ANZCDACC Advisory Notice 6th December 2020

Device:
EMBLEM™ S-ICD Subcutaneous Electrode (Model 3501) current model S-ICD lead/electrode

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Semi-urgent

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. 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).

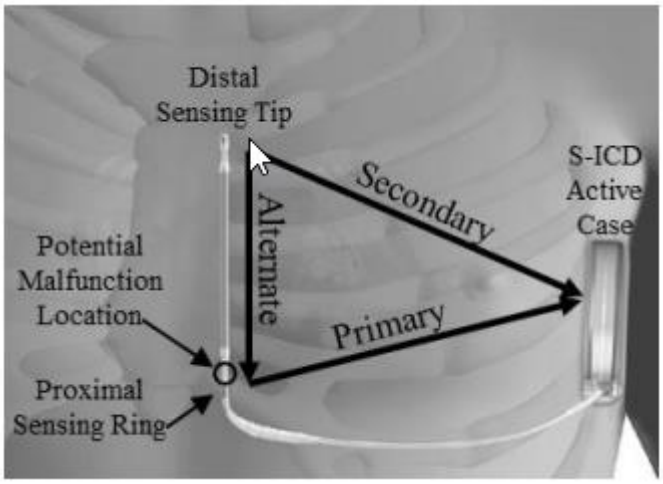

Fig. 1. S-ICD System in vivo depicting programmable sensing configurations and the potential malfunction location.

Number of devices affected in Australia and New Zealand:
Australia: and New Zealand: 676

Presentation:
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.

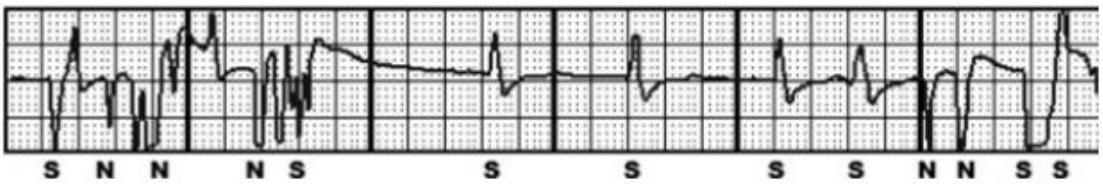

Fig. 2. Example of non-physiologic, mechanical artefact; precursor artefact signals span one or both amplitude limits of the S-ICD.

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.

Table 1. Detection mechanisms based on sensing configuration.

Sensing configuration	Sensing Vector	Fractured conductor Distal Sense (DS) High Voltage (HV)	Effect of Electrode body fracture at a Location Just Distal to Proximal Sense Ring
Primary	Proximal Sense Ring to S-ICD Can	DS	No precursors
		DS and HV	High impedance alert with audible beeping tones.
Secondary	Distal Sense Electrode to SICD Can	DS	Precursors: 1) observation of nonphysiologic, mechanical artifacts in stored event S-ECGs, and 2) cardiac signals appear similar to the Primary vector.
		DS and HV	Precursors and high impedance alert with audible beeping tones.
Alternate	Proximal Ring to Distal Sense electrode	DS	Precursors: 1) observation of nonphysiologic, mechanical artifacts in stored event S-ECGs, and 2) cardiac signals appear isoelectric or near isoelectric.
		DS and HV	Precursors and high impedance alert with audible beeping tones.

Rate of occurrence:
There have been 27 case reports of incidences in a small area distal to the proximal sensing ring at xiphisternum mechanical stress can cause fatigue and migratory cracks in the sensing and high voltage component of the lead/electrode.

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).

There has been 1 death of a person with the device which is yet to be attributed to the advisory

Recommendation:

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. 3 monthly in-clinic follow-up recommended for patients who are programmed to Primary Sensing Configuration as this vector will not show the described artifacts via remote monitoring.

Perform a system follow-up every three months via remote or in-office interrogation for Secondary or Alternate sensing configurations.

3. During follow-ups. For every remote or in-office follow-up:

3.1. 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.

3.2. Review stored episode S-ECGs for non-physiologic, mechanical artifacts, as this may indicate onset of electrode body fracture.

3.3. 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:

3.3.1. Cardiac signals on the S-ECGs of the Primary and Secondary sensing vector look nearly identical; or

3.3.2. Isoelectric S-ECGs in the Alternate sensing vector.

3.4. 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.

- 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 Xray. 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. The Committee recommends physicians closely follow overall S-ICD electrode product performance with respect to the competing risks for transvenous ICDs and decide regarding de novo implantation on a case by case basis.

The ANZCDACC encourage you to report any adverse event or near (potential) adverse event associated with the use of a medical device including any abnormal CIED or lead function. We encourage reporting to ANZCDACC directly via the Committee chair Dr Paul Gould drpgould@gmail.com and to the following regulators.

In Australia, report to the TGA;

Online https://www.tga.gov.au/reporting-problems

In New Zealand, report to Medsafe;

Post Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6145.
Email devices@moh.govt.nz
Fax 04 819 6806