Medical Device Alert

Immediate action

Ref: MDA/2010/012 Issued: 10 February 2010 at 10:00

Device

Teligen implantable cardioverter defibrillators (ICDs) and
Cognis cardiac resynchronisation therapy defibrillators (CRT-Ds) – specific models.
Manufactured by Boston Scientific.

Problem

For devices implanted subpectorally there are risks of:

- loss of shock therapy
- inappropriate shock therapy
- loss of pacing therapy
- loss of anti-tachycardia pacing.

Action by

Cardiologists, cardiac physiologists and cardiothoracic surgeons who implant these devices or who manage implanted patients.

Action

- Review records to identify patients with an affected device implanted subpectorally.
- Recall affected patients for baseline measurements within six weeks, giving priority to those who are pacing-dependent or who have not been followed up within the previous three months.
- Consider programming 'Daily Measurement Alerts' for lead impedance to 'On'.
- Consider prophylactic replacement of affected devices in high risk patients.
- Remind affected patients to contact their clinic if they receive shocks.
- Follow up affected patients at three-month intervals (as stated in the manufacturer's instructions for use).
- Avoid subpectoral implantation of these models.
- Report device failures and adverse incidents to Boston Scientific and the MHRA.

CAS deadlines

Action underway: 10 March 2010
Action complete: 10 May 2010

Contact

Manufacturer
Cait Cowley
Boston Scientific
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Device

Models affected by this alert:

- Teligen ICDs model numbers E102, E110, E111, F102, F110 and F111.
- Cognis CRT-Ds model numbers N106, N107, N108, N118, N119, P106, P107 and P108.

Problem

The manufacturer has established that the bond between the header and case of these specific models can be weakened either from significant forces associated with a subpectoral implant procedure or when a device in a subpectoral position is repeatedly pushed against a rib during contraction of the pectoralis muscle.

The following factors may have an impact on the risk of failure if affected devices are implanted subpectorally:

- exact location of the patient's ribs relative to the device
- body size and/or muscle mass of the patient (risk increases for larger or muscular patients)
- activity level and/or occupation of the patient (risk increases for more active patients)
- increased implantation duration.

The manufacturer issued a Field Safety Notice in December 2009 informing clinicians about this issue.

Extent of the problem
The manufacturer has confirmed that approximately 2,500 affected Teligen and Cognis devices have been distributed on the UK market since these models were released in June 2008. They have estimated that approximately 5% of affected devices are implanted subpectorally worldwide. Devices implanted subcutaneously are not included in this advisory.

To date the manufacturer has confirmed two (non-UK) reports of device malfunction associated with this issue out of approximately 77,000 devices sold worldwide. Both devices required early replacement (at four and five months post-implant) as they had delivered inappropriate shocks. The manufacturer has not identified a mean time-to-failure for this problem.

Identifying failed devices
There are no specific tests to identify a weakened header bond.

Standard in-clinic monitoring and troubleshooting steps for lead-related issues (including isometrics and manipulating the pocket while watching for noise on electrograms and/or inappropriate pacing or shock therapy) are recommended but cannot definitely distinguish a loose header from a failed lead or bad connection of the lead.

Evidence of a weakened header bond is not typically visible via X-ray or fluoroscopy. Should this weakening progress to wire fracture and complete separation of the header from the titanium case it may be visible on X-ray or fluoroscopy.

Early stages of a weakened header bond may only cause subtle lead impedance changes (in the tens or hundreds of ohms), whereas in the later stages there may be a very large change in lead impedance.

If available, the LATITUDE patient management system may also be helpful for monitoring patients.

Availability of modified devices

The manufacturer has made manufacturing process changes to strengthen the bond between the header and case. Modified devices are expected to be available in the UK from February 2010.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

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
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic surgery directors
- Clinical governance leads
- Risk managers

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Primary care trusts to:

CAS liaison officers for onward distribution to all relevant staff including:

- General practitioners

Contacts

Manufacturer

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **2009/011/030/081/012**

Technical aspects
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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 (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

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

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
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:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

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