FIELD SAFETY NOTICE

April 23, 2012

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

Subject: Software Update to Prevent Unexpected Reset in Limited Subset of Devices

Dear Doctor:

Cameron Health has determined that a limited subset of SQ-RX pulse generators ("devices") may enter an unexpected reset state under specific conditions. No devices in the affected population remain available for implant. For devices currently in service, a programmer software update has been developed that eliminates the opportunity for this issue to occur. This programmer software update has been approved by the applicable Notified Body, and relevant National Competent Authorities have been notified. The software update is now available for use in your clinical practice.

Background

Cameron Health has confirmed one (1) occurrence of a device reaching its Elective Replacement Indicator (ERI) where a continuous series of audible tones was emitted. The patient immediately alerted their physician and the device was replaced with another Cameron Health device without further complication.

Cameron Health has determined that after reaching ERI earlier than is typical, this device entered an unexpected state. This unexpected state caused the device to reset repeatedly and continuously emit a series of audible tones. As a result, the device was unable to sustain a communication session with the programmer and therapy was also unavailable. Further investigation indicated that this condition could be initiated in a limited subset of devices under specific conditions.

Details on Affected Devices

The subset of devices that may exhibit this unexpected reset state are those initially shipped with software versions 2.1.135 or earlier and subsequently upgraded to version 2.3.308. Cameron Health records indicate that up to 323 devices worldwide could meet these criteria. No devices implanted after March 2011 are affected.

Devices in the subset operating software version 2.3.308 will enter this unexpected reset state if ERI or a long charge time error is declared. Under typical conditions, none of the affected devices are expected to reach ERI prior to the middle of 2013. Programmer software version 1.90.0 is now available for use in your clinical practice, which eliminates the opportunity for this unexpected reset state to occur.

In the unlikely event that an affected device malfunctions due to an unrelated issue prior to upgrade, and this issue subsequently results in ERI or a long charge time error, then the device will enter this unexpected reset state. This state causes programmer communication and therapy to be unavailable. While in this state, the device battery depletes at an accelerated rate such that the time between the onset of ERI and the End

of Life (EOL) indicators will be significantly less than the nominal three (3) months. However, the device will be continuously emitting a series of audible tones to alert the patient during this period.

No patient injuries or deaths related to this condition have been reported. 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.

Successful connection of an affected device to a Q-TECH programmer operating software version 1.90.0 automatically eliminates the opportunity for this unexpected reset state to occur.

Patient Management Recommendations

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

- Use Q-TECH programmers operating software version 1.90.0 to upgrade affected devices at the next follow-up, recommended within 3 months per current device labeling. Successful connection of an affected device to a Q-TECH programmer operating this software version automatically performs the upgrade.

- As a reminder, consistent with device labeling, an emitted audible tone may be caused by a variety of reasons, all of which require immediate patient follow-up.

Further Information

Cameron Health sincerely regrets the impact of this notice and wants to reassure you that patient safety remains our primary concern.   If you have any questions regarding this notice, 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