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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨١/٢٥
رقم الصادر: ١٣/١/١٤٤٩
بيروت، في: ٢٦ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Implants, active, defibrillators, Q-TECH Model 2020

الجهاز المعني بالمتابعة:

- Implants, active, defibrillators, Q-TECH Model 2020
- Trade Mark: Boston Scientific Ltd
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية
Medicine and Health Care Products Regulatory Agency (UK) MHRA
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف المذكور اعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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Field Safety Notice

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07 March 2013

Subject: Software Update Required -- Q-TECH™ Model 2020 programmers and SQ-RX® Model 1010 pulse generators

Dear Customer,

Boston Scientific CRM wants to make you aware of the following product advisory regarding Cameron Health / Boston Scientific subcutaneous defibrillators (S-ICD® System).

Further to this advice, we wish to restate that you follow up with your patients as follows:

- For patients whose device has been implanted for less than three months, we recommend that you schedule a follow-up visit **as soon as possible** within the next six weeks.

This software upgrade is available immediately and will be done as soon as possible by your local Boston Scientific CRM representative.

Please see the attached information regarding this advisory and the acknowledgment form for this information. When completed, please return this acknowledgment form via fax to 01442 411816 or Sign/Scan and email to uk-quality@bsci.com on or before **Thursday 21st March 2013** to acknowledge that you have received, read and understood the information contained and the actions that are required.

If you have any questions, please do not hesitate to contact your local Boston Scientific CRM representative.

Sincerely,

Terry Nopper
UK Sales and Marketing Director
Boston Scientific Ltd.

Field Safety Notice

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07 March 2013

Subject: Software Update Required -- Q-TECH™ Model 2020 programmers and SQ-RX® Model 1010 pulse generators

Dear Doctor:

This letter provides important patient management information regarding Cameron Health / Boston Scientific subcutaneous defibrillators (S-ICD® System). We have identified a rare condition in which an internal protective fuse can be unintentionally activated while the device is charging its capacitors for shock delivery or induction. Should this occur, the defibrillator would not be able to deliver therapy or communicate with the Q-TECH Model 2020 programmer, and would be unable to emit tones or otherwise respond to magnet application. No patient deaths or injuries have been reported as a result of this behavior; affected devices were replaced without the need for emergency medical care.

A non-invasive, software-based mitigation has been developed to protect the fuse from unintended activation. Your local sales representative will install this new software on all Q-TECH Model 2020 programmers located at your hospital/clinic. When an updated programmer is used to interrogate an SQ-RX Model 1010 pulse generator, new software will automatically be added to the pulse generator to protect the fuse from unintended activation.

Rate of Occurrence
The fuse has been unintentionally activated once during an implant procedure and three times post-implant out of approximately 1,900 devices implanted worldwide. All three post-implant events occurred within one month of implant. Engineering analysis also indicates this condition is more likely to occur early in device life.

Recommendations/Actions
1. Confirm that your Q-TECH Model 2020 programmers have been upgraded with new software, version 1.95.0. To access the software version directly from the programmer, turn the programmer ON, select the "Programmer Settings" button, and then select the "About Programmer" button. Programmer software version can also be viewed on the printed report from a device follow-up. Contact your local Boston Scientific representative if your programmer has not yet been upgraded.

2. Schedule a follow-up visit for each of your S-ICD System patients to update their device with new software:
   - For patients whose device has been implanted for less than three months, we recommend that you schedule a follow-up visit as soon as possible within the next six weeks.
   - For patients whose device has been implanted for three months or more, ensure the next scheduled visit occurs within three months of the previous visit, as recommended in device labeling.

3. At the next follow-up visit, interrogate each patient's device using a programmer with version 1.95.0 software. Interrogation with an updated programmer will automatically add new software to the implanted device to protect the fuse from unintended activation.

4. Resume normal patient follow-up monitoring and programming as directed in device labeling. Devices interrogated using a programmer with version 1.95.0 software are no longer subject to this advisory.

Further Information
An independent panel of physicians has reviewed this device behavior, and regulatory authorities have been notified. Product advisory information is available within the CRM Product Performance Resource Center, found at www.bostonscientific.com. Devices with version 2.4.343 (or newer) software are not subject to this advisory.

Cameron Health/Boston Scientific recognizes the impact of this communication on you, your clinic, and your patients, and wants to reassure you that patient safety remains our primary concern. If you have any questions regarding this communication, please contact your local Boston Scientific representative or Technical Services.

Sincerely,

Terry Nopper
UK Sales and Marketing Director
Boston Scientific Ltd.