Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798
www.bostonscientific.com

Important Medical Device Information

02 November 2018

Dear Doctor,

Cc: Chairman Medical Board and relevant Head of Departments

Boston Scientific is providing important information about the 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). We 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, is no longer manufactured, and any remaining inventory is expired.

Note that this information is not applicable to the EMBLEM™ MRI or EMBLEM S-ICD, as these PGs utilize our proprietary battery design.

Recommendations

- Follow-Up. Consistent with the SQ-RX Model 1010 PG User Manual:
  - Perform in-clinic checks[1] 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.
  - Append the patient's medical record with this letter to maintain awareness of this topic for the remaining service life of their PG

- 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 (see the clinical impact section below).

- CT / BD Alerts. Promptly investigate any beeping tones, CT alerts, or BD alerts and report them to Boston Scientific Technical Services. Using saved PG data, Technical Services can determine if an accelerated battery depletion exists and provide guidance for replacement.

- ERI. To mitigate the rare potential for undetected accelerated battery depletion, replace SQ-RX Model 1010 PGs within 20 days of ERI. If a longer replacement interval is desired, save PG data and contact Technical Service to determine a recommended replacement interval. Note: CT / BD Alerts appearing before or after ERI should always be reported to Technical Services for evaluation.

- Distribution.
  - Distribute this letter to all physicians and healthcare professionals within your organization who need to be aware of this topic.

[1] SQ-RX Model 1010 PGs do not include the capability for remote checks.

Background

The SQ-RX Model 1010 PG provides an Elective Replacement Indicator (ERI) as the PG approaches the end of its expected battery service life. When the battery reaches ERI through normal use, 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 PG 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.

Clinical Impact

Based on the cumulative survival of 94% at 5 years, the SQ-RX Model 1010 PG is meeting overall anticipated performance expectations[2]. 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 behavior. 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 for this behavior 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, whereas the published risk of life-threatening harm from replacement of transvenous implantable cardioverter defibrillators (ICDs) has been reported between 0.1 and 0.44% and major complications between 4 and 5.9%.[3]

Affected Devices

All SQ-RX Model 1010 Pulse Generators are affected and approximately 9,000 remain in service. This PG is no longer available for implantation and any remaining inventory is expired.

Please see refer to Appendix A for the list of affected devices in Singapore. Note that that there are other serial numbers affected globally that are not listed in this letter, should you need any clarification, please contact Boston Scientific Representative.

Additional Information

We will continue to include detailed, up-to-date product performance information within our Product Performance Report, published quarterly at www.bostonscientific.com. Patient safety remains our highest priority. Although we recognize the impact of communications on both you and your patients, we are committed to transparent communication with our physicians to ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely,

[redacted]

Terry Song
Associate Director, QA / RA, ASEAN

---

[2] Based on US survival probability published in the Q3 2018 Product Performance report available online at www.BostonScientific.com/ppr. The SQ-RX Model 1010 PG User's Manual estimates longevity between 4.7 and 5.1 years.

[3] Lewis KB, et. al. Estimating Risks and Benefits of ICD generator replacement: A Systemic Review. PACE 2016 Jul;39(7):709-22 and Gould PG, et al. Outcome of advisory ICD replacement: One year follow-up. Heart Rhythm Dec 2018; 5(12):1675-1681.

Appendix A: List of Affected Devices in Singapore

SICD Model No.	SICD Serial No.
1010	[redacted]
1010	
1010	
1010	
1010	
1010	
1010	
1010	
1010	
1010	
1010	
1010	
1010	
1010	

Boston Scientific

CUSTOMER ACKNOWLEDGEMENT FORM

PRODUCT NAME: Boston Scientific SQ-RX™ Model 1010 Pulse Generator (92297476-FA)

Instructions: **This form must be completed and returned in all cases even if you do not have any affected product.**

Immediately complete form and Scan/e-mail to: Boston Scientific Sales rep OR Fax to #: 64188899

Account #:	**Customer Name:**

Contact Name:
Address:
City: **State:** **Province:** **Postal Code:**
Country:

PLEASE COMPLETE, SIGN AND RETURN THIS FORM AS A CONFIRMATION THAT YOU RECEIVED THIS NOTICE FROM BOSTON SCIENTIFIC (even if you do not have any of the referenced product on the enclosed product listing in your current inventory).

My signature below acknowledges receipt of the Boston Scientific Notice regarding Boston Scientific SQ-RX™ Model 1010 Pulse Generator.

Section to be filled out by Customer:

1. Please Indicate:

Are you a Distributor?

☐ Yes, and we have notified all customers that have been shipped/sold affected product
☐ No

2. Sign and Date to acknowledge this Field Action Notification (must be completed):

Print Name:_____Signature:_____Date:_____

Phone:_____ Fax: _____ E-mail: _____

Date: 02-Nov-2018

Field Action #: 92297476-FA