Date: June 24, 2022

Canadian Heart Rhythm Society
Device Committee

RE: Potential for Intermittent-Reduced-Energy Shock Due in Medtronic Cobalt XT, Cobalt and Crome Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)

Nature of the Advisory:

Medtronic has identified an issue with the Short Circuit Protection (SCP) in their newest generation of ICDs and CRT-Ds. SCP is a safety feature used in many older generations of Medtronic ICDs and is designed to truncate the delivered energy during high voltage therapy to protect the device when unexpected current is detected. SCP events can trigger during delivery of the high voltage biphasic waveform in the presence of a lead insulation breach ("first-phase SCP") or unexpected, additional current in the device HV circuit ("second-phase SCP").

Cobalt/Crome devices can be more sensitive than older ICDs to a non-destructive, secondary current pathway involving the HV circuitry. This secondary current does not impair the device's internal circuitry or battery but may result in the electrical switch that controls current flow during HV delivery to remain intermittently active for longer than intended after delivery of the first phase of the biphasic waveform. When the secondary current flow through the active switch is detected, the SCP feature prevents delivery of the remaining HV energy (second-phase SCP). This failure to deliver the reversed polarity energy results in the device delivering only ~79% of the programmed output as a monophasic waveform (vs. <10 J with a first-phase SCP event due to a lead integrity issue).

This switch-mechanism may be intermittent, resulting in HV therapy sequences delivering both the intended full-energy biphasic waveform and/or a reduced-energy monophasic waveform within the same therapy episode. Importantly, the pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted; nor are HV charging, battery longevity and Bluetooth telemetry.

Potential harms related to a second-phase SCP event include failure to terminate the arrhythmia due to reduced-energy delivery (defibrillation efficacy reduced from 89% to 85% for first shock, and from 99% to 98% for a full series of 6 shocks; overall mortality of 0.002%) and complications associated with device replacement (0.032-0.043%), including unnecessary lead replacement due to misinterpretation of the SCP alert.

In addition, they have identified that the small secondary current with high voltage delivery could be pro-arrhythmic, due to possible current leak at the RV coil. This theoretical risk is very low (<0.002%) and is thought to only occur if the shock pathway is programmed AX>B or any configuration with Active Can/SVC Coil set to "Can Off".

Scope of the problem:

Through 03-June-2022, Medtronic has identified 27 devices that have experienced a reduced-energy shock, which is accompanied by a Short Circuit Protection (SCP) alert. However, while 0.03% has been observed to date, Medtronic projects 0.18% of the ~80,000 distributed devices may experience a second-phase SCP event within 24 months of service life (considering both the increase in SCP events over time as well as the likelihood a patient will need high voltage therapy during that time).

Importantly, as this issue is only observed in patients who receive high voltage therapy, the observed rate in this population was 0.77% (vs. 0.03% of total implant population). When projecting for the population receiving high voltage therapy, the chance of encountering a second-phase SCP event increases to ~5.0% at 24 months.

Medtronic has developed a software update which will resolve occurrences of second-phase SCP events by pausing between phases to let current dissipate before delivering the reversed phase. This will prevent the decreased energy delivery risk but will not prevent the very small risk of pro-arrhythmia from this secondary circuit.

They anticipate that the software update will be available for in-clinic download into implanted devices beginning third to fourth quarter of calendar year 2022, pending regulatory approvals. The update will ensure the full shock energy is delivered in the presence of a secondary, low-level current pathway in the HV circuitry. The software update will require an additional in-clinic follow-up for it to be installed into a patient's device.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue.
- No prophylactic replacement is recommended at this stage.
- Lead replacement is not advised for a **device-related SCP event.**
    - A value of exactly zero (0) ohms for an RV Defib lead impedance alert is an indication that an **SCP event has occurred** during HV therapy. In both **device-related and lead-related SCP events**, the episode text for a treated episode will report lead impedance <20 ohms.
    - A **device-related SCP event** (this advisory) are typically evidenced by the delivery of ~79% of the programmed energy (e.g., 32J if programmed for 40J). This is NOT a lead issue.
    - A **SCP event due to a lead integrity issue** are typically evidenced by <10J delivered.
- Patients should be followed in-person or via remote monitoring at their usual follow-up schedule.
- Patients should be enrolled on the CareLink™ system where possible.
    - While this recommendation applies to all patients with CIEDs, it is especially important in this advisory patient group.
- All affected devices should be reprogramed as follows:
    - **All HV therapies should be programmed to 40J -** This provides the best opportunity to deliver the highest shock energy if the device experiences a second-phase SCP event: in this case, a 32J monophasic waveform will be delivered.
    - **Shock configuration should be B>AX pathway and Active Can/SVC Coil set with Active Can enabled for all shocks across all therapy zones –** This mitigates the risk of proarrhythmia as HV therapy programmed to the AX>B configuration, or any configuration with Active Can/SVC Coil set to "Can Off" creates the potential for residual current to flow back to the heart. This shock configuration programming must be maintained for the life of the device as the software update will not eliminate this very small theoretical pro-arrhythmia risk with Ax>B.

- Reprogramming can occur at the next scheduled follow-up interval for primary prevention implants and secondary prevention patients programmed with all shocks at 40 Joules.
- Consider bringing secondary prevention patients or patients with previous appropriate therapies in for early follow-up and reprogramming if they are not programmed with all shock therapies at 40 Joules.
- Consider DFT testing to ensure a 10J safety margin exists for those suspected to have high defibrillation thresholds
- Device alert tones should be demonstrated to patients at each in-person follow-up to ensure patients 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.
    - The device should be interrogated or a CareLink™ transmission initiated within **72 hours** after an alert tone.
- The CHRS device committee may update these recommendations should more data become available or if there are delays in approval of the software update.

CHRS Device Committee

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