Medical Device Alert

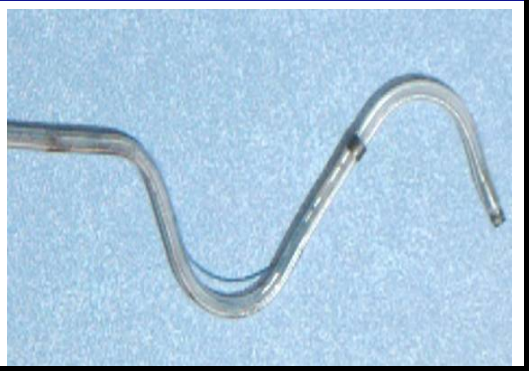
Ref: MDA/2012/021 Issued: 24 April 2012 at 15:30

Device

Left ventricular cardiac resynchronization therapy (CRT) leads.

Bipolar QuickSite and QuickFlex lead models: 1056T, 1058T, 1156T and 1158T.

Manufactured by St Jude Medical.



Problem

Risk of worsening heart failure symptoms due to wear and/or abrasion of lead insulation after implantation.

Action by

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

Action

In line with the advice in St Jude Medical's Field Safety Notice:

1. Do not implant affected bipolar QuickSite or QuickFlex lead models.
2. Quarantine any affected devices and return them to the manufacturer.
3. Identify all patients implanted with an affected device and arrange for an early follow-up to take place within 3 months.
4. Ensure alerts that monitor lead impedance changes outside of the nominal range are programmed and patient alerts are turned on.
5. Review lead performance at 3-monthly intervals following your own standard procedures (see further advice below).
6. Consider the need for further examination e.g. by ECG or fluoroscopy*, if a lead failure is suspected.
7. Prophylactic replacement of these devices is not recommended except in exceptional circumstances.
8. Ensure all patients are enrolled on remote monitoring where possible in discussion with St Jude Medical.

* 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.

Contact

Manufacturer
St Jude Medical UK Ltd

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Email: shogarth@sjm.com

CAS deadlines

Action underway: 01 May 2012

Action complete: 23 May 2012

Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up.

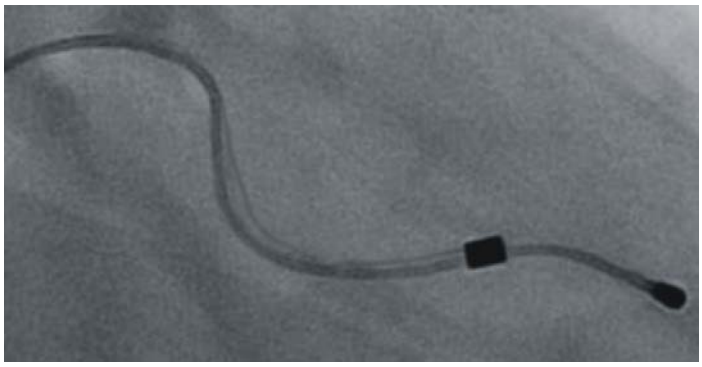
Problem

In December 2010 and December 2011 the MHRA issued Medical Device Alerts MDA/2010/095R and MDA/2011/112. These notices concerned Riata and Riata ST ICD leads (manufactured by SJM) that were experiencing abrasion of silicone, leading to the externalization of cables. Whilst screening these patients the same failure mechanism was observed in a small number of QuickFlex/Quicksite leads implanted to provide additional CRT. The potential clinical consequences of these lead failures is significantly less serious than for the Riata leads as there is no risk of loss of high voltage ICD therapy. SJM has stated that they do not manufacture any other leads which could fail in this manner.

Although the prevalence of confirmed cases of externalized cables among QuickFlex/Quicksite leads is currently low (0.023%) a preliminary assessment by the manufacturer estimates that externalized conductors may be present in 3–4% of the patient population. To date there have been no reports of electrical failure or patient harm associated with externalization of Quicksite/Quickflex leads. Externalized cables have been found to continue to function normally due to their inner protective ETFE coating. If, however, the inner coating were to be breached and the system failed to provide alternative pacing therapy, biventricular pacing/CRT therapy could be lost. This could give rise to reduced heart pumping efficiency, reduced ejection fraction, and ultimately an exacerbation of heart failure.

Approximately 6,000 Quickflex/Quicksite leads have been distributed in the UK since they were first placed on the market in 2004. There have been 2 reports of externalized cables in the UK.

An example of an externalized cable is shown below.



Action

Further advice

- At follow-up:

(i) monitor LV lead impedance and threshold

(ii) consider the possibility of LV lead failure in the event of heart failure deterioration

(iii) full use should be made of remote follow-up to monitor LV lead performance

(iv) remind patients of the importance of contacting their follow-up clinic as soon as possible in the event of any patient alert.

- Ensure that the replacement device has remote/advanced monitoring capabilities if a decision is made to continue to use the lead at routine pulse generator replacement.

- If evidence of a protruding conductor is found, the risks and benefits of lead replacement should be evaluated on a case-by-case basis in discussion with the patient.

- Report all adverse incidents involving these leads 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 and trusts in Wales (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)

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

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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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/021** or **2012/003/029/291/011**

Technical aspects
Simon Holmes or Michelle Kelly
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Floor 4
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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:
Dr Chris Jones
Medical Director
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

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