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Sprint Fidelis Lead Performance Update

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Dear Doctor:

Medtronic is committed to keeping you informed about Sprint Fidelis lead performance and our ongoing vigilance efforts. To that end, we are providing the following summary of our most recent review of performance data and Medical Device Reports (MDR or MedWatch reports) with Medtronic's Independent Physician Quality Panel, and the Panel's updated patient management recommendations.

Lead Performance Update

Since the October 15, 2007 communication about the Sprint Fidelis family of leads, Medtronic and the Independent Physician Quality Panel have continued to analyze performance data from the Medtronic System Longevity Study (SLS) and the Medtronic CareLink® Network, as well as recent third party data. Table 1 below shows lead survival data for Sprint Fidelis from the SLS, the Medtronic CareLink Network and from third party reports at 30 to 45 months from implant recently reviewed by the Panel.

Table 1: Sprint Fidelis Lead Survival Comparison

Data Source	Sample Size (Leads)	30 Months	36 Months	45 Months
SLS (Model 6949)	763	96.8% [+1.2/-1.8]	95.4% [+1.7/-2.8]	94.5% [+2.2/-3.6]
CareLink Network (Model 6949)	21,500	98.2% [+0.2/-0.3]	97.0% [+0.4/-0.5]	96.1% [+0.6/-0.7]
Hauser et al., *HeartRhythm Journal online* Accepted Feb 2009	848	N/A	87.9% [+3.0/-3.1]	N/A
Krahn et al., *HeartRhythm Journal online* Accepted Jan 2009	6,215	96.1% (32 months)	N/A	N/A
VA National ICD Surveillance Program Chun et al. (Abstract)	4,150	N/A	95.0% (38.4 months)	94.2% (41.9 months)

In addition, there is a recent publication by Farwell, et al., (*HeartRhythm*, 2008; 5:1375-1379) that is a subset of Krahn et al.

Review of Medical Device Reports

Approximately 268,000 Fidelis leads have been implanted worldwide. The FDA's MAUDE database currently has 107 Medical Device Reports (MDRs) that include allegations that the Fidelis lead may have caused or contributed to a patient death. Most of these MDRs were not initiated by medical professionals; the majority were initiated by family members or attorneys with minimal supporting data. Medtronic's Independent Physician Quality Panel has reviewed 89 of the 107 reports. It is not possible to determine cause of death with certainty. The Panel has identified 13 patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor.

The Panel noted that four of the 13 deaths were associated with lead extraction, highlighting the risks associated with that procedure. With the exception of the appearance of deaths associated with lead extraction, no new or unexpected trends have been observed.

Patient Management Recommendations

In consultation with the Independent Physician Quality Panel, our patient management recommendations are as follows:

- When a lead fracture is suspected or confirmed, we strongly recommend prompt patient attention. Patients should contact their physician without delay if they experience unexpected shocks.
- The Lead Integrity Alert (LIA) is expected to provide three days advance notice prior to inappropriate therapy to 76% of the patients with lead fractures. As a result, we strongly recommend that all Sprint Fidelis patients who have the ability to upgrade to Lead Integrity Alert do so promptly.
- The risk of prophylactic intervention appears to be greater than the risk of serious injury resulting from lead fracture even for pacemaker dependent patients, except in select individual patient circumstances as determined by the physician.
- Special circumstances may apply to device change-out or upgrade procedures when a lead fracture has not occurred. At least four options are available, each of which carries risks and benefits that should be taken into consideration:
    - Leave a properly performing lead intact; this is likely to be the best choice for the majority of patients.
    - Place a new ICD lead without extraction of the existing lead.
    - Place a pace sense lead without the extraction of the existing lead. This option reflects the observation that approximately 90 percent of Fidelis failures are related to fractures in the pace sense circuit. It is unknown what the failure rate of the high voltage conductor would be should a pace sense conductor failure occur in the existing Sprint Fidelis lead.
    - Unusual patient circumstances may warrant extracting and implanting a new ICD lead. Factors to consider when making this decision include patient life expectancy, age and co-morbidities, number of implanted leads and duration of implant, and patient preference. **Medtronic's Independent Physician Quality Panel recommends that if a lead requires removal, the procedure be performed by a physician with extensive lead extraction experience.** (A new HRS consensus document on lead extraction is expected to be available in May, 2009.)

Keeping Physicians Informed

To keep you informed, Medtronic continues to provide two ways to access regularly updated Sprint Fidelis® lead performance data. The Product Performance Report (PPR) contains SLS performance data for the Sprint Fidelis lead and other Medtronic leads and devices. The PPR is updated and published every six months with both current and past reports available at www.CRDMPPR.medtronic.com. Medtronic continues to post quarterly Sprint Fidelis lead performance updates from both SLS and Medtronic CareLink® online at www.medtronic.com/fidelis.

Medtronic continues to be committed to answering your questions and keeping you informed. If you have any questions or concerns, please contact your Medtronic Representative or Medtronic Technical Services at 1-800-723-4636 (US).

Sincerely,

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