Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL08-02 October 25, 2007

Item: Sprint Fidelis® Defibrillation Leads, manufactured by Medtronic

Specific Incident: Medtronic issued a recall of its Sprint Fidelis® leads, models 6930, 6931, 6948, and 6949 due to a potential for fracture. The Sprint Fidelis® leads are used to deliver therapy in defibrillators, including Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy - Defibrillators (CRT-D). More than 268,000 of the leads have been implanted worldwide, and Medtronic and the FDA estimate that fractures have occurred in less than 1 percent of the leads. Medtronic reports that lead fractures may have contributed to five deaths.

Actions:

1. By close of business (COB) Friday, October 26, 2007, materials management or cardiology staff must remove affected leads from stock; these leads should not be used.

2. By COB Friday, November 9, 2007, electrophysiology/cardiology staff or other appropriate parties must identify all affected patients by implementing each of the following steps **a** through **c** and then implement action 3 below. **It is important that ALL INFORMATION sources be reviewed to insure that patients will not be overlooked, as affected patients may be found on one list and not on another.**

   a) Review the manufacturer's letter (See Attachment 1).

   b) Review the patient list posted on the VA National ICD Surveillance Center intranet website (https://ICDPM.sanfrancisco.med.va.gov). (See Attachment 2.) This list combines patients with affected leads who are already in the Center's database with a list of VA patients provided by Medtronic.

   c) Review your patient records for all patients with implanted Medtronic leads affected by this notification that might have been implanted at a non-VA facility.

3. By COB Friday, December 28, 2007, follow the recommendations contained in Attachment 2. This guidance was prepared by Dr. Edmund Keung, Director of the VA National Surveillance Center, and details the best course of action for your patients.

Source: Medtronic

Contact: Medtronic Technical Services at (800) 505-4636 and your local Medtronic representative or,
Dr. Edmund Keung at the VA National ICD Surveillance Center at (415) 221-4810 Extension 3182, or
Mr. Len Roberts at the VA National ICD Surveillance Center at (415) 221-4810 Extension 3551 or
Mr. Bryanne Patail at the National Center for Patient Safety (NCPS) at (734) 930-5890

Attachments:

1) Medtronic Urgent Medical Device Information dated October 15, 2007.

2) VA National ICD Surveillance Center Guidance dated October 18, 2007.

3) Instructions to access the VA National ICD Surveillance website.

4) Medtronic Sprint Fidelis device-related advisory recommendations for patients with a Boston Scientific CRM ICD or CDT-D.

5) St. Jude medical ICD Programming for Patients implanted with Medtronic Spirit Fidelis Leads.

Links: http://www.medtronic.com/fidelis/ The manufacturer may provide updates on this alert at this site.

The documents related to this recall (the Patient Safety Alert, the manufacturer's physician advisory letters and the Physician device advisory notice from the Heart Rhythm Society) can be downloaded from the National ICD Surveillance Center Website under the section "Safety Alerts and Recalls - Literature" https://ICDPM.sanfrancisco.med.va.gov

ATTACHMENT 1

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

ATTACHMENT 1

- 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.

ATTACHMENT 2

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
4150 Clement Street
San Francisco CA 94121

VA National ICD Surveillance Center

October 18, 2007

Dear colleagues:

This document is to provide you with some general guidelines to deal with the most recent advisory notice issued by Medtronic regarding its Fidelis family of defibrillation lead. This issue has been classified by FDA as a class I recall. Medtronic has suspended distribution of this family of defibrillation leads.

Device affected:

Medtronic Fidelis defibrillator leads:

Device Name	Model Numbers
Sprint Fidelis	6930, 6931, 6948, 6949

The Problem:

Lower then projected all-cause lead survival rate: 97.7% at 30 months.

