REPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
LE DIRECTEUR GÉNÉRAL

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات:
رقم الصادر : ١٢/١/١٤٩٢٣
بيروت، في : ١٧ ايار ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعني بالمتابعة:

- Stimulators, Eon and Eon Mini Implantable Pulse Generators.
  Trade Mark: St. Jude Medical Inc
  Local Representative: Basic Trading

بناء على التقرير الصادر عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود مضاعفات أثناء تشريح الصنف الوارد أعلاه، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة والمتابعة مع الشركة الموردة لاتخاذ الاجراء المناسب.

نرجو تعميم هذه النشرة على المستشفيات المعنية والعمل بموجب التوصيات الصادرة عن الشركة المصنعة والمتابعة مع الشركة الموردة لاتخاذ الاجراء المناسب.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المحفوظات

وثيقة مصدقة للأصل
بيروت في ٢٠ ايار ٢٠١٢
رئيس قسم امانة السر
عناية غصن

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
قسم الديوان
وزارة الصحة العامة

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جانب شركة: Basic Trading

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مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
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مدير عام الصحة

د. وليد عمار

وثيقة مصدقة للأصل
بيروت في ٢٠ ايار ٢٠١٢
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الجمهورية اللبنانية
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قلم الديوان
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ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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Important Medical Device Information Update
Eon™, Eon Mini™ and Brio™ IPG Charging
Eon Product Code 65-3716, Eon Mini Product Code 65-3788 and
Brio Product Code 65-6788

July 26, 2012

Dear Physician,

St. Jude Medical is committed to keeping you informed of product performance and patient safety issues. This letter provides an update to the information we shared with you in our December 19, 2011 communication pertaining to the St. Jude Medical Eon™, Eon Mini™ and Brio™ implantable pulse generators (IPGs). The December 2011 letter informed you of patient complaints of warmth or heating at the IPG implant site during charging for the Eon, Eon Mini and Brio IPG. In this letter we are providing updated occurrence rates and informing you of four instances of patient burns associated with charging the IPGs as described below.

Update:

As of June 30, 2012 the reports of heating while charging remain relatively unchanged on Eon IPGs at 0.44% since our December 2011 communication, while the rate of heating during charging has increased minimally to 0.47% on Eon Mini IPGs. There has been one patient complaint associated with Brio IPGs, or 0.21%. Additionally, the explant rates due to complaints of heating during charging at the implant site also remain unchanged at 0.10% on Eon IPGs since our December 2011 communication, while the explant rates due to complaints of heating during charging at the IPG implant site have increased minimally 0.10% on Eon Mini IPGs. Brio IPG explants remain at zero percent (0%). It is important to note that the long term rates of heating for these devices is unknown and we will continue to monitor complaint data.

We are investigating all possible root causes of heating for implementing appropriate corrective actions. A supplement to our product labeling with additional recommendations from our Medical Advisory Board are contained in this letter to assist you in communicating important steps for those patients who may experience uncomfortable heating while charging. All recommended actions should be taken prior to considering 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 operations, and may include pain, scarring, and infection, as well as complications from anesthesia.

In addition to this labeling supplement, we will be implementing design improvements to the charger to address possible increased energy dissipation when the IPG and charger are misaligned or the IPG is located too near the surface of the skin.

Issue Background:

Heat generation during charging is a result of energy dissipation that occurs when an electromagnetic field is used to inductively transfer energy between two objects. For a neurostimulation system, an electromagnetic field is used to inductively transfer energy between the IPG and charging antenna. During a charging session, patients may feel an increase in temperature at the IPG implant site, but should not feel discomfort or pain. In most cases, patients do not report an uncomfortable temperature increase during charging; however, some patients may report experiencing uncomfortable temperature elevations.

Recommendations:

We realize that each of your patients is unique and we support your clinical judgment in caring for your patients. To assist in your patient care, and following our continuing discussions with our independent Medical Advisory Board, St. Jude Medical recommends the following for patients for whom the temperature at the IPG implant site becomes uncomfortable during charging:

- Stop charging until the discomfort subsides and then resume charging.
- Reposition the charging antennae over the IPG implant site.
- Consider recharging more frequently for less time.
- Avoid tightly inserting the charging wand between the body and a surface that may trap heat, such as a bed or chair.
- If the temperature continues to be uncomfortable, please contact your SJM Representative for evaluation.
- Use of topical anesthetics, medicated balm, and/or pain relief patches on implant site prior to or during charging is not recommended as it may reduce a patient's ability to perceive heat or warmth near or at the implant site.
- Do not charge the device while the patient is asleep.
- Do not consume alcohol immediately prior to or while charging.

In the event that one or more patients or products potentially affected by this notification have been transferred to other institutions, please forward a copy of this update to the respective physician or institution. Please maintain a record of this notice along with the recommendations to ensure effectiveness of this communication.

The Regulatory Authorities have been notified of this action. Please provide your patients with the affected implants the instructions on how to address this correction.

We apologize for any inconvenience this may have caused you or your patients. If you have questions regarding this action, please contact your St. Jude Medical Neuromodulation Representative. We will continue to monitor product performance for opportunities to improve our products, services and instructions for use. We thank you for your continued support.

Sincerely,

Mark Neal
Vice President, Quality
Neuromodulation Division
St. Jude Medical