Medtronic News

Medtronic's StealthStation® Cranial Software Receives FDA Clearance as an Aid for Deep Brain Stimulation Lead Placement

The Company Continues to Pioneer Innovations in Deep Brain Stimulation and Surgical Technologies by Launching the Only Fully-Integrated Procedural Solution for Neurosurgery

DUBLIN and SAN DIEGO - September 26, 2016 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) clearance of StealthStation® Cranial Software as an aid for deep brain stimulation (DBS) lead placement. The software is fully integrated with Medtronic's latest O-arm® Imaging System, providing clinicians with a complete procedural solution for the planning and placement of DBS leads. The announcement was made at the Congress of Neurological Surgeons (CNS) in San Diego.

With Medtronic's DBS Therapy, a small, pacemaker-like device called a neurostimulator is implanted under the skin of the chest and sends electronic signals to an area in the brain that controls movement. Thin wires - called leads - are implanted in the brain and are connected to the neurostimulator by an extension to enable the signals to reach the source of symptoms. The new StealthStation application, which integrates pre-operative planning, intraoperative imaging and technologies to help guide surgeons during cranial procedures, is designed to improve procedural workflow and allow for DBS lead placement with a high level of accuracy.

"The new StealthStation software works seamlessly with O-arm to give me a single solution for pre-operative planning and real-time 3D imaging of the brain in the OR, and that streamlines my workflow for DBS lead placement," said Dr. Jonathan Carlson, MD, PhD, a neurosurgeon at Providence Spokane Neuroscience Institute in Spokane, Wash. "Now I have the essential information I need in one place, giving me - and my patients - even more confidence in the procedure."

In the past 25 years, the StealthStation system has been used in more than 2.25 million procedures. The O-arm system has been used to help more than 200,000 patients over the past decade. Medtronic DBS neurostimulators have been implanted in over 140,000 patients around the world. Medtronic's full-body MR Conditional Activa® DBS neurostimulators help to reduce some of the movement symptoms of certain neurological disorders including Parkinson's disease and essential tremor.

"We alleviate pain, restore health and extend life by providing informed and integrated neurosurgical procedures to our customers and their patients," said Scott Hutton, vice president and general manager of the Neurosurgery business in Medtronic's Restorative Therapies Group. "And as we transform the way the world treats patients with neurologic disorders, we'll utilize the breadth of our broad Brain Therapies portfolio in new and different ways to bring fully-integrated solutions like this to our customers."

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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