



## **Field Safety Corrective Action**

### **Sprint Fidelis® Lead Patient Management Recommendations**

October 15, 2007

Dear Doctor,

This letter provides important information on Sprint Fidelis lead performance and recommendations for ongoing patient management. Our records indicate that you have implanted or are following patients with Sprint Fidelis leads (Models 6930, 6931, 6948, 6949). In consultation with our Independent Physician Quality Panel, we are voluntarily suspending distribution of Sprint Fidelis leads worldwide. This decision is based on a variety of factors detailed in this letter that when viewed together, indicate that suspension of implantation is the appropriate action. You should no longer implant Sprint Fidelis leads, and you should return any unused product to Medtronic.

#### Background

As we reported in March 2007, there are two primary locations<sup>1</sup> where chronic conductor fractures have occurred on Sprint Fidelis leads: 1) the distal portion of the lead, affecting the anode (ring electrode) and 2) near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor. High voltage conductor fractures could result in the inability to deliver defibrillation therapy. Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output. The potential for defibrillation lead fracture to result in or contribute to inappropriate therapies or death has been previously reported.<sup>2</sup> As of October 4, 2007, there have been approximately 268,000 Sprint Fidelis leads implanted worldwide. Based on current information, we have identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor. We have confirmed 665 chronic fractures in returned leads. Approximately 90% of these fractures have occurred in the anode or cathode conductors, while 10% have occurred in the high voltage conductors.

#### Performance Update

Since our March 21<sup>st</sup> communication, we have examined six months additional Returned Product Analysis (RPA) and Medtronic System Longevity Study (SLS) data. In addition, we have performed extensive analysis using the Medtronic CareLink® Network (25,000 devices) [see Appendix A]. These data give us confidence in our current understanding of Sprint Fidelis' performance.

RPA of Sprint Fidelis leads shows a survival of 99.2% at 30 months. However, RPA overstates actual performance since it does not account for leads that are not returned. The Medtronic SLS data for the Model 6949 Sprint Fidelis lead indicate 97.7% [+1.3/-3.0] all-cause lead survival at 30 months. This is consistent with our analysis of Medtronic CareLink Network data from approximately 25,000 Sprint Fidelis leads, which indicate 97.7% [+0.6/-0.8] survival at 30 months. These survival rates are not statistically different from the all-cause lead survival of 99.1% [+0.4/-0.8] for the Model 6947 Sprint Quattro® lead at 30 months from the SLS (see Appendix B). However, we expect this difference will become statistically significant over time if the current failure rates remain constant.

## Recommendations

Medtronic recommends you consider the following as part of routine follow-up for each patient (see Appendix C)

- To reduce the risk of inappropriate detection and therapy due to oversensing, program VF detection for initial Number of Intervals to Detect (NID) to nominal settings (18/24) or longer at physician discretion and Redetect NID to nominal settings (12/16).
- Turn ON Patient Alert™ for RV Pacing, RV Defibrillation, and SVC Defibrillation impedance.
- To optimize effectiveness of the lead impedance alert:
  - Review V Pacing Lead Performance Trend to determine typical chronic impedance value for the patient (typical values for Fidelis leads should be 350-1,000 ohms).
  - Program lead impedance alert threshold for RV Pacing to 1,000 ohms, if the typical chronic impedance for the patient is  $\leq 700$  ohms, or
  - Program lead impedance alert threshold for RV Pacing to 1,500 ohms, if the typical chronic impedance for the patient is  $> 700$  ohms.
  - Program lead impedance alert threshold for RV Defibrillation and SVC Defibrillation to 100 ohms.

The patient management recommendations set forth above should increase the likelihood that a fracture will be detected by Patient Alert and decrease the likelihood of inappropriate therapies. Based on our review of the available data, there does not appear to be a benefit to more frequent follow-up.

