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IMPORTANT MEDICAL DEVICE RECALL

May 24, 2011

Re: Eon Mini™ Product Code 65-3788 (SCS)

Dear Doctor,

This letter is written to provide you with information pertaining to the Eon Mini™ Model 3788, Implantable Pulse Generator (IPG). It is part of St. Jude Medical's commitment to continuously inform and educate customers about technical and product performance issues. As part of our systematic tracking and product monitoring, St. Jude Medical's analysis of complaint data revealed 79 reports of Eon Mini IPGs that have lost the ability to communicate or recharge, resulting in loss of pain relief and possible subsequent explant. 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 reoperations, and may include pain, scarring, and infection, as well as complications from anesthesia.

This recall relates only to defects of the internal battery component that is fully contained within the outer hermetically sealed IPG titanium can. Our records indicate that you may have implanted potentially affected device(s) or have a potentially affected device(s) in your product inventory. See a list of model serial numbers in Attachment A for implanted devices and Attachment B for unimplanted device(s) we show are within your product inventory. St. Jude Medical plans to recall the unimplanted Eon Mini IPGs identified with the specific serial numbers listed in Attachment B. Please follow the instructions discussed in the section of **Recommendations** below.

Issue Summary:
Product investigation and analysis conducted as a result of the reports of inability to communicate or recharge the Eon Mini IPG identified a defective battery as the root cause. The duration between recharges became progressively shorter until the IPG failed to charge or there was a sudden loss of power which resulted in device replacement. After thorough investigation and analysis of the potential root causes of battery malfunctions we determined that weld failures within the internal battery of the IPG caused most of these reports. The weld failures caused the batteries to leak electrolyte and prevented them from holding a charge. The battery is fully contained within the outer hermetically sealed titanium main IPG can (casing), and therefore, will not leak electrolyte into the body. Extensive review of our battery supplier's manufacturing processes identified a need to improve process controls, which we have comprehensively addressed. No reports of this battery failure mode have been received for batteries manufactured with these improved process controls.

Loss of stimulation for pain relief or the inability of the IPG to recharge due to a defective battery may require an explant for product replacement. Please review the instructions in Items 1 through 3 of the **Recommendations** section below to determine whether or not to explant the potentially affected IPG listed in Attachment A (implanted devices).

Rate of occurrence:

The current battery failures caused by this defect represent 0.46% of the total IPG devices affected by this recall; the long term failure rates for these devices are not known at this time. We have taken corrective action and implemented improved process controls and continue to monitor complaint data to determine the effectiveness of the corrective actions. Devices with serial numbers not contained within Attachment A or Attachment B are not impacted. It should be noted that the stated rate of occurrence refers to units of reported failure; a greater percentage may be defective.

To properly address these issues, please see the Recommended Actions below.

Recommendations:

St. Jude Medical understands that each patient is different and recommends you discuss this issue with your patient as necessary. To further assist in your patient care, and following discussions with our outside Medical Advisory Board, St. Jude Medical recommends:

- For product that does not match the serial number listing in Attachment A or Attachment B, no actions are necessary.
- For product within your **unimplanted inventory** that matches the serial number listing in Attachment B, please contact your SJM Representative to have the device returned to St. Jude Medical. A replacement device will be provided at no additional cost to you.
- For **implanted product** that matches the serial number listing in Attachment A, as advised by our Medical Advisory Board:

    1. **We recommend that you do not unnecessarily explant the devices associated with this advisory if the IPGs are functioning as intended.**
    2. If the duration between recharges becomes significantly shorter or there is a sudden loss of power, contact your St. Jude Medical representative to evaluate if
        - the recharge burden is within normal operating expectations based on the patient's programmed parameters,
        - the device is approaching normal end of life expectancy, or
        - a device replacement is warranted.
    3. If device replacement is required due to weld failures within the inner battery, St. Jude Medical will provide a replacement IPG at no charge.

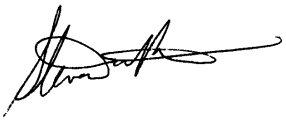
Transfer of this Information:

By informing you of this situation, St. Jude Medical is conducting a voluntary medical device recall. This recall is being conducted to the physician level. In the event that one or more patients have transferred to other institutions for their care, please forward a copy of the 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.

St. Jude Medical is committed to keeping customers informed about important product information. If you have questions regarding this action, please contact your St. Jude Medical Neuromodulation Division Representative.

Please rest assured that we will continue to monitor supplier and product performance for opportunities to improve our products, services and instructions for use, in order to continue providing the highest standards of health care instrumentation. We thank you for your continued support.

Sincerely,



Steven Robertson
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