# Medical Device Alert

Ref: MDA/2011/051 Issued: 19 May 2011 at 14:00

## Device

Implantable cardioverter defibrillator (ICD) lead.

Sprint Fidelis, model numbers: 6930, 6931, 6948 and 6949

Manufactured by Medtronic.

## Problem

Risk of inappropriate shocks and loss of therapy.

Increased risk that the high voltage conductor will fracture if the pace-sense conductor has previously fractured in the same lead.

## Action by

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

## Action

Identify patients where:

1) the pace-sense conductor has fractured,
2) a new pace-sense lead has been inserted and
3) the high voltage conductor remains in use.

For these patients, consider the need to implant a new high voltage conductor at elective device change, taking into account the age and clinical circumstances of the patient.

If these patients are at high risk of sudden cardiac death in the event of high voltage conductor failure, then consider elective lead replacement before device change.

Where a new conductor fracture occurs, implant a new high voltage lead.

Where a lead is functioning normally, continue with existing patient management recommendations and use of Medtronic Lead Integrity Alert (LIA). This should be done taking into account the recent update in long term lead survival data presented in the Field Safety Notice of April 2011.

## CAS deadlines

Action underway: 26 May 2011

Action complete: 22 August 2011

## Contact

**Manufacturer**
Mrs Lezlie Bridge
Medtronic

Tel: 01923 212 213
Fax: 01923 225 273

Email: lezlie.j.bridge@medtronic.com

# Problem

In March 2009 Medtronic issued a Field Safety Notice (FSN) advising clinicians that one option for dealing with this problem was to implant a new pace-sense lead while maintaining the use of the high voltage conductor.

However, Medtronic estimates that the survival for the Sprint Fidelis high voltage conductor is 77.7% at 21 months if a pace-sense conductor fracture has previously occurred. Therefore, Medtronic no longer recommends this course of action and has issued another FSN (April 2011). All other patient management recommendations in the March 2009 FSN remain unchanged.

# 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)
- Primary care trusts in England (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:

- A&E departments
- Arrhythmia nurses
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Clinical governance leads
- Coronary care departments
- Coronary care nurses
- Medical directors
- Risk managers

## Independent distribution

### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Independent treatment centres

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/2011/0051** or **2011/004/004/291/016**

**Technical aspects**
Ms Sam Baxter or Mr Guido Fumagalli
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7242 / 7144
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**Clinical 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
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 Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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