**Medtronic's Independent Physician Quality Panel believes it is inappropriate to prophylactically remove Sprint Fidelis leads except in unusual individual patient circumstances. We support this position.**

Lead extraction carries risks that should be considered in patient management. Published literature suggests major complications (death or surgical intervention) from lead extraction range from 1.4-7.3%.<sup>3,4</sup>

As always, with confirmed lead failure the risk of extraction should be weighed against the risk of adding an additional lead (see Appendix D).

We are notifying regulatory agencies of this communication. We will continue to provide performance updates every six months via our Product Performance Report.

Nothing is more important to Medtronic than patient safety. We are committed to answering your questions and keeping you informed. We regret any difficulties this may cause you and your patients. If you have questions or concerns, please contact your Medtronic Representative.

Sincerely,

Country Manager

Appendix Document Attached

1 The two primary locations described above account for 90% of the chronic fractures identified by RPA. The remaining 10% of chronic fractures occurred in DF-1 connector leg and the proximal portion of the RV coil.

2 Kleemann T, Becker T, Doenges K, et al., K. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. *Circulation*. May 15, 2007; 115(19): 2461 - 2463.

3 Byrd CL, Wilkoff BL, et al. Intravascular extraction of problematic or infected permanent pacemaker leads: 1994-1996. U.S. Extraction Database, MED Institute. *PACE* May 2000; 23(5): 927-928.

4 Bracke FA, Meijer A, vanGelder LM. Lead extraction for device related infections: a single centre experience. *Europace*, May 2004;

6(3): 243-247.

## **APPENDIX A**

### **Vigilance Process for Sprint Fidelis® Leads**

**October 2007**

This attachment accompanies Medtronic's physician letter dated October 15, 2007 and provides background information on our vigilance process.

#### **Vigilance Process Overview**

Medtronic's vigilance process is multifaceted and comprehensive. All complaints with or without returned product and associated trends are analyzed, and qualifying events are reported to regulatory agencies. As part of Returned Product Analysis (RPA), Medtronic analyzes all explanted and returned leads to characterize the failure mode, if any. The Medtronic System Longevity Study (SLS) is leveraged to understand, monitor, and report lead survival. We developed a proprietary methodology to analyze data from the Medtronic CareLink® Network database to estimate lead integrity and lead performance. Using RPA, SLS, and CareLink™ Network data, we are able to implement the most comprehensive vigilance process for assessing the performance of Fidelis leads.

#### **Returned Product Analysis (RPA)**

The Medtronic RPA Lab analyzes all leads or partial lead segments that are returned to us. The purpose of the analysis is to identify the failure mode, if any. If a failure mode is found, the data are categorized and stored in a database intended for trending and analysis. All the leading CRM device manufacturers use RPA as a tool to estimate device performance; however, the protocols for product analysis and reliability estimates differ among manufacturers.

RPA's primary benefit is that it can help identify the nature of the failure in most cases and correlate the failure mode to the clinical presentation of the failure mode. In addition, it helps proportionally categorize all the failure modes associated with a given lead model. RPA's primary limitation is under-reporting. Not all malfunctioning leads are explanted and returned to the manufacturer due to a number of factors including explant related clinical risks to the patient.

#### **System Longevity Study (SLS)**

For over 24 years, Medtronic has conducted a System Longevity Study (SLS) which is a prospective multicenter study designed to monitor the performance of market-released cardiac therapy products. SLS data is updated every six months and published in our Product Performance Report. This ongoing measurement of lead performance provides prospective information that is not available through RPA.

SLS enrollments for Fidelis Model 6949 represent more than 50 physicians from 17 centers, 14 located in the United States and Canada. As of July 31, 2007, for Model 6949, SLS has 654 leads with a mean follow-up time of 15.1 months, a median follow-up of 12.4 months, and a cumulative follow-up of 9,894 months. The effective sample size between

27 and 30 months of implant time is 84 patients. The limitations of SLS include a smaller sample size, particularly at the leading edge of implant time.

