FHRS Senior Vice President and Chief Medical Officer, RM	Olaf Hedrich, MD, FACC, FHRS Vice President, Medical Safety, RM

[4] Gold MR, Lambiase PD, El-Chami MF, et al. Primary Results from the Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED) Trial. 10.1161/CIRCULATIONAHA.120.048728.

Please complete the form & Send it to:
«Customer_Service_Fax_Number»

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Acknowledgement Form – Product Advisories

EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Models A209 and A219)
EMBLEM™ S-ICD Subcutaneous Electrode (Model 3501)

92400926D , 92384167 & 92628736-FAs

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notices

dated December 2020 for the

EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Models A209 and A219)
EMBLEM™ S-ICD Subcutaneous Electrode (Model 3501)

NAME* _____ Title _____

Telephone _____ Department _____

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

Urgent Field Safety Notice

December 2020

Subject: **Important Medical Device Advisory** Update to August 2019 Advisory – A total subset of approximately 38,350 active EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Models A209 and A219) with an elevated likelihood for early replacement (Boston Scientific Field Action Reference: 92400926D-FA)

Summary

- Boston Scientific is expanding an August 2019 advisory device population to a total of approximately 38,350 active EMBLEM S-ICDs (Models A209 and A219) with an elevated likelihood of a low voltage capacitor causing accelerated battery depletion.
  - This depletion behavior can be detected by observing an unexpected decrease in Remaining Battery Life to ERI or an earlier than expected ERI/EOL[1] battery status.
  - The appearance of the unexpected decrease is associated with the battery management algorithm, not rapid depletion. Analysis of returned devices indicates that at least three months of battery capacity remain before the battery reaches a depleted state.
- Recommendations to manage this behavior are included within this letter.
- The most common outcome of this malfunction is earlier than expected S-ICD replacement. There have been no reported deaths associated with this behavior.
- In August 2018, Boston Scientific transitioned S-ICDs to an alternative low voltage capacitor. EMBLEM S-ICDs built with this low voltage capacitor have not exhibited this depletion behavior.
- All EMBLEM S-ICDs with the original low voltage capacitor are included in either the original or the expanded advisory population and none are available for implantation.
- Boston Scientific is actively developing a software enhancement intended to detect and provide healthcare professionals an alert to this depletion behavior.
- To determine if a device is included in this or any other advisory, enter the model/serial number at www.BostonScientific.com/lookup.

[1]As an S-ICD's battery capacity approaches depletion, the battery monitoring algorithm indicates that it's time to replace the S-ICD through the Elective Replacement Indicator (ERI) and subsequently alerts that the battery is approaching End Of Life (EOL).

Dear Physician or Healthcare Professional,

This letter provides important information about the expansion of the August 2019 EMBLEM™ Subcutaneous Implantable Defibrillators (S-ICDs) (Models A209 and A219) advisory population to a total of approximately 38,350 active S-ICDs. These S-ICDs are demonstrating an elevated likelihood for early replacement associated with compromised electrical performance of a low voltage capacitor causing premature battery depletion. Recommendations to manage this potential battery depletion behavior are included below.

You are receiving this letter because you may be following one or more patients with an EMBLEM S-ICD built with an original low voltage capacitor. There are no affected devices still available for implantation. The EMBLEM S-ICDs currently being distributed (since August 2018) include a different low voltage capacitor, which has not exhibited this depletion behavior. Please distribute this letter to all other physicians and healthcare professionals within your organization who need to be aware of this topic.

Description

The EMBLEM S-ICD includes low voltage capacitors designed to support the system's power supply. Boston Scientific has determined that latent release of small amounts of hydrogen within the S-ICD may, in some devices, cause the function of the low voltage capacitor to become electrically compromised over time, which results in accelerated depletion of the battery. The susceptibility of an S-ICD to this hydrogen-induced accelerated battery depletion mechanism is dependent upon the amount of hydrogen accumulation within the S-ICD and the susceptibility of the low voltage capacitor to hydrogen.

