Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2016/007 Issued: 21 June 2016 at 14:00

Bipolar QuickSite and QuickFlex lead models: 1056T, 1058T, 1156T and 1158T manufactured by St Jude Medical – risk of worsening heart failure symptoms due to wear and/or abrasion of lead insulation after implantation.

Summary

Change to 2012 advice – current data supports the withdrawal of MDA/2012/021 and reversion to normal 6-monthly patient follow-up, combined with the remaining advice already given, listed under Action.

Action

- Return patient follow-up to the standard practice of reviewing lead performance at 6-monthly intervals, following your own standard procedures.
- Prophylactic replacement of these devices is not recommended except in exceptional circumstances.
- Ensure all patients are enrolled on remote monitoring where possible, in discussion with St Jude Medical.

Action by

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

Deadlines for actions

Actions underway: 05 July 2016
Actions complete: 21 July 2016

Department of Health, Social Services and Public Safety www.dhsspsni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Update on MHRA advice

MHRA issued Medical Device Alert MDA/2012/021 in April 2012 advising UK hospitals not to implant QuickSite and QuickFlex leads, and to follow up every 3 months all patients already implanted with these leads.

The risk to patients involves worsening heart failure symptoms due to wear and/or abrasion of the lead's softer, outer silicone insulation after implantation (referred to as externalised conductors). However, the likelihood of an electrical anomaly or adverse clinical event is low, as the lead will continue to function normally as long as the harder, inner insulation remains intact.

Approximately 6,000 QuickSite and QuickFlex leads were implanted in the UK since they were first sold in 2004. They were discontinued, and unused product recalled in 2012. Around 2,600 active leads are estimated to remain implanted in UK patients today.

Although the prevalence of confirmed cases of externalised conductors among these leads was only 0.023% in April 2012, at that time the manufacturer estimated that this problem could in fact be present in as much as 3-4% of the patient population. Four years later, a review of the latest data suggests the overall rate for externalised conductors is currently no more than 0.15%.

Based on the present low occurrence rate and the low risk of a clinical event, the MHRA is now advising UK hospitals to revert back to UK standard practice of 6-monthly follow up for patients implanted with these leads. However, it remains important that as many patients as possible with compatible ICDs benefit from additional home monitoring, and centres are encouraged to consider this option. Currently the manufacturer estimates that just over 10% of UK patients with leads remaining in active use are being followed by remote monitoring.

Manufacturer contacts

St Jude Medical UK Ltd

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Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)
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

- EBME departments
- Medical directors
- Medical libraries
- Radiology departments
- Risk managers

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:
- General practitioners
- General practice managers
- General practice nurses

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2016/007** or **2012/003/029/291/011.**

Technical aspects
Feza Haque or Simon Holmes, MHRA
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Email: feza.haque@mhra.gsi.gov.uk or simon.holmes@mhra.gsi.gov.uk

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Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland

Alerts in Northern Ireland are distributed via the NI SABS system.

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

Northern Ireland Adverse Incident Centre
CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

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

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the forms on our website.

Scotland

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

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division
Welsh Government

Tel: 02920 823 624 / 02920 825 510

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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).