

Important Medical Device Safety Information
Eon™ and Eon Mini™ Charging Systems

July 26, 2012

Dear Patient:

St. Jude Medical is providing patients and physicians with important information about their Eon and Eon Mini Charging Systems (Models: 3701, 3711, and 3721).

In a letter dated December 19, 2011, St. Jude Medical informed physicians of patient complaints of warmth or heating at the implant site during charging for the Eon and Eon Mini spinal cord stimulators. Your physician may have informed you of the letter and the recommendations to avoid uncomfortable heating. This letter provides you with our current and expanded recommendations on how to reduce heating while charging the spinal cord stimulator and an update of patient complaints. We are also providing the same recommendations to your physician.

As you know, the Charging System is used to charge your spinal cord stimulator for the management of your chronic pain. St. Jude Medical has informed your doctor that a number of cases have been reported in which discomfort associated with heating occurred at the device site while patients were using the Charging System to charge their spinal cord stimulator. In three cases, patients received a burn to the skin (one second-degree and two first-degree burns) at the implant site. This information applies only to the specific model of the charging systems listed above. Our records indicate that you may have one of these charging systems.

During charging, it is normal to feel an increase in temperature at the implant site; however, you should not feel pain or discomfort. In most cases, patients do not report an uncomfortable temperature increase during charging; however, some patients have reported uncomfortable or intolerable temperature elevations. St. Jude Medical has received 325 total patient complaints of warmth or heating at the device implant site during charging for the Eon and Eon Mini spinal cord stimulation systems, which equates to 0.46% of total implants as of June 30, 2012. Some physicians or patients have requested explant surgery to address uncomfortable temperature elevations. These reports resulted in a total of 72 explants for the Eon and Eon Mini spinal cord stimulators, or a rate of 0.10% of total implants. Explant surgery, as with any surgery, presents a risk to 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.

As communicated to your physician, the information in this letter is a supplement to the directions for use in the product labeling. In addition, we will be implementing design improvements to the charger to address possible increased heating when the spinal cord stimulator and charger are misaligned or the spinal cord stimulator is located too near the surface of the skin. We will keep you informed of product improvements and any additional patient directions for use through our website, www.poweroveryourpain.com.

Recommendations

St. Jude Medical and its independent Medical Advisory Board recommend the following for patients while charging:

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

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. Please maintain this letter with your charger directions for use.

We regret any concerns that this may cause you or your family. St. Jude Medical is dedicated to providing the most reliable medical products and will continue to work closely with your physician to ensure that we provide all of the latest information to continue to manage your spinal cord stimulation system in the best possible way. If you have any questions or concerns, please contact your St. Jude Medical representative or St. Jude Medical Neuromodulation Division at 1-866-240-6741.

Sincerely,



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