Incidence: 268,000 Sprint Fidelis leads implanted worldwide; 665 fractures confirmed in returned leads

The root cause for the higher than expected failure rate is conductor fractures, which have occurred in two locations of the lead:

1. The distal portion of the lead, affecting the anode (ring electrode)
2. Near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and in the high voltage conductor (DF-1 connector leg and the proximal portion of the RV coil). Fractures at the high voltage conductor is accounted for 10% of all Sprint Fidelis conductor fractures.

Potential consequences of the failure include:

- Inability to deliver defibrillation therapy.
- Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, over-sensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output.

Recommendations:

- Medtronic's Independent Physician Quality Panel does not recommend prophylactic removal of Sprint Fidelis leads except in unusual patient circumstances.
- Review in detail **Attachment 1** (Patient Management Recommendations for Sprint Fidelis Leads of the Medtronic Physician Letter), **Attachment 4** (Medtronic Sprint Fidelis device-related advisory recommendations for patients with a Boston Scientific CRM ICD or CDT-D) and **Attachment 5** (equivalent St. Jude medical ICD Programming for Patients implanted with Medtronic Spirit Fidelis Leads).
- Within 60 days, as suggested by the VA Alert Memo, perform an interrogation on your patients with the affected leads and reprogram the ICD with the help of the following guidelines.

  <u>For Medtronic ICD and CRT-D connected to a Fidelis lead</u>:

1. To reduce the risk of inappropriate detection and therapy due to over-sensing, consider increasing Number of Intervals to Detect (NID) for VF detection based on patients' clinical history.
   a. For patients with ICD implanted for primary prevention who have yet to receive a shock therapy or who have had VF shock therapy only associated with mild symptoms pre-shock:
      i. If the current VF initial NID is 12/16, increase the value to 18/24 or longer.
      ii. If the current VF redetection NID is 9/12 or lower, increase the value to 12/16 or long.
   b. Since increasing the NID will delay therapy in the event of a true VF event, greater caution must be exercised using this approach in devices that already have longer than average charge times and in patients who had syncope or collapse with VF prior to a successful shock therapy.
2. Program Patient Alert ON for RV Pacing, RV Defibrillation, and SVC Defibrillation impedance. Demonstrate and familiarize patients with the High urgency Patient Alert tone and the programmed Alert Time. Instruct the patient to contact their clinicians and perform a Carelink remote monitoring (if applicable).
3. Program lead impedance alert as follows: If the chronic RV pacing impedance is ≤ 700 ohms, program the upper limit of the new alert threshold to 1000 ohms. If it is > 700 ohms, program the new threshold to 1500 ohms. Set the new alert limit to 100 ohms for the RV and SVC shock impedance thresholds.
4. For wireless ICD and CRT-D, program the Patient Home Monitor to "Yes", select Lead/Device Integrity Alerts and set parameters for alerts notifications accordingly. If the condition is met for anyone of the selected alerts, a full data transmission will be uploaded immediately to the Carelink website for posting and viewing (Medtronic CareAlert transmission) by the patients' clinicians and by the staff of the VA National ICD Surveillance Center. If you want to be notified immediately by Medtronic - at 3 AM (CareAlert notification) you will have to provide contact information to the VA National ICD Surveillance Center so that this feature can be activated for you. A new wireless transmission protocol will be re-sent to all clinics shortly.

<u>For Guidant ICD and CRT-D connected to Fidelis leads</u>:

In most Guidant ICD/CRT-D devices (exceptions are Ventak Prizm VR/DR, Contak CD2/2HE and Contak Renewal 1/2), pacing and shock impedances can be programmed ON and set to the same alert trigger levels (1000 or 1500 ohms for pacing and 100 ohms for shock) as Medtronic devices. But the device will not emit an alert tone when the pacing impedance level is out of range (it is therefore important for these patients to be enrolled in the Latitude remote monitoring program). For Vitality DR HE, the Contak Renewal 3 and 4 families of CRT-D, the device will emit a beeping tone every 6 hours if the shock impedance is out of range.

Increase the Initial Detection Duration from 1.0 to 1.5-2.0 s with the same above considerations for implant indications and therapy history. Redetection Duration is non-programmable.

