



# Medtronic

## News Release

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### **FDA Classifies Previously Announced Medtronic Physician Advisory on Small Subset of Kappa and Sigma Pacemakers as Class I Recall**

**MINNEAPOLIS - June 10, 2009** - Medtronic, Inc. (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) has classified Medtronic's previously announced physician advisory about a small subset of Kappa® and Sigma® series pacemakers, identified at increased susceptibility for separation of bonded interconnect wires from the electronic circuit, as a Class I recall. Notification to U.S. FDA, physicians and patients began May 18, 2009. As of the date of this news release, more than 95 percent of physicians following affected devices in the United States have confirmed receipt of the notification. The FDA's classification of Medtronic's Important Patient Safety Information does not alter the patient management recommendations already provided in the May 2009 letter, and physicians need not take any new action.

It is important to note that not all Medtronic Kappa and Sigma pacemakers are included in the advisory. Medtronic's May 2009 communication to physicians involves a small subset of approximately 2 percent of the 1.7 million Kappa and Sigma pacemakers implanted worldwide since 1997. Medtronic has identified an increased susceptibility for separated interconnect wires in a specific subgroup of 10,000 of these devices in the U.S. that remain in patients. Most of the devices in the potentially affected subset have been implanted for five years or longer and may be nearing normal elective replacement time.

In this limited subset of Kappa and Sigma series pacemakers, the issue can lead to loss of rate response, premature battery depletion, loss of telemetry, or no output, potentially causing patient symptoms such as fainting and lightheadedness. Patients who experience these symptoms are reminded to seek medical attention immediately.

Patients can determine if their device is included in the identified subset by entering their device serial number at [www.KappaSigmaSNList.medtronic.com](http://www.KappaSigmaSNList.medtronic.com). Patients whose serial numbers match any of those found on the Web site should contact their physician to determine an appropriate course of action. Patients without Internet access, or who have these models of devices but are unsure if their devices are included in this advisory may also contact Medtronic Patient Services at 800-551-5544.

After consultation with the company's Independent Physician Quality Panel, Medtronic's May 2009 letter recommended that:

- Physicians should consider device replacement for patients who are both pacemaker dependent and who have been implanted with a device in the affected subsets.
- Physicians should continue routine follow up in accordance with standard practice for those patients who are not pacemaker dependent.

**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 forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's Annual Report on Form 10-K for the year ended April 25, 2008. Actual results may differ materially from anticipated results.**

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