Sprint Fidelis® Lead Patient Management Recommendations Update
Models 6949, 6948, 6931, 6930

April, 2011

Dear Doctor,

Medtronic is committed to keeping you informed about Sprint Fidelis lead performance and our ongoing vigilance efforts. We are providing a summary of the most recent performance data from our CareLink database along with updated patient management recommendations, developed with the Independent Physician Quality Panel's guidance.

If a Fidelis pace-sense conductor fracture has occurred, we recommend implanting a new high voltage lead, with or without extraction of the Fidelis lead. It is no longer a recommended option to implant a pace-sense lead while maintaining use of the Fidelis high voltage conductors after a Fidelis pace-sense conductor fracture has occurred.

High Voltage Conductor Performance after a Pace-Sense Conductor Fracture

Table 1 shows the performance of the high voltage conductors of the Sprint Fidelis Model 6949 lead following a pace-sense conductor fracture. The analysis, while limited by a small sample size, indicates there is an increased risk for a high voltage conductor fracture if a pace-sense conductor fracture has previously occurred.

Table 1: Model 6949 High Voltage Conductor Survival after a Pace-Sense Conductor Fracture

Months after a Pace-Sense Conductor Fracture	0	6	12	18	21
N (leads)	182	120	88	63	54
High Voltage Conductor Survival	100%	98.7%	89.0%	80.3%	77.7%

Additional Sprint Fidelis Analyses

Patient Age: An analysis was performed by patient age, showing higher lead survival with increased patient age. This analysis was done by decade and a graph of this Model 6949 data is provided in Appendix A. Similar trends were observed for Lead Models 6931 and 6948. For patients under the age of 40, lead performance is 88.8% [+2.2/-2.7] for Model 6949, 79.5% [+3.3/-3.9] for Model 6931, and 93.6% [+3.3/-6.7] for Model 6948 at 4 years.

Patient Gender: Lead Model 6949 survival is statistically higher in male patients than female patients (p-value < 0.001), with lead survival of 91.9% [+0.5/-0.5] for men and 89.0% [+0.9/-1.0] for women at 5 years.

Device Type: No statistical difference in Lead Model 6949 performance was noted between patients with single-chamber ICDs, dual-chamber ICDs, or cardiac resynchronization therapy (CRT-D) devices.

Device Change-Out: Lead Model 6949 performance after device change-out is similar to lead performance without device change-out. Nonetheless, the Sprint Fidelis lead should be handled carefully to ensure the connector legs are not bent or stretched during a device change-out procedure.

Updated Patient Management Recommendations

The Lead Integrity Alert (LIA) provides three days advance notice prior to inappropriate therapy to 76% of patients with lead fractures[1]. As a result, we strongly recommend that all Sprint Fidelis patients who have the ability to upgrade to Lead Integrity Alert do so promptly. Also ensure that high voltage lead impedance alerts (maximum of 100 ohms) are programmed. When a lead fracture is suspected or confirmed, immediate patient attention is strongly recommended. Physicians should inform their patients to seek medical attention without delay if they experience unexpected shocks.

- **If a Fidelis lead fracture of any type has occurred, we recommend implanting a new high voltage lead with or without extraction of the Fidelis lead.**
- In patients with normal device function and no manifestation of lead fracture, no action is recommended. The risk of prophylactic intervention appears to be greater than serious injury resulting from lead fracture even for pacemaker dependent patients, except in select individual patient circumstances as determined by the physician.
- In the event of a device change-out or upgrade procedure, with no manifestation of lead fracture, consider the patient age and lead model data above, as well as patient life expectancy, co-morbidities, ease of extraction related to implant time, patient preference, etc., for the following options:
    - Leave a properly performing lead intact.
    - Implant a new ICD lead without extraction of the existing lead.
    - Carefully consider all factors before prophylactic placement of a pace-sense lead given the data in Table 1, which shows an increased risk of high voltage conductor fracture if a pace-sense conductor fracture has previously occurred.
    - Individual patient circumstances may warrant extracting and implanting a new ICD lead. If warranted, Medtronic's Independent Physician Quality Panel recommends the lead extraction procedure be performed by a physician with extensive lead extraction experience.[2]

Keeping Physicians Informed

The most recent Sprint Fidelis lead performance curves are available in Appendix A. Sprint Fidelis lead performance data can also be found at www.medtronic.com/fidelis and will be updated semi-annually. Medtronic's website also has a selected list of peer-reviewed publications related to Fidelis lead performance and extraction. Medtronic is committed to answering your questions and keeping you informed. If you have any questions or concerns, please contact your Medtronic Representative on 01923 212 213.

