

Important Medical Device Correction Update Eon™ Charging System

July 21, 2014

Dear Physician,

You are receiving this letter as a follow-up to the Important Medical Device Correction Update letter you received from St. Jude Medical in July 2012 regarding excessive warmth or heating at the implant site during charging for the Eon™ implantable pulse generators (IPGs). In the July 2012 letter St. Jude Medical informed you that we would be implementing design improvements to the charging system. This letter is to announce the availability of the newly designed Eon™ Charging System Model 3726 to mitigate excessive heating while charging. Note that the charger and the charging antenna have both been redesigned in the new charging system. St. Jude Medical has received complaints of excessive heating while charging that in a small number of cases has resulted in burns or explants which are mitigated by the Eon™ Charging System Model 3726. St. Jude Medical will be exchanging patient chargers for the new Eon™ Charging System Model 3726 free of charge. The new Eon™ Charging System includes the charger, charging antenna, accessories and carrying case.

St. Jude Medical is in the process of sending a letter to all registered patients with an Eon™ IPG to make them aware that the new Model 3726 charging system is available at no charge. A copy of the patient letter is enclosed.

In their letters, patients will be informed that they should contact St. Jude Medical at 888-801-7499 (8:00 am to 5:00 pm EST) to coordinate the replacement of their charger. Even though St. Jude Medical will be contacting patients directly, please remind your Eon™ patients at office visits that occur during the exchange period to contact St. Jude Medical for a charger replacement.

While the new charger is designed to address the issue of excess heating during charging, it is normal to feel some warmth at the implant site or charging antenna, but the patient should not feel discomfort or pain. Lastly, only a portable charger is being made available for exchange and, since some patients currently have a wall charger (Model 3701), the instructions provided in the shipping box and your local representative or Customer Service are available to educate patients on the use of their new charger to ensure a smooth transition.

In addition to making this new charger available to all currently implanted patients, the Eon™ Charger Model 3726 will be provided to new patients at the time of implant. As a reminder, the new Eon™ Model 3726 charger cannot be used with the Eon Mini™ IPG (Model 3788). Patients are being instructed to return all components of their Eon™ charging systems in a prepaid return mailer. The components from the old charging system are not compatible with the new Model 3726 charging system. Please encourage your patients to return their old charger(s) and antenna(s) using the mailer provided.

Until such time that your patients have had their chargers replaced, please inform patients using Eon™ Wall Charger Model 3701 and/or Eon™ Portable Charger Model 3711 to continue charging following the supplemental instructions from our July 2012 letter.

- 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 antenna 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.

We have notified the regulatory authorities, including the U.S. Food and Drug Administration, of this action.

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 Representative or call 888-801-7499 (8:00 am to 5:00 pm EST). We always look for ways to improve our products, services and instructions for use and will continue to monitor product performance for those opportunities. Thank you for your on-going support.

Sincerely,



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