Medtronic, Inc.
8200 Coral Sea St NE
Mounds View, MN 55112

Medtronic

October 27, 2008

Kristine E. Zuroski
Recall and Emergency Coordinator
U. S. Department of Health and Human Services
Food and Drug Administration
Minneapolis District Office
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401

RE: FDA Recall Numbers Z-0067-2008 thru Z-0070-2008

Dear Ms Zuroski:

This correspondence is in response to the letter received from Mr. W. Charles Becoat, Director, Minneapolis District, Food and Drug Administration dated November 1, 2007 regarding the Medtronic, Inc. Sprint Fidelis® Lead Patient Management Recommendations **Urgent Medical Device Information** communication.

Product Hold Order (PHO) A29440 was initiated on 10/15/07 to retrieve unimplanted Fidelis leads and to ensure that the returned leads are inventoried and quarantined to prevent unintended use or shipment. When the product hold order was issued all devices with the indicated Models were "flagged" in the distribution system (SAP), which restricts the capability of movement other than to the controlled warehouse location. Policy Procedure Field Shared Services Product Hold Order Control Procedure 020-010 governs control of physical inventory held in this physical location.

1. Number of consignees notified of the recall, date and method of notification

On 10/13/07 Medtronic sent the Urgent Medical Device Information communication to (b) (4) physicians who were identified as either the implanting physician or who are following patients implanted with the Fidelis lead models 6930, 6931, 6948 or 6949. The notification was sent via UPS Next Day.

On 10/17/07 Medtronic sent the communication to (b) (4) hospitals with the Fidelis lead models 6930, 6931, 6948 or 6949 invoiced or consigned to the hospital but not registered as implanted. The notification was sent via first class mail.

On 2/14/08 Medtronic sent the Urgent Medical Device Information communication to (b) (4) additional physicians who were identified after the 10/13/07 mailing. These physicians were added to the notification database as a result of processing information received from the Device Registration Form, confirmation sheets and database updates after the initial communication was sent. The form is part of the package contents. The same information was included in this notification as was in the initial physician notification. A cover letter explaining why they did not receive the initial mailing was also included. The notification was sent via UPS Next Day.

The total number of physicians notified as of the date of this report is (b) (4)
The total number of hospitals notified as of the date of this report is (b) (4)

2. The number of consignees responding to the recall communication.

   As of October 27, 2008, (b) (4) physician confirmations have been received.
   As of September 30, 2008, all (b) (4) hospital confirmations have been received.

3. Number of consignees that did not respond.

   As of October 27, 2008, (b) (4) physicians remain unconfirmed.
   As of September 30, 2008, all hospitals are confirmed.

4. The number of consigned devices retrieved from hospitals or other consignee inventories, and the quantity of product accounted for.

   As of October 27, 2008, (b) (4) Fidelis leads have been have been returned and are now being held in a secured area or have been scrapped.
   As of October 27, 2008, (b) (4) Fidelis leads have been accounted for.

5. Date, number, type (telephone, visit, etc.) and results of effectiveness checks that were made.

   Confirmed that (b) (4) physicians and (b) (4) hospitals received the communication.
   Sales Reps are instructed to visit each physician and/or hospital in their area to confirm receipt of communication and to respond to any questions.

6. The estimated time frame for completion of the recall, or when the recall was completed

   Estimated time for completion is (b) (4)

7. Amount of the product on hand at your firm when the recall began, and the disposition of this product.

   To be supplied in the closing report

8. Corrective actions taken to prevent recurrence of this problem.

   To be supplied in the closing report

9. Number and summary of complaints received about lead fractures.

   To be supplied in the closing report.

If you have any questions regarding this report please contact me (763-526-2344) at your convenience.

Sincerely,

MEDTRONIC, INC.

Michael G. Holgers
Director of Regulatory Compliance
Cardiac Rhythm Disease Management

FDA Statement

FOR IMMEDIATE RELEASE
October 15, 2007

Media Inquiries:
Karen Riley, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

Statement on Medtronic's Voluntary Market Suspension of Their Sprint Fidelis Defibrillator Leads

Statement by Daniel Schultz, M.D., director of the Center for Devices and Radiological Health:

Medtronic's decision to voluntarily remove its Sprint Fidelis defibrillation leads from the market is in the best interest of patient safety.

These electronic wires are prone to fracture in a small number of patients which can cause the defibrillator to deliver unnecessary shocks or not operate at all. Based on our initial review of reported adverse events, some deaths and major complications have occurred after the leads have fractured.

Defibrillators are life-saving products for patients with a heart rhythm abnormality. We know it can be frightening for a patient to learn that a product they rely on so much might have a serious defect. However, patients can be assured that the likelihood of fracture is very low and FDA is committed to ensuring that the risk to patients is minimized.

Background:

Today, Medtronic announced it was voluntarily suspending distribution of its Sprint Fidelis defibrillation leads because a small number of fractures have been detected. As a result of Medtronic's action, no more Sprint Fidelis leads will be sold or manufactured and any remaining product should be pulled from inventory and returned to the company. Patients who are implanted with this lead are encouraged to contact their physicians for further information.

Medtronic first notified physicians in March about the fracture rate at that time and the proper method for implantation. Additional data on adverse events accumulated since then has prompted today's action.

Implantable cardioverter defibrillators (ICDs) and Cardiac Resynchronization Therapy-Defibrillators (CRT-Ds) are used to treat abnormal heart rhythms that can cause the heart to stop suddenly. ICDs and CRT-Ds shock the heart back into normal rhythm by sending a pulse of energy through an electronic wire or lead that is connected to the heart.

