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IMPORTANT MEDICAL DEVICE RECALL

December 19, 2011

Re: Eon Mini™ Product Code 65-3788 (Spinal Cord Stimulator) Manufactured Before September 30, 2010

Dear Physician,

This letter provides important information pertaining to the Eon Mini implantable pulse generators (IPGs) manufactured before September 2010. As part of St. Jude Medical's routine tracking and product monitoring, we have received 112 reports of Eon Mini IPGs that lost the ability to communicate or recharge due to a workmanship issue resulting in loss of pain relief and subsequent explant. After thorough analysis, we have determined the cause of these reports to be related to process variances in the positioning of the internal battery and printed circuit board, causing a short, and therefore, prematurely depleting battery voltage. Our post-marketing surveillance received 112 reports of premature battery depletion out of the 25,255 devices covered by this voluntary recall.

Our records indicate that you have implanted potentially affected device(s) or have a potentially affected device(s) in your product inventory. Patients who experience this failure mode may require a premature explant surgery. 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. We are therefore writing to inform you of the issue and to pass on additional advice from our outside Medical Advisory Board on patient management.

Issue Summary:
In the 112 complaints reported to date, product investigation and analysis identified a processing condition related to the positioning of components. Patients may have experienced a sudden loss of power or the duration between recharges became progressively shorter until the IPG failed to charge resulting in device replacement. The investigative analysis indicates that when the negative battery strap of the internal IPG battery comes into contact with the micro-processor board, a short to the IPG battery can occur, leading to this failure mode. We have taken corrective action and, as part of our normal post-marketing surveillance process, will continue to review complaint data to monitor the effectiveness of the corrective action.

In September 2010, we improved our manufacturing instructions to clarify the spacing of the internal battery component, to ensure proper component positioning, and to enhance inspection instructions. To ensure the effectiveness of the improved manufacturing and inspection instructions, and that process variations are not affecting our currently manufactured product, we have retrained all manufacturing operators and inspectors on the procedures for battery strap assembly and verification. Additional manufacturing process controls are also being considered.

Rate of occurrence:
The current IPG failures attributed to this defect represent 0.44% of the total Eon Mini IPGs affected by this voluntary recall. The long-term failure rates for these devices are not known at this time. Devices with serial numbers listed in Attachment A were manufactured prior to the implementation of the improvements in manufacturing. Devices manufactured after September 2010 are not impacted by this voluntary recall.

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, we are providing you with a list of all serial numbers we show have been distributed to you (see Attachment A). Following discussions with our outside Medical Advisory Board, St. Jude Medical recommends:

- For product that does not match the serial number listing, no actions are necessary.
- For **unimplanted inventory** that matches the serial number listing in Attachment A, 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, as advised by our Medical Advisory Board:
    - **It is recommended that you do not unnecessarily explant the devices associated with this advisory if the IPGs are functioning as intended.**
    - If there is a sudden loss of power or if the duration between recharges becomes significantly shorter, contact your St. Jude Medical Representative to evaluate if
        - the recharge interval 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.
    - If device replacement is required due to IPG failure related to this voluntary recall notice, 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 voluntary recall is being conducted to the physician level. In the event that one or more patients or products potentially affected by this voluntary recall have been transferred to other institutions, please forward a copy of this 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.

Please accept our apologies for any inconvenience this may have caused you or your patients. 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.

We will continue to monitor our manufacturing process controls and product performance for opportunities to improve our products, services and instructions for use. We thank you for your continued support.

Sincerely,

Steven Robertson
Vice President, Quality Assurance
St. Jude Medical, Neuromodulation Division