

June 2017

SUBJECT: Urgent Field Safety Notice- Ref. 92127890-FA – S-ICD Memory Corruption

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 resulting in a patient death, which occurred in May of this year.

Our investigation concluded that the S-ICD delivered an atypical amount of energy due to memory corruption inside the device, which contributed to the death. We are providing this information to you in order to address questions and concerns you or your patients may have about this event. Although we have determined that this event is unlikely to reoccur, Boston Scientific is actively developing an S-ICD software update to provide additional protection against this device behaviour. We expect software to be completed in July with submissions to Regulatory Authorities shortly thereafter¹.

Investigation

In the three weeks following notification of this event, Boston Scientific conducted a thorough 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 an ionized subatomic particle² interacting with a specific memory location.

Based on information received during the investigation, Boston Scientific does not believe 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 utilising 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.

As a result of the root cause investigation of this event, a single scenario was identified that could lead to this behaviour 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 to produce this behaviour 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.

¹The S-ICD software that addresses this device behaviour will be v4.04 or higher

²Cosmic ray, alpha particle, neutron, or high energy proton

Rate of Occurrence

This experience represents one (1) observed event in approximately 37,000 S-ICDs distributed worldwide. Data analysis from our investigation determined that the probability of corruption of the specific location in memory that produces this device behaviour within an S-ICD would be approximately 1 in 300,000 over five years. Therefore, Boston Scientific concludes that reoccurrence is highly unlikely. However, we are developing software mitigations for EMBLEM™ S-ICDs (Model A209 and A219) and SQ-RX™ S-ICDs (Model 1010) to prevent this device behaviour from occurring in the future. It is important to note that this device behaviour has not been observed with any Boston Scientific transvenous defibrillators or pacemakers.

Recommendations

In consultation with our Patient Safety Advisory Board, Boston Scientific recommends the following 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 behaviour.
- 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 behaviour.

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. You will receive additional communication when software is available in your country. If you have additional questions regarding this communication or would like to report any clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely,



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