In EMBLEM S-ICDs, battery capacity is determined with a two-phase battery monitoring algorithm. At the beginning of battery life, the algorithm determines battery capacity using both implant time and charging cycles and then transitions to using solely the battery's voltage to determine capacity later in life. Since the algorithm's early-life inputs are independent of battery voltage, the estimated percentage of Remaining Battery Life to ERI will decrease at the same rate whether the battery is depleting normally or in an accelerated fashion.

When the battery reaches the level at which the battery monitoring algorithm transitions to determining capacity solely using voltage, a device experiencing accelerated depleting battery will exhibit a relatively large, unexpected decrease in Remaining Battery Life to ERI (e.g., between follow-ups, an unexpected decrease from 60% at the preceding check to 18% at the check 3 months later). This unexpected decrease is a phenomenon of the S-ICD's battery monitoring algorithm response to accelerated battery depletion and the shift to solely using battery voltage later in life.

Boston Scientific's ongoing manufacturing continuity program identified an opportunity to strengthen the low voltage capacitor supply chain and developed an alternative, functionally equivalent source of low voltage capacitors. The full transition of this currently used low voltage capacitor in the EMBLEM S-ICD occurred in August 2018 and precedes the formal investigation of this malfunction pattern.

Since the original August 2019 advisory communication, the number of non-advisory hydrogen-induced accelerated battery depletion malfunctions has increased significantly. These malfunctions are all associated with devices built using the original low voltage capacitor. Boston Scientific is therefore expanding the advisory population to include all EMBLEM S-ICDs built with original low voltage capacitors.

Clinical Impact

There have been no serious injuries or deaths reported beyond early device replacement. The median implanted age range of devices with confirmed hydrogen-induced accelerated battery depletion events is approximately 41 months with a range of 3 to 60 months. Using save-to-disk or LATITUDE™ data, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device. Based on an analysis of returned devices exhibiting this depletion behavior, projections indicate that at least 21 days of therapy is available after the battery status indicates ERI, independent of subsequent EOL initiation.

Table 1 identifies the projected rate of occurrence for hydrogen-induced accelerated battery depletion in each EMBLEM S-ICD (Model A209 and A219) advisory subset. The potential for life-threatening harm is determined based on the projected occurrence rate, likelihood the battery reaches a depleted state and is unable to provide therapy between follow-ups, and a subsequent untreated ventricular arrhythmia leads to death.

Advisory Population	Approximate Active Implanted Population Size	Projected Occurrence Rate at 5 years	Potential for Life-Threatening Harm at 5 years
August 2019	350	15.1%	1 in 50,000 (0.002%)
December 2020	38,000	3.7%	1 in 250,000 (0.0004%)

Table 1. Statistics of EMBLEM S-ICD (Model A209 and A219) advisory populations for hydrogen-induced accelerated battery depletion.

To date, there have been zero confirmed malfunctions reported for this depletion behavior in EMBLEM S-ICD devices manufactured with the currently used low voltage capacitors, which have been available for distribution since August 2018.

Recommendations

1. Remote monitoring. Enroll and monitor patients through the LATITUDE NXT Patient Management System to facilitate prompt detection of accelerated depletion or alert conditions such as ERI or EOL during the interval between in-office device checks. Instruct patients to comply with weekly remote checks and interrogations.

2. Follow-up interval. Perform a system follow-up every 3 months per labeling via remote or in-office interrogation.

3. During follow-ups. Promptly investigate any suspected indication of accelerated battery depletion, and contact Boston Scientific Technical Services for assistance as needed.

4. Demonstrate beeping tones. During the next in-office follow-up visit, demonstrate the device beeper to the patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu.

    - For patients not monitored by LATITUDE, repeat the beeper demonstration following any MRI scan as strong magnetic fields may cause permanent loss of beeper volume; and
    - Remind patients to promptly contact their physician if beeping tones are heard from their device as this may be an indication of ERI and/or EOL.

