HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

TELIGEN™ implantable cardioverter defibrillators (ICD) and COGNIS™ cardiac resynchronisation therapy devices (CRT-D)

Model/serial number: See below list.

Device family	Model numbers
COGNIS CRT-D	N106/N107/N208/N118/N119/N120/P106/P107/P108
TELIGEN DR ICD	E110/E111/F110/F111
TELIGEN VR ICD	E102/E103/F102/F103

Priority 2 – Warning

HPRA Safety Notice: SN2014(41) **Issue Date: 22nd October 2014**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Manufacturer: Boston Scientific	V22088

ISSUE
There is a risk of rapid battery depletion with the potential for loss of therapy and a requirement for early device replacement. Additional serial numbers of devices are affected since the manufacturer's original notification in August 2013.

ACTION OR RECOMMENDATIONS

HPRA advises users to:

1 Identify **newly affected** patients according to Boston Scientifics' latest Field Safety Notice (FSN).

2 Schedule patients **already identified** from the August 2013 notification and the **newly affected** patients for an in-clinic follow-up at first opportunity, but within 3 months, to download improved software into their device.

3 Interrogate the device using a programmer which has received the new software (Model 2868, Version 3.04) provided by Boston Scientific. This will automatically download software upgrades from the programmer into the patient device, enhancing detection of a compromised LV capacitor before therapy is impacted.

4 If a 'Code 1003' alert is seen on the programmer screen, contact Boston Scientific Technical Services to help clarify the time to 'End Of Life' (EOL) of the device. Note that 'Approximate time to Explant' and 'Time Remaining' estimates displayed on the programmer are not accurate when this capacitor malfunction has occurred.

5 Schedule device replacement taking into account guidance provided by Boston Scientific Technical Services.

6 Ensure that all audible alerts have been programmed 'ON' and remind patients to contact their clinics immediately if they hear beeping.

7 Consider the benefits of monitoring patients at home using the LATITUDE™ Patient Monitoring System.

Note: Prophylactic replacement of these devices is not recommended.

TARGET GROUPS

All cardiologists and cardiac physiologists who manage patients implanted with ICDs and CRT-Ds.

BACKGROUND

Boston Scientific has recently introduced updated programmer software (Model 2868, version 3.04) that enhances the effectiveness of the Safety Architecture tools. Boston Scientific is recommending that patients with a device in the advisory population be scheduled for an in-clinic follow-up at first opportunity, but within 3 months, using a programmer with the new software.

In-clinic interrogation with an updated programmer will automatically download Safety

Architecture software upgrades from the programmer into individual patient devices, enhancing detection of a compromised LV capacitor before therapy delivery is impacted. See Appendix B of the attached FSN for additional information on how to identify the current version of programmer software.

A list of advisory devices (model and serial number) implanted at or followed by your clinic/centre is attached to this safety notice. In addition, an on-line search tool is available at http://www.bostonscientific.com/ppr to determine if a specific model/serial number combination is within the advisory subset.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Lisa Austin
RA Coordinator
Boston Scientific
Breakspear Way
Hemel Hempstead
Herts., HP2 4TZ
UK

Telephone: +44 1442 411 672
Fax: +44 1422 411 816
E-mail: UK-Quality@bsci.com
Website: www.bostonscientific.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace , Dublin 2

Telephone: +353 1 6764971
Fax: +353 1 6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie