REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٢٥
رقم الصادر: ١٢/١/٢٥٩٥٣
بيروت، في: ٥ - آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Biventricular pacemaker, Consulta CRT-P & Syncra CRT-P

الجهاز المعني بالمتابعة:

- Biventricular pacemaker, Consulta CRT-P & Syncra CRT-P
- Trade Mark: Medtronic Inc
- Local Representative: Intermedic S.A.L/Prime Medical/Tamer Frères S.A.L

بناء على التوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الجهاز المذكور أعلاه مما قد يؤثر على سلامة المريض، 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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Medtronic

URGENT FIELD SAFETY NOTICE

Medtronic Consulta® CRT-P and Syncra® CRT-P

Recall

10 June, 2013

Medtronic Reference: FA583

Dear Healthcare Professional (Hospital Administrator, OR Manager, and Risk Manager),

Medtronic recently identified an issue with a subset of Consulta® CRT-P and Syncra® CRT-P devices during production. **As of May 30, 2013, there have been no reported or confirmed device failures.** However, because of the potential for malfunction, Medtronic is requiring the return of **non-implanted** devices manufactured between April 1 and May 13, 2013 for re-inspection. The issue is unique to specific Consulta and Syncra CRT-P devices and no other Medtronic device models are affected.

This issue was identified as a result of an internal investigation that indicated a recent trend of increasing manufacturing rejects related to the weld of a connector bracket. An out-of-specification weld could result in a loss of device hermeticity and compromised device functionality. Although the risk of occurrence is believed to be very low and has not been observed in any implanted devices, we want to re-inspect the connector bracket weld on specific non-implanted devices to confirm that it meets specification.

After consultation with Medtronic's Independent Physician Quality Panel, **there are currently no specific patient management recommendations for implanted Consulta and Syncra CRT-P device patients**. Patients should continue to be followed regularly in accordance with product labeling.

Our records indicate you have potentially affected devices as shown on the attached device list. Medtronic requests that you:

Immediately return non-implanted Consulta and Syncra CRT-P devices found in the attached device list to Medtronic. Consulta CRT-P and Syncra CRT-P devices not on this list remain available for patient implant. Your local Medtronic representative will assist you with this device return.

If you have any questions please contact your local Medtronic representative.

The Competent Authority of your country has been informed of this action.

We apologize for the inconvenience this may cause you; please be assured that patient safety and product quality remain our primary concern.

Sincerely,

BU Manager