#### **CareLink Network Analysis**

Our CareLink data analysis was designed to overcome the limitations of RPA (under-reporting) and SLS (relatively small sample size). Using a proprietary algorithm, we analyzed data from over 25,000 devices enrolled on the CareLink Network remote monitoring system to determine lead integrity. The triggered files were reviewed by technical experts and compared with Medtronic Device Registration Services and RPA databases to confirm lead integrity. In the event we could not confirm the lead status, we contacted the physicians directly to verify the status of the lead. The addition of this data gives us increased confidence in our analysis of Fidelis' performance (see Appendix B).

In addition to confirming lead fractures, our analysis of the CareLink Network also identified other causes for abnormal parameters, including findings related to the set screws in up to 20% of the confirmed lead integrity issues.

**Medtronic is committed to ensuring the highest standards of product reliability. We will continue to provide performance updates every six months via our Product Performance Report.**

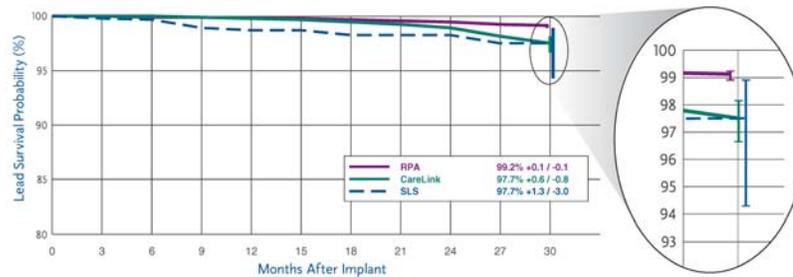
## APPENDIX B

### Performance Update for Sprint Fidelis® Leads (Models 6930, 6931, 6948, 6949) October 2007

This attachment accompanies Medtronic's physician letter dated October 15, 2007 and provides performance information on Sprint Fidelis leads. Below are the current performance data for Sprint Fidelis Model 6949 using Returned Product Analysis (RPA), System Longevity Study (SLS), and data from the Medtronic CareLink® Network. Refer to Appendix A for descriptions of the datasets.

**FIGURE 1**

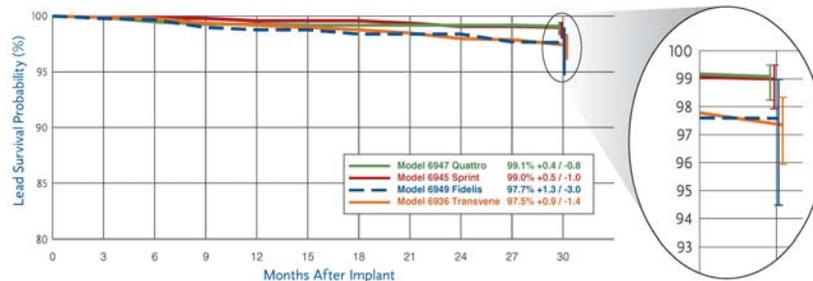
Survival probability of Fidelis Model 6949 at 30 months was estimated using the RPA, SLS, and CareLink Network datasets. Survival at 30 months per RPA, SLS, CareLink Network datasets is 99.2%, 97.7% and 97.7%, respectively. Ranges shown in the graph designate 95% confidence interval. CareLink Network data offers a relatively large sample size at the leading edge. 95% Confidence range for SLS data is relatively large due to limited sample size at the leading edge (see table). CareLink dataset analysis overcomes this limitation.



Data Source	Effective Sample Size										
	0 mo	3 mo	6 mo	9 mo	12 mo	15 mo	18 mo	21 mo	24 mo	27 mo	30 mo
RPA	173,867	165,617	148,558	131,384	114,299	97,666	81,297	65,045	49,392	34,324	21,122
Carelink	24,043	23,834	23,035	21,257	18,525	15,245	11,894	8,529	5,264	2,573	757
SLS	654	631	568	483	390	315	262	216	173	130	84

**FIGURE 2**

Performance of Sprint Fidelis Model 6949 lead compared to other Medtronic ICD leads (Sprint Quattro Model 6947, Sprint™ Model 6945, and Transvene™ Model 6936). Cumulative survival based on Medtronic's SLS.