Yours sincerely

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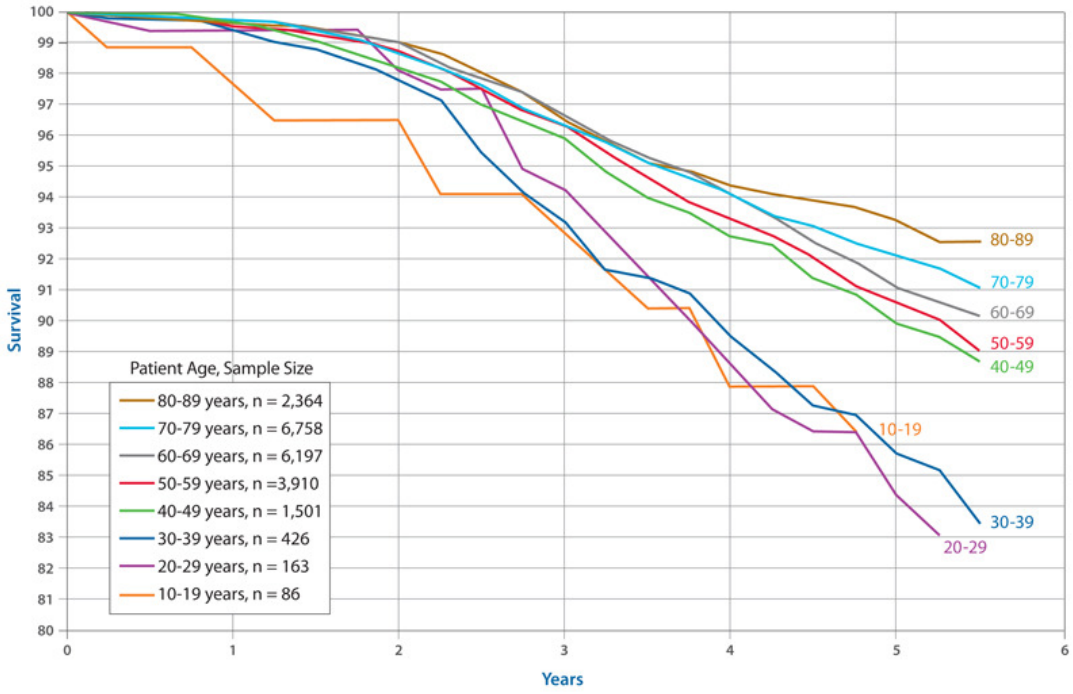
1: Swerdlow C, Gunderson, B, et al. "Downloadable Algorithm to Reduce Inappropriate Shocks Caused by Fractures of Implantable Cardioverter-Defibrillator Leads", Circulation, November 2008, 118: 2122-2129.

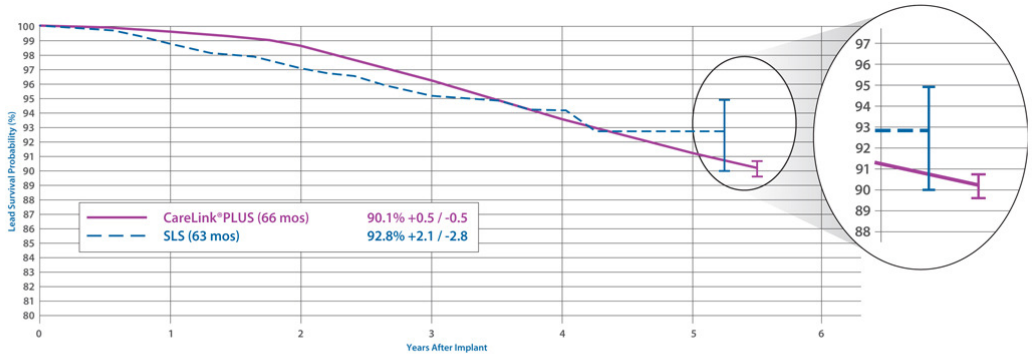
2: "Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management", Heart Rhythm, Vol 6, No 7, July 2009.

