Date: July 25 2025 (updated September 2025, updated December 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 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, Boston Scientific 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 **Boston Scientific Generator** 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 Boston Scientific 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 Boston Scientific 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

CHRS Device Committee
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Addendum – September 2025, updated December 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. Lead integrity remains the primary concern.
2. Lead monitoring capabilities
    a. Alternate Vendor (Medtronic, Abbott) pulse generators can detect a gradual rise in subthreshold shock impedance, facilitating early identification of lead failure
    b. Medtronic
        i. Medtronic reports RV Defib and SVC Defib lead impedance as separate values. When monitoring Boston Scientific RELIANCE ePTFE leads it is recommended that the RV Defib lead impedance is used as the relevant value when these leads are attached to Medtronic systems
    c. Abbott
        i. In Single Coil (SC) systems, the measurement of RV-Can impedance is equivalent in Boston Scientific and Abbott defibrillators.
        ii. When the shock configuration is programmed as Dual Coil (DC), Abbott defibrillators display individual trends and generate alerts for each of the three component vectors (RV-SVC, RV-Can, and SVC-Can), unlike Boston Scientific devices, and list the most recent daily combined impedance measurement. For DC systems, the relevant impedance value is RV-Can.
3. **Medtronic ICD pulse generator connected to a Boston Scientific RELIANCE ePTFE lead**
    a. 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/Voltage 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 HVSI ohms Medtronic vs. 160 ohms HVSI 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
4. **Abbott ICD pulse generator connected to a Boston Scientific RELIANCE ePTFE lead**
    a. Due to differences in design, Abbott pulse generators are not at risk of a waveform timeout (Code-1005 equivalent fault) and deliver full output therapy.
        i. Specifically, important differences exist in:
            1. Energy/Voltage Delivery:
                a. 40J/896 V Abbott (some pulse generators 36J/850 V) vs. 35J Boston Scientific
            2. Option to program Waveform Mode to fixed Pulse Width (aka Optimized Precision Shock Technology or DeFT Response) on Abbott devices
                a. Allows optimized shock duration at any impedance
                b. Prevents delivery of shock with extended pulse widths

3. By default, Waveform Mode is programmed to fixed Tilt
    a. At impedances > 145 ohms Boston Scientific truncates the shock waveform, delivering a 20.1 msec monophasic shock
    b. **Abbott devices never switch to monophasic.** At impedances > 115 ohms, Abbott delivers a biphasic shock with a 12 msec pulse width for each phase

5. **Response of the CHRS Device Committee:**
    a. **Boston Scientific RELIANCE ePTFE defibrillation lead integrity** should be monitored as above
        i. Boston Scientific ePTFE leads with a low-voltage shock impedance value (or High Voltage Lead Impedance (HVLI) on Abbott devices) >150 ohms (particularly combined or RV-Can) should be considered for replacement based on patient-specific factors, as outlined above. This recommendation is independent of the brand of pulse generator used, given the uncertainty regarding shock efficacy in this situation.
    b. **The Medtronic generator should be programmed** as follows:
        i. All HV therapies should be programmed to maximum output (35J or 40 J)
        ii. Consider enabling the RV Defib Lead Impedance CareAlert and setting the Max RV Defib Lead Impedance value to monitor for increasing impedance
        iii. 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
            1. This minimizes the risk of unintended current pathway in the device header (e.g., glassed feedthrough), reducing the potential for a Short Circuit Protection (SCP) event.
            2. 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).
    c. The **Abbott generator should be programmed** as follows:
        i. **All HV therapies should be programmed to maximum output (40 J/896 V or 36 J/850 V),** particularly if RV-Can HVLI is above 90 ohms.
        ii. **Program Waveform Mode to fixed Pulse Width** using DeFT Response.
        iii. **Maintain shock polarity as programmed**, as Abbott devices are not subject to Code-1005 time-out error and do not automatically switch to monophasic.
        iv. **Set High Voltage Lead Impedance (HVLI) Monitoring Upper Limit** to benefit from alerts for impedances (e.g. above 90 or 125 ohms).
            1. Note - when programmed to dual coil shocking configuration, alerts will be generated when RV-SVC or SVC-Can HVLI is greater than the programmed limit while the RV-Can HVLI is still in range. Decisions for action should be based on the RV-Can HVLI. If SVC HVLI is high and an RV-Can shocking configuration is considered safe for the patient, reprogramming the shock configuration from a dual coil to single coil configuration may be considered to simplify follow-up.
            2. For remotely monitored patients, ensure the HVLI alert is enabled in Merlin.net.

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