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## **IMPORTANT PATIENT SAFETY INFORMATION**

Kappa<sup>®</sup> 600/700/900 Series Implantable Pulse Generators  
Sigma<sup>®</sup> 100/200/300 Series Implantable Pulse Generators

May 18, 2009

Dear Health Care Professional,

We are writing to advise you about an issue with specific subsets of Kappa<sup>®</sup> and Sigma<sup>®</sup> series pacemakers that may fail at a higher than expected rate due to separation of wires that connect the electronic circuit to other pacemaker components (e.g., battery, connector). This may present clinically as loss of rate response, premature battery depletion, loss of telemetry, or no output. We are also updating the performance and patient management recommendations of a different subset of Sigma devices with the same possible clinical presentation, previously reported in a November 2005 advisory. Medtronic is communicating this information to Health Canada.

Since 1997, there have been over 1.7 million Kappa and Sigma devices implanted worldwide. Combining the new subsets of Kappa and Sigma pacemakers subject to this advisory with the Sigma pacemakers from the 2005 advisory brings the total number of active devices now affected to 36,900 (~2% of all Kappa/Sigma devices implanted). There are approximately 3,200 actively implanted devices in Canada.

Some patients, whose devices experience a wire separation resulting in a loss of pacing output, will experience a return of bradycardia symptoms (e.g. fainting or lightheadedness). In rare cases involving pacemaker dependent patients, loss of pacing output may result in death or serious injury. Medtronic has received two reports of patient death where it is possible but unclear whether this issue may have been a factor. None of these deaths were in Canada.

### **New Kappa and Sigma Safety Information**

Worldwide, an estimated 15,200 active Kappa devices and 6,100 active Sigma devices, manufactured primarily between November 2000 and November 2002, are affected by this advisory. Most of these devices have been implanted in patients for five years or longer and may be nearing normal elective replacement time.

Medtronic has observed 285 Kappa devices and 131 Sigma devices with this failure mechanism from these new Kappa and new Sigma device subsets. This represents 0.49% (Kappa) and 0.88% (Sigma) of the original affected implant population. Our modeling predicts failure rates of 1.1% (Kappa) and 4.8% (Sigma) over the remaining lifetime of these pacemakers due to this issue. There is no provocative testing that can predict which specific devices may fail, and no device programming can mitigate this issue if it occurs.

### **Performance Update to 2005 Sigma Advisory**

In November 2005, Medtronic issued an advisory regarding a different subset of Sigma pacemakers. This advisory was related to wire separations caused by a particular cleaning solvent used in manufacturing and is not related to the current Kappa/Sigma wire separation issue. There are currently an estimated 15,600 active implants from this 2005 Sigma device subset.

Our original modeling predicted a failure rate from 0.17% to 0.30% over the remaining lifetime of these pacemakers and our advisory recommended that physicians determine whether device replacement was warranted. However, updated modeling predicts a failure rate of 3.9% over the remaining device life, and revised patient management recommendations are provided below.

A copy of the November 2005 Sigma advisory is available on Health Canada's website at:  
[http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/\\_2005/pacemaker-stim\\_card\\_3\\_hpc-cps-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2005/pacemaker-stim_card_3_hpc-cps-eng.php)

## Summary of Affected Devices

Product	Estimated # active devices in subset	Observed failure rate	Predicted lifetime failure rate	Estimated Average Remaining Life
New Kappa Subset	15,200	0.49%	1.1%	1.2 years
New Sigma Subset	6,100	0.88%	4.8%	3.8 years
2005 Sigma Subset	15,600	0.55%	3.9%	3.3 years
Total	36,900			

### Patient Management Recommendations

We realize that each patient requires unique clinical consideration and we support your judgment in caring for your patients. After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following recommendations for patients in the new Kappa, new Sigma, and 2005 Sigma subsets referenced in the table above:

- Physicians should advise their patients to seek medical attention immediately if they experience symptoms (e.g., fainting or lightheadedness).
- Physicians should consider device replacement for patients who are both pacemaker dependent and who have been implanted with a device in the affected subsets. Medtronic will offer a supplemental device warranty if the device is not already at elective replacement time.
- Physicians should continue routine follow up in accordance with standard practice for those patients who are not pacemaker dependent.

Patient queries may be directed to 1-800-268-5346, CRDM Patient Relations, to assist patients.

### Physician and Patient Support

Attached are the specific model and serial numbers referenced in the table above of affected devices you are following according to our device registration records. You may also look up specific serial numbers online to determine if they are affected at [www.KappaSigmaSNList.medtronic.com](http://www.KappaSigmaSNList.medtronic.com).

We will continue to monitor and analyze failure rates and to provide regular updates on the ongoing actual performance of these subsets and all Kappa and Sigma devices in our Product Performance Report, available at [www.medtronic.com/crm/performance](http://www.medtronic.com/crm/performance).

### Continued Vigilance – Unaffected Devices

There is an additional subset of Kappa devices where we have observed a much lower rate of occurrence of this issue. Approximately 96,000 devices of this subset remain active. We have observed a failure rate of approximately 0.04% in this subset and our modeling predicts a failure rate of 0.12% over the remaining device life. After review with our Independent Physician Quality Panel, we do not recommend any specific actions for this group of devices. We will continue to monitor performance and inform you if any specific patient management recommendations are warranted.

We regret any difficulties this may cause you and your patients. If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative or Medtronic's Customer Relations Coordinator at 1 800 268-5346.

Sincerely,



Jodi Brendel  
Vice President, CRDM Sales and Marketing  
Medtronic of Canada Ltd.



**Medtronic**

Managing marketed health product-related adverse incidents depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse incidents are generally presumed to underestimate the risks associated with health product treatments. Any incident or other serious or unexpected adverse incidents for medical devices in patients using Kappa<sup>®</sup> 600/700/900 series implantable pulse generators (IPGs) or Sigma<sup>®</sup> 100/200/300 Series IPGs should be reported to Medtronic, or to Health Canada at the following address:

Medtronic of Canada Ltd.  
6733 Kitimat Road  
Mississauga, Ontario L5N 1W3  
Tel: 1 800 268 5346

**OR**

Health Products and Food Branch Inspectorate  
HEALTH CANADA  
Address Locator: 2003D  
Ottawa, Ontario K1A 0K9  
Tel: The Inspectorate Hotline: 1 800 267 9675

The Medical Devices Problem Report Form and Guidelines can be found on the Health Canada web site.

[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep\\_md\\_prob-rap\\_inc\\_im\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep_md_prob-rap_inc_im_tc-tm_e.html)  
[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/mavprfmd-rioevraim\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/mavprfmd-rioevraim_tc-tm_e.html)