### DEVICE:
Medtronic Sigma® implantable pacemakers:

<table>
<thead>
<tr>
<th>Model Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD203</td>
</tr>
<tr>
<td>SDR203</td>
</tr>
<tr>
<td>SS203</td>
</tr>
<tr>
<td>SSR203</td>
</tr>
<tr>
<td>SD303</td>
</tr>
<tr>
<td>SDR303</td>
</tr>
<tr>
<td>SS303</td>
</tr>
<tr>
<td>SSR303</td>
</tr>
<tr>
<td>SS103</td>
</tr>
<tr>
<td>SDR306</td>
</tr>
<tr>
<td>SVDD303</td>
</tr>
</tbody>
</table>

See list of affected serial numbers distributed in the UK on our website at [http://www.mhra.gov.uk](http://www.mhra.gov.uk)

### PROBLEM:
Failure of interconnecting wires within the pacemakers may cause:
- loss of pacing output from atrial and/or ventricular ports
- premature battery depletion
- intermittent or total loss of telemetry
- undersensing
- high lead impedance values
- loss of rate response
- device reset to manufacturer’s default settings.

### ACTION BY:
All cardiologists and cardiac physiologists who manage patients implanted, or to be implanted with any of these devices.

### ACTION:
See detailed actions on page 2 and 3.

### DISTRIBUTED to:
- NHS Trusts (England)
- Healthcare Commission (CHAI)
- Chief Executives*
- Headquarters

* via CE Bulletin

### CONTACTS:
Details of manufacturer/National Pacing & ICD Database, and MHRA contacts for technical and clinical aspects.
Change of address or removal from address list for Healthcare Commission.

▶ Further information supplied in the following pages.

The full text of this notice is on our website: [http://www.mhra.gov.uk](http://www.mhra.gov.uk)
PROBLEM:
Medtronic has advised MHRA that some Sigma® pacemakers from the listed model ranges may be subject to failures which could result in any of the behaviours listed on page 1. Medtronic issued letters to clinicians about this issue in November 2005 (see Appendices 1 and 2).

Medtronic's analyses of 19 returned Sigma® pacemakers has identified a failure mode where separation of interconnecting wires between certain electronic components, can seriously affect the performance of the device.

Analysis has identified that the wire separation is associated with the use of an incorrect cleaning solvent during circuit board manufacturing that contained an antioxidant. The solvent, which was only used for a limited manufacturing period, resulted in surface contamination of electrical connection areas prior to wire bond connection. Extensive testing and analysis by Medtronic has now confirmed that use of this cleaning solvent can lead to a reduction in strength of the wire bond connections and these connections may separate over time. No mean time to failure has been established for this failure mode. However, there have been no failures less than 17 months post implant.

There is no provocative testing that can be performed to identify when any of the affected devices may fail.

Failure rates are currently low at approximately 0.05%. To date, 19 Sigma® failures have been confirmed where wire bond connections have separated. Medtronic estimates that approximately 28,000 devices remain implanted worldwide. In the UK 1 failure by this mode has been confirmed to date out of an estimated 1,700 devices that remain implanted. The UK failure occurred at implant duration of 36 months with the patient presenting with shortness of breath. Subsequent clinical checking confirmed no pacing output or telemetry.

Medtronic has received no reports of serious injuries or deaths due to this problem.

Affected Sigma® pacemakers may be identified by accessing the Medtronic website http://SigmaSNList.medtronic.com

ACTION:
- Identify and return to Medtronic all un-implanted devices that are potentially affected http://www.mhra.gov.uk
- Identify all patients that have affected pacemakers and where last follow-up was longer than six months, arrange for pacemaker follow-up as soon as possible, giving priority to pacemaker dependant patients.
- At follow-up confirm that the device is performing as expected. Abnormal device behaviours may include:
  - intermittent or total loss of pacing output in either or both of the atrial/ventricular ports
  - intermittent or total loss of telemetry
  - unanticipated premature battery depletion
  - unexplained increases in lead impedance(s) in unipolar or bipolar mode
  - undersensing
  - loss of rate response function (where applicable and programmed on)
  - ‘power on reset’ - return to manufacturer's default settings

Continued on next page
ACTION (continued):

- Advise patients to contact their follow-up clinic immediately if they experience a return of symptoms (e.g. syncope / light-headedness or shortness of breath).
- Consider elective device replacement if any of the above device behaviours are detected, especially for pacemaker dependant patients giving consideration to each patient’s medical history, degree of pacemaker dependency and the relative risks of an invasive procedure.
- Consider scheduling subsequent pacemaker follow-up at intervals no longer than six months, for all potentially affected pacemakers, to monitor for signs of device degradation.
- Report all incidents of device failure to the MHRA and Medtronic.
- Report explants to the National Pacing and ICD Database (see Contacts).

