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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧/٢٥٥
رقم الصادر: ١٢/١/٢٥٢٩
بيروت، في: ٣ تشرين الأول ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR & VR Implantable Cardioveter-Defibrillators (ICDs)

الجهاز المعني بالمتابعة:

- COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR & VR Implantable Cardioveter-Defibrillators (ICDs)
- Trade Mark: Boston Scientific Ltd
- Local Representative: Medilife s.a.l

بناء على التقرير الصادر عن الوكالة الأوسترالية TGA والذي يشير الى وجود خلل في عمل الصنف الوارد أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن الوكالة الأوسترالية TGA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
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Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2013-RN-00906-1
Product Name/Description[iii]	COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR & VR Implantable Cardioveter-Defibrillators (ICDs) Affected model numbers: COGNIS CRT-D : N106, N107, N118, N119, P106, P107 TELIGEN DR ICD: E110, F110 TELIGEN VR ICD: E102, F102 Manufactured prior to December 2009 ARTG Numbers: 154034, 154033, 154039 & 154037
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Commencement Date[vi]	29/08/2013
Responsible Entity[vii]	Boston Scientific Pty Ltd
Reason / Issue[viii]	Boston Scientific has determined that the performance of a low voltage capacitor in a subset of COGNIS CRT-Ds and TELIGEN ICDs manufactured prior to December 2009 may be compromised over time, causing increased current drain that can lead to premature battery depletion. All cases reported to date have been detected by diagnostic tools within Boston Scientific's Safety Architecture before device function was compromised. "Safety Architecture" refers to a set of diagnostic monitoring which periodically assess device performance, including battery voltage, power consumption, and charge time, and have proven effective in identifying instances of unexpected battery use (via programmer alert screens or replacement indicators) before therapy becomes unavailable.
Recall Action[ix]	Hazard Alert
Recall Action Instructions[x]	There are no additional clinical recommendations beyond the current standard of patient care and normal device monitoring. - Remind patients to contact the clinic if beeping is heard from their device, as instructed in the patient manual. - Physicians should promptly investigate alerts and unanticipated replacement indicator messages. - Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens [24 hours per day / 7 days per week]. Technical Services can facilitate an evaluation of "save-to-disk" information (while the device is still implanted) to help clarify available replacement time. For more details, see http://www.tga.gov.au/safety/alerts-device-cognis-crt-d-and-teligen-icd-130903.htm .