



## News Release

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### Medtronic Voluntarily Suspends Distribution of Sprint Fidelis® Defibrillation Leads

*Physician Experts Advise Against Prophylactic Replacement of Implanted Leads*

**MINNEAPOLIS - October 15, 2007** - Medtronic, Inc. (NYSE:MDT) said today that it has voluntarily suspended worldwide distribution of the Sprint Fidelis® family of defibrillation leads because of the potential for lead fractures. In addition, the company recommends against new implants of the leads (Sprint Fidelis Models: 6930, 6931, 6948, 6949).

The Sprint Fidelis leads are used to deliver therapy in defibrillators only, including Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy - Defibrillators (CRT-Ds). Approximately 268,000 Sprint Fidelis leads have been implanted worldwide. This action does not affect Medtronic pacemaker patients.

The U.S. Food and Drug Administration (FDA) intends to issue a public statement regarding Medtronic's decision at [www.fda.gov](http://www.fda.gov).

Medtronic, its Independent Physician Quality Panel, and Bruce Lindsay, M.D., Professor of Medicine, Director of Cardiac Electrophysiology, Washington University School of Medicine and President of the Heart Rhythm Society (HRS), do not recommend that patients seek prophylactic replacement of Sprint Fidelis leads, as the risks of removal or insertion of another lead exceed the small risk to patients of a lead fracture. Medtronic has provided patient management recommendations that should reduce risks in the affected population and recommends that patients with questions consult their physicians. Information is also available for patients and physicians at [www.medtronic.com/fidelis](http://www.medtronic.com/fidelis).

This decision is based on a variety of factors that, when viewed together, indicate that suspending distribution is the appropriate action. Based on Medtronic's extensive performance data, Sprint Fidelis lead viability is trending lower than Medtronic's Sprint Quattro® lead at 30 months (97.7% Sprint Fidelis vs. 99.1% Sprint Quattro). This difference is not statistically significant; however, if the current lead fracture rates remain constant, it will become so over time. Medtronic believes that given this

performance trend and its ability to identify the primary fracture locations, this action is in patients' best interest.

Lead fractures may present clinically as audible alerts, inappropriate shocks and/or loss of output. Based on current information regarding the 268,000 implanted leads, Medtronic has identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor.

"There is nothing more important to us than the safety and well-being of patients," said Bill Hawkins, president and chief executive officer of Medtronic. "We take all matters of product quality very seriously and believe this action is the right thing to do given currently available information."

### **Medtronic Outreach to Physicians and Patients**

In conjunction with Medtronic's Independent Physician Quality Panel, Medtronic today communicated, via letter and direct outreach with more than 13,000 physicians worldwide, the Sprint Fidelis lead performance data and updated patient management recommendations for patients who are implanted with Sprint Fidelis leads. These recommendations include device programming and patient management recommendations that will ensure a patient's device is set to more effectively monitor for potential problems and provide an audible alert in the event of lead fractures.

"Medtronic has acted responsibly to address concerns about the possibility of lead fractures and to minimize harm to patients," said Kevin Hackett, M.D. of Columbus Cardiology Consultants and member of Medtronic's Independent Physician Quality Panel. "The Physician Panel has reviewed Medtronic's data and believes they are taking the correct action."

### **Information for Patients**

Medtronic recommends that patients, who believe they may have a Fidelis lead, consult with their physicians. It is important to note that Medtronic pacemaker patients are not affected by this action. Medtronic will communicate directly to affected patients and encourage them to contact their physicians for more information. Medtronic has established the following website - [www.medtronic.com/fidelis](http://www.medtronic.com/fidelis) - and a toll-free number (1-800-551-5544 ext. 41835) for patients seeking information.

### **Investor Conference Call/Webcast**

Medtronic will host an investor webcast later this morning at 8:15 a.m. eastern time / 7:15 a.m. central time. To listen to the live audio webcast or a replay of the webcast, please refer to the Investor Relations webpage at <http://investorrelations.medtronic.com/>.

### **About Medtronic**

Medtronic, Inc. ([www.medtronic.com](http://www.medtronic.com)), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

**Any statements made about the anticipated regulatory review or approval are forward-looking statements and subject to risks and uncertainties such as those described in Medtronic's Annual Report on Form 10-K for the year ended April 27, 2007. Actual results may differ materially from anticipated results.**

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