

IMPORTANT MEDICAL DEVICE CORRECTION

December 19, 2011

Re: Eon™ Product Code 65-3716 (Spinal Cord Stimulation)
Eon Mini™ Product Code 65-3788 (Spinal Cord Stimulation)

Dear Physician,

This letter is written to provide you with important information pertaining to the St. Jude Medical Eon and Eon Mini implantable pulse generators (IPGs). As of November 30, 2011, St. Jude Medical has received 110 patient complaints of warmth or heating at the IPG implant site during charging for the Eon IPG and 116 reports of similar symptoms for the Eon Mini IPG, respectively. These reports resulted in 28 explants for Eon IPGs and 24 explants for Eon Mini IPGs. The reason for explant is believed to have been due to heating at the IPG pocket site. There has been no report received to date of tissue damage associated with the reported complaints. 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.

Our subsequent investigations indicated that our existing labeling for these devices did not adequately address patients who may feel elevated heating during charging. To address this issue, we are introducing changes to our product labeling. The content of these labeling changes is contained in this letter to assist you in communicating important steps for those patients who may experience uncomfortable heating while charging.

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. 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 0.40% of the total Eon IPGs and 0.35% 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 0.07% of the total Eon Mini IPGs implanted. It should be noted that the stated rate of occurrence refers to 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 have taken corrective action by revising directions for use in the product labeling and continue to monitor complaint data to determine the effectiveness of the corrective action.

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 discussions with our outside 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

Upon approval by the Food and Drug Administration, these updated recommendations will be included in our Patient and Clinician directions for use.

In informing you of this situation, St. Jude Medical is conducting a voluntary medical device correction. This correction is being conducted to the physician level. In the event that one or more patients or products potentially affected by this recall have been transferred to other institutions, please forward a copy of this documentation to the respective physician or institution. Please maintain a record of this notice along with the recommendations to ensure effectiveness of this communication. The Food and Drug Administration has been notified of this action.

We apologize for any inconveniences 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,



Steven Robertson
Vice President, Quality Assurance
St. Jude Medical, Neuromodulation Division