Important Patient Information

Sprint Fidelis® Lead Performance

May 9, 2008

Re: Sprint Fidelis® Lead Performance Update (Models 6949, 6948, 6931, 6930)

Open Letter to Sprint Fidelis Lead Patients:

We recently provided doctors with an update to our October 2007 communication about Sprint Fidelis leads. We told them the chance there will be a problem with your Sprint Fidelis lead remains small, and our recommendations to your doctor remain unchanged.

As a reminder, a defibrillation system consists of a device implanted near the shoulder and one or more defibrillation leads connecting the device to the heart. The information we provided to your doctor applies to your Sprint Fidelis lead only, not your implanted heart device.

The information we provided your doctor is more detailed, since he or she is in the best position to know how to manage your care in light of your specific health considerations. If you have questions about your Sprint Fidelis lead, please contact your doctor's office.

If you have additional questions, please contact Medtronic Patient Services at 1(800) 551-5544.

Sincerely,

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

Contact Us

Medtronic
Patient Services
1(800) 551-5544 x41835

Last updated: 3 Aug 2008

Sprint Fidelis® 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® Network, and Returned Product Analysis (RPA). Table 1 below shows lead survival data for Model 6949 from the SLS, the Medtronic CareLink® Network, and RPA at 30 months from implant.

Table 1: Sprint Fidelis Lead Performance at 30 Months (Model 6949 lead survival data)1

Data Source	Data as of October 15, 2007 30 Months	Data as of May 7, 2008 30 Months
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)

Data Source	33 Months	36 Months	39 Months
SLS	96.7% [+1.6/-3.1]	96.7% [+1.6/-3.1]	n/a[2]
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.

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.

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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%3 and 7.3%4; 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™ and Medtronic CareAlert® 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, 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).

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

References

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.
2. 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.
3. 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.
4. Bracke et al, Lead extraction for device related infections: a single-centre experience. Europace. May 2004; 6(3):243-247.

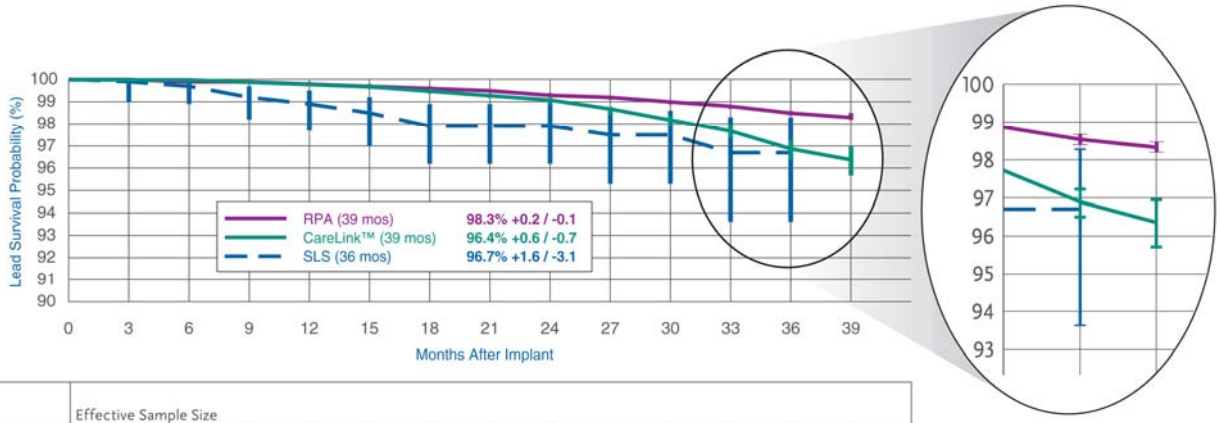
Contact Us

Medtronic
Technical Services
1(800) 723-4636 (US)

