

May 18th, 2009

Advisory Notification/Response



Canadian Heart Rhythm Society Device Advisory Committee (CHRS DAC)

Re: Subset of Kappa[®] 600/700/900 and Sigma[®] 100/200/300 Series pacemaker implantable pulse generators 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.

Class of Advisory: Class 1

Urgency of Advisory: Urgent

Nature of the Advisory: This advisory involves the reliability of the bond that fixes the conductor wire within the generator housing, which may result in wire separation and possible abrupt loss of pacing function in a specific lot of devices. This represents a mechanism of failure in 0.49% (Kappa) and 0.88% (Sigma) of the original affected implant population, with projections of failure rates of 1.1% (Kappa) and 4.8% (Sigma) over the remaining lifetime of these pacemakers due to this issue. 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. Medtronic has investigated the 7 non-fatal cases of concern in Canada that were reported to them in an informal query by the CHRS DAC in late 2008, and has established that this defect was responsible for abrupt failure in all of the cases. This is unrelated to previous inquiries regarding the reliability of the longevity calculator, that was subsequently the subject of a Medtronic communication with an updated position from the CHRS DAC recently posted on the CHRS website (www.chrsonline.ca).

Scope of the Problem: This advisory affects ~2% of all Kappa/Sigma devices implanted, or approximately 3200 devices in Canada and 36,000 devices worldwide. The advisory also provides an update of an advisory regarding Sigma pacemaker IPGs from 2005 suggesting a similar 3.9% projected failure rate due to wire separations caused by a particular cleaning solvent used in manufacturing. These patients are included in the 3200 affected Canadian patient estimate.

Response of the Canadian Heart Rhythm Society

Recommendations:

1. The CHRS DAC encourages physicians to promptly notify patients with potentially affected devices of this issue, being careful to emphasize the low rate of failure due to this issue. The CHRS DAC recommends that Physicians and Hospitals/Clinics communicate the nature of the advisory to all affected patients within 7 days, focusing initially on more urgent contact with dependent patients. A sample notification letter is available at www.chrsonline.ca (coming online May 19th, 2009). Some patients may hear about this issue in the lay press and will require reassurance.

2. The CHRS DAC agrees with the manufacturer's independent safety board's recommendation to replace the IPG in all dependent patients. Implant centers should endeavor to perform replacement within 30 days of the advisory whenever possible, ideally as soon as feasible within the constraints of the affected facility and its resources. Physicians are reminded that many apparently dependent patients may have underlying rhythm if the pacing rate is reduced gradually, or with administration of isoproterenol.
3. The CHRS DAC recognizes that affected patients that are not pacing dependent and their Physicians may choose to proceed with early IPG replacement because of potential concern of unpredictable failure, influenced by the proportion of pacing, preimplant symptoms and patient preference. Given the recognized risk of device replacement (5% complications), the CHRS DAC encourages individualized decision-making that would favor deferring replacement until the generator reaches elective replacement indicator (ERI).
4. The CHRS DAC encourages each centre to schedule follow-up visits according to Canadian guidelines (Gillis AM et al, Can J Cardiol 2003;19(1):21-37) or manufacturers recommendations at their discretion, since there is no evidence that increased follow-up will alter patient outcome in this situation.



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Appendix regarding advisory processing by the CHRS DAC

Advisories are divided in 2 classes depending on the gravity of the consequence to the patient of the potential device malfunction. The term "Class I Advisory" applies when device replacement should be considered because of the reasonable probability that the malfunction or potential malfunction could result in death or significant harm to the patient. The term "Class II advisory" applies when the advisory involves non-life threatening malfunctions or potential malfunctions. This classification system is consistent with the "recall" classification of Health Canada. When a device advisory is released, it is directed to the attention of the Committee Chair, or a Working Group member if the Chair is unavailable. Depending on the urgency and scope of the advisory, communication is via e-mail, fax or telephone. The Chair has the responsibility to classify the advisory as Urgent requiring response within 2 business days, semi-urgent requiring response within 5-10 working days, or routine requiring response within 20 working days. The required urgency of a response depends on both the number of potential patients affected and the actual threat to the patient (i.e. premature battery depletion, abrupt failure, inappropriate ICD shocks, etc.). Committee members discuss advisories by e-mail, and when needed, a conference call lead by the Chair is used to arrive at a consensus regarding recommendations. Recommendations are drafted and circulated by e-mail to the entire Committee and require response within a finite period determined by the urgency of the advisory. Consensus recommendations are forwarded to the CHRS executive and made available to all implant and follow-up centers in Canada by e-mail and posted on the CHRS website (www.chrsonline.ca).

Important Links Related to the Kappa/Sigma Advisory:

Canadian Heart Rhythm Society Website: Device Advisory and Recall Section

<http://www.chrsonline.ca/members/advisories.htm>

Medtronic Site including Physician Letter:

<http://www.medtronic.com/product-advisories/physician/>

Health Canada site including Physician Letter:

<http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/index-eng.php>