5. Evaluate risk. The potential for life-threatening harm due to accelerated depletion is greatest for:
    - Patients with a history of life-threatening ventricular arrhythmias such as secondary prevention indication or previous appropriate shock for VT/VF[1];
    - Patients who are unable to be reliably followed remotely or in person every 3 months; or
    - Patients who are not monitored via LATITUDE and are unable to hear beeping tones.

6. Replacement. Replace any affected EMBLEM S-ICD suspected of exhibiting accelerated battery depletion within 21 days of ERI. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE.

[1] VT: Ventricular Tachycardia; VF: Ventricular Fibrillation

- In other cases of high risk, as indicated by the factors listed above, consider prophylactic device replacement after taking individual patient preferences and circumstances into account through a process of shared decision-making.
- Return explanted devices to Boston Scientific. A no cost Return Product kit is available from your local Boston Scientific representative.

7. Records. For each patient with an affected EMBLEM S-ICD, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

Adverse reactions or quality problems experienced with the use of this device may be reported in accordance with all applicable local regulations and to Boston Scientific.

Please complete the attached acknowledgement form. It is mandatory for each customer to return this form to Boston Scientific. When completed, please return the Form to «Customer_Service_Fax_Number» by **24 December 2020**.

Affected Devices

A subset of devices manufactured before August 2018 with the original low voltage capacitor.

Model	GTIN
A209	00802526575181; 00802526575143; 00802526544101; 00802526575129; 00802526548406; 00802526575211; 00802526575136; 00802526575105; 00802526575204; 00802526575112; 00802526575167; 00802526575228; 00802526599002; 00802526575174; 00802526577147
A219	00802526581519; 00802526584404; 00802526584411; 00802526590436; 00802526590429; 00802526590405

Additional Information

We will be submitting an enhancement to EMBLEM S-ICD's Battery Depletion Alert to detect this behavior earlier. Up-to-date product performance information, including this topic, and a device lookup tool is available within our Product Performance Resource Center at www.bostonscientific.com/ppr. Patient safety remains our highest priority. Although we recognize the impact of communications on both you and your patients, we are committed to transparent communication with our physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance

Urgent Field Safety Notice

December 2020

Subject: **Important Medical Device Advisory** - EMBLEM™ S-ICD Subcutaneous Electrode (Model 3501) with a potential for electrode body fracture (Boston Scientific Field Action Reference: 92384167-FA).

Summary

- Approximately 47,000 EMBLEM S-ICD[1] Subcutaneous Electrodes (Model 3501) have been distributed worldwide since 2017 with an overall survival probability of 99.4% at 33 months[2].
- Boston Scientific has received 27 reports of electrode body fractures at a location just distal to the proximal sense ring.
- During onset of an electrode body fracture, some cases report oversensing non-physiologic artifacts in stored episodes and inappropriate shock therapy (IAS) in select programmed sense configurations.
- If the high voltage conductors fracture, an electrode will be unable to deliver defibrillation therapy and a high impedance alert will be initiated via programmer, LATITUDE™, and/or beeping tones.
- The cumulative occurrence rate for this specific electrode body fracture location is 0.2% at 41 months with a potential for life-threatening harm of 1 in 25,000 (0.004%) at 10 years. There has been a single reported patient death related to this behavior.
- Recommendations provided in this letter are intended to assist healthcare professionals in prompt identification of a potential electrode body fracture, as well as in evaluating the competing risks of alternative treatments of sudden cardiac death (SCD).
- The incremental risk of an electrode failure due to the behavior described in this advisory should be viewed within the context of established transvenous (TV) ICD lead complications/risk of failure documented broadly in the literature and specifically in head-to-head studies of S-ICD *vs*. TV-ICD outcomes (refer to the Appendix for additional details). For this reason, the EMBLEM S-ICD Subcutaneous Electrode (Model 3501) continues to be available to support those patients who will benefit from this therapy for treatment of SCD.

