Date: December 4th, 2020

Canadian Heart Rhythm Society
Device Committee

ADVISORY: Boston Scientific: Electrical Overstress During Delivery of High-Voltage Therapy (Boston Scientific Field Action Reference: 92628736-FA)

Nature of the Advisory:

Variations in the header assembly have resulted in the development of a small pathway allowing for moisture ingress. This can cause a shorting condition to occur during delivery of high-voltage therapy, resulting in the inability to deliver effective shock therapy. This malfunction will result after delivery of a high-voltage shock as the inability to interrogate the device or by error/alerts codes with the need for pulse generator replacement.

At present, there is no available method to detect whether an individual device is vulnerable to this condition prior to its occurrence.

Scope of the problem:

Between May 2015 and December 2017, a subset of approximately 3,350 EMBLEM S-ICDs were manufactured with variations in the header assembly. Not all S-ICDs built during this timeframe were exposed to these process variations. None of the potentially affected S-ICDs remain available for implant. In Canada, the estimation is that 46 S-ICDs with this overstress vulnerability were implanted.

Boston Scientific has confirmed six (6) events of electrical overstress following delivery of high-voltage therapy in the 3,350 (0.17%) EMBLEM S-ICDs (Model A209 and A219) manufactured. Based on Boston Scientific calculations, the projected occurrence rate for this electrical overstress behavior in the affected S-ICDs is 0.3% 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.

Response of the CHRS Device Committee:

- We recommend that patients be notified about the advisory.
- Patients with affected S-ICDs vulnerable to overstress should be followed according to manufacturer's labeling every 3 months either in person or via remote monitoring.
- All patients with S-ICDs should be enrolled in remote monitoring if possible. This recommendation applies to all patients with CIEDs but is especially important in this advisory patient group.
- The patient alert tones should be demonstrated to patients at each in-person follow-up to ensure they are able to hear them. Patients should be instructed to notify their follow-up device clinic as soon as possible if they hear the alert tone.
    - 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.
- Remind patients to promptly contact their device clinic if beeping tones are heard from their device, if a shock is delivered, or if any LATITUDE communicator transmissions are unsuccessful.
- Device clinics should obtain an interrogation remotely or in person as soon as possible after any of the above conditions.
- Prophylactic device generator replacement is not recommended for most patients at this time.
- However, since there is no available method to detect whether an individual device is vulnerable to this condition, device replacement should be considered in higher-risk patients through a shared decision-making process. Higher-risk patients include those:
    - With a secondary prevention indication
    - With a primary prevention indication and subsequent appropriate ICD therapies
    - Where frequent follow-up or remote monitoring is not possible.
    - Unable to hear device tones, have planned prolonged travel, or live remote from medical facilities.

If you have any questions, please contact your local Boston Scientific representatives. Contact Boston Scientific Technical Services for assistance as needed 1-800-227-3422.

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