For wireless devices, the devices are interrogated daily. If the pacing impedance level is exceeded, a fax alert will be sent to the local clinicians on record and a yellow flag transmission report will appear on the Latitude Website for review. If the shock impedance is exceeded, a page will go out to the local BSI representative and the local physicians will be contacted directly. A red flag transmission report will appear on the Latitude Website for review.

For non-wireless devices, as per present VA National ICD Surveillance protocol, patients enrolled in the Latitude program are prompted to perform a device check by the Communicator every Monday. The notification process will be the same as for wireless devices.

<u>For St. Jude Medical ICD and CRT-D connected to Fidelis leads</u>:

In St. Jude Medical devices, the alert trigger level for pacing impedance is non-programmable (200-2000 ohms) and shock impedances are not measured at all. There is no beeping tone notification. For the Atlas II and Epic II families, a vibratory alert will be sent out by the devices when the pacing impedance is out of range. The number of intervals for VF detection can be increased from 12 (nominal) to 16 intervals with the same above considerations for implant indications and therapy history. VF redetection is fixed at 6 intervals. Please contact your local St. Jude Medical representative for assistance in programming the detection durations. Enrollment in the St. Jude Medical remote monitoring (Merlin.net) via the VA ICD Surveillance Program is strongly recommended.

5. Monitoring Frequency: According to Medtronic, more frequent follow-up will not provide a significant benefit. However, their data showed that monthly and weekly review of lead fracture prediction criteria (see below) would identify an estimated 36% and 49% of patients with lead fracture, respectively. More frequent transmissions may allow us to detect early "non-sustained VT" caused by noise from lead fracture and to correct the problem before inappropriate shocks are delivered. Accordingly, enroll patients in the remote monitoring service provided by the VA National ICD Surveillance Center, if the patients have not been using the service. Remote monitoring intervals will be set to monthly for this group of patients unless the referring VA facility requests a different schedule.

   Lead Fracture Prediction Criteria:

   a) Frequent aborted non-sustained tachycardia events, especially with RR interval of less than 200 ms (from over-sensing of noise)
   b) Sensing Integrity Counter > 300 counts or >30 counts and average >10 counts/day since first count
   c) Abrupt increase in lead impedance values (greater than 2X baseline)

- A new Safety Alert Management Utility module has been added to the VA National ICD Surveillance website site to assist you to identify and track your actions steps in response to the recall. Instructions will be distributed shortly by the Surveillance Center.

Some numbers to consider:

Medtronic reported that in patients 58 years of age and older, the Sprint Fidelis 30-month survival rate is statistically better than in patients under 58 (98.4% versus 97.5%). Most of our veterans are above 60 years old.

Ed Keung, MD
Director, Western Pacemaker Surveillance Center
Ph: 415-221-4810, extension 3182
Edmund.Keung@va.gov