Model	Effective Sample Size										
	0 mo	3 mo	6 mo	9 mo	12 mo	15 mo	18 mo	21 mo	24 mo	27 mo	30 mo
6947 Quattro	1,354	1,310	1,231	1,170	1,114	1,059	1,016	978	942	906	863
6945 Sprint	1,158	1,104	1,028	990	953	912	868	823	782	745	712
6949 Fidelis	654	630	567	482	389	314	262	216	172	129	84
6936 Transvene	1,349	919	865	830	797	764	723	684	654	623	594

We continue to analyze data in various subsets in order to determine possible factors influencing performance. The Sprint Fidelis Model 6949 survival rate at 30 months for different patient age groups is as follows. In patients 58 years of age and older, Sprint Fidelis 30-month survival rate is statistically better than in patients under 58 [98.4% versus 97.5%, respectively, with a 90% confidence interval], as determined by RPA and CareLink™ Network datasets. In patients under the age of 21, the Sprint Fidelis 30-month survival rate is statistically lower than Sprint Quattro® [96.2% versus 99.4%, respectively, with a 95% confidence interval] based on RPA; however, because of sample size limitations we cannot confirm this difference with the SLS or CareLink Network dataset.

If you have questions or concerns, please contact your Medtronic Representative

## APPENDIX C

### Patient Management Recommendations for Sprint Fidelis® Leads

October 2007

This attachment accompanies Medtronic's physician letter dated October 15, 2007 and provides greater detail on our recommendations for the ongoing management of patients with Sprint Fidelis leads.

#### Follow-Up of Chronically Implanted Leads

Based on our review of the available data, there does not appear to be a significant benefit to more frequent follow-up.

The effectiveness of routine monitoring or lead impedance alerts for identifying a lead integrity problem before an inappropriate shock occurs may be enhanced when VF initial Number of Intervals to Detect (NID) are set to nominal values of 18/24 or longer (since longer NIDs reduce the risk of inappropriate detection of short bursts of oversensing). Redetect NID should be set to 12/16.

In the event of a suspected lead fracture, a complete clinical evaluation should be performed. In addition, we recommend the following:

1. Review of device diagnostic data including VT/VF episode log and stored episodes to look for evidence of aborted, non-sustained events. Review the EGMs from treated events for evidence of lead noise oversensing.
2. When at least two (2) of the following three (3) criteria indicate abnormal values, the likelihood of a lead integrity issue is higher.<sup>1</sup>
  - Lead Status Report: Sensing Integrity Counter (measure of general oversensing near ICD blanking)  
Abnormal values: > 300 counts (this will generate an observation on the Quick Look™ screen on GEM® III or later models) OR  
> 30 counts and average > 10 counts/day since first count
  - Non-Sustained Episode Report  
Abnormal values: ≥ 2 Non-Sustained Tachyarrhythmia (NST) with average RR interval < 200 ms
  - Lead Impedance Report
    - Inspect the lead impedance trend report to determine the patient's typical chronic impedance value.
    - Compare average daily/weekly impedance to the patient's typical chronic impedance value. If one or more impedance values are greater than 2x the baseline, then the lead impedance should be considered abnormal.

#### Viewing the Sensing Integrity Counter Data

##### On the Model 2090 Programmer:

1. Interrogate the device
2. Select Data -Device/Lead Diagnostics
3. Select Battery and Lead Measurements
4. Select [Open Data]
5. Select Print to print the screen information

Note: If the Sensing Integrity Counter > 300, the programmer displays a Quick Look observation.

