

FIELD SAFETY ADVISORY

June 1, 2011

Subject: Cameron Health SQ-RX® Pulse Generator, Model Number 1010

Dear Doctor:

Cameron Health has determined that a specific subset of SQ-RX pulse generators (“devices”) may not achieve the five (5) year typical longevity due to premature battery depletion. Although the longevity of these devices may be shortened, therapy remains available through the onset of the Elective Replacement Indicator (ERI). This subset of devices also has the potential for the time between the onset of the ERI and End of Life (EOL) indicators to be less than the nominal three (3) months. The risk for premature battery depletion is due to a specific condition within an individual battery cell. No affected devices remain available for implant.

Details on Affected Devices

Cameron Health has confirmed one (1) occurrence of a device experiencing premature battery depletion due to this condition. This patient heard the ERI audible tone, met with their physician, and had their device replaced six (6) months after initial implantation. Upon analysis of this device, it was determined the premature battery depletion was the result of a condition caused by the battery manufacturing process. This condition only exists in a limited set of battery cells.

Cameron Health conducted a systematic analysis of all implanted devices worldwide and identified two populations at risk for premature battery depletion due to this condition:

- Population I consists of 18 devices that were confirmed through manufacturing records to contain the condition within a battery cell. Bench testing and engineering analysis estimate that 33.1% [+20.8/-19.5] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There has been one (1) confirmed occurrence in this population to date.
- Population II consists of 386 devices for which manufacturing records cannot exclude the possibility of the condition existing within a battery cell. Bench testing and engineering analysis estimate that 3.3% [+2.2/-1.8] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There have been zero (0) confirmed occurrences in this population to date.

The above estimates are based on all available engineering and field performance data. However, this is a relatively small dataset. As such, the actual rates for premature battery depletion due to this condition may be different than the estimates provided above. Cameron Health will continue to monitor the actual performance of the affected populations and will provide a written advisory update in the event the actual rates exceed predicted estimates.

Premature battery depletion due to this condition may result in the time between the onset of the ERI and EOL indicators to be less than the nominal three (3) months. Therapy remains available through the onset of ERI, but may not be available throughout the period between ERI and EOL. For devices that experience premature battery depletion,

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the timing and depletion profile will vary. The audible tone and programmer screen alerts (e.g., ERI and EOL) continue to function normally for these affected devices.

No patient injuries or deaths related to this condition have been reported. No affected devices remain available for implant. Regulatory authorities have been notified of this device condition.

Devices Affected

Attached are the specific serial numbers of affected devices you are following according to our records. No affected devices remain available for implant.

Patient Management Recommendations

Cameron Health, in consultation with our independent Physician Advisory Board, recommends the following for the affected populations:

- If a device experiences an unexpected decline in battery voltage leading to ERI, schedule replacement as soon as possible.
- Communicate to patients that, consistent with device labeling, an emitted audible tone requires immediate follow-up by their physician. Once triggered, the audible tone will sound for 16 seconds every 9 hours until the trigger condition has been resolved. As a reminder, a Cameron Health Model 4520 magnet placed over the device may be used to demonstrate the audible tone.
 - o For patients implanted with devices in Population I, Cameron Health recommends this communication occurs as soon as practical.
 - o For patients implanted with devices in Population II, Cameron Health recommends this communication occurs at the next follow-up.

Warranty Program

The warranty offered with each device applies to all advisory devices experiencing premature battery depletion.

Further Information

Cameron Health sincerely regrets the impact of this advisory on you and your patients and wants to reassure you that patient safety remains our primary concern. If you have any questions regarding this advisory, or if we can be of assistance, please contact your local Cameron Health Representative or Cameron Health Customer Service at the following: 1 (877) 742-3411 (U.S.), +800 7423 4 968 or +31 26 3550260 (International).

Sincerely,



Ryan Majkrzak
Vice President, Quality Systems

Attachment: Affected devices for patients you are following

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