Medtronic, Inc.
Cardiac Rhythm Disease Management
7000 Central Ave. NE
Minneapolis, MN 55432
www.medtronic.com

Urgent Medical Device Information

Sprint Fidelis® Lead Patient Management Recommendations

October 15, 2007

Dear Doctor,

This letter provides important information on Sprint Fidelis lead performance and recommendations for ongoing patient management. Our records indicate that you have implanted or are following patients with Sprint Fidelis leads (Models 6930, 6931, 6948, 6949). In consultation with our Independent Physician Quality Panel, we are voluntarily suspending distribution of Sprint Fidelis leads worldwide. This decision is based on a variety of factors detailed in this letter that when viewed together, indicate that suspension of implantation is the appropriate action. You should no longer implant Sprint Fidelis leads, and you should return any unused product to Medtronic.

Background

As we reported in March 2007, there are two primary locations[1] where chronic conductor fractures have occurred on Sprint Fidelis leads: 1) the distal portion of the lead, affecting the anode (ring electrode) and 2) near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor. High voltage conductor fractures could result in the inability to deliver defibrillation therapy. Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output. The potential for defibrillation lead fracture to result in or contribute to inappropriate therapies or death has been previously reported.[2] As of October 4, 2007, there have been approximately 268,000 Sprint Fidelis leads implanted worldwide. Based on current information, we have identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor. We have confirmed 665 chronic fractures in returned leads. Approximately 90% of these fractures have occurred in the anode or cathode conductors, while 10% have occurred in the high voltage conductors.

Performance Update

Since our March 21st communication, we have examined six months additional Returned Product Analysis (RPA) and Medtronic System Longevity Study (SLS) data. In addition, we have performed extensive analysis using the Medtronic CareLink® Network (25,000 devices) [see Appendix A]. These data give us confidence in our current understanding of Sprint Fidelis' performance.

RPA of Sprint Fidelis leads shows a survival of 99.2% at 30 months. However, RPA overstates actual performance since it does not account for leads that are not returned. The Medtronic SLS data for the Model 6949 Sprint Fidelis lead indicate 97.7% [+1.3/-3.0] all-cause lead survival at 30 months. This is consistent with our analysis of Medtronic CareLink Network data from approximately 25,000 Sprint Fidelis leads, which indicate 97.7% [+0.6/-0.8] survival at 30 months. These survival rates are not statistically different from the all-cause lead survival of 99.1% [+0.4/-0.8] for the Model 6947 Sprint Quattro® lead at 30 months from the SLS (see Appendix B). However, we expect this difference will become statistically significant over time if the current failure rates remain constant.

Recommendations

Medtronic recommends you consider the following as part of routine follow-up for each patient (see Appendix C)

- To reduce the risk of inappropriate detection and therapy due to oversensing, program VF detection for initial Number of Intervals to Detect (NID) to nominal settings (18/24) or longer at physician discretion and Redetect NID to nominal settings (12/16).
- Turn ON Patient Alert™ for RV Pacing, RV Defibrillation, and SVC Defibrillation impedance. For Concerto® and Virtuoso® devices enrolled on the Medtronic CareLink™ Network, turn ON the CareLink CareAlert® notifications for these same parameters

- To optimize effectiveness of the lead impedance alert:
  - Review V Pacing Lead Performance Trend to determine typical chronic impedance value for the patient (typical values for Fidelis leads should be 350-1,000 ohms).
  - Program lead impedance alert threshold for RV Pacing to 1,000 ohms, if the typical chronic impedance for the patient is ≤ 700 ohms, or
  - Program lead impedance alert threshold for RV Pacing to 1,500 ohms, if the typical chronic impedance for the patient is > 700 ohms.
  - Program lead impedance alert threshold for RV Defibrillation and SVC Defibrillation to 100 ohms.

The patient management recommendations set forth above should increase the likelihood that a fracture will be detected by Patient Alert and/or Medtronic CareAlert notifications and decrease the likelihood of inappropriate therapies. Based on our review of the available data, there does not appear to be a benefit to more frequent follow-up.

Medtronic's Independent Physician Quality Panel believes it is inappropriate to prophylactically remove Sprint Fidelis leads except in unusual individual patient circumstances. We support this position.

Lead extraction carries risks that should be considered in patient management. Published literature suggests major complications (death or surgical intervention) from lead extraction range from 1.4-7.3%.[3,4] As always, with confirmed lead failure the risk of extraction should be weighed against the risk of adding an additional lead (see Appendix D).

Additional Communication

The HRS-recommended Physician Device Advisory Notice for this communication is attached. The information in this letter will be posted on Medtronic.com on October 15th. Consistent with the HRS[5] recommendations on device advisory communications we will be informing patients with affected devices, advising them to contact you for more information. The patient letter will be sent on October 22nd.

We are notifying regulatory agencies of this communication. We will continue to provide performance updates every six months via our Product Performance Report.

Nothing is more important to Medtronic than patient safety. We are committed to answering your questions and keeping you informed. We regret any difficulties this may cause you and your patients. If you have questions or concerns, please contact your Medtronic Representative or Medtronic Technical Services at 1(800) 723-4636 (US).

Sincerely,

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

Appendix Document Attached

1 The two primary locations described above account for 90% of the chronic fractures identified by RPA. The remaining 10% of chronic fractures occurred in DF-1 connector leg and the proximal portion of the RV coil.

2 Kleemann T, Becker T, Doenges K, et al., K. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. *Circulation*. May 15, 2007; 115(19): 2461 - 2463.

3 Byrd CL, Wilkoff BL, et al. Intravascular extraction of problematic or infected permanent pacemaker leads: 1994-1996. U.S. Extraction Database, MED Institute. *PACE* May 2000; 23(5): 927-928.

4 Bracke FA, Meijer A, vanGelder LM. Lead extraction for device related infections: a single centre experience. *Europace,* May 2004; 6(3): 243-247.

5 Recommendations from the HRS task force on device performance policies and guidelines. Carlson MD, et al. Heart Rhythm Journal 2006, 3, 1250-73.