[1]Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)
[2]Boston Scientific Q4 2020 Product Performance Report (PPR) available online at www.BostonScientific.com/ppr.

Dear Healthcare Professional,

This letter provides important information about the performance of approximately 47,000 EMBLEM S-ICD Subcutaneous Electrodes (Model 3501) and includes recommendations for managing patients with chronically implanted systems and new S-ICD candidates. You are receiving this letter because one or more patients with an implanted electrode may be under your care. Please distribute this letter to all other physicians and healthcare professionals within your organization who need to be aware of this topic.

Description
During assembly of the EMBLEM S-ICD Subcutaneous Electrode, a small amount of adhesive is applied to a location just distal to the proximal sense ring. Over time, mechanical stresses on the electrode body at this location may create the potential for a fatigue crack to initiate from the outer lumen. This crack then propagates inward toward the center-oriented distal sense conductor, eventually resulting in a fracture of the two high voltage conductors. To date, Boston Scientific has received 27 reports of electrode body fractures at this location; refer to Figure 1 for an image of the S-ICD system *in vivo*, note the potential fracture location with respect to the programmable sensing configurations (i.e., Primary, Secondary or Alternate).

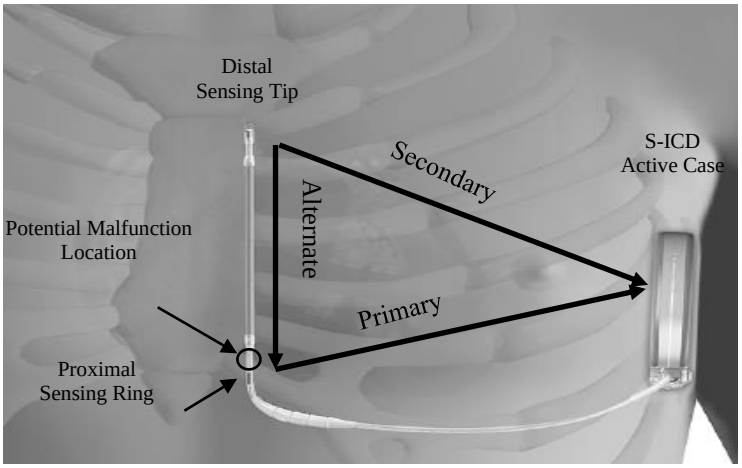

Figure 1. S-ICD System *in vivo* depicting programmable sensing configurations and the potential malfunction location.

Detectability
Manifestation of this fracture can be detected in two ways: non-physiologic mechanical artifacts and/or the presence of a high impedance alert condition. The method of detection, as well as timing of detection, are dependent on programmed sensing configuration and progression of conductor fractures. A distal sense conductor fracture may be detected via non-physiologic, mechanical artifact precursors (see Figure 2) stored in episode electrograms (S-ECGs) within systems programmed to Secondary or Alternate sensing configurations. These precursor artifact signals may also result in an inappropriate shock. S-ICD systems programmed to an Alternate or Secondary sense configuration have exhibited precursor artifact signals as-early-as two months before the fatigue crack propagates to the high voltage conductors. If both high voltage conductors fracture, shock therapy will be unavailable.

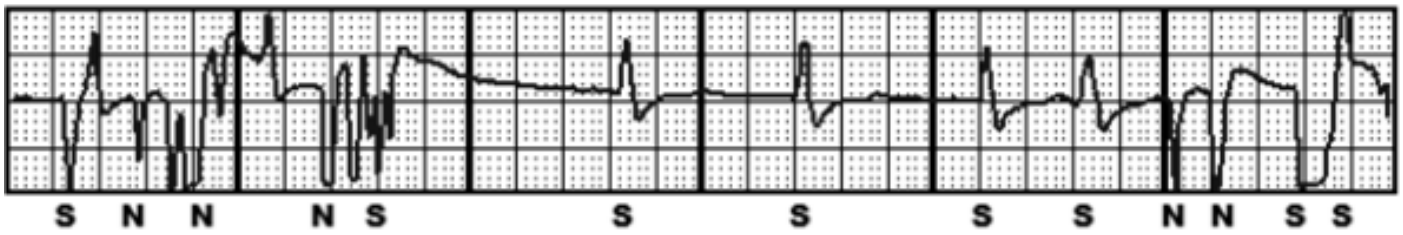

Figure 2. Example of non-physiologic, mechanical artifact; precursor artifact signals span one or both amplitude limits of the S-ECG.

