

Important Medical Device Correction Update
Eon™ and Eon Mini™ IPG Charging
Eon Product Code 65-3716 and Eon Mini Product Code 65-3788

July 26, 2012

Dear Physician,

St. Jude Medical is committed to keeping you informed of product performance and patient safety issues. This letter provides an update to the information we shared with you in our December 19, 2011 communication pertaining to the St. Jude Medical Eon and Eon Mini implantable pulse generators (IPGs) for spinal cord stimulation. The December 2011 letter informed you of patient complaints of warmth or heating at the IPG implant site during charging for the Eon and Eon Mini IPG. In this letter we are informing you of three instances of patient burns associated with charging the IPGs as described below.

Update:

As of June 30, 2012, St. Jude Medical has received 127 total patient complaints of warmth or heating at the IPG implant site during charging for the Eon IPG and 198 reports of similar symptoms for the Eon Mini IPG. These reports resulted in total of 29 explants for Eon IPGs and 43 explants for Eon Mini IPGs. As of June 30, 2012, we have received three reports of skin surface burns (one 2nd degree and two 1st degree burns) believed to be associated with heating during charging. Explant surgery, as with any surgery, presents a risk to patient health. Adverse events associated with an unplanned surgery may be comparable to adverse events associated with planned operations, and may include pain, scarring, and infection, as well as complications from anesthesia.

We are investigating all possible root causes of heating for implementing appropriate corrective actions. A supplement to our product labeling, with recommendations from our Medical Advisory Board, are contained in this letter to assist you in communicating important steps for those patients who may experience uncomfortable heating while charging.

In addition to this labeling supplement, we will be implementing design improvements to the charger to address possible increased energy dissipation when the IPG and charger are misaligned or the IPG is located too near the surface of the skin.

Issue Background:

Heat generation during charging is a result of energy dissipation that occurs when an electromagnetic field is used to inductively transfer energy between two objects. For a neurostimulation system, an electromagnetic field is used to inductively transfer energy between the IPG and charging antenna. During a charging session, patients may feel an increase in temperature at the IPG implant site, but should not feel discomfort or pain. In most cases, patients do not report an uncomfortable temperature increase during charging; however, some patients may report experiencing uncomfortable temperature elevations.

Rate of Occurrence:

The reports of heating while charging are associated with 0.44% of the total Eon IPGs and 0.47% of the total Eon Mini IPGs implanted, and the rate of explant due to complaints of heating is 0.10% of the total Eon IPGs implanted and 0.10% of the total Eon Mini IPGs implanted. It should be noted that the stated rate of occurrence refers to the devices associated with the reported complaints. A greater percentage may be affected, as long term rates of heating occurrence for these devices are not known at this time. We continue to monitor complaint data to determine the effectiveness of the labeling changes and recommendations suggested below.

Recommendations:

We realize that each of your patients is unique and we support your clinical judgment in caring for your patients. To assist in your patient care, and following our continuing discussions with our independent Medical Advisory Board, St. Jude Medical recommends the following for patients for whom the temperature at the IPG implant site becomes uncomfortable during charging:

- Stop charging until the discomfort subsides and then resume charging.
- Reposition the charging antennae over the IPG implant site.
- Consider recharging more frequently for less time.
- Avoid tightly inserting the charging wand between the body and a surface that may trap heat, such as a bed or chair.
- If the temperature continues to be uncomfortable, please contact your SJM Representative for evaluation.
- Use of topical anesthetics, medicated balm, and/or pain relief patches on implant site prior to or during charging is not recommended as it may reduce a patient's ability to perceive heat or warmth near or at the implant site.
- Do not charge the device while the patient is asleep.
- Do not consume alcohol immediately prior to or while charging.

We are sending a notification to patients containing the recommendations set forth above. We will also post the patient notification letter on the St. Jude Medical Neuromodulation patient website (www.poweroveryourpain.com). In the event that one or more patients or products potentially affected by this notification have been transferred to other institutions, please forward a copy of this update to the respective physician or institution. Please maintain a record of this notice along with the recommendations to ensure effectiveness of this communication.

The Regulatory Authorities, including the U.S. Food and Drug Administration, have been notified of this action. This correction is being conducted to the patient level.

We apologize for any inconvenience this may have caused you or your patients. If you have questions regarding this action, please contact your St. Jude Medical Neuromodulation Division Representative. We will continue to monitor product performance for opportunities to improve our products, services and instructions for use. We thank you for your continued support.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Neal", written in a cursive style.

Mark Neal
Vice President, Quality
Neuromodulation Division
St. Jude Medical