Battery and Lead Measurements Report	
Device: D1AT930	Serial Number: DAT012SIMR
Patient:	ID: _____
	Date of Visit: 04-Apr-2003 08:00:02
	Physician: * * *
Last Interrogation: 04-Apr-2003 08:00:02	
<b>Battery Voltage</b> (ERI=2.61 V)	<b>Lead Impedance</b>
09-Jan-1997 03:07:42 Voltage 3.38 V	05-Jan-1997 08:34:50 A. Pacing 257 ohms RV Pacing 256 ohms RV Defib 128 ohms SVC Defib 129 ohms
<b>Last Capacitor Formation</b>	<b>Sensing</b>
08-Jan-1997 20:23:33 Charge Time 13.0 sec Energy 1.9 - 30 J	01-Jan-1994 00:00:01 P-Wave Amplitude 5.3 mV R-Wave Amplitude 9.4 mV
<b>Last Charge</b>	<b>Last High Voltage Therapy</b>
09-Jan-1997 09:40:16 Charge Time 9.4 sec Energy 0.0 - 20 J	10-Jan-1997 02:09:54 Measured Impedance <20 ohms Delivered Energy 28 J Waveform Biphasic Pathway AX>B
<b>Sensing Integrity Counter</b> (if >300 counts, check for sensing issues) Since 13-Jan-1994 22:41:21 Short V-V Intervals 17	
<b>Atrial Lead Position Check</b> No measurement since reset.	

**APPENDIX C (continued)**  
**Patient Management Recommendations for Sprint Fidelis® Leads**  
 October 2007

**Setup of Performance Parameters to Follow Chronically Implanted Leads**

Properly setting the thresholds for Lead Impedance alerts is critical to triggering the Patient Alert™. If the Patient Alert feature is enabled and the impedance is out of range, a device tone alert will sound. During the early stages of a conductor fracture, the impedance may significantly increase (e.g., two-fold increase) compared to the typical chronic impedance for a patient.

Medtronic recommends enabling the following Lead Impedance Out of Range Patient Alerts and establishing the associated maximum impedance threshold value as shown in the following table:

Lead Impedance Alert	Recommended Maximum Impedance Threshold Value
RV Pacing	1,000 ohms, if the typical chronic impedance for the patient is ≤ 700 ohms 1,500 ohms, if the typical chronic impedance for the patient is > 700 ohms
RV Defibrillation	100 ohms
SVC Defibrillation	100 ohms

**Reducing the Risk of Inappropriate Shocks Due to Lead Noise Oversensing**

To reduce the risk of inappropriate shocks due to lead noise oversensing, Medtronic recommends programming parameters for VF detection duration to the nominal values as follows:

- VF initial NID (number of intervals to detect) = 18/24 or longer
- Redetect NID = 12/16

Clinicians should consider programming VF initial NID to 24/32 in Marquis® and later devices (i.e., Marquis, Maximo®, Intrinsic®, InSync Marquis™ family, EnTrust®, Virtuoso®, Concerto®) to further reduce the risk of inappropriate shocks due to lead noise oversensing. Programming VF initial NID to 24/32 in Marquis and later devices is estimated to have minimal impact on the total time to VF shock (compared to GEM III and earlier devices with NID = 18/24), thus minimizing the risk of delayed therapy or syncope.

Estimated Values	GEM III and Earlier Initial NID = 18/24	Marquis and Later Initial NID = 18/24	Marquis and Later Initial NID = 24/32
Detection Time	5.4 seconds	5.4 seconds	7.2 seconds
Charge Time	7-14 seconds	7-9 seconds	7-9 seconds
Total Time to VF shock	12.4-19.4 seconds	12.4-14.4 seconds	14.2-16.2 seconds
Lead Noise Shock Reduction (compared to initial NID = 12/16)	Estimate a 15-29% reduction in inappropriate shocks	Estimate a 15-29% reduction in inappropriate shocks	Estimate a 27-67% reduction in inappropriate shocks

A retrospective review of Fidelis lead fracture data indicated:

- That reducing the HV impedance alert from 200 ohms to 100 ohms would have provided an additional week's notice for 26% of high voltage conductor fractures. There are no data to suggest that increasing the follow-up frequency for patients will provide additional benefit.
- With RV Pacing Impedance Alert set to 1,000 ohms, 47% of patients would have four or more days notice, an additional 2% would have two days notice, and an additional 2% would have one day notice.
- Manual review of other lead fracture prediction criteria (short interval counts, non-sustained VT, impedance trends, etc.), would identify an estimated 36% of patients if performed monthly, or 49% if performed weekly.