Appendix A Sprint Fidelis Performance

Model 6949 Lead Performance by Age **April 2011**

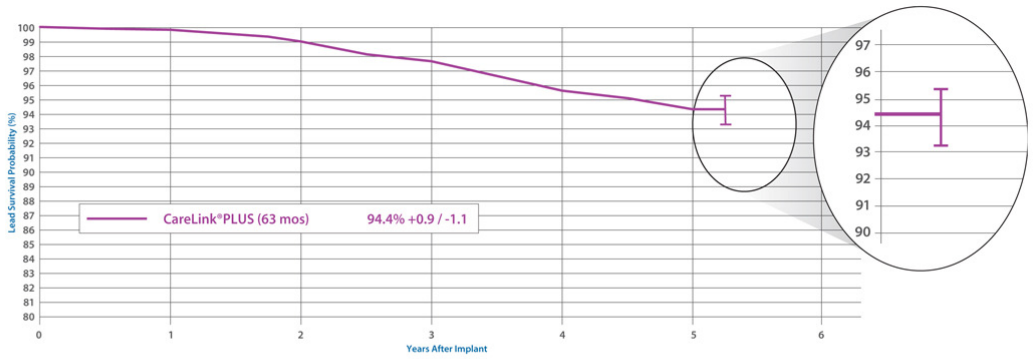


Sprint Fidelis® Model 6949 Lead Performance **November 2010**
Dual Coil, Active fixation



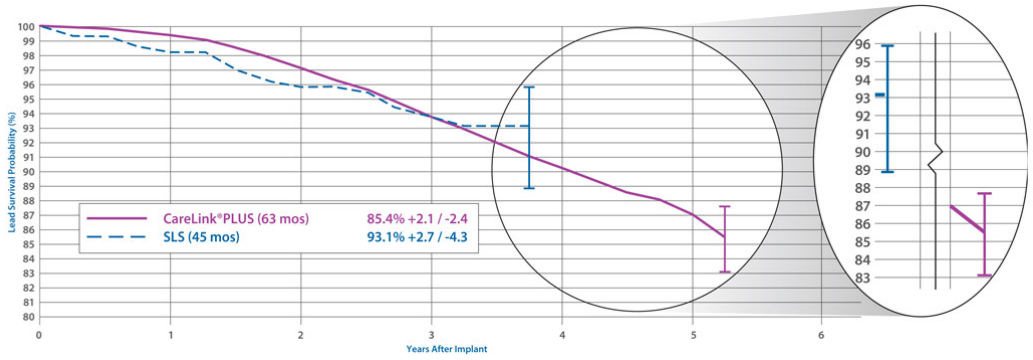
Model 6949	0 yr	1 yr	2 yr	3 yr	4 yr	5 yr	
CareLink PLUS	21,500	21,181 99.6% [+0.1/-0.1]	20,050 98.6% [+0.2/-0.2]	17,812 96.2% [+0.3/-0.3]	15,553 93.6% [+0.3/-0.4]	6,780 91.2% [+0.4/-0.4]	at 66 mos: 1,866 90.1% [+0.5/-0.5]
SLS	797	710 98.8% [+0.6/-1.1]	615 97.1% [+1.0/-1.6]	469 95.2% [+1.4/-1.9]	211 94.2% [+1.6/-2.3]	69 92.8% [+2.1/-2.8]	at 63 mos: 39 92.8% [+2.1/-2.8]

Sprint Fidelis® Model 6948 Lead Performance **November 2010**
Dual Coil, Passive fixation



Model 6948	0 yr	1 yr	2 yr	3 yr	4 yr	5 yr	
CareLink PLUS	4,512	4,371 99.9% [+0.1/-0.1]	4,112 99.1% [+0.2/-0.3]	3,391 97.7% [+0.4/-0.5]	1,678 95.7% [+0.6/-0.7]	238 94.4% [+0.9/-1.1]	at 63 mos: 53 94.4% [+0.9/-1.1]

Sprint Fidelis® Model 6931 Lead Performance **November 2010**
Single Coil, Active fixation



Model 6931	0 yr	1 yr	2 yr	3 yr	4 yr	5 yr	
CareLink PLUS	4,274	4,105 99.4% [+0.2/-0.3]	3,794 97.1% [+0.5/-0.6]	2,906 93.8% [+0.7/-0.8]	1,328 90.3% [+1.0/-1.1]	219 87.0% [+1.5/-1.7]	at 63 mos: 78 85.4% [+2.1/-2.4]
SLS	294	259 98.2% [+1.1/-2.5]	222 95.8% [+1.9/-3.2]	140 93.8% [+2.4/-4.0]	at 45 mos: 42 93.1% [+2.7/-4.3]		