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?]

Get free weekly updates about FDA press releases, recalls, speeches, testimony and more.