

Medtronic Sprint Fidelis Lead Advisory Update
Canadian Heart Rhythm Society Device Advisory Committee



April 23rd, 2009

Dear Colleagues:

The CHRS Executive has requested an update regarding the position of the CHRS Device Advisory Committee (CHRS DAC) on the management of patients with Medtronic Sprint Fidelis family of ICD leads (Models 6930, 6931, 6948 and 6949). This is an update to the Member Statement from October of 2007. There is also a posted update from Medtronic that can be accessed at <http://www.medtronic.com/fidelis>. The CHRS DAC and several other groups have consistently found the major mechanism of failure of the lead is the pace sense component. Because the rate of failure appears to be accelerating, there is growing concern about the durability and reliability of these leads, particularly in patients that are pacemaker dependent. This is particularly the case because the window of simple traction based lead removal during planned replacement may be closing.

Response of the Canadian Heart Rhythm Society

The Canadian Heart Rhythm Society (CHRS) is dedicated to the safety of our patients, to best practices and to the development of open, transparent processes. An active and ongoing electronic discussion has been held with all members of the CHRS DAC since the advisory announcement 18 months ago. Routine replacement of these leads in patients with normal lead function is strongly advised against, since the complications of this strategy is almost certainly higher than a “watch and wait” approach. This balance of risk and benefit may favor replacement in select patients undergoing procedures such as generator change where the lead is accessed routinely as part of a necessary procedure. There is insufficient evidence to advocate a general course of action in patients undergoing generator change.

Recommendations:

1. Routine removal and/or replacement of normally functioning leads is not advised. This may not be the case for all patients, such as the patient with borderline performance values and frequent device use. Decisions regarding lead replacement should be individualized.
2. Lead removal and/or replacement may be considered in patients undergoing planned procedures such as generator replacement, other lead replacement or upgrade. Factors favoring replacement include pacing dependence, previous documented ventricular arrhythmia and young, physically active patients that are at higher risk of lead fracture.
3. Optimal strategy for those patients that are considered for replacement/removal may include simple traction and replacement when feasible, replacement with an ICD or dedicated pace sense lead, or formal lead extraction. The choice of

- strategy should include an informed discussion with the patient, and consideration of local expertise with lead extraction.
4. Careful monitoring including use of remote monitoring technology should be encouraged whenever feasible to optimally detect lead failure and prevent inappropriate shocks. Follow-up centers are encouraged to implement the Lead Integrity Alert software, which has been shown to reduce the risk of inappropriate shocks.



Andrew Krahn, MD
Chair, CHRS Device Advisory Committee

Important Links Related to the Fidelis 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/sprint-fidelis/PHYSLETTER-2009-03-13.htm>

Health Canada site including Physician Letter:

http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2007/leads-sondes_hpc-cps_e.html