Technical Education Letter
Sprint Fidelis lead model 6930, 6931, 6948, 6949

March 2007

Dear Doctor,

Medtronic has received reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their centers with Sprint Fidelis leads. While current overall Sprint Fidelis performance is consistent with other leads, Medtronic is actively investigating these reports, has reviewed them with our Independent Physician Quality Panel, and would like to share what we know at this time.

Through detailed assessment of reported fractures, we have identified two primary locations where conductor fractures have occurred: 1) distal portion of the lead and 2) near the anchoring sleeve tie down. The distal conductor fractures affect the anode (ring electrode) and fractures that occur around the anchoring sleeve affect the cathode (helix tip electrode). Fractures at both locations appear to present clinically as over-sensing, increased interval counts and inappropriate shocks. Medtronic has worked closely with physicians who have experienced fractures and conducted significant bench testing in an attempt to reproduce the fractures and identify root cause. At this point, our investigation suggests that variables within the implant procedure may contribute significantly to these fractures.

For distal conductor fractures, our investigation has identified severe bending or kinking of the distal end of the lead over the lead body while passing through tortuous vasculature as a significant contributing factor. If the lead is severely bent or kinked at the distal end, the conductor may be compromised such that the conductor may fracture after implant due to chronic fatigue from natural cardiac motion. The venous structure or pathway, venous access location, length of introducer sheath and lead insertion force are all factors that may contribute to severe bending or kinking of the lead. Medtronic recommends avoiding severe bending or kinking of the lead during implantation. If you encounter excessive resistance resulting in severe bending or kinking while advancing the lead, please remove the lead and return it to Medtronic.

For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area. We are still investigating and actively partnering with physicians to better understand this type of fracture. If excessive kinking or bending is observed during lead suturing and/or pocket formation, Medtronic recommends the lead be re-sutured and/or the pocket reassembled per guidelines in the Medtronic lead implant manual. In addition, positioning the anchoring sleeve against or near the vein may be helpful.

Sprint Fidelis lead models 6949, 6948, 6931, and 6930 were market released in the U.S. and internationally in September 2004. Performance of model 6949, the Sprint Fidelis lead currently followed in our System Longevity Study, indicates survival is 98.9% at two years. Sprint Fidelis 6949 performance based on return product analysis shows 99.86% chronic fracture-free survival at two years. Both evaluation methods suggest performance is in line with other Medtronic leads (see relative Medtronic performance data on the following page).

Medtronic is committed to ensuring the highest standards of product reliability. As we learn more, we will share additional information and technical guidance through our sales and technical representatives. If you have questions or concerns, please contact your Medtronic Representative.

Relative Performance of Sprint Fidelis 6949 vs. other Medtronic Leads

Sprint Fidelis is enrolled in Medtronic's System Longevity Study which tracks chronic lead performance. At this time, we have enrolled 487 model 6949 leads in this study with 6,156 cumulative months of follow up. Results indicate survival is 98.9% at two years based on complications occurring beyond 30 days of implant. The following table summarizes data from Medtronic's System Longevity Study comparing the Sprint Fidelis lead with Sprint and Sprint Quattro:

System Longevity Study

Lead Model	Survival at 2 years
Sprint (6945)	99.1%
Sprint Quattro (6947)	99.3%
Sprint Fidelis (6949)*	98.9%

Medtronic has examined the chronic fracture performance of this lead through Returned Product Analysis. The Sprint Fidelis lead appears to perform in line with other Medtronic leads in the market:

Returned Product Analysis

Lead Model	Chronic Fracture-Free Survival at 2 years
Sprint (6945)	99.92%
Sprint Quattro (6947)	99.94%
Sprint Fidelis (6949)*	99.86%

* Due to the small implant sample size of Sprint Fidelis models 6948, 6931, and 6930, the System Longevity Study and Returned Product Analysis data is based on Sprint Fidelis 6949 leads only.