Medical Device Alert

Immediate action

Amendment: format of model numbers.

Ref: MDA/2010/095R Reissued: 16 December 2010 at 16:00

Device

Implantable cardioverter defibrillator (ICD) leads.

Riata and Riata ST – all models.
Manufactured by St Jude Medical.

Problem

Risk of inappropriate therapy due to wear and/or abrasion of lead insulation.

Action by

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

Action

- Identify all patients implanted with Riata or Riata ST ICD lead models.
- Arrange for follow-up at three-month intervals to review lead performance following your own standard procedures.
- 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 audible patient alert.
- Report all lead adverse incidents to the MHRA and to St Jude Medical.

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

CAS deadlines

Action underway: 23 December 2010

Action complete: 16 March 2011

Contact

Manufacturer
St Jude Medical UK Ltd
Tel: 01798 207 600
Fax: 01789 207 601
Email: shogarth@sjm.com

Device

Amendment: format of model numbers.
Riata and Riata ST model numbers: 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042.

Problem

To date the MHRA has received 39 confirmed reports of insulation damage on Riata or Riata ST ICD leads. Of these reports, the manufacturer identified 28 where insulation damage was confirmed by laboratory analysis and 11 confirmed through clinical observation. Approximately 4,500 Riata and Riata ST leads have been distributed in the UK since they were first placed on the market in 2002.

In the UK, incidents have been reported for leads implanted for 12 to 72 months, with the highest numbers of incidents for those implanted for 12 to 24 months.

Reported incidents have included:

- delivery of inappropriate shocks
- oversensing caused by noise on the lead
- changes in impedance and pacing thresholds
- loss of sensing resulting in non-detection of arrhythmia.

St Jude Medical has issued a Field Safety Notice and has informed the MHRA that it plans to cease supply of all Riata and Riata ST leads, which do not incorporate the Optim insulation, by 31 December 2010. All defibrillation leads currently manufactured by St Jude Medical use the new Optim insulation.

In 2006, the manufacturer improved the insulation for new Riata leads. New leads are known as Riata ST Optim. The manufacturer has provided data on Riata ST Optim leads that suggests an 80% reduction in the rate of abrasion-related failure at 44 months post-implantation, compared with the previous design.

Action

- Where appropriate for patients, clinicians could consider the following:
  - > 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.

- If a lead failure is suspected, consider the need for further examination e.g. by ECG or X-ray*.

***** 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.

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 (Chief Executives)
- Primary care trusts in England (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:
- A&E departments
- Arrhythmia nurses
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Clinical governance leads
- Coronary care departments
- Coronary care nurses
- Medical directors
- Risk managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
This alert should be read by:
- Hospitals in the independent sector

Please note: CQC and OFSTED do not distribute these alerts. 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/2010/095** or **2010/009/013/081/021**

Technical aspects
Michelle Kelly or Sam Baxter
Medicines & Healthcare products Regulatory Agency, Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7145 or 7242
Fax: 020 8754 3965
Email: michelle.kelly@mhra.gsi.gov.uk
Email: sam.baxter@mhra.gsi.gov.uk

Clinical aspects
Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency, Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

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Email: nicola.lennard@mhra.gsi.gov.uk

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:

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

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk