



Follow up on Field Safety Notice issued in July 2012
Eon Mini™ IPG Charging
Eon Mini Product Code 65-3788

Sept 4, 2013

Dear Customer,

You are receiving this letter as a follow-up to the Important Medical Device Safety Information letter you received from St. Jude Medical in July 2012 regarding the potential for excessive warmth or heating at the implant site during charging for the Eon Mini spinal cord stimulators. In the July 2012 letter, St. Jude Medical informed you that we would be implementing design improvements to the charger to address the possibility of increased energy dissipation during charging. We would now like to inform you that a replacement charger, which is intended to address this concern, is available.

This letter is intended to:

- Briefly remind you of the issue and our commitment.
- Describe the corrective action(s).
- Provide patient management recommendations.

If you need any further information or support concerning this issue, please contact your local St. Jude Medical Representative at [REDACTED].

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,

Mark Neal
Vice President, Quality Assurance

Follow up on Field Safety Notice issued on July 2012

Potential for warmth or heating at the IPG implant site during charging.

Affected products	Eon Mini IPG Model 65-3788 EON Mini Charger Model 3721 Eon Mini Charger Accessory, Model 3719
Problem description	Some patients have reported experiencing an uncomfortable temperature increase at the IPG implant site during charging, with a small number of patients reporting burns at the implant site.
Corrective action	<ul style="list-style-type: none"> • The Eon Mini Charger Model 3721 and Eon Mini charger accessory Model 3719 are discontinued. Please refrain from providing them to patients and place available stock in quarantine. • Eon Mini LE Charger Model 3722 replaces the Model 3721. • Eon Mini LE Charger Accessory Model 3720 replaces the model 3719. • As of now, the Eon Mini Charger LE Model 3722 is provided for any new implants. • Your St. Jude Medical representative will retrieve the 3721 and 3719 models and will replace them with Model 3722 and 3720 at no cost. • Eon Mini 65-3788 which are unused shall be placed in quarantine and will be retrieved and replaced at no cost with updated instructions for use with recommended maximum depth of implant (2.25cm).
Benefit of the new charger	The new Eon Mini LE Charger Model 3722 and Eon Mini LE Charger Model 3720 reduce the potential for uncomfortable temperature increases that may be felt near the spinal cord stimulator while recharging by automatically turning the energy it delivers on and off to reduce the rise in temperature of the spinal cord stimulator and of the charger wand during charging. This will require patients to charge longer or more frequently to achieve a full charge.
Limitations of the new charger	The Eon Mini LE Charger Model 3722 or Eon Mini LE Charger 3720 may not be able to charge the IPG at an implant depth greater than 2.25 cm (the Model 3721/3719 was labeled for depth up to 2.50 cm).

Formateret tabel

<p>Patient management recommendations</p>	<ul style="list-style-type: none"> • We recommend the prompt replacement of the charger for patients who report or have reported excessive heating during charging • For other patients, replacement of the charger is suggested at the next follow up. • Upon replacement, proper charging function of the Eon Mini LE Charger Model 3722/3720 should be confirmed. <p>In case of difficulties with the charging function of the Eon Mini LE Charger Model 3722/3720 due to depth of implant, patient should continue to use the Eon Mini Charger Model 3721/3719 (i.e. older charger), following the precautions provided in the July 2012 letter. <u>Those precautions are as follows:</u></p> <ul style="list-style-type: none"> • <u>If the temperature at the implant site becomes uncomfortable during charging:</u> <ul style="list-style-type: none"> ○ <u>Stop charging until the discomfort subsides and then resume charging;</u> ○ <u>Reposition the charging antenna over the implant site;</u> ○ <u>Consider recharging more frequently for less time;</u> ○ <u>If the temperature continues to be uncomfortable, please contact your physician, SJM representative, or St. Jude Medical Technical Services.</u> • <u>Avoid tightly inserting the charging wand between the body and a surface that may trap heat, such as a bed or chair.</u> • <u>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.</u> • <u>Do not charge the device while asleep.</u> • <u>Do not consume alcohol immediately prior to or while charging.</u>
<p>Further information and support</p>	<p>If the 3721/3719 charger is not exchanged at this time (patient declines replacement) and issues arise in the future, SJM will be limited on the support that can be provided on the 3721/3719 chargers. The charger will be exchanged to model 3722/3720 at that time.</p> <p>To ease retrieval of Model 3721 and 3719 chargers, a list of Eon Mini IPGs supplied to your hospital is attached.</p> <p>Your St. Jude Medical representative is at your disposal to support you with the implementation of this action.</p>

Formateret: Skrifttype: 10 pkt

Formateret: Skrifttype: (Standard) Arial, 10 pkt

Formateret: Skrifttype: 10 pkt

Formateret: Normal, Ingen punkttegn eller nummerering

Formateret: Listeafsnit, Indrykning: Venstre: 0,48 cm