Last updated: 3 Aug 2008

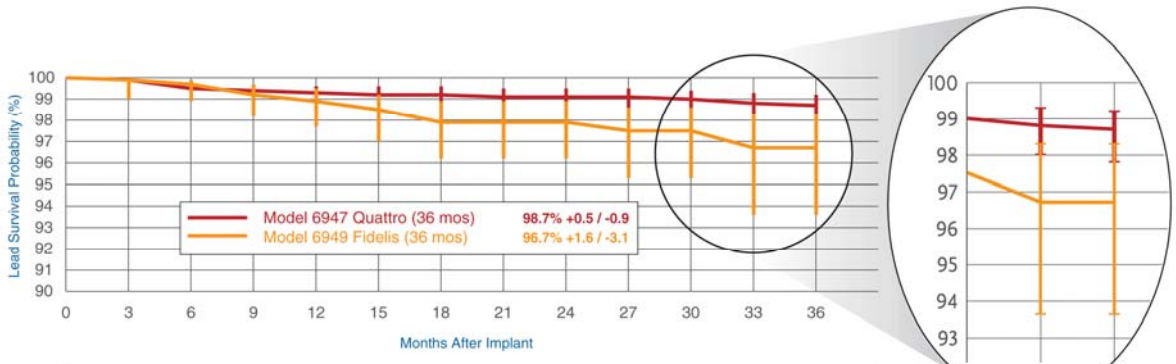
APPENDIX I
Performance Update for Sprint Fidelis® Leads (Models 6949, 6948, 6931, 6930)[5]

Sprint Fidelis Lead Survival Probability (RPA, SLS,[6] 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

[5] 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.

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. 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:

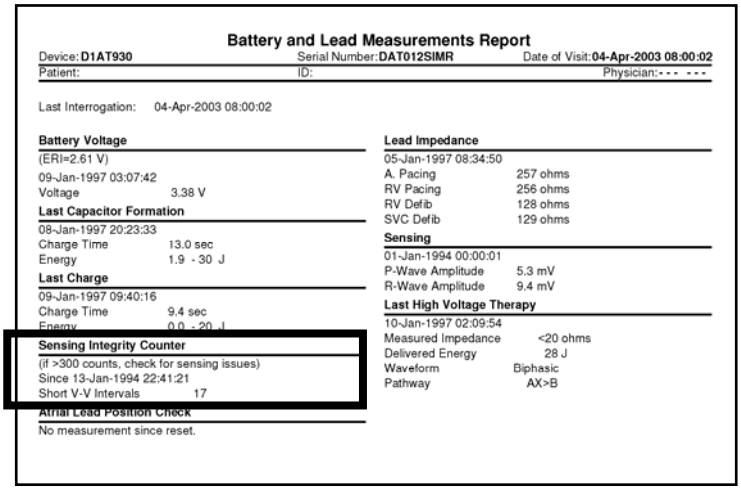
1. Review of device diagnostic data including VT/VF episode log and stored episodes to look for evidence of aborted, non-sustained events. Review the EGMs from treated events for evidence of lead noise oversensing.
2. When at least two (2) of the following three (3) criteria indicate abnormal values, 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.

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 Date of Visit: 04-Apr-2003 08:00:02
Patient: ID: Physician: --- ---

Last Interrogation: 04-Apr-2003 08:00:02

Battery Voltage
(ERI=2.61 V)
09-Jan-1997 03:07:42
Voltage 3.38 V

Last Capacitor Formation
08-Jan-1997 20:23:33
Charge Time 13.0 sec
Energy 1.9 - 30 J

Last Charge
09-Jan-1997 09:40:16
Charge Time 9.4 sec
Energy 0.0 - 20 J

Sensing Integrity Counter
(if >300 counts, check for sensing issues)
Since 13-Jan-1994 22:41:21
Short V-V Intervals 17

Atrial Lead Position Check
No measurement since reset.

