Medical Device Alert

Ref: MDA/2013/007 Issued: 21 February 2013 at 12:30

Device

Isoline implantable cardioverter defibrillator (ICD) leads.
All models: 2CR5, 2CR6 and 2CT6.
Manufactured by Sorin Group Italia Srl.

Problem

Risk of inappropriate shocking, pacing inhibition or shocking inhibition due to internal insulation abrasion.

Action by

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

Action

- Do not implant any Isoline ICD leads.
- Identify and return to Sorin any of these leads which have not been implanted.
- Identify all patients implanted with affected models and arrange a follow-up as soon as practicable (within 3 months).
- Ensure programming parameters are set to maximise the chance of detecting lead issues and avoiding inappropriate therapy, in accordance with advice in the manufacturer's Field Safety Notice.
- 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.
- Follow up patients at 3-monthly intervals.
- At pulse generator replacement, if a decision is made to continue to use the lead, ensure that the replacement generator has remote/advanced monitoring capabilities.
- If there is evidence of a problem with a lead, the risks and benefits of lead replacement 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.

CAS deadlines

Action underway: 07 March 2013

Action complete: 21 March 2013

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

Contact

Manufacturer
Sorin Group Italia Srl
David Thierman
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Email: david.thierman@sorin.com

Problem

Sorin has identified abrasion of internal silicone insulation in 30 returned Isoline leads. This equates to 0.2% of worldwide sales since product launch in 2005. However, the proportion is expected to rise, partly as a result of closer patient follow-up subsequent to this field action. Only one of these incidents occurred in the UK out of approximately 380 leads distributed and none of the incidents was fatal. These incidents typically presented as inappropriate shocks and low pacing impedance, as well as ventricular oversensing where pacing was inhibited. Affected leads were implanted for between 2 months and 4.5 years prior to failure.

Analysis of returned leads revealed insulation abrasion, where the microcables contained within the defibrillator coil were not directly covered with ETFE polymer coating. This abrasion occurred predominantly under the right ventricular electrode, but also under the superior vena cava electrode, when torsion or compression of the lead had occurred. For electrical malfunction to occur, the microcable must abrade towards, and make contact with, the pacing-sensing conductor. Microcable abrasions occur within the defibrillator coil and cannot be detected by X-ray imaging.

Sorin has suspended distribution of all models of the Isoline lead and is recalling all un-implanted stock. The company communicated this to all its customers in an 'Urgent Medical Device Field Safety Notice' issued on 28 January 2013.

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/2013/007** or **2013/001/029/081/032**

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

Tel: 020 3080 7145 or 7240
Fax: 020 8754 3965

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simon.holmes@mhra.gsi.gov.uk

Clinical aspects
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London SW1W 9SZ

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Fax: 020 8754 3965

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

Tel: 029 2082 3922

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