Medical Device Alert

Ref: MDA/2014/035 Issued: 16 September 2014 at 14:00

Device

EllipseTM VR/DR implantable cardioverter defibrillators (ICDs).
Model numbers CD1277, CD1377, CD2277, CD2377 (all -36, -36Q, -36C and -36QC suffixes). All serial numbers distributed before the field action.

Manufactured by St Jude Medical.

Problem

Potential for delayed or insufficient energy defibrillation therapy due to a capacitor fault.

Action

1. Identify affected ICDs, and if any unimplanted devices are found these should be returned to St Jude Medical, as detailed in their Field Safety Notice (FSN).
2. Identify affected patients and schedule them for a follow-up evaluation within 3 months to discuss this issue, giving priority to high risk patients.
3. Interrogate the ICD and perform a manual capacitor maintenance charge, noting the time to reach full charge.
4. Contact St. Jude Medical's technical support for further advice if the charge time exceeds 15 seconds or if an alert for 'capacitor charge time limit reached' is triggered. Consider replacing ICDs that have experienced repeated, extended charge timeout warnings.
5. Ensure that appropriate vibratory alarms are enabled. Test the patient's sensitivity to the alarm and remind them to contact their clinic immediately if it is triggered, as this could be due to a capacitor charge timeout.
6. Ensure that Merlin remote monitoring is in place wherever possible and that remote monitoring alarms are enabled.
7. Reduce the ICD's automatic capacitor maintenance interval by reprogramming to every 4 months.
8. Repeat the above patient review at normal follow-up intervals.

Action by:
All cardiologists and cardiac physiologists who manage patients implanted with ICDs

CAS deadlines

Action underway: 23 September 2014

Action complete: 17 November 2014

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
St Jude Medical UK Ltd
Technical Services
0046 8 474 4147
or
Sean Hogarth
Tel: 01789 207 600
Email: shogarth@sjm.com

Problem

St Jude Medical issued a FSN, dated 19 August 2014, describing a potential failure mode which can delay or reduce the therapy that can be delivered by the ICD. The problem has been traced to an ICD capacitor defect, accompanied in some returned devices with evidence of arcing between the capacitor anode and cathode. Analysis so far indicates that it is not possible to predict which ICDs will suffer this failure or when it may occur, so despite a low failure rate of 0.42%, all patients and clinicians will need to be vigilant. All affected ICDs will exhibit extended charge times, evident not only during device testing / maintenance but also when preparing to deliver therapy. To date all potential failures reported to St Jude Medical have been identified through timeout warnings triggered by automated capacitor maintenance or during in-clinic testing, rather than being associated with serious adverse events.

The manufacturer has confirmed that all affected ICDs should now have been retrieved from hospital supplies and they are currently replacing them with newly designed product not expected to be susceptible to this failure mode. Replacement product can be identified according to the serial numbers detailed at the end of the FSN, and by the green label fixed to the ICD packaging.

Affected devices have in most cases ‘recovered’ and perform normally after an extended charge timeout. From bench testing of returned devices, the manufacturer has confirmed that the likelihood of the ICD continuing to perform normally after an extended charge timeout is far greater among those ICDs with capacitors manufactured since a process improvement at the start of August 2012 (93% recovery), compared to those manufactured before (50% recovery). St Jude Medical will be able to provide advice for ICDs exhibiting extended charge times on whether the device incorporates the earlier or later more reliable capacitors. Subsequent automated or manual capacitor testing should also help demonstrate whether there is a persistent problem following an initial timeout event. In-clinic testing and reducing the capacitor maintenance interval to every 4 months (from the standard 6-monthly interval) will enable earlier detection of a possible problem, but it is important to be aware that their combined effect will reduce the remaining device longevity by almost 20%. Clinicians should take this into account in their management of individual patients.

Any device that has experienced repeated, extended charge timeout warnings should be considered for replacement. Prophylactic explant is not generally recommended, but may need to be considered in exceptional circumstances such as for very high risk patients, or those unable to cope with the psychological effects of this issue.

Distribution

This MDA has been sent to:

- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)
- Special health authorities for information

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 consultants
- A&E departments
- A&E directors
- A&E nurses
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiac physiologists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads

- Coronary care departments
- Coronary care nurses
- Medical directors
- Nursing executive directors

Independent distribution

Establishments registered with the Care Quality Commission (CQC)

This alert should be read by:

- Care homes providing nursing care (adults)
- 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

Manufacturer

Sean Hogarth
St Jude Medical UK Ltd
Capulet House
Stratford Business and Technology Park
Stratford-upon-Avon, CV37 7GX

Tel: 01789 207 600
Fax: 01789 207 601

Email: shogarth@sjm.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/035** or **2014/008/014/081/019**

Technical aspects

Simon Holmes or Hazel Randall
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7240 or 7287
Fax: 020 8754 3965

Email: simon.holmes@mhra.gsi.gov.uk
hazel.randall@mhra.gsi.gov.uk

Clinical aspects

Camilla Fleetcroft
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

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Fax: 020 8754 3965

Email: camilla.fleetcroft@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
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

Email: improvingpatientsafety@wales.gsi.gov.uk