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 the 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.

There are an estimated 365,000 active leads.

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

<u>CHRS Device Committee</u>
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Addendum – September 11, 2025

In response to concerns raised by the community regarding the use of "mixed" systems – specifically cases where the Boston Scientific RELIANCE ePTFE defibrillation lead is paired with an ICD pulse generator from a different manufacturer - the device advisory committee consulted industry partners and has issued the following guidance.

1. **Medtronic ICD pulse generator** connected to a **Boston Scientific RELIANCE ePTFE lead**
    a. Lead integrity remains the primary concern.
    b. Lead monitoring capabilities
        i. Medtronic pulse generators are able to detect a gradual rise in subthreshold shock impedance, facilitating early identification of lead failure
    c. Due to differences in design, Medtronic pulse generators are not at risk of a waveform timeout (Code-1005 equivalent fault) and are likely to deliver full energy therapy.
        i. Specifically, important differences exist in:
            1. Energy Delivery:
                a. 40J Medtronic (some pulse generators) vs. 35J Boston Scientific
            2. First phase tilt:
                a. 50% Medtronic vs. 60% Boston Scientific
            3. Waveform timeout threshold:
                a. 200-250 ohms Medtronic vs. 147 ohms Boston Scientific
            4. Waveform timeout response:
                a. At 20.1ms, Boston Scientific truncates the shock waveform
                b. At 25.2ms, Medtronic delivers the second phase of the waveform at the current voltage in the opposite polarity
    d. **Response of the CHRS Device Committee:**
        i. **Boston Scientific RELIANCE ePTFE defibrillation lead integrity** should be monitored as above
            1. Boston Scientific ePTFE leads with a low-voltage shock impedance value >150ohms should be considered for replacement based on patient-specific factors, as outlined above.
        ii. **The Medtronic generator should be programmed** as follows:
            1. **All HV therapies should be programmed to maximum output (35J or 40 J)**
            2. **In the subset of Medtronic devices with B>AX polarity recommendations, shock configuration should be B>AX (coil to can) pathway in all therapy zones**
                a. This minimizes the risk of unintended current pathway in the device header (e.g., glassed feedthrough), reducing the potential for a SCP event.
                b. With this programming the potential for a reduced- or no-energy HV therapy returns to baseline historical performance (0.002% at five (5) years and 0.005% at nine (9) years).