For systems programmed in Primary sensing configuration, these precursor artifact signals are not encountered because the fracture initiates just distal to the proximal sensing ring. As a result, inappropriate shocks (IAS) will not be observed in Primary. In Primary sensing configuration, the first indication of an electrode fracture in the described location is the detection of a high impedance condition (i.e., alert with beeping tones). Based on the automated weekly integrity test's algorithm, the alert condition occurs no later than eight days after both high voltage conductors fracture. This may occur sooner following an ambulatory shock post conductor fracture. If a fracture is suspected, radiographic imaging can aid in assessment of electrode integrity. Refer to Table 1 for a summary of the detection mechanisms based on sensing configuration.

Sensing Configuration	Sensing Vector	Fractured Conductor	Effect of Electrode Body Fracture at a Location Just Distal to Proximal Sense Ring
Primary	Proximal Sense Ring > S-ICD Active Case	Distal Sense	No precursors
		Distal Sense and High Voltage	High impedance alert with audible beeping tones.
Secondary	Distal Sense Electrode > S-ICD Active Case	Distal Sense	Precursors: 1) observation of non-physiologic, mechanical artifacts in stored event S-ECGs, and 2) cardiac signals appear similar to the Primary vector.
		Distal Sense and High Voltage	Precursors and high impedance alert with audible beeping tones.
Alternate	Proximal Ring > Distal Sense Electrode	Distal Sense	Precursors: 1) observation of non-physiologic, mechanical artifacts in stored event S-ECGs, and 2) cardiac signals appear flatlined or near flatlined.
		Distal Sense and High Voltage	Precursors and high impedance alert with audible beeping tones.

Table 1. Detection mechanisms based on sensing configuration.

Clinical Impact

The occurrence rate for EMBLEM S-ICD Subcutaneous Electrode (Model 3501) body fractures at a location just distal to the proximal sense ring is 0.2% at 41 months and the potential for life-threatening harm is 1 in 25,000 (0.004%) at 10 years. To date, there have been 27 reported electrode body fractures at this location; the earliest indication of fracture presented at a median age of 9 months (range 2 to 33 months).

One report of death has been received involving a U.S. patient whose electrode experienced a fracture in this location. In this case, a high impedance alert was reported 12 months after implant. Detailed review of S-ECGs identified non-physiologic artifacts during an atrial fibrillation episode three months prior to the high impedance alert. X-ray imaging confirmed an electrode body fracture just distal to the proximal sense ring. Electrode replacement was recommended but ultimately not performed. The S-ICD and electrode were not returned for analysis; therefore, electrode malfunction cannot be ruled out as a contributing factor.

Recommendations

1- Remote monitoring**.** Enroll and monitor patients through LATITUDE remote monitoring to facilitate detection of high electrode impedance alert or non-physiologic, mechanical artifacts on stored S-ECGs during the interval between in-office device checks. Instruct patients to comply with weekly remote interrogations.

2- Follow-up interval. Perform a system follow-up every three months via remote or in-office interrogation.

3- During follow-ups**.** For every remote or in-office follow-up:
   - Promptly investigate any high impedance alerts in-clinic, as this may indicate an electrode body fracture and an inability of the system to provide therapy.
   - Review stored episode S-ECGs for non-physiologic, mechanical artifacts, as this may indicate onset of electrode body fracture.
   - During in-clinic follow-up, capture all sensing vectors, and review for the following conditions, any of which may indicate onset of electrode body fracture:
     - cardiac signals on the S-ECGs of the Primary and Secondary sensing vector look nearly identical; or
     - flatline S-ECGs in the Alternate sensing vector.
   - Assess sensing performance in-clinic during isometrics and/or posture changes if any of the following is observed: non-physiologic, mechanical artifacts and/or high electrode impedance alerts. If isometrics and/or posture changes provoke non-physiologic, mechanical artifacts, this may indicate onset of an electrode body fracture.