**ACTION DEADLINES FOR THE SAFETY ALERT BROADCAST SYSTEM (SABS)**

Trust managers should ensure that measures to implement the ‘Actions’ specified above are planned and completed in line with the following SABS deadlines.

<table>
<thead>
<tr>
<th>Deadline (Action underway)</th>
<th>Deadline (Action complete)</th>
</tr>
</thead>
<tbody>
<tr>
<td>23 January 2006</td>
<td>24 April 2006</td>
</tr>
</tbody>
</table>

Action plan to be agreed and actions started. All actions to be completed.

Further information about SABS can be found at www.info.doh.gov.uk/sar/cmopatie.nsf

DISTRIBUTION:

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

**TRUSTS to:**

- Liaison officers (for onward distribution)
- Accident & emergency departments
- Cardiac pacemaker/ICD physiologists
- Cardiologists with pacemaker/ICD responsibilities
- Cardiothoracic surgeons
- Clinical governance leads
- Medical directors
- Nursing executive directors
- Risk managers

**HEALTHCARE COMMISSION (CHAI) to:**

- Headquarters (for onward distribution)
- Hospitals in the independent sector

CONTACTS:

Enquiries to the manufacturer or the National Pacing and ICD Database should be addressed to:

David G Dunham BSc PhD
Regulatory Affairs Manager – UK & Ireland
Medtronic Ltd
Suite One Sherbourne House
Croxley Business Centre
Watford WD18 8WW
Tel: 01923 212 213
E-mail: david.dunham@medtronic.com

National Pacing and ICD Database
PO Box 9205
Bridge of Weir
Strathclyde
PA11 3DZ
Tel: 01505 612 829
Fax: 01505 612 829
E-mail: mwc@btconnect.com

Continued on next page
CONTACTS (continued):

Enquiries to the MHRA should quote reference number 2005/011/023/061/006 and be addressed to:

**Technical aspects:**
Miss Anna Richter or Mr Peter Solesbury  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ  
Tel: 020 7084 3223 / 3215  
Fax: 020 7084 3106  
E-mail: anna.richter@mhra.gsi.gov.uk  
    peter.solesbury@mhra.gsi.gov.uk

**Clinical aspects:**
Dr Susanne Ludgate  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ  
Tel: 020 7084 3123  
Fax: 020 7084 3111  
E-mail: susanne.ludgate@mhra.gsi.gov.uk

**Change of address or removal from address list for Healthcare Commission:**
Healthcare Commission  
Finsbury Tower  
103-105 Bunhill Row  
London EC1Y 8TG  
Tel: 020 7448 0842  
E-mail: contacts@healthcarecommission.org.uk

---

**HOW TO REPORT ADVERSE INCIDENTS**

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (http://www.mhra.gov.uk).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre  
Medicines and Healthcare products Regulatory Agency  
Market Towers, 1 Nine Elms Lane, London SW8 5NQ  
Telephone 020 7084 3080 or Fax 020 7084 3109  
or e-mail: aic@mhra.gsi.gov.uk  
(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: http://www.mhra.gov.uk

MHRA is an executive agency of the Department of Health  
© Crown Copyright 2005  
Addressees may take copies for distribution within their own organisations
IMPORTANT PATIENT MANAGEMENT INFORMATION

November 2005

Dear Doctor (With affected devices)

In accordance with Medtronic's commitment to keeping you informed about the performance of our products, we write to advise you about an issue observed during ongoing returned product analysis. This concerns a specific subset of Sigma® series pacemakers that may fail due to separation of interconnect wires from the hybrid circuit. This failure mechanism may present clinically as loss of rate response, premature battery depletion, high lead impedance, intermittent or total loss of telemetry, or no output. There have been no reported patient injuries or deaths due to this issue.

Medtronic has advised the Medicines and Healthcare products Regulatory Agency (MHRA) and the action Medtronic is taking.

Affected Devices
There are approximately 28,000 active implants worldwide with approximately 1700 in the UK. A list of affected devices is attached or you can check affected serial numbers online at http://SigmaSNList.medtronic.com.

Root Cause
Separation of interconnect wires has been observed on hybrid terminal blocks. In October 2005, we completed testing and analysis identifying the root cause of these failures and the affected population. Hybrid circuits used in this subset of devices were cleaned during manufacturing with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time.

