Medical Device Alert

Ref: MDA/2014/039 Issued: 07 October 2014 at 11:30

Device

TELIGEN™ implantable cardioverter defibrillators (ICD) and COGNIS™ cardiac resynchronisation therapy devices (CRT-D) manufactured by Boston Scientific.

Problem

Risk of loss of therapy due to rapid battery depletion. Additional serial numbers of devices are affected since the manufacturer's original notification in August 2013.

Action

1. Identify newly affected patients according to Boston Scientific's latest Field Safety Notice or look-up tool and schedule them for an in-clinic visit as soon as possible (within 3 months at the latest).
2. Interrogate the device using a programmer which has received the new software provided by Boston Scientific. This will automatically download improved software for detecting a failing capacitor.
3. 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.
4. Schedule device replacement taking into account time to EOL prediction provided by Boston Scientific.
5. Ensure that all audible alerts have been programmed 'ON' and remind patients to contact their clinics immediately if they hear beeping.
6. Consider the benefits of monitoring patients at home using the LATITUDE™ Patient Monitoring System.
7. Schedule patients already identified by MDA/2013/072 for follow-up within 3 months to download their ICDs with the improved software for detecting a failing capacitor.
8. This notice replaces MDA/2013/072 issued in September 2013.

Note:
Prophylactic replacement of these devices is not recommended.

Action by

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

CAS deadlines	Contact
Action underway: 21 October 2014 Action complete: 04 November 2014 **Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up and testing.**	**Manufacturer** Lisa Austin Boston Scientific Tel: 01442 411 600 Email: UK-Quality@bsci.com

Device

The manufacturer has issued a Field Safety Notice (FSN) in relation to the second subset of affected devices. This notice has been distributed to clinics that have implanted these devices and conduct routine patient follow-up, and also to clinics equipped with compatible programmers.

Device family	Affected model numbers
COGNIS CRT-D	N106/N107/N118/N119/P106/P107/P108
TELIGEN DR ICD	E110/F110/F111
TELIGEN VR ICD	E102/F102/F103

You can check specific device–serial number combinations to find out if they are affected here (http://www.bostonscientific.com/webapp/emarketing/lookup.jsp?us_pop_flag=no). This look-up tool differentiates newly identified devices from those already subject to the 2013 advisory notice.

Problem

In August 2013 Boston Scientific notified users about a subset of COGNIS™ CRT-Ds and TELIGEN™ ICDs that had experienced an increased rate of premature battery depletion due to a problem with a low voltage (LV) capacitor. The manufacturer has now identified a second subset of devices from subsequent clinical experience and analysis, which is expected to be affected by the same capacitor issue. This adds an additional 885 UK patients to the previous total of approximately 1,000 UK patients identified in August 2013.

With this FSN the manufacturer has also notified pacing clinics about the recent introduction of updated Safety Architecture software that will improve early detection of diminished LV capacitor performance. In particular this software enhances detection rates for ICDs later in their device life, and provides a new alert indicator on the programmer screen and the LATITUDE™ remote patient monitoring system (if used).

The manufacturer has confirmed that the current prevalence of failures within the original advisory population has risen from 0.67% in August 2013 to 2% to date, with the newly identified devices expected to perform similarly. The latest FSN provides important additional information on cumulative survival rates* for devices both within and outside the advisory subset population to help with future patient management.

*United States data, correct up to 21 July 2014

Distribution

This MDA has been sent to:

- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)
- Special health authorities for information

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons

- Cardiothoracic surgery directors
- Clinical governance leads
- Coronary care departments
- Coronary care nurses
- Nursing executive directors

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

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Hemel Hemsptead, HP2 4TZ
Tel: 01442 411 600
Email: UK-Quality@bsci.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/039** or **2013/008/029/291/001**

Technical aspects

Guido Fumagalli or Simon Holmes
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7144 or 7240
Fax: 020 8754 3965
Email: guido.fumagalli@mhra.gsi.gov.uk
simon.holmes@mhra.gsi.gov.uk

Clinical aspects

Dr Camilla Fleetcroft
Medicines & Healthcare Products Regulatory Agency
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London SW1W 9SZ
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How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate,
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Email: improvingpatientsafety@wales.gsi.gov.uk