



Medtronic, Inc.  
Cardiac Rhythm Disease Management  
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## **Sprint Fidelis<sup>®</sup> Lead Performance Update**

(Models 6949, 6948, 6931, 6930)

May 7, 2008

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 updated performance information.

### **Summary**

- **Sprint Fidelis lead performance continues to be in line with the information provided in October 2007.**
- **In consultation with the Independent Physician Quality Panel, our patient management recommendations remain unchanged.**
  - 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.
  - 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.
  - Implementation of our patient management recommendations is expected to provide two days advance notice prior to inappropriate therapy to 49% of the patients with lead fractures. The remainder will receive less than two days advance notice or no notice. This percentage may vary by implanted device.
- **Future plans include device enhancements and additional information to improve patient management.**
  - We are developing new software that can be downloaded into approximately 93% of Medtronic implanted devices worldwide (98% in the US) to increase the likelihood of fracture detection prior to inappropriate therapy. Approximately 75% of patients should get three or more days notice with the new software. The software will be available later this year, subject to regulatory approval.
  - Quarterly performance updates will be posted on the Medtronic website beginning in August at [www.medtronic.com/fidelis](http://www.medtronic.com/fidelis).

### **Performance Update**

Since our October 15, 2007, communication about the Sprint Fidelis family of leads, we have continued to analyze performance data from the Medtronic System Longevity Study (SLS), the Medtronic CareLink<sup>®</sup> Network, and Returned Product Analysis (RPA). Table 1 below shows lead survival data for Model 6949 from the SLS, the Medtronic CareLink<sup>®</sup> Network, and RPA at 30 months from implant.

**Table 1: Sprint Fidelis Lead Performance at 30 Months (Model 6949 lead survival data)<sup>1</sup>**

<b>Data Source</b>	<b>Data as of October 15, 2007 30 Months</b>	<b>Data as of May 7, 2008 30 Months</b>
SLS	97.7% [+1.3/-3.0]	97.5% [+1.1/-2.2]
CareLink™ Network	97.7% [+0.6/-0.8]	98.2% [+0.2/-0.3]
RPA	99.2% [+0.1/-0.1]	99.0% [+0.0/-0.1]

Table 2 below shows lead survival data for Model 6949 from the SLS, CareLink Network, and RPA at 33, 36, and 39 months from implant. Because fewer leads have reached 33, 36, and 39 months of implant time, the confidence intervals shown in Table 2 are comparatively larger than those in Table 1. As more leads reach 33, 36 and 39 month implant points, our understanding of Sprint Fidelis lead performance will continue to increase.

**Table 2: Sprint Fidelis Lead Performance at 33, 36, and 39 Months (Model 6949 lead survival data)**

<b>Data Source</b>	<b>33 Months</b>	<b>36 Months</b>	<b>39 Months</b>
SLS	96.7% [+1.6/-3.1]	96.7% [+1.6/-3.1]	n/a <sup>2</sup>
CareLink Network	97.7% [+0.3/-0.3]	96.9% [+0.4/-0.5]	96.4% [+0.6/-0.7]
RPA	98.8% [+0.0/-0.1]	98.5% [+0.1/-0.1]	98.3% [+0.2/-0.1]

Medtronic recognizes that your clinical decisions would benefit from a greater understanding of the likely future performance of Sprint Fidelis leads. Despite considerable efforts, there are no models to reliably predict in vivo lead survival. Although our investigation into sub-populations is ongoing, we have no data to suggest alterations to our current patient management recommendations are warranted. We are committed to monitoring and communicating the survival performance of leads with the longest implant time (i.e., the leading edge). At this time, there is no evidence that the lead survival curve is flattening at the leading edge. Thus, we expect the lead survival curve to continue to show a downward trend. Please refer to Appendix I for complete lead survival curves.

### **Patient Management Recommendation**

After consideration of the updated performance data, as well as ongoing reviews by our Independent Physician Quality Panel, we continue to recommend the patient management actions described in our letter of October 15, 2007. These recommendations are attached in Appendix II. Also refer to the November 2007 Directo Update to Patient Management Recommendations.

