December 4th, 2020

Canadian Heart Rhythm Society
Device Committee

ADVISORY: Boston Scientific EMBLEM S-ICD Subcutaneous Electrode (Model 3501). (Boston Scientific Field Action Reference: 92384167-FA)

Nature of the Advisory:

Fractures of the EMBLEM S-ICD Model 3501 subcutaneous electrode have been reported. 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. Cumulative mechanical stress at this site is believed to be the cause of these fractures. The fracture may result in failure of the distal sensing tip, which can produce non-physiologic artifact and inappropriate shock therapies if the sensing vector includes this electrode (secondary and alternate vectors). The fracture may also result in fracture of the high voltage conductors, which could result in failure to deliver shock therapies.

Scope of the problem:

The advisory applies to the EMBLEM S-ICD Model 3501 electrode, which also serves as the only electrode currently available on the market for use with the EMBLEM S-ICD system. To date, there have been 27 reports of electrode body fracture out of a total of ~ 47,000 implanted electrodes worldwide. The estimated occurrence rate for this specific issue is 0.2% at 41 months, with evidence of fracture becoming apparent at a median age of 9 months (range 2 – 33 months). There has been one reported patient death that may be related to this issue. Of note, there are no identified procedural techniques or implant considerations that alter the probability of this lead fracture.

Response of the CHRS Device Committee:

- We recommend that patients be notified about the advisory.
- Patients with S-ICDs 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.
- Note that the S-ICD will **not** automatically communicate with the bedside Latitude Communicator. Remind patients that they will need to physically interact with the communicator in order to transmit the data. Instruct patients to adhere with weekly remote interrogations.

- The patient alert tones should be demonstrated to the 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.
- Indicators of potential lead fracture may be identified on remote follow-up and should prompt an in-clinic visit. These may include:
    - High impedance alerts.
    - Non-physiologic artifacts on stored episode S-ECG.
    - Inappropriate shocks.
    - Audible S-ICD tones.
- During in-clinic follow-up, all sensing vectors should be captured. Onset of electrode body fracture may manifest as:
    - Non-physiologic, mechanical artifacts during isometrics and/or posture changes.
    - Nearly identical S-ECGs on the Primary and Secondary sensing vectors.
    - Flatline S-ECGs on the Alternate sensing vector.
- In patients where initial screening before implantation showed both the Primary and Secondary vectors to be appropriate, reprogramming the sensing vector to the Secondary vector may allow for earlier detection of lead fracture via the identification of non-physiologic noise events, but may increase the risk of inappropriate shocks.
    - While this trade-off might be reasonable in certain clinical situations, further advice regarding this strategy will be made available pending further data collection.
- Imaging with PA and left-lateral chest X-Ray is recommended if a lead fracture is suspected.
    - Further advice regarding this strategy will be made available pending further data collection.
- Any lead with confirmed structural compromise should be replaced.
- Prophylactic lead replacement is not recommended.
- As the advisory lead is currently the only one available on the market, clinicians should balance the risk of S-ICD lead failure (estimated rate of 0.22% / year) versus transvenous lead failure (≤ 0.40% / year) and discuss this with patients as part of the decision-making process.
- At time of S-ICD replacement, all sensing vectors (S-ECG signals) should be reviewed to detect any sign of lead fracture. Chest X-Ray and/or lead fluoroscopy prior to the generator replacement may be considered. Further advice regarding this strategy will be made available pending further data collection.

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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