ATTACHMENT 3

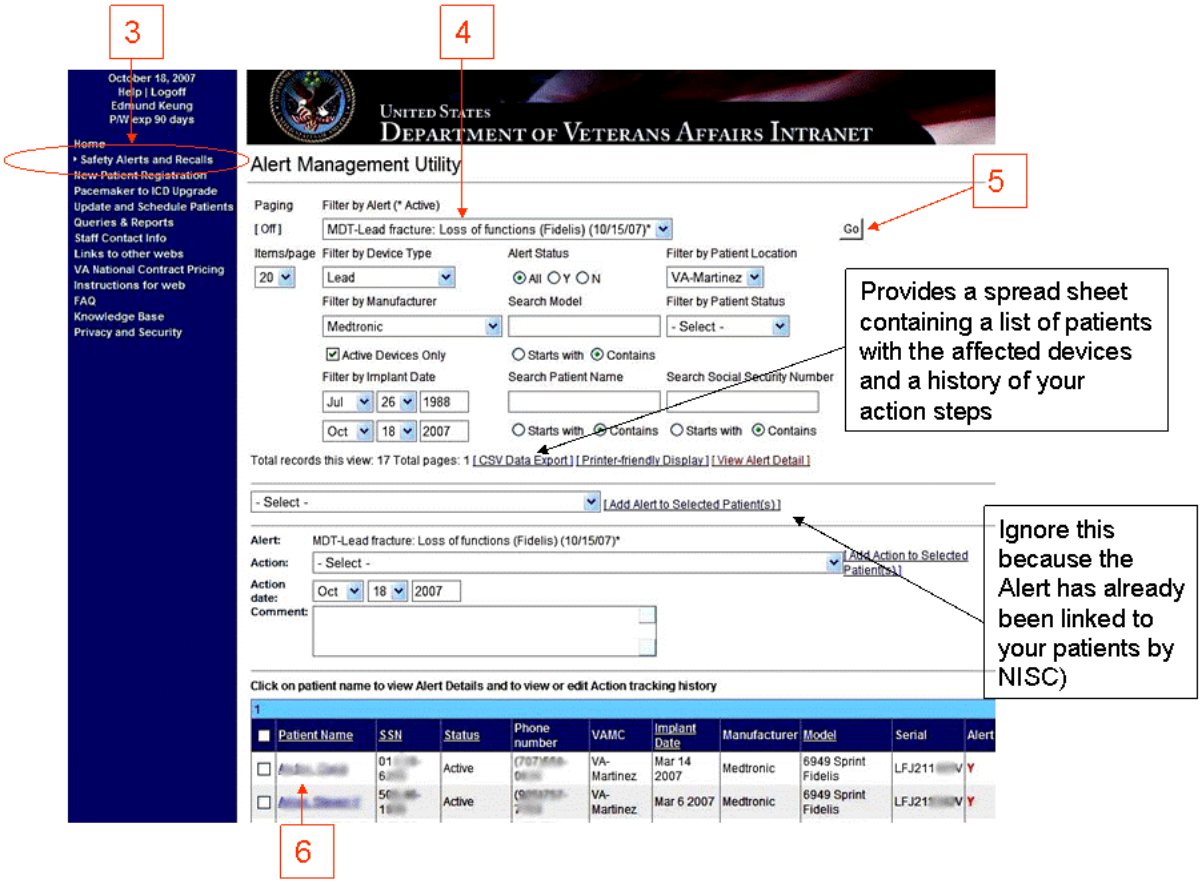
Instructions on how to access the VA National ICD Surveillance center database.

Perform the following steps to access your patient list of active Fidelis leads on the VA National ICD Surveillance Center. We created a new module to assist you to manage safety alerts and recalls. This version is limited to the present Fidelis lead recall:

1. VA intranet URL: https://ICDPM.sanfrancisco.med.va.gov
2. You have to register as a user first. Len Roberts, our administrator (Leonard.Roberts@va.gov) will review the information you provided and grant you access within 24 hours or less
3. After you log in, click on <Safety Alerts and Recall> and <Alert Management Utility>
4. Select MDT-Lead fracture: Loss of function (Fidelis) (10/15/07) from the Filter by Alert dropdown list.
5. Click "Go" to obtain your list

The device alert status is listed in the far right corner under the column heading Alert (Y=Yes). Do not forget that there may be more than one page for the list, depending on how many patients you have. You can export the table to an Excel spreadsheet by clicking on the [CSV Data Export] button or just print it.

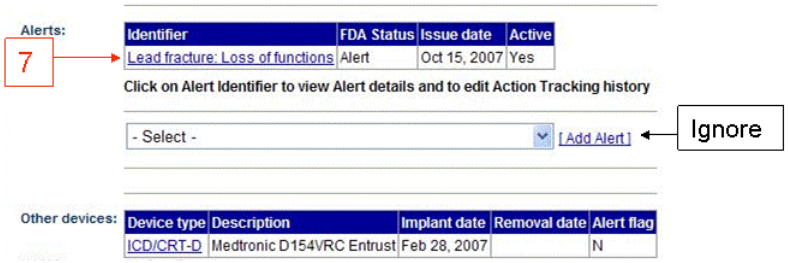
The medical centers listed under the column VAMC are the hospitals where they had their device implanted or the follow-up clinics, according the records of the National ICD Surveillance Center and Medtronic.



