المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication رسالة سلامة

Potential for Electrode Body Fracture

Device/ Product Description:	EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (Model 3501)	
Manufacturer:	Boston Scientific Cardiac	
Problem Summary:	Mechanical stresses on the electrode body (at a location just distal to the proximal sense ring) may create the potential for a fatigue, eventually resulting in a fracture of the two high voltage conductors. Occurrence of this issue could lead to life-threatening harm if not detected and the required action performed. For more information, please check Below… If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center	
	AR name:	FAROUK, MAAMOUN TAMER & COMPANY
	Assigned Contact Person:	Rayyan AlMohareb
	Mobile/Phone:	+(966) 509971110
	Email:	regulatory@tamergroup.com

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).

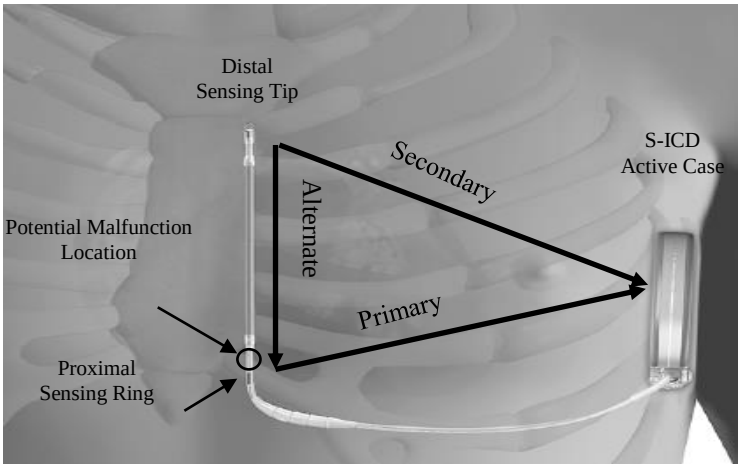

Figure 1. S-ICD System *in vivo* depicting programmable sensing configurations and the potential malfunction location.

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.

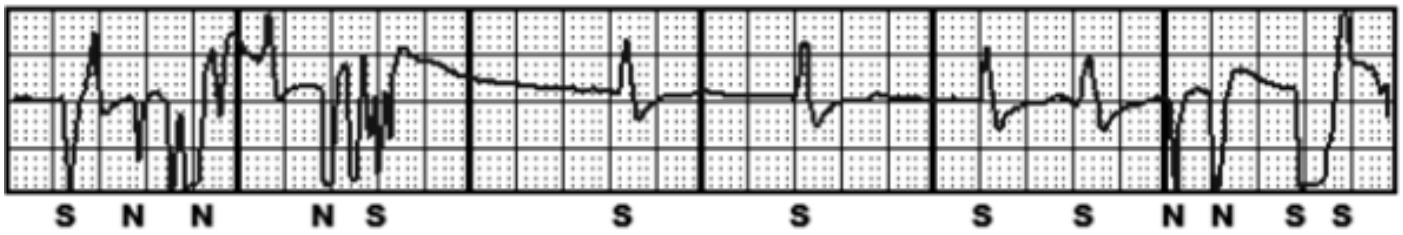

Figure 2. Example of non-physiologic, mechanical artifact; precursor artifact signals span one or both amplitude limits of the S-ECG.

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.

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

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.

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,

[redacted]

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