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Sprint Fidelis Leads

Models 6949, 6948, 6931, 6930

Update to Patient Management Recommendations

Clarification regarding the most common questions

November 2007

Introduction

Since the Field Safety Corrective Action letter regarding the Sprint Fidelis lead was distributed on October 15, we have spoken with many physicians and hospital staff members and met with several regulatory authorities. Inevitably, some questions were asked for which the response requires more detailed knowledge of the underlying data than available in the field. The purpose of this communication is to provide clarification regarding the most common questions.

For your convenience we also enclose a one page document summarizing our recommendations of October 15th. We suggest you to place this document in proximity of your Medtronic 2090 programmer.

We will continue to provide performance update every 6 months via our Product Performance Report.

Scheduling the initial patient follow-up

For patients who do not have Patient Alert activated

Based on our review of the available data, there is only a marginal benefit to immediately reprogram patients instead of waiting for their next visit. However, for those patients who do not have Patient Alert activated and who have not been planned for a follow-up visit soon, **you may want to consider scheduling programming earlier, if practicable.**

It is important that patients are instructed to call the clinic immediately upon receiving unexpected shocks or hearing the audible alert. Conductor fractures have commonly been detected by the Patient Alert feature of the ICD or by the patient reporting to hospital with inappropriate shocks. For specific patients who cannot hear the alert, you may instruct a partner or caregiver to listen for the alert at the selected time of day.



Fidelis Lead implanted with non-Medtronic ICD

Best source of advice: the manufacturer of the implanted ICD

Our programming recommendations for Medtronic ICDs have been based on detailed analysis of clinical and technical data regarding the behaviour of our devices with respect to detection and charge times and the effects of delaying a shock. As we do not have such data for non-Medtronic ICDs we cannot provide detailed programming instructions **with sufficient certainty** about their adequacy.

Of course, we can recommend to mimic our suggested recommendations and settings. The best source of advice, however, will be the representative of the manufacturer of the implanted ICD, with whom we will be happy to discuss particular cases of course.

“Individual” patient situations

To be based on clinical judgment

The chance of a problem with a Sprint Fidelis lead **is small**. The risk of serious complications from lead removal are greater than the risk of lead fracture. For this reason, our Independent Physician Quality Panel recommended against prophylactic removal of Fidelis leads **except in unusual individual patient circumstances**. Prophylactic addition of a pace-sense lead or the placement of another ICD lead in parallel to a Fidelis lead also carries many of these same clinical risks (e.g., infection, pneumothorax).

We have received questions about patients that may be at elevated risk in case of a lead fracture, such as pacemaker dependent patients or patients with frequent life threatening arrhythmias. Patient Alert or inappropriate shocks have been providing timely identification of lead fracture in a great majority of these cases. In addition, truly pacemaker dependent patients are **very rare** in the ICD population. However, we recognize that physicians may determine that the benefit of prophylactic replacement outweighs the risk in unusual individual patient circumstances.

We received a number of questions related to the risks in pediatric patients. Lead failures are known to be more common in the young, probably due to the size of the vessels, anatomic challenges and relatively higher levels of physical activity. Lead failure also seems to be more common in younger patients with a Fidelis but the population is too small for definite conclusions.



Other sources of information

The websites of the European Heart Rhythm Association, your country's Heart Rhythm Association, the Heart Rhythm Society and your country's Regulatory Authority may provide independent and professional guidance concerning the Fidelis Field Safety Corrective Action.

If you need any additional information, please contact your local Medtronic sales representative.

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SPRINT FIDELIS® FAMILY

(6949/6948/6931/6930)

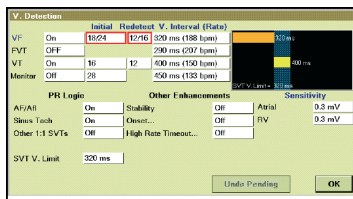
Programming Recommendations

For additional information, see the Field Safety Corrective Action dated October 15, 2007. Medtronic recommends you consider the following as part of initial follow-up for each patient.