Low Probability of Occurrence
As part of the ongoing returned product analysis, Medtronic has observed 19 devices (approximately 0.05%) that have exhibited this failure mechanism. There is no provocative testing that can predict which devices may fail. Implant duration for the 19 failures ranged from 17-38 months. Our modeling predicts a failure rate from 0.17% to 0.30% over the remaining lifetime of these pacemakers.
Appendix 1 to MDA/2005/072

Medtronic’s letter to clinicians with affected devices

Recommendations
We realise that each of your patients is unique, and we support your clinical judgment in caring for them. To assist physicians in their patient care and after discussion with our physician consultants, Medtronic offers the following recommendations:

- Medtronic does not recommend replacement of these devices prior to normal elective replacement (ERI), based on the low probability of occurrence of a serious event in this population.
- Continue routine follow up in accordance with standard practice or at least every six months and inform patients to seek immediate attention if they experience return of symptoms (e.g. syncope or light headedness).
- Determine whether device replacement is warranted on a case-by-case basis based upon consultation with patients, review of the individual patient’s medical history and consideration of the relative risks of an invasive procedure.

Physician Support
We regret the difficulties this may cause you and your patients. The information in this letter will be posted on Medtronic.com on December 5, 2005. We will provide you with regular updates on the ongoing actual performance in our Product Performance Report, available at www.medtronic.com/crm/performance.

Should you elect to replace a device for a specific patient, Medtronic will provide a replacement device in accordance with the terms of the applicable product warranty.

Your Medtronic representative will evaluate and replace any inventory in your center(s) affected by this action.

If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative.

Yours sincerely

David G. Dunham BSc. PhD
Regulatory Affairs Manager – UK & Ireland

Attachment - Serial number listing of affected devices distributed in the UK
IMPORTANT PATIENT MANAGEMENT INFORMATION

November 2005

Dear Doctor (Without affected devices),

In accordance with Medtronic’s commitment to keeping you informed about the performance of our products, we write to advise you about an issue observed during ongoing returned product analysis. Please note that this issue concerns only a specific subset of Sigma® pacemakers that have been identified and none of the affected devices were implanted at your center. However, in a desire for transparency and considering the possible movement of patients between centers, we would like to update you on our findings.

These affected pacemakers may fail due to separation of interconnect wires from the hybrid circuit. This failure mechanism may present clinically as loss of rate response, premature battery depletion, high lead impedance, intermittent or total loss of telemetry, or no output. There have been no reported patient injuries or deaths due to this issue.

Medtronic has advised the Medicines and Healthcare products Regulatory Agency (MHRA) and the action Medtronic is taking.

Affected Devices
There are approximately 28,000 active implants worldwide with approximately 1700 in the UK. A serial number list of affected devices is attached, or you can check affected serial online at http://SigmaSNList.medtronic.com.

Root Cause
Separation of interconnect wires has been observed on hybrid terminal blocks. In October 2005, we completed testing and analysis identifying the root cause of these failures and the affected population. Hybrid circuits used in this subset of devices were cleaned during manufacturing with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time.

Low Probability of Occurrence
As part of the ongoing returned product analysis, Medtronic has observed 19 devices (approximately 0.05%) that have exhibited this failure mechanism. There is no provocative testing that can predict which devices may fail. Implant duration for the 19 failures ranged from 17-38 months. Our modeling predicts a failure rate from 0.17% to 0.30% over the remaining lifetime of these pacemakers.
Appendix 2 to MDA/2005/072

Medtronic’s letter to clinicians without affected devices

Medtronic Limited
Suite One
Sherbourne House
Croxley Business Centre
Watford, Herts WD18 8WW
Telephone: 01923 212213
Facsimile: 01923 241004

Recommendations
We realise that each of your patients is unique, and we support your clinical judgment in caring for them. To assist physicians in their patient care and after discussion with our physician consultants, Medtronic offers the following recommendations:

- Medtronic does not recommend replacement of these devices prior to normal elective replacement (ERI), based on the low probability of occurrence of a serious event in this population.
- Continue routine follow up in accordance with standard practice or at least every six months and inform patients to seek immediate attention if they experience return of symptoms (e.g. syncope or light headedness).
- Determine whether device replacement is warranted on a case-by-case basis based upon consultation with patients, review of the individual patient’s medical history and consideration of the relative risks of an invasive procedure.

Physician Support
We regret the difficulties this may cause you and your patients. The information in this letter will be posted on Medtronic.com on December 5, 2005. We will provide you with regular updates on the ongoing actual performance in our Product Performance Report available at www.medtronic.com/crm/performance.

Should you elect to replace a device for a specific patient, Medtronic will provide a replacement device in accordance with the terms of the applicable product warranty.

If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative.

Yours sincerely

David G. Dunham BSc. PhD
Regulatory Affairs Manager – UK & Ireland

Attachment  - Serial number listing of affected devices distributed in the UK