ST. JUDE MEDICAL
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Q&A FOR MARCH 2012 BRIO™ IPG (MODEL 6788) FIELD CORRECTIVE ACTION

1. **What products are impacted by this field corrective action?**

   The Brio IPG (Model 6788) is the only neuromodulation product addressed in this field corrective action. No other IPGs, leads or accessories across the chronic pain and neurological disorders businesses will be impacted.

2. **Are all Brio devices impacted by this field corrective action or only certain serial numbers?**

   It is important to note that **all** Brio IPGs (both implanted and in inventory) are potentially impacted by this action.

3. **Why is St. Jude Medical taking this field corrective action?**

   We are taking this voluntary action because of our commitment to patient safety and to the delivery of high quality products. St. Jude Medical received reports of therapy degradation associated with a small number of Brio IPGs at a very limited number of hospitals.

   An analysis of returned devices found that fluid had intruded into the IPG header assembly leading to diminished or loss of therapy. Septum damage, which can occur during implant, was found in a majority of the explanted devices and can contribute to fluid intrusion into the IPG header assembly. We are taking a proactive approach by issuing a voluntarily field corrective action for the Brio IPG and implementing improvements to the product.

4. **How prevalent is the issue identified in the letter?**

   Fluid intrusion into the IPG header assembly has resulted in St. Jude Medical receiving eleven (11) complaints from a very limited number of hospitals reporting Brio devices with confirmed low impedance readings and patients experiencing diminished or loss of therapeutic stimulation. This represents 2.84% of the total population of implanted Brio devices. Eight (8) or 2.06% of the total population of implanted Brio devices have been explanted due to low impedance readings and patients experiencing diminished or loss of therapeutic stimulation. In all eight (8) cases, the patients were re-implanted with a new DBS IPG and DBS therapy resumed.

5. **Why does this issue result in diminished or lost therapy?**

   Fluid intrusion into the IPG header assembly creates an undesirable low impedance path for current to flow, diverting a portion of the therapeutic current away from the patient's neural target. Depending on the proportion of current that is diverted, the Brio IPG may not have sufficient range of therapeutic output to compensate for the current loss.

   Electrical modeling has determined that in the worst case, the therapeutic current can be reduced by upwards of 75%, requiring a 4X increase in stimulation amplitude to compensate. A required increase in amplitude of this magnitude is outside the range of typical DBS therapeutic settings and potentially outside of the output capability of the Brio IPG.

6. What actions is St. Jude Medical recommending clinicians take immediately?

St. Jude Medical is informing physicians to immediately discontinue the implantation of the Brio IPG and isolate the device(s) for return to St. Jude Medical. A local St. Jude Medical representative will collect the unused inventory. Any unused inventory will be replaced with product once inventory becomes available.

If you have a patient who is experiencing diminished or loss of therapy, consult the troubleshooting steps recommended in the field corrective action letter.

St. Jude Medical's independent medical advisory board recommends that physicians do not unnecessarily explant Brio IPGs that are providing appropriate therapy.

7. What steps should the SJM field representative and/or physician take to troubleshoot the device if they believe there is an issue?

For patients with implanted product who experience diminished or loss of therapy, use the following steps to diagnose the situation:

1) Rule out common causes of diminished or lost therapy by following the troubleshooting steps provided in the Brio IPG Clinician's Manual Troubleshooting Section.
2) Use the Brio Clinician Programmer (not the Athena Programmer) to interrogate the system for low impedance values.
    - Do monopolar impedance checks on all lead contacts. Any channel reading "Low" (< 200 Ohms) may indicate fluid intrusion on that channel.
    - Perform a monopolar impedance check on all channels without a lead connection (typically channels 5-8 and 13-16) using the Brio Clinician Programmer. A result reading less than 3000 Ohms indicates potential fluid intrusion into the header assembly.
3) Attempt to recapture therapy by adjusting IPG settings.
    - First, increase the amplitude or pulse width to compensate for diverted current. It is recommended that patient amplitude control be prescribed to allow patients to adjust therapy as needed.
    - Second, program a bipolar stimulation field (i.e., not using IPG can as anode), using electrodes that did not read "Low" in Step 3.
4) If adjusting the IPG's therapy settings does not recover therapy for the patient, consider replacing the Brio IPG with a St. Jude Medical Libra™ or LibraXP™ IPG, another manufacturer's device, or another St. Jude Medical Brio IPG when available. St. Jude Medical will provide a replacement IPG at no charge or issue a credit note for the explanted Brio IPG.

8. How will St. Jude Medical reimburse customers for replacement devices?

For unimplanted inventory, clinicians and/or facilities should immediately return any impacted product for a full reimbursement.

If the clinician elects to explant a Brio IPG due to believed fluid in the IPG header assembly, St. Jude Medical will either (1) provide a Libra or LibraXP replacement device at no charge(the sales representative should indicate on the invoice a no-charge replacement for Brio explant), or (2) if the physician elects to replace the explanted Brio IPG with a Medtronic device, we will issue a credit note for the explanted Brio IPG. For either option, THE BRIO IPG MUST BE RETURNED TO PLANO FOR ANALYSIS.

