ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

St. Jude Medical
Neuromodulation Division
6901 Preston Road
Plano, TX 75024
Tel 972 309 8000
Fax 972 309 8150

IMPORTANT MEDICAL DEVICE INFORMATION UPDATE
Eon Mini™ Product Code 65-3788 (SCS) and Brio™ Product Code 65-6788

July 26, 2012

Dear Physician,

This letter provides an important update to the previous recall notification letter, dated May 24, 2011, pertaining to the Eon Mini Model 3788 and Brio Model 6788 implantable pulse generators (IPGs) inner battery cracking issues. As part of St. Jude Medical's product monitoring, we have received a total of 216 reports out of 35,053 Eon Mini and Brio IPGs that lost the ability to communicate or recharge due to an inner battery weld issue resulting in loss of pain relief and subsequent explant. Our records indicate that you have implanted potentially affected device(s) or have a potentially affected device(s) in your product inventory.

Issue Summary:

Product investigation and analysis conducted by St. Jude Medical concerning reports of the inability to communicate or recharge the Eon Mini IPG has identified weld cracks in the IPG's inner battery as the cause of this issue. In May 2011 we reported a weld failure that caused the batteries to leak electrolyte and prevented them from holding a charge. Thorough analysis of additional batteries with weld cracks and review of the manufacturing processes at the battery supplier has identified the need to more frequently maintain and replace welding fixtures to assure complete alignment between the welding apparatus and the battery. It is important to note that the battery is contained within the hermetically-sealed IPG case and cannot leak outside the IPG casing.

St. Jude Medical has already implemented additional process controls with our supplier to address this new failure mechanism. Extensive sample testing of batteries contained in IPGs beyond the recalled population and within our inventory shows the cause of the weld failures has been mitigated. We will continue to investigate and eliminate all possible root causes, test battery lots, and monitor product performance to ensure integrity of this component.

Rate of Occurrence:

As of June 30, 2012 we have received 216 reports of Eon Mini and Brio IPGs out of a population of 35,053 distributed devices affected by this field action (0.62%) where the device lost the ability to communicate or recharge due to the development of a crack in the inner battery weld resulting from this new failure mechanism. The long term failure rates for these devices are not known at this time. We have taken corrective actions and implemented improved process controls and continue to monitor complaint data to determine the effectiveness of the corrective actions. It should be noted that the stated rate of occurrence refers to the units of reported failure. A greater percentage may be defective.

Recommended Actions:

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. However, if you received an IPG from another source or a patient has transferred from another physician, please contact your St. Jude Medical Neuromodulation Division representative to check those serial numbers for potentially affected devices.
- For unimplanted product that matches devices listed in the serial number listing in Attachment A, do not implant the device and please contact your St. Jude Medical 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:
    - We recommend that you do not unnecessarily explant the devices associated with this advisory if the IPGs are functioning as intended.
    - 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 characteristics, or
        - a device replacement is warranted.

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:

Through this communication, St. Jude Medical is conducting a voluntary medical device recall notification. 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. Regulatory Authorities have been notified of this action.

St. Jude Medical is committed to keeping customers informed about important product information and to ensuring that we deliver you the highest quality devices possible. If you have questions regarding this update, please contact your St. Jude Medical Neuromodulation Division Representative.

Please accept our apologies for any inconvenience this issue may cause you or your patients. 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.

Sincerely,

[redacted]

[redacted]
Vice President, Quality
Neuromodulation Division
St. Jude Medical