Date: July 25 2025

Canadian Heart Rhythm Society - Device Committee

RE: Boston Scientific RELIANCE ePTFE defibrillation leads with an increased potential to exhibit a gradual rise in low-voltage shock impedance

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Nature of the Advisory:

During post market surveillance, Boston Scientific (BSC) has observed a pattern of gradually rising **low-voltage shock impedance** (LVSI) measurements in association with expanded polytetrafluoroethylene (ePTFE) coated single coil (SC) and dual coil (DC) RELIANCE™ defibrillation leads manufactured between 2002 and 2021 that are no longer available for distribution.

A pattern of gradually rising LVSI over several years is associated with the accumulation of a calcific encapsulant over the shock coil(s) that may reduce the electrical conductivity and increase the LVSI and high-voltage shock impedance (HVSI) impedance. If HVSI exceeds 145Ω, BSC defibrillators, by design, limit shock duration of the first shock phase to 20ms. If this occurs, the shock's bi-phasic waveform is truncated and a monophasic shock is delivered, potentially reducing shock efficacy. If this occurs an impedance alert (Code 1005) will be displayed.

This impedance rise often happens late after implant and may not occur until 8 or more years post implant.

Clinical Impact

The *potential for life-threatening harm* due to arrhythmic death (non-conversion of a sustained ventricular arrhythmia from a reduced shock energy due to high impedance) is estimated at 0.0021% (1 in 47,500 in ePTFE leads). This risk may be higher in patients with frequent ventricular arrhythmias requiring frequent shocks.

The *most common harm* is early lead replacement (0.42% at 10 years with ePTFE leads vs. 0.01% with non-ePTFE leads). Deaths have been reported because of extraction of ePTFE leads exhibiting a gradual rise in LVSI.

Scope of the problem:

This phenomenon is more prevalent with Boston Scientific RELIANCE ePTFE defibrillation leads compared to non-ePTFE defibrillation leads from Boston Scientific and other manufacturers.

Approximately 1 in 15 (6.4%) ePTFE leads will experience a gradual rise in LVSI at 10 years.

Of the ePTFE leads experiencing a gradual rise in LVSI, less than a third (30% of Single Coil and 14% of Dual Coil) will reach a 28-day average LVSI >150Ω in the 5 years following the detection of a gradual rise in LVSI.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue.
- Patients should be followed according to their usual schedule, remotely or in person.
- All patients should be enrolled on the LATITUDE home monitoring system, where possible.
    - This recommendation applies to all patients with CIEDs but is especially important in this advisory patient group as it can facilitate early detection
- During routine follow-up:
    1. Determine the most recent 28-day average LVSI not affected by delivery of a shock (LVSI may transiently lower following a high voltage shock)
        - If there are any sudden changes in impedance, visually estimate the 28-day average LVSI prior to the impedance change.
    2. Review HVSI for all shocks from the most recent episode since the last system check
- Interpretation and recommended actions based on LVSI and HVSI:
    - **Low-Voltage shock impedance -** recent 28-day average not affected by shock delivery
        - **Single Coil >90 Ω or Dual Coil >70 Ω**
            - Program Shock Polarity to Initial (RV-) and all shocks to maximum energy
                - Reversed (RV+) polarity systems exhibiting a gradual rising LVSI have a lower defibrillator-determined shock success rate.
                - Reversed (RV+) polarity shocks are 4.5 times more likely to initiate a high, delivered shock impedance alert (Code-1005),
        - **Single Coil or Dual Coil >150 Ω**
            - Lead replacement may be considered based on patient-specific factors, including comorbidities and risk of ventricular arrhythmias.
                - These patients, even when programmed to Initial (RV-) polarity, have a ~25% likelihood of a shock-associated Code-1005, with an associated decrease in the first shock success rate
            - Contact BSC Technical Services for additional technical guidance to support informed lead replacement decision-making.
    - **High-Voltage shock impedance, Code-1005 Alert**
        - Lead replacement should be considered.
            - The urgency for lead replacement should be commensurate with the likelihood of the patient requiring shock therapy.
        - Contact BSC Technical Services for additional technical guidance to support informed lead replacement decision-making.
- If lead replacement is planned, carefully consider the risk/benefit of extraction vs abandonment
    - These leads may pose an increased risk of extraction-related complications based on implant time and likely coil calcification

The CHRS device committee may update these recommendations should more data become available

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