4- Imaging**.** If an electrode body fracture is suspected, perform chest radiography in PA and left lateral view projections, ensuring the entire electrode length can be visualized to enable differential diagnosis of competing causes of high impedance or artifact signals. Portable X-ray images typically provide insufficient clarity to evaluate electrode integrity. In the absence of any indications of electrode fracture, surveillance X-rays are not recommended.

5- Shocks and beeping tones. During the next in-office follow-up visit, demonstrate the device beeper to the patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu.
   - For patients not monitored by LATITUDE, repeat the beeper demonstration following any MRI scan, as strong magnetic fields may cause permanent loss of beeper volume; and
   - Remind all patients to promptly contact their physician if beeping tones are heard from their device or if a shock is delivered.

6- Evaluate risk. The potential for life-threatening harm due to an electrode body fracture is greatest for:
   - patients with a history of life-threatening ventricular arrhythmias such as secondary prevention indication or previous appropriate shock for VT/VF;
   - patients who are unable to be reliably followed remotely or in person every three months; or
   - patients who are not monitored via LATITUDE and are unable to hear beeping tones.

7- Replacement. Following consultation with Boston Scientific Technical Services, promptly replace any electrode that is indicated to have compromised integrity as evidenced by non-physiologic, mechanical artifacts, high impedance alert, and/or X-ray. Routine prophylactic replacement of an electrode without evidence of fracture is not recommended. Return explanted devices to Boston Scientific.

8- De novo and replacement S-ICD candidates. Consider overall S-ICD performance with respect to the competing risks for transvenous ICDs. The Product Performance Report[1] includes up-to-date performance data on Boston Scientific transvenous leads and subcutaneous electrodes.

9- Records. For each patient with an EMBLEM S-ICD Subcutaneous Electrode (Model 3501), append their medical record with this letter to maintain awareness of this topic for the remaining service life of the electrode.

Boston Scientific Technical Services is available to assist with troubleshooting system integrity. Adverse reactions or quality problems experienced with the use of this product may be reported in accordance with all applicable local regulations and to Boston Scientific.

[1]Available online at www.BostonScientific.com/ppr

Please complete the attached acknowledgement form. It is mandatory for each customer to return this form to Boston Scientific. When completed, please return the Form to «Customer_Service_Fax_Number» by **24 December 2020**.

Affected Devices

Model	GTIN
3501	00802526597305; 00802526599200; 00802526599101; 00802526586804; 00802526603105; 00802526603402

Additional Information

Up-to-date product performance information, including this topic, and a device lookup tool is available within our Product Performance Resource Center at www.bostonscientific.com/ppr. Patient safety remains our highest priority. Although we recognize the impact of communications on both you and your patients, we are committed to transparently providing timely, relevant information to you. If you have additional questions or would like to report a clinical event, please contact your Boston Scientific representative or our Technical Services team.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance

APPENDIX

According to the 2017 HRS Expert Consensus on Lead Management and Extraction,[1] the expected target annual failure rate for ICD leads should be ≤ 0.4%. This rate is based on data comprising several available (transvenous) leads with robust 5 to 10-year follow-up data. There are not currently published target rates for the S-ICD electrode's performance. However, the annual failure rate for current Model 3501 S-ICD Electrode is 0.22% according to Boston Scientific's Post Market Quality System. Note that this is below the rate referenced as the standard for TV-ICD leads. The incremental risk of an electrode failure due to the behavior described in this advisory should be viewed within the context of established transvenous TV-ICD lead complications/risk of failure documented broadly in published literature and specifically in head-to-head studies of S-ICD *vs*. TV-ICD outcomes.