When a defibrillator lead is slightly more prone to fracture, it doesn't mean that every lead will break. Most leads will function well, as is the case with Sprint Fidelis. In the infrequent circumstance where a lead actually breaks, or "fractures," the lead may send false signals that cause inappropriate defibrillator shocks, or therapies such as pacing or shocks may not be delivered.

Current adverse event information indicates that fractures have occurred in less than 1 percent of the approximately 268,000 of these leads implanted worldwide. We don't know if this rate of adverse events will remain constant or increase over the life of these leads.

FDA considers Medtronic's action to be a product recall, as defined by FDA regulations, and we will soon be issuing a recall classification for this action. We recognize that some patients and health care professionals might inappropriately interpret the word "recall" to mean that the devices must be surgically removed and returned to the manufacturer. Although the leads should no longer be implanted in patients, we do not mean to imply that these leads should be surgically removed.

The leads continue to function properly in the vast proportion of patients. Although there is no test to predict which lead will fracture, FDA agrees with Medtronic's recommendation that defibrillator settings be adjusted at the patient's next scheduled follow-up visit with their doctor. Doing so may increase the likelihood that a fracture will be detected before a patient is harmed.

Neither FDA, Medtronic, nor representatives of the Heart Rhythm Society, recommend the routine surgical removal of a fractured lead because removal carries risks. Instead, physicians should weigh the benefits and risks of either continuing to use the lead with careful monitoring or capping the lead so it is no longer useable and implanting a different model.

Patients should recognize that a small number of Sprint Fidelis leads are used with defibrillators made by manufacturers other than Medtronic. If patients have reason to believe that they have a Sprint Fidelis lead or if they do not know the model of their lead, they should contact their health care professional.

FDA will continue to monitor information on these devices and will take whatever other actions may be necessary.

#

Questions and Answers for Consumers

RSS Feed for FDA News Releases [what's this?]

Consumer Update Main Consumer Health Information Page

Medtronic Recalls Sprint Fidelis Cardiac Leads Questions and Answers for Consumers

What are Sprint Fidelis Leads?

Manufactured by Medtronic, Inc., Sprint Fidelis Leads are specific models of cardiac electrodes (thin wires) that connect an implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) directly to the heart. ICDs and CRT-Ds are devices that protect patients when life-threatening heart rhythms occur.

How do defibrillators work?

Defibrillators monitor heart rhythms. They deliver an electrical shock or rapid pacing to restore normal rhythm when life-threatening, irregular heartbeats are detected. These devices keep the heart from going too fast. They are surgically implanted for patients who are at risk of sudden cardiac arrest.

What is Medtronic announcing about the Sprint Fidelis Leads?

Medtronic, Inc., is announcing that it is voluntarily suspending worldwide distribution of the Sprint Fidelis family of defibrillation leads. This includes four Sprint Fidelis Models: 6930, 6931, 6948, and 6949. FDA considers this removal action to be a medical device recall. Medtronic is advising physicians to stop implanting the leads and to return unused products to the firm.

How do I know if I have a Sprint Fidelis lead?

You may have a patient card that identifies the implanted devices you have. If you have any uncertainty about your devices, you should contact your physician.

Does this action affect other Medtronic devices?

This action does not affect patients who have Medtronic devices that are pacemakers. While defibrillators keep the heart from going too fast, pacemakers keep the heart from going too slowly. This action also does not affect patients who have Medtronic ICDs or CRT-Ds without a Sprint Fidelis lead.

What is a medical device recall?

A recall is an action taken when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health. A recall for an implantable medical device does not always mean that the device has to be removed.

Why are the Sprint Fidelis Leads being recalled?

The devices are being recalled because of the potential for lead fractures. These electronic wires are prone to fracture in a small number of patients. This could cause the defibrillator to deliver unnecessary shock or to not operate at all. Some deaths and other serious injuries have been reported in which a fracture in a Sprint Fidelis lead may have been a possible or likely contributing factor.

How many people have had this device implanted?

As of October 4, 2007, there have been approximately 268,000 Sprint Fidelis leads implanted worldwide, including 172,000 Sprint Fidelis leads implanted in the United States.

What should patients do if they have had a Sprint Fidelis lead implanted?

- Patients who have had the Sprint Fidelis lead implanted should contact their physician, especially if they have experienced multiple shocks, lightheadedness, fainting, or palpitations.
- Patients should not routinely seek removal of the device. The risks of removal in most patients exceed the small risk of lead fractures. Therefore, it is generally recommended to leave functioning leads in place. There are two alternatives to removing the lead. One is to continue using the lead while monitoring closely for signs of fracture. A second is to surgically add a replacement lead. Adding a replacement lead does not require removing the Sprint Fidelis lead. If the Sprint Fidelis is left in a patient without being used, it must be "capped", which means covering the tip with a small plastic insulation.
- Patients can call Medtronic at this toll-free number: 1-800-551-5544, ext. 41835.

What additional advice has been given to protect patient health?

Medtronic has provided guidance to physicians on how to reduce the risks in affected patients and ensure that devices are set to more effectively monitor for potential fractures. These patient management recommendations are available at http://www.medtronic.com/fidelis/

How should problems with Sprint Fidelis leads be reported?

Problems should be reported to FDA's MedWatch Adverse Event Reporting program.

- Online (www.fda.gov/medwatch/report.htm)
- Fax (800-332-0178)
- Regular mail (use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787).

FDA Statement
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01724.html

Date Posted: October 15, 2007

RSS RSS feed for Consumer Updates [what is RSS?]
