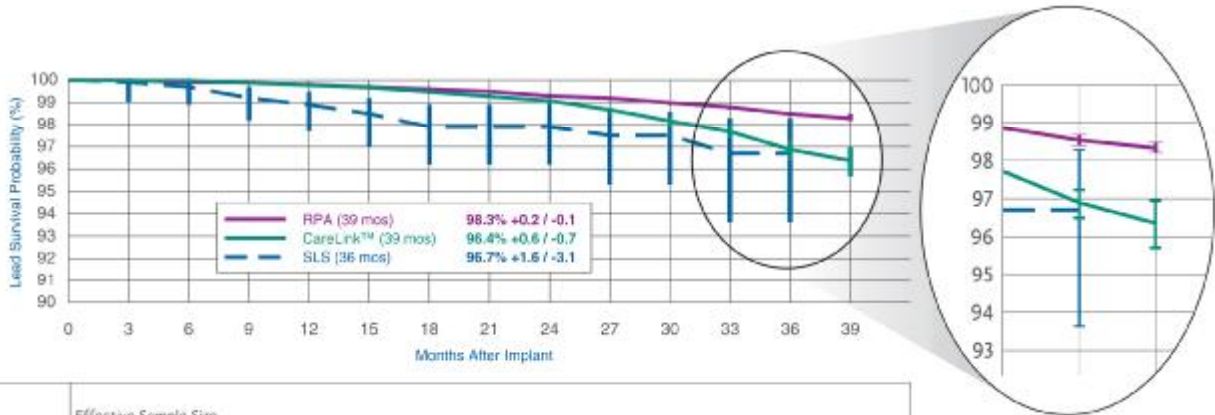


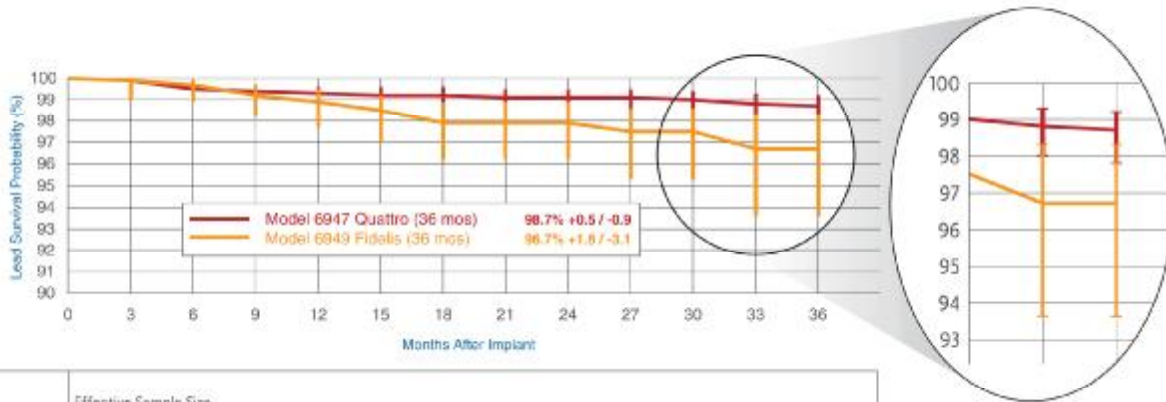
**APPENDIX I**  
**Performance Update for Sprint Fidelis® Leads (Models 6949, 6948, 6931, 6930)<sup>5</sup>**

**Sprint Fidelis Lead Survival Probability (RPA, SLS,<sup>6</sup> and CareLink Network)**



Model 6949	Effective Sample Size													
	0 mo	0-3 mo	3-6 mo	6-9 mo	9-12 mo	12-15 mo	15-18 mo	18-21 mo	21-24 mo	24-27 mo	27-30 mo	30-33 mo	33-36 mo	36-39 mo
RPA	185,526	182,172	174,280	162,545	146,952	130,313	113,684	97,181	81,004	65,116	49,673	34,989	21,980	11,256
CareLink™	21,500	21,442	21,248	20,878	20,307	19,287	17,721	15,656	13,209	10,148	6,798	4,132	2,254	951
SLS	735	724	693	636	552	463	375	304	252	206	164	123	80	41

**Sprint Fidelis Lead versus Quattro® Lead SLS Survival Probability**



Model	Effective Sample Size												
	0 mo	0-3 mo	3-6 mo	6-9 mo	9-12 mo	12-15 mo	15-18 mo	18-21 mo	21-24 mo	24-27 mo	27-30 mo	30-33 mo	33-36 mo
Model 6947 Quattro	1,367	1,320	1,237	1,177	1,126	1,076	1,024	972	927	889	854	817	773
Model 6949 Fidelis	735	724	693	636	552	463	375	304	252	206	164	123	80

<sup>5</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>6</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.

## APPENDIX II

### The following are the Patient Management Recommendations issued as part of an October 15 communication Patient Management Recommendations for Sprint Fidelis® Leads October 2007

This attachment accompanies Medtronic's physician letter dated May 7, 2008, 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	
Model: 2090	Serial Number: 1012128101
Date: 04/29/2008 05:50:02	Time: 10:12:12 AM
<b>Battery Voltage</b> Voltage: 10.17 V Last Charge: 10.17 V Charge Time: 18.0 sec Last Charge: 10.17 V Charge Time: 9.4 sec	<b>Lead Impedance</b> Right: 257 Ohm Left: 259 Ohm SV: 1.0 Ohm SV: 1.0 Ohm <b>Swing</b> Right: 994.70 Ohm Left: 994.70 Ohm <b>Lead High Voltage</b> Right: 997.70 Ohm Left: 997.70 Ohm
<b>Sensing Integrity Counter</b> Total Counts: 1064 Since Last Charge: 1064 Avg. Count/Day: 1064	Max. Impedance: 259 Ohm Deferral Energy: 25 J Max. Power: 1.0 W Max. Temp: 38.0 C

