Medical Device Alert

Ref: MDA/2012/061 Issued: 10 September 2012 at 11:30

Device

Implantable cardioverter defibrillator (ICD) leads.
Riata and Riata ST – all silicone coated models.
Manufactured by St Jude Medical.

Problem

Risk of inappropriate shock or therapy failure due to wear of lead insulation after implantation.

These patient follow-up recommendations replace those given previously in MDA/2010/095 and MDA/2011/112.

Action by

All cardiologists and cardiac physiologists who manage patients implanted with ICD leads.

CAS deadlines

Action underway: 24 September 2012

Action complete: 08 October 2012

Contact

Manufacturer
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Action

- Continue to follow up all patients implanted with Riata or Riata ST ICD lead models to identify any changes in lead performance, according to your own standard procedures (see further advice below). Undertake this:
  - at three-month intervals (in clinic or via remote monitoring) to -
    - monitor for HV lead noise using an unused EGM channel
    - turn on RV AutoCapture™ (or equivalent) pacing to monitor pacing thresholds
  - and at six-month intervals (in clinic) to -
    - ensure high voltage lead integrity (HVLI) testing is performed.
- At box change, if a decision is made to continue to use the lead, ensure that the replacement device has remote/advanced monitoring capabilities.
- Consider the need for further examination e.g. by ECG or fluoroscopy*, if a lead failure is suspected.
- If a lead failure is confirmed, the risks and benefits of lead replacement options should be evaluated on a case-by-case basis in discussion with the patient.

Note: Prophylactic lead explantation is not recommended, other than in exceptional clinical circumstances.

* In all cases, the benefit of fluoroscopic screening should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of The Ionising Radiation (Medical Exposure) Regulations 2000.

Problem

In December 2011, the MHRA issued a Medical Device Alert (MDA/2011/112) recommending enhanced patient follow-up for all patients implanted with Riata and Riata ST lead models. At that time the frequency of follow-up was stratified according to lead model. Current evidence suggests that the difference in prevalence of externalised cables between 8Fr and 7Fr lead models is decreasing.

St Jude Medical has recently issued a Field Safety Notice (dated 13 July 2012) detailing phase I of a Riata lead evaluation study to investigate the prevalence of externalised cables using fluoroscopy. The clinical significance of externalised cables will not, however, be evident until phase II of the study is completed; this is unlikely to be before the end of 2013. For this reason this Medical Device Alert is focusing on detection of early signs of functional lead failure, as these lead models continue to fail at a higher rate.

Action

Further advice

- Where appropriate for patients, follow-up should continue to include:

  > provocative testing (e.g. shoulder/arm movements and deep respiration), which may help reveal an intermittent problem

  > increasing the detection time of the VT zone to reduce the risk of oversensing and inappropriate shocks

  > ensuring the SVT discriminators are on, where applicable

  > ensuring that the lead impedance alarms are programmed on.

- Remind patients of the importance of contacting their follow-up clinic as soon as possible in the event of therapy delivery and/or the onset of any patient alert.
- Report all lead adverse incidents to the MHRA and to St Jude Medical.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

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:

- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiac physiologists
- Cardiologists
- Cardiothoracic surgeons
- Clinical governance leads
- Medical directors
- 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

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/061** or **2012/007/020/081/010**

Technical aspects
Michelle Kelly or Simon Holmes
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Floor 4
151 Buckingham Palace Road
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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

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

Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk