Medtronic News

Medtronic Issues Communication about the Potential for Reduced Battery Performance in a Small Percentage of SynchroMed(R) II Implantable Drug Infusion Pumps

Update to July 2009 Letter to Healthcare Professionals

MINNEAPOLIS, Jul 08, 2011 (BUSINESS WIRE) --

As part of its ongoing commitment to keep patients and physicians informed about product performance and safety, Medtronic, Inc. (NYSE: MDT) is issuing an urgent Medical Device Correction to provide physicians with additional information about the potential for reduced battery performance in a small percentage of its SynchroMed(R) II Implantable Drug Infusion Pumps. Medtronic first communicated about this issue in a July 2009 letter to physicians. This issue does not involve Medtronic external insulin pumps for diabetes.

Medtronic is not retrieving the product from the field or recommending surgical removal of the devices unless a patient's pump demonstrates reduced battery performance.

Medtronic's analysis of the issue indicates it is related to the formation of a film within the pump battery that may impact battery performance. This can lead to the sudden loss of therapy and the return of underlying symptoms and/or withdrawal symptoms. Patients receiving intrathecal baclofen therapy are at risk for baclofen withdrawal syndrome, which can lead to a life-threatening condition if not treated quickly and effectively. Medtronic encourages patients to carry their patient identification cards with them at all times and to contact their physicians immediately if they experience a return of symptoms or hear a device alarm.

Medtronic is working to obtain U.S. approval for a battery design change intended to prevent the issue from occurring in future pumps. This design change has been implemented in several regions, including Europe, Australia, New Zealand, Canada, Africa and India.

As of May 31, 2011, there have been 55 confirmed cases of this issue from approximately 139,653 SynchroMed II pump implants worldwide. While the SynchroMed II pump was designed to last up to 84 months, these events occurred between 45 and 78 months after implant. All but one of the cases occurred in pumps with batteries manufactured prior to March 17, 2005. Returned product analysis of these pumps showed that the alarms were functioning as designed.

Patient safety is Medtronic's top priority. Patients with questions relating to this issue are encouraged to talk with their physicians or contact Medtronic Patient Services at 1-800-510-6735, Monday - Friday, 8 a.m. to 5 p.m. CDT. Patient information can also be found on Medtronic's website, located at http://medtronic.com/productadvisory.

Please report any malfunctions or adverse events related to a device to Medtronic Neuromodulation Technical Services at, 1-800-328-0810, Monday-Friday, 8 a.m. to 5 p.m. CDT, and the FDA's MedWatch Program at http://www.fda.gov/MedWatch.

Copies of the July 2011 letter and the July 2009 letter are available through Medtronic's Web site at http://professional.medtronic.com/iddadvisories or http://professional.medtronic.com/itbadvisories.

Medtronic's intrathecal drug delivery systems are used to treat chronic, intractable pain and for the management of severe spasticity of cerebral or spinal origin.

About Medtronic

Medtronic, Inc. (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 periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

SOURCE: Medtronic, Inc.

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