Medical Device Alert

Immediate action

Ref: MDA/2009/038 Issued: 10 June 2009 at 12:30

Device

Implantable pacemakers.
Medtronic Kappa® 600/700/900 series and Sigma® 100/200/300 series IPGs.

Specific serial numbers may be entered online to determine if they are affected (http://KappaSigmaSNList.medtronic.com).

Problem

Certain Kappa® and Sigma® series pacemakers may suffer sudden unexpected failure giving rise to bradycardia symptoms (fainting or light headedness). Serious injury or death may occur in pacemaker dependent patients.

Action by

Cardiac physiologists, cardiologists, cardiothoracic surgeons who implant these pacemakers or who manage implanted patients.
Physiological measurement technicians.

CAS deadlines

Action underway: 29 June 2009

Action complete: 04 September 2009

Action

- Consider replacing all affected pacemakers in pacing dependent patients.
- Advise patients to seek medical treatment immediately if they experience a return of their bradycardia symptoms.
- Follow up all other patients implanted with affected pacemakers at intervals of no more than six months.
- Report any incidents involving Kappa® and Sigma® pacemaker failures to the MHRA and Medtronic.

Contact

Manufacturer
Dr David Dunham
Medtronic Limited

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Link to full Medical Device Alert

Problem

Medtronic has informed the MHRA that some Kappa® and Sigma® series pacemakers may fail at a higher than expected rate due to separation of wires within the pacemaker electronic circuitry. They issued a Field Safety Notice to address this problem in May 2009. Medtronic has confirmed that, in the UK, approximately 3,500 affected Sigma® and Kappa® pacemakers were distributed and has estimated that approximately 1,100 potentially affected pacemakers currently remain implanted. The 1,100 implants are estimated to represent approximately 2 % of all Kappa® and Sigma® pacemakers implanted.

The separation of the wires within these pacemakers may lead to premature battery depletion, loss of telemetry, loss of output or loss of rate response. This is a sudden pacemaker failure with no reliable means to predict when it may occur.

Through post-market surveillance and manufacturing traceability studies, the manufacturer has identified certain pacemakers which may fail at a higher rate due to use of certain lots of a specific component. The manufacturer has yet to establish a specific root cause and is continuing to investigate.

This Medical Device Alert also applies to a subset of the Sigma® devices which were already covered by the previous Medical Device Alert issued in December 2005 relating to the lifting of wire bonds due to the use of a cleaning solvent during the manufacturing process.

Furthermore, a previous Kappa® advisory of March 2002 also involved the fracture of the wires connecting the electronic circuit to the power supply. However, Medtronic has confirmed that each of the root causes associated with these previous Sigma® and Kappa® advisories is different to that giving rise to the wire separation subject to this current Medical Device Alert.

Medtronic has confirmed that the current number of failures reported worldwide represent 0.49 % and 0.88% of the affected Kappa® and Sigma® pacemaker populations respectively. However, the predicted failure rate due to this problem over the lifetime of these pacemakers is 1.1% for Kappa® and 4.8 % for Sigma. Most affected pacemakers have been implanted for five years or longer.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- NHS Boards in Scotland (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

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 physiologists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Clinical governance leads
- Risk managers

Care Quality Commission (CQC) (England only) to:
Headquarters for onward distribution as appropriate to:
- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- FECs registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Primary care trusts to:
CAS liaison officers for onward distribution to all relevant staff including:
- General practitioners

Change of address or removal from address list for Care Quality Commission:
National Contact Centre
Care Quality Commission
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 03000 61 61 61

E-mail: enquiries@cqc.org.uk

Contacts

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/038 or 2009/005/019/291/006**

Technical aspects
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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 (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523 704
Fax: 02890 523 900

E-mail: 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 https://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

E-mail: iric.nss@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

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Welsh Assembly Government
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