Lead Impedance
05-Jan-1997 08:34:50
A. Pacing 257 ohms
RV Pacing 256 ohms
RV Defib 128 ohms
SVC Defib 129 ohms

Sensing
01-Jan-1994 00:00:01
P-Wave Amplitude 5.3 mV
R-Wave Amplitude 9.4 mV

Last High Voltage Therapy
10-Jan-1997 02:09:54
Measured Impedance <20 ohms
Delivered Energy 28 J
Waveform Biphasic
Pathway AX>B

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:

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.

[1] 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

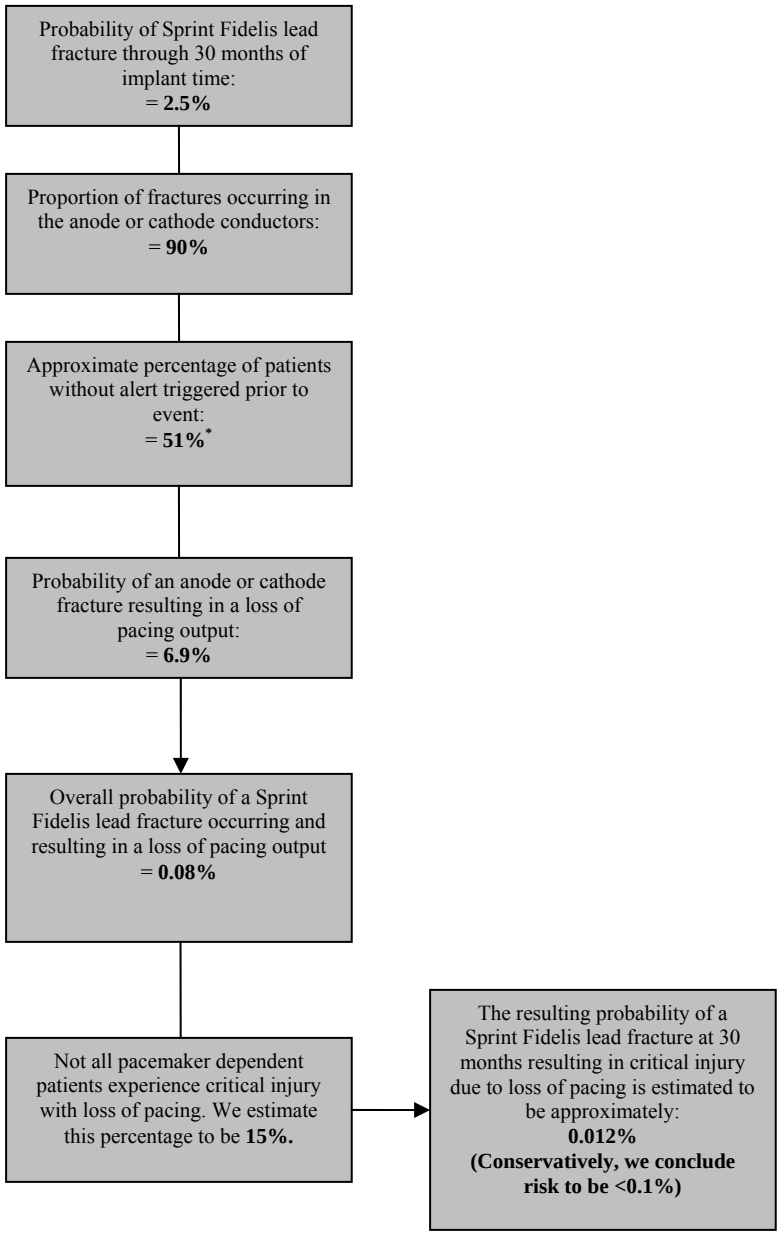
1,000	X	0.01[b]	X	0.9	X	0.51	=	4.6[c]
1,000 patient sample Hypothetical sample of 1,000 patients with the same age distribution and implant length distribution as the overall Sprint Fidelis lead population.[a]		**Fracture rate over the next 12 months** 1.0% is the fracture rate expected over the next 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.

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.

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Minneapolis, MN 55112
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Medtronic Cardiac Rhythm Disease Management
Medtronic, Inc.

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