TV Lead and Subcutaneous Electrode[2] Products		**Annualized Rate**
All TV lead failure rate expectation[3]		≤0.40%
Model 3501	Electrode complications/ malfunctions (inclusive of fractures)	0.22%
	Electrode fracture rate distal to proximal sense (exclusive of other complications/malfunctions)	0.07%
Model 3010 and 3401 electrode complications and malfunctions		0.19%

[1]Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berul CI, Birgersdotter-Green UM, Carrillo R, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Hear Rhythm [Internet]. 2017;14(12):e503–51. Available from: https://doi.org/10.1016/j.hrthm.2017.09.001

[2]Model 3501 includes 33-month follow-up data; Model 3010 and 3401 include 96-month follow-up data based on data cited within Boston Scientific's Product Performance Report Q4 2020; available online at www.BostonScientific.com/ppr

[3]Ibib – 2017 HRS expert consensus

Urgent Field Safety Notice

December 2020

Subject: **Important Medical Device Advisory** – a subset of approximately 3,350 EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Model A209 and A219) with a potential for electrical overstress during delivery of high voltage therapy (Boston Scientific Field Action Reference: 92628736-FA).

Summary

- Boston Scientific has confirmed six (6) events of electrical overstress following delivery of high voltage therapy in EMBLEM S-ICDs (Model A209 and A219).
- Over time, due to variations in header assembly, a very small pathway may develop that allows moisture ingress, enabling a shorting condition to occur during delivery of high voltage therapy.
- The most common clinical outcome associated with this malfunction is early device replacement. There have been no serious injuries reported.
- Between May 2015 and December 2017, a subset of approximately 3,350 EMBLEM S-ICDs were manufactured with variations in the header assembly.
- No affected S-ICDs remain available for implant.
- Recommendations to manage this behavior are included within this letter.
- Enclosed is a list of affected EMBLEM S-ICDs associated with your patients. To determine if a device is included in this or any other advisory, enter the model/serial number at www.BostonScientific.com/lookup.

Dear Physician or Healthcare Professional,

Boston Scientific is informing you about the potential for a specific subset of approximately 3,350 EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Model A209 and A219) to experience a malfunction during high voltage therapy delivery, necessitating device replacement due to electrical overstress. You are receiving this letter because you may be following one or more patients with an affected EMBLEM S-ICD that is included within this identified subset. No affected S-ICDs remain available for implant. This letter provides important information about the detection and management of this potential device malfunction. Please distribute this letter to all other physicians and healthcare professionals within your organization who need to be aware of this topic.

Description

Boston Scientific has confirmed six (6) events of EMBLEM S-ICD electrical overstress malfunctions that have occurred in association with delivery of high voltage therapy. These events manifested clinically by the subsequent inability to interrogate the device or by display of device-based errors/alerts. Boston Scientific Technical Services recommended device replacement in each instance, and no serious patient injury or death has been reported.

Laboratory analysis of the returned devices confirmed evidence of electrical overstress damage in the device feedthrough area. Investigation has shown that, over time, variations in header assembly allowed a very small pathway for moisture ingress enabling a shorting condition to occur during delivery of high voltage therapy. Each of the devices exhibiting electrical overstress were built within a specific timeframe (between May 2015 through December 2017); a header assembly subprocess was found to be subject to process variations directly contributing to this behavior. There is no available method to detect whether an individual device is vulnerable to this condition prior to its occurrence. It is important to note that not all S-ICDs built during this timeframe were exposed to these process variations.

