

Important Medical Device Safety Information
 Eon™ Charging System

July 21, 2014

Dear Patient,

You are receiving this letter as a follow-up to the **Important Medical Device Safety Information** letter you received from St. Jude Medical dated July 2012 regarding the potential for excessive warmth or heating at the implant site during charging of Eon™ spinal cord stimulators. In the July 2012 letter, St. Jude Medical informed you that we would be implementing design improvements to the charging system to address possible excessive energy dissipation during charging. We are pleased to inform you that a replacement portable charger, which has been redesigned to address this concern, is now available at no charge. Please call 888-801-7499 (8:00 am to 5:00 pm EST, Monday through Friday) to exchange your Eon™ Wall Charger Model 3701 and/or Eon™ Portable Charger Model 3711 for a newly redesigned Eon™ Portable Charger Model 3726. Please have your charger with you when you call. Both the Eon™ Wall Charger Model 3701 and Eon™ Portable Charger Model 3711 are now obsolete and are being replaced with the Eon™ Portable Charger Model 3726. 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. Your physician has also been notified of the availability of the new charger.

Identification of Chargers Eligible for Exchange: Your chargers which are eligible for exchange will have “Model 3701” or “Model 3711” printed in black letters on the label on the back of the charger. This marking is shown in Diagram 1 below.

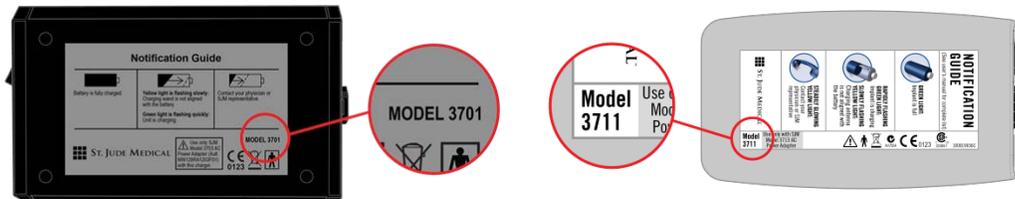


Diagram 1. Model Number Location on Chargers Eligible for Exchange

Your chargers which are eligible for exchange may look like either of the chargers shown in Diagram 2 below.



Diagram 2. Old Eon™ Chargers and Charging Antennas, Model 3701 and Model 3711

When you call to initiate the exchange, the St. Jude Medical representative will coordinate the shipment of a new Eon™ Charging System, Model 3726 at no charge to you. The new charging system includes the charger, charging antenna, accessories and carrying case. The components from the old charging system are not compatible with the new Model 3726 charging system and are to be returned to St. Jude Medical. In addition to your new charging system, the delivery will also include a pre-paid return mailer to return your old charger(s) and antenna(s). The St. Jude Medical representative will explain the return process during your call.

The new Eon™ Portable Charger Model 3726 will be provided with instructions. These instructions are especially important for current users of the Eon™ Wall Charger Model 3701 to follow because the process for charging your device is slightly different. Specifically, the new portable charger has rechargeable batteries that must be recharged by plugging the portable charger into a wall outlet before you can use the portable charger to charge your Eon™ spinal cord stimulator. Please refer to the new Eon™ Portable Charger Model 3726 manual for instructions on charging the charger prior to charging your spinal cord stimulator. The replacement Eon™ Portable Charger Model 3726 is shown in Diagram 3. Note that the new charging antenna has also been redesigned and is now solid like your patient programmer antenna and does not contain an opening like your old antenna shown in Diagram 2.



Diagram 3. New Eon™ Charging System Model 3726

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 you should not feel discomfort or pain. While you await delivery of your new charger, continue to follow the supplemental directions for use from the July 2012 letter when charging your system.

- 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. St. Jude Medical is dedicated to making the exchange of your charging system easy for you and we regret any inconvenience to you or your family. If you have any questions or concerns throughout this process, please call St. Jude Medical at 888-801-7499 (8:00 am to 5:00 pm EST, Monday through Friday).

Sincerely,



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