Program Number of Intervals to Detect (NID)

VF Initial: 18/24 or 24/32*
VF Redetect: 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. See Appendix C of the October 15, 2007 Patient Management Recommendations for more details.

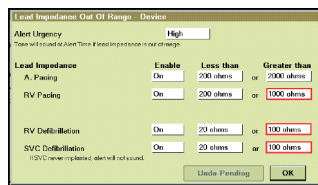


Optimize Effectiveness of Patient Alerts

Turn on Patient Alerts for RV Pacing, RV Defibrillation, and SVC Defibrillation impedance.

RV Pacing:

If patient's typical chronic impedance is:	Set RV pacing lead impedance "greater than" to:
≤ 700 Ω	1000 Ω
> 700 Ω	1500 Ω



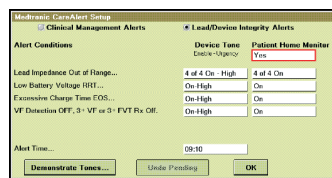
RV Defibrillation: 100 Ω
SVC Defibrillation: 100 Ω

Alerts in the CareLink™ Network

For Concerto® and Virtuoso® devices enrolled on the CareLink Network, turn on the CareLink Alerts for the same parameters as above.

Program Patient Home Monitor to "Yes."

This setting is available in Concerto® and Virtuoso® devices only.



Follow-Up Recommendations

The information below summarizes the recommendations in the October 15, 2007, Sprint Fidelis® Lead Field Safety Corrective Action. In the event of a suspected lead fracture, a complete clinical evaluation should be performed. In addition, we recommend review of device diagnostic data, including the VT/VF episode log and stored episodes to look for evidence of aborted, non-sustained events. Review EGMs for evidence of lead noise oversensing. We recommend that the following be monitored as part of routine follow-up for each patient. If two of the three indicate abnormal values, the likelihood of a lead integrity issue is higher.

1. Sensing Integrity Counter (SIC)

Access the SIC on the battery/lead information screen. A value of > 300, or if there are > 30 counts with an average of > 10 counts per day (counts divided by the number of days between the current date and the "since" date), would indicate an abnormal value.

Sensing Integrity Counter		
(if >300 counts, check for sensing issues)		
Since	23-Aug-2006 14:20:56	
Short V-V Intervals		474

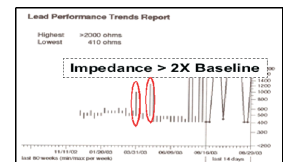
2. Non-Sustained Tachyarrhythmia (NST) Episodes

Access the NST episodes via the Episodes and Counters screen. 2 or more episodes with an average RR interval of < 200 ms would indicate an abnormal value.

SVT/NST Episode List Report						
Episodes Last Cleared: 2 NST < 200 ms						
ID#	Date/Time	A. Cycle	V. Cycle	Duration	Reason	
(No data since last session)						
547	Sep 05 08:59:24	640 ms	230 ms	6 beats	Non-Sustained	
548	Sep 05 08:59:40	670 ms	190 ms	7 beats	Non-Sustained	
549	Sep 05 08:59:37	660 ms	230 ms	6 beats	Non-Sustained	
544	Sep 05 08:54:28	650 ms	200 ms	6 beats	Non-Sustained	
543	Sep 05 08:54:16	650 ms	200 ms	5 beats	Non-Sustained	
542	Sep 05 08:53:07	650 ms	150 ms	9 beats	Non-Sustained	
541	Sep 05 08:46:34	650 ms	250 ms	5 beats	Non-Sustained	

3. Lead Performance/Impedance Trends

Access the Lead Performance Trends Report via the battery/lead information screen. If one or more impedance measurements is greater than two (2) times the baseline value, then lead impedance should be considered abnormal.



Reference

Gunderson BD, Patel AS, Bounds CA, Shepard RK, Wood MA, Ellenbogen KA. An algorithm to predict implantable cardioverter-defibrillator lead failure. *J Am Coll Cardiol.* November 2, 2004;44(9):1898-1902.



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