<sup>1</sup> Gunderson BD, Patel AS, Bounds CA, et al. An algorithm to predict implantable cardioverter-defibrillator lead failure. *J Am Coll Cardiol.* November 2, 2004;44(9):1898-1902.

## APPENDIX D Lead Extraction Risks October 2007

This attachment accompanies Medtronic's physician letter dated October 15, 2007 and provides information concerning risks inherent in lead extractions.

**Medtronic's Independent Physician Quality Panel believes it is inappropriate to prophylactically remove Sprint Fidelis® leads except in unusual individual patient circumstances. We support this position.**

Extraction of chronic leads entails substantial risks of patient morbidity and mortality. Reported complications<sup>1</sup> include: lead breakage and migration; avulsion of veins, myocardium or the tricuspid valve; tears of the myocardium or veins; hemothorax, tamponade, perforation, emergency cardiothoracic surgery, pulmonary emboli, and death.

In evaluating whether to extract any cardiac lead, physicians must weigh the risks and benefits of leaving the lead in place in comparison to those of removal. Major complications from lead extraction, defined as death or the requirement of a significant surgical intervention, have been reported in multiple series to be in the range of 1.4-7.3% of patients.<sup>2,3</sup> Factors reported to increase the risk of major complications include: duration of implant, female gender, and large removal sheaths.<sup>4,5</sup>

Medtronic Sprint Fidelis performance data indicate all-cause lead survival of 97.7% at 30 months (SLS, Medtronic CareLink® Network analysis). High voltage conductor fractures could result in the inability to deliver defibrillation therapy. Anode or cathode conductor fractures at either of the primary fracture locations may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output. Utilization of the patient management recommendations will increase the likelihood that a fracture will be detected by Patient Alert™ (see Appendix C) and decrease the likelihood of inappropriate therapies. Based on current information, we have identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor. (0.0018% of approximately 268,000 implants worldwide). By comparison, the risk of major complications (cardiac surgery or death) with lead extraction is 1.4-7.3%.

It has been reported that limited physician experience (< 50 procedures) may significantly increase the risk of complications from extraction.<sup>6</sup> For this reason, **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.**

These recommendations are consistent with the HRS Policy Statement on recommendations for extraction of chronically implanted leads.<sup>7</sup>

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<sup>1</sup> Byrd CL, Wilkoff BL, in *Clinical Cardiac Pacing and Defibrillation*, Ellenbogen, Kay and Wilkoff editors. WB Saunders 2000, Techniques and Devices for Extraction of Pacemaker and Implantable Cardioverter Defibrillator Leads: 695-709.

<sup>2</sup> Byrd et al, Intravascular extraction of problematic or infected permanent pacemaker leads: 1994-1996. U.S. Extraction Database, MED Institute. *PACE*. 1999;22(9):1349-1357.

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

<sup>4</sup> Byrd et al. *PACE*. 1999;22(9):1349-1357.

<sup>5</sup> Kennergren et al, Laser-assisted lead extraction: the European experience. *Europace*. August 2007; 9(8):651-656.

<sup>6</sup> Byrd et al. *PACE*. 1999;22(9):1349-1357.

<sup>7</sup> NASPE Policy Statement: Recommendations for Extraction of Chronically Implanted Transvenous Pacing and Defibrillator Leads: Indications, Facilities, Training. Love CJ, Wilkoff BL, et al. *PACE*. 2000; 23, 544-551.