ANZCDACC Advisory Notice 18th of January 2019

Device: Cameron Health Incorporated (Boston Scientific) SQ-RX Model 1010

(First generation Subcutaneous Implantable Cardioverter Defibrillator (S-ICD))

ARTG: 219499 (Discontinued)

TGA Reference: RC-2018-RN-01427-1

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Routine

Number of CIEDs affected in Australia and New Zealand:

229

Description:

There is a potential for a shortened replacement interval after a Charge Time (CT) / Battery Depletion (BD) alert has occurred or after the battery status reaches Elective Replacement Indicator (ERI) in the first-generation Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) system's SQ-RX™ Model 1010 Pulse Generator (PG).
Boston Scientific have observed an elevated rate of these PGs experiencing latent battery malfunctions resulting in accelerated battery depletion and a shortened replacement interval. The SQ-RX Model 1010 PG (which was acquired from Cameron Health Incorporated) is no longer available for implantation and is no longer manufactured, and any remaining inventory is expired.

The SQ-RX Model 1010 PG provides an Elective Replacement Indicator (ERI) as the PG approaches the end of its expected battery service life. Normally when the battery reaches ERI, there is sufficient capacity to support up to 90 days of continued operation, including up to 6 maximum energy charges/shocks before fully depleting. However, if the ICD experiences a latent battery malfunction resulting in accelerated battery depletion, the reserve battery capacity available beyond ERI may not be sufficient to support the full 90-day interval or additional shock therapy before depleting. The rate of depletion for a latent battery malfunctions varies.

The SQ-RX model 1010 PGs include separate monitors for charging and battery performance. The Charge Time (CT) alert is designed to detect unsuccessful charging of the high voltage capacitors within 44 seconds. The Battery Depletion (BD) alert is designed to detect higher rates of accelerated battery depletion. When an alert condition occurs, the patient is notified through beeping tones and the clinician user is notified through programmer messages. Most battery malfunctions exhibit a sufficient rate of accelerated depletion to be detected by one of these alerts. Some battery malfunctions exhibit a slower rate of accelerated depletion, which is not detected as an alert condition. Based on an analysis of accelerated battery depletion events where only ERI presented (no alert condition), at least one maximum energy shock has been determined to be available for at least 20 days after ERI.

Risk:

Based on the cumulative survival of 94% at 5 years, the SQ-RX Model 1010 PG is meeting overall anticipated performance expectations of 4.7 to 5 years. Approximately 9,000 active PGs remain in service. The projected occurrence rate for latent battery malfunctions for SQ-RX Model 1010 PGs is up to 2% at 5 years.

There have been no reports of injuries or deaths associated with this anomaly. Laboratory analysis of returned PGs with latent battery malfunctions has shown some depletions to a level at which therapy would not have been available if not replaced in accordance with the recommendations above. Based on a 3-month follow-up interval, the potential for life- threatening harm from this anomaly is 0.006% (1 in 16,667) at 5 years. However, the potential for life-threatening harm is greater for secondary prevention patients or those who have received appropriate therapy previously, patients with longer follow-up intervals, and/or patients who are unable to hear beeping tones. For these patients, the benefit associated with prophylactically replacing the PG may outweigh the risks associated with a shortened replacement interval due to latent battery malfunction. To date, there are no published data on complication rates associated with S- ICD replacements.

Presentation:

When an alert condition occurs the patient is notified through beeping tones and the clinician user is notified through programmer messages. Excessive charge time, battery depletion and ERI will all trigger this alert. Once triggered, the beeper sounds for 16 seconds every 9 hours until the trigger is resolved.

Advice:

1. Evaluate Risk. The potential for life-threatening harm is greater for patients who have experienced life-threatening ventricular arrhythmias, patients not followed every 3 months, and/or patients who are unable to hear beeping tones. For these patients, the benefit associated with prophylactically replacing the PG may outweigh the risks associated with a shortened replacement interval due to latent battery malfunction

2. Follow-Up. Consistent with the SQ-RX Model 1010 PG User Manual:
    - Perform in-clinic checks every 3 months as the PG is not capable of remote patient management;
    - If it has been more than 3 months since a patient's last in-clinic follow-up, schedule a follow-up within the next month and every 3 months thereafter;
    - During the next follow-up visit, demonstrate the beeper by applying a magnet over the PG to elicit beeping tones; and
    - Remind patients to promptly contact their physician if beeping tones are heard from their PG as this may be an indication of a CT / BD alert or ERI.
3. Alerts. Promptly investigate any beeping tones, CT alerts, BD alerts or ERI notification and report them to Boston Scientific Technical Services. Using saved PG data, Technical Services can determine if any accelerated battery depletion exists and provide the necessary guidance for replacement.

The ANZCDACC encourage you to report any adverse event or near (potential) adverse event associated with the use of a medical device including any abnormal CIED or lead function. We encourage reporting to

ANZCDACC directly via the Committee chair Dr Paul Gould drpgould@gmail.com and to the following regulators.

In Australia, report to the TGA;

Online	https://www.tga.gov.au/reporting-problems

In New Zealand, report to Medsafe;

Post	Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6145.
Email	devices@moh.govt.nz
Fax	04 819 6806