9. **What financial assistance will St. Jude Medical be offering in the event of an explant resulting from fluid intrusion into the IPG header assembly?**

   If adjusting the IPG's therapy settings does not recover therapy for the patient and the physician elects to replace the Brio IPG with a St. Jude Medical Libra or LibraXP IPG or another manufacturer's device, St. Jude Medical will provide a replacement IPG at no charge or issue a credit note for the explanted Brio IPG. If there is a request to assist the patient with out of pocket expenses not covered by insurance, or if the customer is requesting that St. Jude Medical pay for the replacement procedure, contact Marta Munson in the NMD Legal Department (marta.munson@sjmneuro.com, + 1 972-309-8531) prior to making any commitments to the customer. Any reimbursement to patients or payment of procedure costs must be approved in advance by NMD Plano.

10. **What drove the timing of this field corrective action?**

    St. Jude Medical is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient. St. Jude Medical decided to take this voluntary action at the point when the facts were understood and the root causes clearly identified.

11. **The Brio system has been on the market for 2 ½ years. Why is this issue just now being discovered?**

    St. Jude Medical actively monitors all of its products and took this voluntary action promptly after all facts were understood and the root causes clearly identified. This product has had limited distribution, and we are actively engaged with all customers who have experienced this issue.

12. **Does this problem affect Brio IPG product availability?**

    Yes. While improvements are being implemented, the Brio IPG will not be available for implant. Libra and LibraXP systems for the symptomatic treatment of Parkinson's disease will continue to be available for implant.

13. **What is going to happen to the Brio device?**

    St. Jude Medical is implementing improvements to the Brio IPG in response to this issue. Typically, these improvements take 60 to 90 days to develop, test, and implement. St. Jude Medical is committed to the Brio platform and the improved product will be made available upon regulatory approval.

14. **Have all the regulatory agencies been notified of this field corrective action?**

    Yes, all relevant regulatory agencies have been notified.

15. **How should I approach the DBS business while the Brio improvements are being implemented?**

    While it is unfortunate that there will be a supply interruption for the market leading DBS rechargeable IPG, it is important to remain focused on the DBS space. Remind your clinician partners that both Libra and Libra XP are viable options that provide unique patient benefits.

16. **Are the header assemblies on the Libra systems different than Brio?**

    The Libra and LibraXP IPGs do not have the same header assembly design as the Brio IPG.

17. **Is the issue of fluid intrusion only related to the Brio IPG or is there a problem with the IS-1 Pocket Adapter, as well?**

    The Brio IPG (Model 6788) is the only neuromodulation product addressed in this field corrective action. No other IPGs, leads and accessories across the chronic pain and neurological disorders franchises will be impacted.

18. **What materials do I have to help address concerns associated with this field corrective action?**

    You have access to the letter that was sent directly to physicians along with the content provided in the Q&A document and PowerPoint presentation. Additionally, both you and your physicians have access to knowledgeable St. Jude Medical personnel to address additional questions and/or concerns.

19. **What should I do if my physicians or I have questions that have not been addressed in the materials provided?**

    All outstanding questions not covered in the materials provided should be addressed to either your direct leadership or the contacts that will be provided to you under separate cover.

20. **What actions are we specifically asking St. Jude Medical field personnel to take immediately?**

    Proactively approach customers, share a brief summary of the issue, quarantine and return all unused inventory to the Belgium distribution center by April 20, 2012.

21. **Will St. Jude Medical be sending any communication to patients?**

    No, but physicians are free to pass this information along to patients if they believe it is appropriate. If a physician would like to communicate with their patients, St. Jude Medical can provide them with a template letter for their convenience.

22. **When will I be able to resume Brio IPG implantation?**

    St. Jude Medical is implementing improvements to the Brio IPG in response to this issue. Typically, these improvements take 60 to 90 days to develop, test, and implement. St. Jude Medical is committed to the Brio™ platform and the improved product will be made available upon regulatory approval.

23. **What changes are being made to the Brio IPG to ensure fluid intrusion into the IPG header assembly does not happen in the future?**

    St. Jude Medical is implementing improvements to the Brio IPG in response to this issue.

24. **Is St. Jude Medical exiting the DBS market?**

    No! St. Jude Medical is committed to deep brain stimulation (DBS) therapy, and the company continues to sell its Libra and LibraXP systems for the symptomatic treatment of Parkinson's disease. This action does not affect any ongoing DBS clinical studies.

25. **Does this field corrective action affect any St. Jude Medical clinical studies?**

    This action does not affect ongoing DBS clinical studies.

26. **Have the failures resulted in any adverse events to date other than loss of therapy and a potential revision surgery?**

    Not to our knowledge.

27. How long after implant is this issue typically seen?

To date, most but not all reports have occurred soon after implantation.

28. Is there a quality problem at St. Jude Medical's Neuromodulation Division?

The very short answer to that question is "no." It is no secret that the Neuromodulation Division is operating under an FDA warning letter. NMD has dedicated a large number of resources to improve design, manufacturing, and quality. We are proud of our accomplishments to date and we will continue to elevate quality for the neuromodulation industry.

29. Will the FDA be notified about this field corrective action?

Even though the Brio system is not approved in the United States, St. Jude Medical will be sending the FDA a notification letter on this international field corrective action. The FDA may classify this field corrective action as a Class II recall. In a Class II recall, there is either a possibility that the device will cause temporary or reversible health problems, or there is a remote chance that the device will cause serious health problems.