Clinical Impact

The projected occurrence rate for this electrical overstress behavior is 0.3% at 5 years, and the most common clinical outcome is early device replacement. Although there have been no serious injuries reported to date, the potential exists for life-threatening harm due to an inability to provide defibrillation therapy. We estimate that the probability of the hypothetical worst-case harm associated with loss of ambulatory ventricular tachycardia/ventricular fibrillation therapy resulting in death is 0.09% at 5 years. An occurrence of electrical overstress malfunction can be identified by the inability to perform a device interrogation (in-clinic or remotely via LATITUDE) or by device-based errors/alerts. Of the six confirmed events resulting in early replacement, four were reported as inability to interrogate, one displayed prolonged charge time alerts, and one exhibited premature battery depletion. Boston Scientific Technical Services was consulted for troubleshooting guidance and recommended prompt device replacement in each case.

Recommendations

- Follow-up interval. In the next 6 weeks, discuss this advisory with your patient to ensure awareness, to review their individual clinical status and perspective, and to determine their individual risk status. Perform a system follow-up every 3 months per labeling thereafter via remote or in-office interrogation.

- Remote monitoring. Enroll and monitor patients through the LATITUDE NXT Remote Patient Management System to facilitate prompt detection of accelerated battery depletion or device-related alert conditions during the interval between in-office device checks. Instruct patients to comply with weekly remote checks and interrogations, as well as to inform their clinic if they are unsuccessful in interrogating their device.

- During follow-ups. Promptly investigate any suspected indication of inability to interrogate, premature battery depletion, or prolonged charge time alerts. Contact Boston Scientific Technical Services for assistance as needed.

- Shocks, beeping tones, and counseling. During the next in-office follow-up visit, demonstrate the device beeper to the patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu.
  - For patients not monitored by LATITUDE, repeat the beeper demonstration following any MRI scan, as strong magnetic fields may cause permanent loss of beeper volume; and
  - Remind patients to promptly contact their physician if beeping tones are heard from their device, if a shock is delivered, or if any LATITUDE communicator transmissions are unsuccessful.
  - Reinforce that your patient should promptly report any new or unexpected symptoms suspicious for a ventricular tachyarrhythmia by contacting their clinic and, if applicable, perform a remote interrogation via LATITUDE.

- Evaluate risk. The potential for life-threatening harm due to this device malfunction is greatest for:
  - Patients with a history of life-threatening ventricular arrhythmias such as secondary prevention indication or previous appropriate shock for ventricular tachycardia/ventricular fibrillation;
  - Patients who are unable to be reliably followed remotely or in person every three months; or
  - Patients who are not monitored via LATITUDE and are unable to hear beeping tones.

- Replacement. Promptly replace any affected EMBLEM S-ICD suspected of exhibiting electrical overstress.
  - Boston Scientific does not recommend routine prophylactic device replacement.
  - In cases of high risk (as indicated by the factors listed above) or other relevant considerations, consider prophylactic device replacement after taking individual patient preferences and circumstances into account through a process of shared decision-making.
  - Return explanted devices to Boston Scientific. A no cost Return Product kit is available from your local Boston Scientific representative.

- Records. For each patient with an affected EMBLEM S-ICD, append their medical record with a copy of this letter to maintain awareness of this topic for the remaining service life of the device.

Any adverse events or quality problems experienced with use of this product should be reported in accordance with all applicable local regulations and to Boston Scientific.

Please complete the attached acknowledgement form. It is mandatory for each customer to return this form to Boston Scientific. When completed, please return the Form to «Customer_Service_Fax_Number» by **24 December 2020**.

Affected Devices

A subset of devices manufactured between May 2015 and December 2017.

Model	GTIN
A209	00802526575181; 00802526575143; 00802526544101; 00802526575129; 00802526548406; 00802526575211; 00802526575136; 00802526575105; 00802526575204; 00802526575112; 00802526575167; 00802526575228; 00802526599002; 00802526575174; 00802526577147
A219	00802526581519; 00802526584404; 00802526584411; 00802526590436; 00802526590429; 00802526590405

Additional Information

Patient safety remains Boston Scientific's highest priority. As such, we are committed to transparent communication with our physician customers to ensure you have timely, relevant information for managing your patients. Boston Scientific will publish detailed, up-to-date product performance information for this topic within our Product Performance Report at www.BostonScientific.com. If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance