Medtronic Limited
Suite One
Building 5
Croxley Green Business Park
Watford, Herts WD18 8WW
Telephone: 01923 212213
Facsimile: 01923 241004

URGENT FIELD SAFETY NOTICE

Patient safety information

Kappa® 600/700/900 Series IPGs
Sigma® 100/200/300 Series IPGs

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Dear

We are writing to advise you about an issue with specific subsets of Kappa® and Sigma® 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 has informed the Medicines and Healthcare products Regulatory Agency (MHRA) of this communication.

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).

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.

New Kappa and Sigma Issue
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 issue. 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.

Summary of Affected Devices

Product	Estimated number active devices	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 realise 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.
- Physicians should continue routine follow up in accordance with standard practice or at least every six months for those patients who are not pacemaker dependent.

Physician and Patient Support
This communication is in line with the recommendations of EHRA on device advisories. Attached are the specific model and serial numbers referenced in the table above of affected devices you are following according to our records. You may also look up specific serial numbers online to determine if they are affected at **http://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.

Continued Vigilance
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 on 01923 212213.

Yours sincerely

D. G. Dunham.

Regulatory Affairs Manager – UK & Ireland