Urgent Field Safety Notice

June 2017

SUBJECT: Urgent Field Safety Notice- Ref. 92127890-FA – S-ICD Memory Corruption - (S-ICD Systems: SQ-RX™ model 1010, EMBLEM™ model A209 and EMBLEM™ MRI model A219).

Dear Doctor,

Boston Scientific is committed to prompt and transparent communication about matters of patient safety. We want to inform you, as a physician who manages the care of patients with an S-ICD system, of a single, isolated S-ICD event that resulted in a device-related patient death in May of this year. We are providing the following information to you in order to address questions and concerns you or your patients may have about this event.

Boston Scientific engineers have determined that this patient's S-ICD repeatedly delivered an atypical amount of energy (similar to the arrhythmia induction function) because a specific memory location was corrupted by radiation[1] within the environment. This repeated atypical energy delivery prevented S-ICD arrhythmia detection/treatment and ultimately contributed to the patient death.

This device behavior has been simulated in a laboratory setting by corrupting two specific adjacent bits of device memory on similar model S-ICDs. Testing results correlated with information available from this event. Although this device behavior is highly unlikely to reoccur, Boston Scientific is actively developing an S-ICD software update to mitigate the effects of memory corruption by preventing atypical energy delivery. We expect software to be completed in July with submissions to Regulatory Authorities shortly thereafter[2]. You will receive additional communication when software is available in your country.

Root Cause Investigation

In the three weeks following notification of this event, Boston Scientific conducted an immediate investigation of the clinical data, performed a detailed analysis of the returned S-ICD system, assessed the system's software, and initiated work on an update to the software. Based on the information available, we have concluded that the memory corruption was due to a transient change of the S-ICD operating state caused by what engineers refer to as a single event upset (SEU). An SEU is a change of state in the device memory induced by environmental radiation interacting with a specific memory location.

Based on information received during the investigation, it does not appear that the patient was subjected to any readily identifiable external source of ionized particles (e.g., ionizing radiation therapy) prior to the event. All electronic devices utilizing integrated circuits are susceptible to SEUs. Cardiac implantable electronic devices include mechanisms to detect and correct memory corruption in order to reduce the occurrence of potentially adverse malfunctions. However, device memory corruption is not always detectable. This is especially true if corruption impacts multiple bits in an area of memory that is expected to change as software performs device operations, as was the case in this event.

Root cause investigation of this event identified a single scenario that could lead to this behavior in an S-ICD. Boston Scientific engineers simulated this scenario by corrupting two specific adjacent bits of memory on representative S-ICDs within a laboratory setting. Testing demonstrated energy output similar to the arrhythmia induction function, correlating with information available from this event. Additional simulations were performed in attempts to produce this behavior and no other scenarios were identified. Boston Scientific has concluded that the corruption of the two adjacent memory locations in this event was due to an SEU.

[1] Ionized subatomic particle such as an alpha particle, neutron, or high energy proton

[2] The S-ICD software that addresses this device behavior will be v4.04 or higher

Observed Rate
This experience represents one (1) observed event in approximately 37,000 S-ICDs distributed worldwide. Given the rarity of this single event observed to date, a precise projection of occurrence cannot be derived with confidence. Engineering analysis of S-ICD device memory design and recorded instances of SEUs in fielded devices was conducted during our root cause investigation of this event. Based on this analysis, the probability of corruption of the specific location in memory that produces this device behavior within an S-ICD was determined to be approximately 1 in 300,000 over five years. Although reoccurrence of this device behavior is highly unlikely, Boston Scientific is developing software mitigations for EMBLEM™ S-ICDs (Model A209 and A219) and SQ-RX™ S-ICDs (Model 1010) to prevent this from occurring in the future. It is important to note that this particular device behavior cannot occur with any Boston Scientific transvenous defibrillators or pacemakers due to differences in hardware and software.

Recommendations
In consultation with our Patient Safety Advisory Board, Boston Scientific recommends NO changes to clinical follow-up due to this single event. Specifically, for patients with S-ICD systems:

- Continue using the S-ICD system to detect and treat life-threatening ventricular tachyarrhythmias;
- Keep scheduled LATITUDE™ and/or in clinic follow-ups; and
- Follow the precautions identified in the S-ICD user's manual when radiation therapy is prescribed.

Furthermore, Boston Scientific does NOT recommend the following:

- Early or off-cycle follow-ups are not recommended. This type of memory corruption cannot be detected, thus additional S-ICD checks do not reduce the potential for this device behavior.
- Prophylactic S-ICD replacement or explant is not recommended. The risks associated with such an additional surgical procedure significantly outweigh the risk of reoccurrence of this device behavior.

Until the software mitigation update is available, this S-ICD behavior represents an additional, small risk that should be considered when evaluating the relative risks associated with all available ICD therapy options.

Additional Information
Patient safety is our highest priority. As stated above, we have provided this communication to address questions or concerns that may arise from this event. If you require additional information regarding this communication or would like to report any clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely,

Renold Russie
Vice President, Quality Assurance