Medtronic News

Medtronic Announces FDA Classification of Deep Brain Stimulation Lead Cap Communication

MINNEAPOLIS - May 2, 2013 - In keeping with its commitment to keep physicians informed about product performance and safety, Medtronic, Inc. (NYSE: MDT) issued an Urgent Medical Device Correction notification in February 2013 to provide physicians with information concerning the potential for deep brain stimulation (DBS) lead damage associated with the use of the lead cap provided in Medtronic DBS lead kits and dystonia therapy kits. The U.S. Food and Drug Administration (FDA) has classified the communication as a Class I Recall.

Medtronic has received reports of DBS leads being damaged due to twisting of the connector within the lead cap during the surgical procedure. The DBS lead cap is included in DBS lead kits and dystonia therapy kits and is sometimes used temporarily to protect the end of a DBS lead after it has been implanted. The DBS lead cap is not used in all DBS procedures, and is not permanently implanted. Depending on the extent of lead damage due to twisting of the connector during the placement and removal of the lead cap, lead replacement may be required or optimal therapy may not be achieved.

In the case of lead damage, if at the beginning of therapy patients are receiving therapy as expected, they are not likely to be affected by this issue. Patients with questions relating to this issue are encouraged to talk with their physicians.

A manufacturing change intended to address the issue is currently under FDA review, and in the meantime Medtronic has issued modified instructions to physicians who may use DBS lead caps.

Any malfunctions or adverse events related to a device should be reported to Medtronic Neuromodulation Technical Services at 1-800-707-0933, weekdays from 7 a.m. to 6 p.m. CST, and the FDA's MedWatch Program at http://www.fda.gov/MedWatch.

About Medtronic DBS Therapy

DBS therapy uses a surgically implanted medical device, similar to a pacemaker, to deliver mild electrical pulses to precisely targeted areas of the brain. The therapy is currently approved in many locations around the world, including Europe and the United States, for the treatment of the disabling symptoms of essential tremor, advanced Parkinson's disease and chronic intractable primary dystonia, for which approval in the United States is under a Humanitarian Device Exemption (HDE). In Europe, Canada and Australia, DBS therapy is approved for the treatment of refractory epilepsy. The therapy is also approved for the treatment of severe, treatment-resistant obsessive-compulsive disorder in the European Union and in the United States under an HDE.

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.

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Contacts:
Justin Ihle
Public Relations
+1-763-526-0911

Jeff Warren
Investor Relations
+1-763-505-2696

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