APPENDIX I
Performance Update for Sprint Fidelis® Leads (Models 6949, 6948, 6931, 6930)¹

Sprint Fidelis Lead Survival Probability (RPA, SLS, ⁶ and CareLink Network)

<table>
<thead>
<tr>
<th>Model 6949</th>
<th>Effective Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0-3 mo</td>
</tr>
<tr>
<td>RPA</td>
<td>183,326</td>
</tr>
<tr>
<td>CareLink™</td>
<td>21,500</td>
</tr>
<tr>
<td>SLS</td>
<td>715</td>
</tr>
</tbody>
</table>

Sprint Fidelis Lead versus Quattro® Lead SLS Survival Probability

<table>
<thead>
<tr>
<th>Model</th>
<th>Effective Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0-3 mo</td>
</tr>
<tr>
<td>Model 6947 Quattro</td>
<td>1,567</td>
</tr>
<tr>
<td>Model 6949 Fidelis</td>
<td>735</td>
</tr>
</tbody>
</table>

¹ 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.

⁶ 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.
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. The use of Medtronic CareLink® to facilitate remote access to the device information is suggested.

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.¹
   - 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.

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### 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.

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### Battery and Lead Measurements Report

<table>
<thead>
<tr>
<th>Device: D1ATBE20</th>
<th>Date of Val: 04-Apr-2009 09:04:02</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID: 00</td>
<td>Physician: 00</td>
</tr>
<tr>
<td>Last interrogation: 04-Apr-2009 08:00:02</td>
<td></td>
</tr>
</tbody>
</table>

**Battery Voltage**

- 3.28 V

**Last Capacitor Formation**

- 01-Jan-1997 00:00:00
- Energy: 1.9 - 20 J

**Last Charge**

- 06-Jan-1997 09:40:15
- Charge Time: 5.6 sec
- Charge: 108 J

**Leadbattery Impedance**

- 05-Jan-1997 03:34:10
- Pacing: 257 ohms
- RV Def: 129 ohms
- SVC Def: 129 ohms

**Lead Impedance**

- 05-Jan-1997 03:34:10
- RV: 257 ohms
- RV Def: 129 ohms
- SVC Def: 129 ohms

**Screening**

- 05-Jan-1997 03:34:10
- P Wave Amplitude: 5.3 mV
- R Wave Amplitude: 9.4 mV

**Lead High Voltage Therapy**

- 19-Jan-1997 02:36:14
- Measured Impedance: <20 ohms
- Collected Energy: 28 J
- Waveform: Device
- Patency: XX/XX
**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. For Concerto®/Virtuoso® patients enrolled on the Medtronic CareLink® Network, a Medtronic CareAlert® Notification will also be transmitted if Medtronic CareAlert Notification for lead impedance is programmed ON. 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:

<table>
<thead>
<tr>
<th>Lead Impedance Alert</th>
<th>Recommended Maximum Impedance Threshold Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RV Pacing</td>
<td>1,000 ohms, if the typical chronic impedance for the patient is ≤ 700 ohms</td>
</tr>
<tr>
<td></td>
<td>1,500 ohms, if the typical chronic impedance for the patient is &gt; 700 ohms</td>
</tr>
<tr>
<td>RV Defibrillation</td>
<td>100 ohms</td>
</tr>
<tr>
<td>SVC Defibrillation</td>
<td>100 ohms</td>
</tr>
</tbody>
</table>

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®, 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.

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

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.

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

<table>
<thead>
<tr>
<th>1,000</th>
<th>×</th>
<th>0.01 b</th>
<th>×</th>
<th>0.9</th>
<th>×</th>
<th>0.51</th>
<th>=</th>
<th>4.6 c</th>
</tr>
</thead>
</table>

1,000 patient sample
Hypothetical sample of 1,000 patients with the same age distribution and implant length distribution as the overall Sprint Fidelis lead population.a

Fracture rate over the next 12 months
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.

Anode and cathode conductor fractures
Approximately 90% of the fractures observed are in the anode and cathode conductors (pace/sense circuit).

Fractures with short notice or no notice
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.

Number of patients
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.

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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.

Probability of Sprint Fidelis lead fracture through 30 months of implant time: = 2.5%

Proportion of fractures occurring in the anode or cathode conductors: = 90%

Approximate percentage of patients without alert triggered prior to event: = 51%

Probability of an anode or cathode fracture resulting in a loss of pacing output: = 6.9%

Overall probability of a Sprint Fidelis lead fracture occurring and resulting in a loss of pacing output = 0.08%

Not all pacemaker dependent patients experience critical injury with loss of pacing. We estimate this percentage to be 15%.

The resulting probability of a Sprint Fidelis lead fracture at 30 months resulting in critical injury due to loss of pacing is estimated to be approximately: 0.012%
(Conservatively, we conclude risk to be <0.1%)

*This percentage may vary by implanted device.