As stated in the October communication, Medtronic's Independent Physician Quality Panel does not recommend prophylactic intervention except when the physician determines that individual patient circumstances warrant. If a fracture is suspected, Medtronic and the Panel strongly recommend prompt attention to reduce the likelihood of inappropriate therapy or loss of pacing output. Patients should contact their physicians without delay if they experience unexpected shocks.

### **Oversensing During Interrogation (Non-Wireless Session)**

In rare instances (approximately 1% of fractured leads), patients may experience inappropriate therapy during interrogation of a Medtronic device either in-office or via the CareLink Network. This oversensing, which is not unique to the Sprint Fidelis lead models, occurs only in leads with fractures that cause a complete open circuit. If oversensing during in-office device interrogation is observed, quickly remove the programming head. CANCEL the interrupted interrogation and manually load the software for the specific device model. Reposition the programmer head over the device and immediately select SUSPEND. For more information, contact your Medtronic representative or call Medtronic Technical Services at 1-800-723-4636 (US). Later this year, subject to regulatory approval, software enhancements will eliminate this oversensing issue.

<sup>1</sup> Due to the small implant sample size of Sprint Fidelis models 6930, 6931 and 6948, the SLS, CareLink Network and RPA data are based on Sprint Fidelis 6949 leads only.

<sup>2</sup> Since the lead survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the lead survival curve when the number of leads entering an interval is less than 50 leads.

### Advance Notice

As previously noted, programming to our management recommendations will not result in every fracture being detected prior to delivery of inappropriate therapy. Forty-nine percent of the Sprint Fidelis lead patients who experience a fracture will receive more than two days advance notice. The remainder will receive less than two days advance notice or no notice. To help you consider what this may mean in your practice, we have projected the clinical experience a hypothetical clinic of 1,000 Sprint Fidelis lead patients might have over the next 12 months in Appendix III.

We are developing new software that can be downloaded into approximately 93% of Medtronic implanted devices worldwide (98% in the US) to increase the likelihood of fracture detection prior to inappropriate therapy. Approximately 75% of patients should get three or more days notice with the new software. The software will be available later this year, subject to regulatory approval.

### Pacemaker Dependent Patients

We have had numerous questions about the risk to pacemaker dependent patients in the event of lead fracture. Based on currently available data, we estimate the critical injury risk to be less than 0.1% for the majority of pacemaker dependent patients through 30 months of implant time (see Appendix IV). The published risk of major complications from lead extraction has been shown to be between 1.4%<sup>3</sup> and 7.3%<sup>4</sup>; in addition there are known risks of reoperation. Thus, prophylactic intervention appears to pose greater patient risk than the risk of critical injury from lead fracture.

### **Future Device Enhancements and Information**

Medtronic is working to improve device functionality to increase fracture detection prior to inappropriate therapy. In addition to the new software described above, we are also developing improvements to future generations of devices to enhance their ability to differentiate true VT/VF from device-detected VT/VF, as well as improve future Patient Alert<sup>TM</sup> and Medtronic CareAlert<sup>®</sup> Notification capabilities.

As part of our commitment to keep you informed about Sprint Fidelis lead performance, we will publish quarterly System Longevity Study all-cause lead survival curves for the 6949 lead model at [www.medtronic.com/fidelis](http://www.medtronic.com/fidelis), starting in August. We will also continue to provide updates in our semiannual Product Performance Report. In addition, we will communicate any performance trends that warrant changes to our patient management recommendations.

We continue 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,



Reggie Groves  
Vice President, Quality and Regulatory  
Medtronic Cardiac Rhythm Disease Management  
Medtronic, Inc.

<sup>3</sup> Byrd et al, Intravascular extraction of problematic or infected permanent pacemaker leads: 1994-1996. U.S. Extraction Database, MED Institute. *PACE*. September 1999;22(9):1349-1357.

<sup>4</sup> Bracke et al, Lead extraction for device related infections: a single-centre experience. *Europace*. May 2004; 6(3):243-247.