

April 21st, 2009

Advisory Response Notification



Canadian Heart Rhythm Society Device Advisory Committee

Re: Boston Scientific COGNIS® CRT-Ds and TELIGEN® ICDs. Inappropriate therapy associated with certain right ventricular (RV) lead complications may occur more frequently if the Respiratory Sensor is programmed On.

Dear CHRS DAC Committee Members,

Class of Advisory: Class II (non-life threatening malfunction or potential malfunction)

Urgency of Advisory: Routine (requiring response within 20 working days)

Nature of the Advisory: Boston Scientific has determined that if certain RV lead complications such as chronic lead fracture or acute lead connection issues were to occur with the Respiratory Sensor programmed On, *additional* oversensing may occur, thereby increasing the probability of inappropriate therapy. Five to eight successive inappropriate shocks could leave the device unable to treat an actual arrhythmia until the current episode ends. This has not occurred to date. The greatest extent of inappropriate therapy that has been observed to date occurred in a single pacemaker-dependent patient with a fractured lead.

Scope of the Problem: Boston Scientific estimates that the Respiratory Sensor is programmed On in approximately 8,000 COGNIS and TELIGEN devices worldwide. The Respiratory Sensor is nominally On in Canada. Inappropriate therapy (temporary pacing inhibition, inappropriate ATP pacing or shocks) has been reported 15 times (0.2%).

Response of the Canadian Heart Rhythm Society

Recommendations:

1. CHRS DAC agrees with the manufacturer's recommendation to turn the respiratory sensor OFF in all patients, which will not affect normal device function.
2. The optimal timing of reprogramming affected patients will depend on the local center's frequency of routine follow-up and the frequency with which the Respiratory Sensor is programmed On. Preliminary discussion suggests most patients will be reprogrammed within 3 months, and all patients within 6 months.

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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).