



رقم المحفوظات: ١١/٢٨
رقم الصادر: ١٣/١/٥٨٠
بيروت، في: ٠٥ - كانون الثاني ٢٠١٢

جانب شركة Basic Trading Company

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Implants, active, pacemaker, Accent SR and Accent DR

الجهاز المعنى بالمتابعة:

- Implants, active, pacemaker, Accent SR and Accent DR
- Trade Mark: St. Jude Medical Inc
- Local Representative: Basic Trading Company

بناء على التقرير الصادر عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

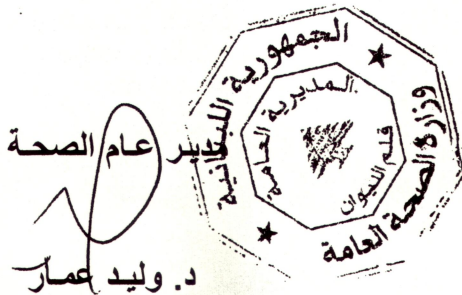
الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خلل في عمل هذا الصنف مما يؤدي الى مضاعفات على المريض ، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات





رقم المحفوظات: ٤٩/٢٥
رقم الصادر: ١٢/١/٥٨,
بيروت، في: ٥ - كانون الثاني ٢٠١٢

جانب نقيب الاطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Implants, active, pacemaker, Accent SR and Accent DR

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بناء على التقرير الصادر عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

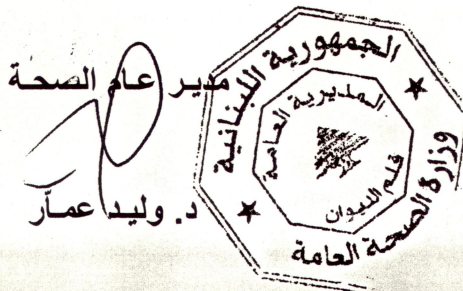
الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خلل في عمل هذا الصنف مما يؤدي الى مضاعفات على المريض ، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصية الصادرة.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات





رقم المحفوظات: ٢٨/٢٥
رقم الصادر: ١٣/١/٥٨
بيروت، في: ٥ - كانون الثاني ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز د. بي. م. وس
Implants, active pacemaker, Accent SR and Accent DR

الجهاز المعنى بالمتاب:

- Implants, active, pacemaker, Accent SR and Accent DR
- Trade Mark: St. Jude Medical Inc
- Local Representative: Basic Trading Company

بناء على التقرير الصادر عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خلل في عمل هذا الصنف مما يؤدي الى مضاعفات على المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

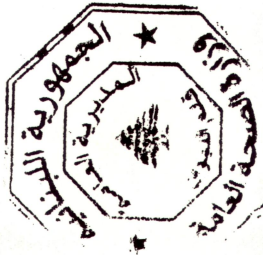
مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

دير عام الصحة
د. وليد عمار





رقم المحفوظات: ٤٩٢٥
رقم الصادر: ١٣/٧٥٨٠
بيروت، في: ٥ - كانون الثاني ٢٠١٣

جانب نقيب الاطباء في الشمال/طرابلس

الموضوع: إشعار بمتابعة جهاز طبي معروس

Implants, active, pacemaker, Accent SR and Accent DR

الجهاز المعنى بالمتابعة:

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بناء على التقرير الصادر عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

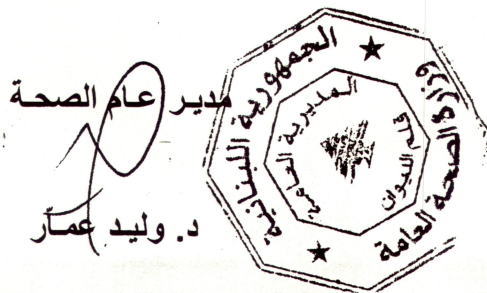
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مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
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FIELD SAFETY NOTICE

St. Jude Medical Accent SR Model PM1110 and Accent DR Model 2112 Pacemakers Potential for the Inability to Provide Rate Responsive Sensor Driven Pacing Rates

7th December 2012

Dear Customer,

As part of St. Jude Medical's focus on reliability and safety we continuously monitor the performance of our products. We have identified that a subset of Accent SR single chamber model PM1110 and Accent DR dual chamber model PM2112 pacemakers will not provide a change in sensor driven (rate responsive) pacing rates in response to patient physical activity due to an incorrect software setting. All other programmed parameters, features and functions operate as designed. A non-invasive programmer software solution that will correct the issue in all affected, implanted devices will be available once regulatory approval has been completed. This letter is intended to provide you with information regarding:

- What the issue is
- Clinical implications and patient management recommendations
- The action planned by St. Jude Medical to correct the issue for implanted devices

This document contains important information for the continued safe and proper use of your equipment

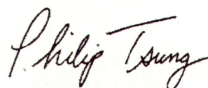
Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

If you need any further information or support concerning this issue, please contact your local St. Jude Medical Representative or Technical Support at +46 8 474 4147

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,



Philip Tsung

Vice President, Quality Assurance



Affected products	<p>A specific subset of Accent SR model PM1110 and Accent DR model PM2112 devices manufactured between July 2012 and November 2012 have been identified to exhibit the inability to provide a change in sensor driven pacing rates in response to patient physical activity. A list of affected units distributed to your hospital is provided in the annex. No other devices outside this list are affected.</p>
Problem description	<p>Due to an incorrect software setting, these pacemakers will not provide a change in sensor driven (rate responsive) pacing rates in response to patient physical activity. In devices programmed to a rate-responsive mode, the pacemaker will function in a basic programmed mode and will not provide a sensor driven rate increase when the patient is physically active. All other programmed parameters, features and functions operate as designed, e.g. an Accent DR device programmed to DDDR will appropriately track atrial activity and properly function in the DDD mode.</p>
Clinical implications	<p>Patients who are chronotropically incompetent and have their device programmed to a rate responsive mode will not experience a sensor driven rate increase when they are physically active. This could result in symptoms associated with reduced exercise tolerance.</p>
Number of devices affected	<p>There have been approximately 8 200 of the subject devices distributed internationally. Approximately 6 000 of them are estimated to be implanted.</p>
Action to be taken immediately	<ul style="list-style-type: none">• Do not implant affected units (list of affected units distributed to your hospital is provided in annex).• Place affected units in quarantine. Those units will be retrieved and replaced by your SJM sales representative.
Patient management recommendations	<ul style="list-style-type: none">• Identify affected patient• Review your patient's clinical indications for pacing and determine the clinical need for rate responsive, sensor driven pacing.• In the event that a patient requires rate responsive sensor driven activity pacing and exhibits clinical symptoms due to the lack of increased pacing rates with exercise, please contact your local Sales Representative or our Technical Support• Continue to follow patients on their standard follow-up schedule.



ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Further Action planned

A non-invasive programmer software solution that will correct the issue in all affected, implanted devices will be available once regulatory approval has been completed. Once the programmer software solution is available, the sensor anomaly can be automatically corrected at follow up by a simple interrogation of the pacemaker. Follow up of patients exhibiting clinical symptoms due to the lack of increased pacing rates with exercise should be prioritized.

Further information and support

If you need any further information or support concerning this issue, please contact your local St. Jude Medical Representative or Technical Support at +46 8 474 4147.