ST. JUDE MEDICAL

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Important Product Usage Information

Eon™, Eon™ C and Eon Mini™ Rechargeable IPG, Prodigy™ Chronic Pain System, Genesis™ Primary Cell IPG
Octrode™, and Quattrode™ leads

October 10th, 2014

Dear Customer,

The purpose of this letter is to inform you that the indication for St. Jude Medical's (SJM) occipital nerve stimulation (ONS) therapy for the treatment of intractable chronic migraine is being removed from the product instructions for use.

The European Notified Body with which SJM worked on CE mark for this indication, decided that the available data provided through post market clinical follow up was not compelling enough to demonstrate that the benefit of the therapy outweighs the risk at this time. As a result, the inclusion of this specific indication on the Australian Register of Therapeutic Goods has also been removed.

St. Jude Medical asks you to refrain from using the Genesis™, Eon™, Eon™ C, Eon™ Mini, and Prodigy™ SCS devices and associated programmers, as well as the Octrode™ and Quattrode™ leads, for the purpose of occipital nerve stimulation. Please note that these products are still available for use as an aid in the management of chronic, intractable pain of the trunk and/or limbs.

It is important to note that no new risks or abnormal trends have been identified with either these devices or with the ONS therapy. Regarding patients who have already been treated for ONS therapy, St. Jude Medical is not recommending a change in the way patients are followed. The factors impacting the individual patient risk / benefit analysis performed as part of the initial treatment decision remain unchanged.

St. Jude Medical remains committed to investing in the research and development of ONS technology as we recognize the potential it offers to improve the lives of patients who have failed multiple therapies and currently do not have adequate treatment options for their intractable chronic migraine. For this reason, St. Jude Medical will continue to monitor patients enrolled in our RELIEF Migraine study to compile the necessary data to demonstrate that the benefits of occipital nerve stimulation for chronic migraine outweigh the risks. With these data, we plan to collaborate with the European Notified Body to discuss reinstating the approval for this indication.

Required Government Regulatory Authorities received a copy of this letter.

If you need further information or support concerning this issue, please contact your local SJM sales representative.

St. Jude Medical is committed to providing the highest quality products and support. We apologize for any inconvenience this change may cause.

Respectfully,

Harry Janiski

Harry Janiski
Vice President, Global Operations and Supply Chain Quality
St. Jude Medical