If you choose to use the Alert Management Utility Module to assist you in tracking and managing the recall, please follow the instructions below.

6. Click on a patient's name in the above list table and you will be taken to page 1 of the patient's detail alert page.

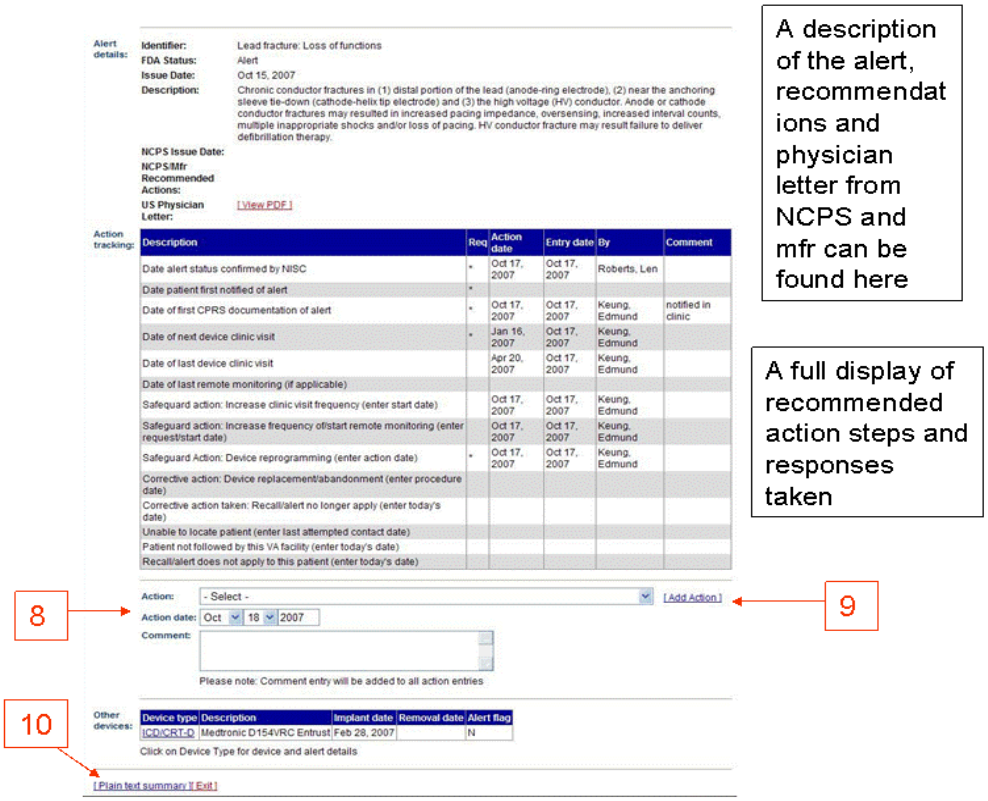
7. Click on the appropriate Alert Identifier (if there is more than one alert affecting the device) to go to page 2 to view the alert details and to enter your actions in response to this alert.



8. Click on the Action dropdown manual to select the alert action accomplished and enter its appropriate Action date and Comment.

9. Click the [Add Action] button to a link this action to the patient. Repeat #8 and #9 for each applicable action step.

10. Click the [Plain text summary] button to obtain a text-file of the information displayed on this page. The content can be copied and pasted onto a CPRS progress note for record keeping.