**APPENDIX II (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 Medtronic CareAlert Notifications 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 III

## An Illustration of Impact of Current Patient Management Recommendations for a Hypothetical Clinic of 1,000 Sprint Fidelis Lead Patients over the Next 12 Months

<b>1,000</b>	×	<b>0.01<sup>b</sup></b>	×	<b>0.9</b>	×	<b>0.51</b>	=	<b>4.6<sup>c</sup></b>
<p><b>1,000 patient sample</b></p> <p>Hypothetical sample of 1,000 patients with the same age distribution and implant length distribution as the overall Sprint Fidelis lead population.<sup>a</sup></p>		<p><b>Fracture rate over the next 12 months</b></p> <p>1.0% is the fracture rate expected over the next 12 months. This is calculated by projecting the risk of fracture on the lead survival curve for this population.</p>		<p><b>Anode and cathode conductor fractures</b></p> <p>Approximately 90% of the fractures observed are in the anode and cathode conductors (pace/sense circuit).</p>		<p><b>Fractures with short notice or no notice</b></p> <p>The patient recommendations will provide 2 or more days of advance notice to 49% of patients. The remaining 51% of patients will receive less than 2 days of advance notice or no advance notice.</p>		<p><b>Number of patients</b></p> <p>Over the next 12 months using the hypothetical sample of 1,000 patients, 9 will have an anode or cathode fracture. Of those, 4.6 patients will have less than 2 days of advance notice or no advance notice. This is 0.46% of the sample. 4.4 patients will have 2 or more days of advance notice. This is 0.44% of the sample.</p>

a: The median patient age is 67 (age at time of lead implant) and the median implant time is 20.5 months.

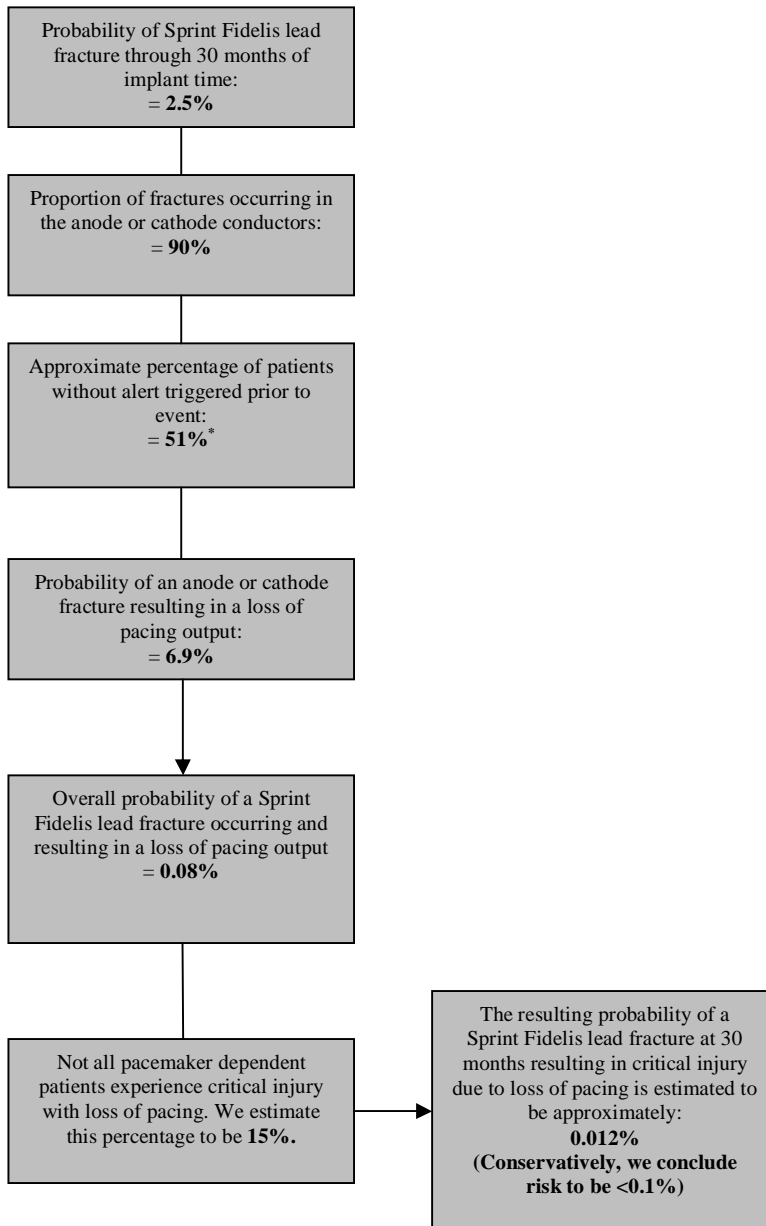
b: This represents an estimate of the average rate of fracture over the next 12 months based on currently available data.

c: Medtronic recognizes that not all patients will hear the alert when it is triggered. The new software described in this performance update is intended to enhance the patient alert and increase the likelihood that fractures will be detected prior to inappropriate therapy.

## Appendix IV

### Probability that a Sprint Fidelis Lead Fracture may Result in Critical Injury from Loss of Pacing

This appendix calculates the critical injury risk for a pacemaker dependent patient programmed according to Medtronic's recommendations who experiences a Sprint Fidelis 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.



\*This percentage may vary by implanted device.