ATTACHMENT 4

Boston Scientific

MEMORANDUM

To: Boston Scientific CRM Field Force

From: CRM Technical Services, St. Paul

Date: October 19, 2007

Subject: Medtronic Sprint Fidelis device-related advisory recommendations for patients with a Boston Scientific CRM ICD or CRT-D

Medtronic Inc. initiated a product advisory[1] on October 15, 2007 regarding lead fractures within their Sprint Fidelis defibrillator lead family (models 6930, 6931, 6948, and 6949, manufactured from September 2004 through October 15, 2007). Medtronic has advised that doctors no longer implant Sprint Fidelis leads and return any unused product to Medtronic. Medtronic's Independent Physician Quality Panel believes it is inappropriate to prophylactically remove Sprint Fidelis leads except in unusual individual patient circumstances.

The United States Food and Drug Administration (FDA) classified this action as a Class I Recall. As stated in the FDA announcement[2], "Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of the product will cause serious injury or death."

Boston Scientific CRM device registration records indicate that a significant number of Boston Scientific CRM ICDs and CRT-Ds have been implanted with Sprint Fidelis leads. For this reason, CRM Technical Services is providing information to facilitate interpretation of Medtronic device-related advisory recommendations for those patients implanted with a Medtronic Fidelis lead and a Boston Scientific CRM defibrillator.

This information may be shared with your customers. However, it is important for you and your customers to understand that these are ***not*** Boston Scientific recommendations, but rather an interpretation of Medtronic device-related advisory recommendations as applicable to Boston Scientific ICDs and CRT-Ds, to be considered by physicians if clinically appropriate.

If your customers have additional questions regarding the performance or clinical application of Sprint Fidelis leads, they should contact Medtronic Technical Services at 1.800.723.4636 (US). For questions regarding Boston Scientific CRM products and services, contact US Technical Services at 1.800.CARDIAC (227.3422) or European Technical Services at +32 2 416 7222.

CRM Technical Services, St. Paul

[1] View Medtronic physician letter at http://www.medtronic.com/fidelis/physician-letter.html
[2] View FDA information at http://www.fda.gov/cdrh/recalls/recall-101507.html

ATTACHMENT 4

Interpreting Medtronic Advisory Recommendations for situations in which a Medtronic Sprint Fidelis lead is attached to a Boston Scientific defibrillator

Medtronic Recommendations Medtronic recommends you consider the following as part of routine follow-up for each patient (see Appendix C)	**Boston Scientific CRM's interpretation of Medtronic's device-related advisory recommendations for those patients implanted with a Medtronic Fidelis lead and a BSC defibrillator:** [note: more information on Boston Scientific device features can be found in the respective system guides]
• 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).	• Detection and redetection criteria in Boston Scientific ICDs and CRT-Ds consist of a non-programmable rate detection window (8 of 10 intervals), followed by a programmable **Duration** timer to ensure that an arrhythmia is sustained before treatment is initiated (1 to 60 seconds, depending on zone configuration).
• 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	• For Boston Scientific ICDs and CRT-Ds, Clinical Events (including out-of-range Daily Measurements) can be displayed on the programmer during an in-office follow-up visit. Activate all desired Daily Measurements within the implanted device (program to **ON** and select limit).[1] Daily Measurements / Clinical Events of interest: – High daily right ventricular pacing lead impedance – High daily shock lead impedance – High shock lead impedance during shock delivery • Several Boston Scientific ICDs and CRT-Ds beep when a shock lead impedance Daily Measurement is out-of-range.[2] All Boston Scientific ICDs and CRT-Ds beep if an out-of-range shock lead impedance is detected during shock delivery. • For all patients actively enrolled in Boston Scientific's LATITUDE® Patient Management system,[3] a Clinical Event Notification (Red Alert) will be triggered when a Clinical Event (including an out-of-range Daily Measurement listed above) occurs. However, the desired Daily Measurement must be activated (programmed **ON**) within the implanted device to generate a corresponding LATITUDE Red Alert. The LATITUDE remote monitoring system can be configured to conduct weekly checks using wanded communication, while RF devices can be configured for daily or weekly checks.
• To optimize effectiveness of the lead impedance alert:	• To use Boston Scientific CRM Clinical Events monitoring capabilities, consider the following:
○ 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).	○ Review all available stored diagnostic information, such as daily/weekly measurements (including ventricular pace impedance), EGMs, diverted and non-sustained episode counters, shock lead impedance measured during last shock, etc. for evidence of compromised lead integrity.
○ Program lead impedance alert threshold for RV Pacing to 1,000 ohms, if the typical chronic impedance for the patient is ≤ 700 ohms, or	○ Using the programmer's Daily Measurement Setup screen, program the Daily Measurement referred to as "Ventricular Pace Impedance" to **ON**. Program a maximum limit of 1000 ohms[4] if the weekly average impedance has recently been at or below 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.	○ Using the programmer's Daily Measurement Setup screen, program the Daily Measurement referred to as "Ventricular Pace Impedance" to **ON**. Program a maximum limit of 1500 ohms[4] if the weekly average impedance has recently been above 700 ohms.
○ Program lead impedance alert threshold for RV Defibrillation and SVC Defibrillation to 100 ohms.	○ Using the programmer's Daily Measurement Setup screen, program the Daily Measurement referred to as "Shock Impedance" to **ON**. Program a maximum limit of 100 ohms.[5]

[1]Daily Measurements are not available in VENTAK PRIZM® VR/DR, CONTAK® CD2 / 2 HE, CONTAK RENEWAL® 1/2
[2]VITALITY® DR HE, CONTAK RENEWAL 3/3 HE/3 RF/3 RF HE/4/4HE/4RF/4 RF HE
[3]The LATITUDE Patient Management System is not available for all ICDs and CRT-Ds in all geographies
[4]Non-programmable nominal of 2500 ohms in VITALITY DR HE, CONTAK RENEWAL 3/3 HE/3 RF/3 RF HE/4/4 HE/4 RF/4 RF HE
[5]Non-programmable nominal of 125 ohms in VITALITY DR HE, CONTAK RENEWAL 3/3 HE/3 RF/3 RF HE/4/4 HE/4 RF/4 RF HE

ATTACHMENT 5

ST. JUDE MEDICAL

CARDIAC RHYTHM MANAGEMENT DIVISION

Technical Services
701 East Evelyn Ave
Sunnyvale, CA 94086
T: 800-722-3774
F: 866-739-0040

Equivalent St. Jude Medical ICD Programming for Patient's Implanted with Medtronic's Sprint Fidelis Leads

On October 15, 2007, Medtronic issued a Dear Doctor Letter[1] with specific recommendations to manage patients implanted with Sprint Fidelis leads (models 6930, 6931, 6948, 6949) and Medtronic ICD's. In order to detect the possibility of lead fracture and prevent inappropriate therapy Medtronic gave the following recommendations:

- *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 programming equivalents with St. Jude Medical ICDs are as follows:

Current & Promote ICDs	Epic II & Atlas II ICDs	All other SJM ICDs
Program the number of intervals for VF detection to 12 (nominal) or longer (16, 25, or 40 intervals) at physician discretion. VF redetection is fixed at 6 intervals.	Program the number of intervals for VF detection to 12 (nominal) or longer (16 intervals) at physician discretion. VF redetection is fixed at 6 intervals.	Program the number of intervals for VF detection to 12 (nominal) or longer (16 intervals) at physician discretion. VF redetection is fixed at 6 intervals.
Ensure the Patient Notifier triggers are on for high voltage lead impedance (HVLI), Possible HV Circuit	Ensure the Patient Notifier triggers are on for Possible HV Circuit Damage and RV Pacing Lead Impedance. These devices do not	The devices do not have Patient Notifier triggers.

Damage, and RV Pacing Lead Impedance. These devices have programmable impedance limits, so please program in accordance with Medtronic's recommendations above.	have programmable impedance limits.	

If you have any additional questions, please feel free to contact Technical Services at 1-800-722-3774.

1. http://www.medtronic.com/fidelis/physician-letter.html

ST. JUDE MEDICAL CARDIAC RHYTHM MANAGEMENT DIVISION