Medtronic News

Medtronic SureTune(TM)3 Earns CE Mark for Deep Brain Stimulation Therapy

Data Presented at the 17th Quadrennial Meeting of the World Society for Stereotactic and Functional Neurosurgery in Berlin

DUBLIN and BERLIN - June 28, 2017 - Medtronic plc (NYSE: MDT) today announced it has received CE (Conformité Européenne) Mark for SureTune(TM)3 software for deep brain stimulation (DBS). SureTune3 provides patient-specific visualization of lead location and simulated volume of neural activation to help physicians make decisions on how to program - or tune - their patient's DBS therapy.

Medtronic DBS therapy has CE Mark approval for diseases such as Parkinson's disease and treats symptoms such as tremor via a surgically implanted medical device, similar to a cardiac pacemaker, that delivers mild electrical pulses to precisely targeted areas of the brain. Electrical stimulation of these areas normalizes the brain circuits that control symptoms. More than 10 million people worldwide are living with Parkinson's disease.1

SureTune3's advancements streamline the physician's workflow and allow StealthStation(TM) surgical planning information to be imported. SureTune3 also contains a 3D deformable atlas to allow physicians to more precisely define anatomical structures, or the exact region in the brain that must be stimulated to alleviate symptoms. The SureTune3 system is fully downloadable with the option to work over a hospital's server so clinical multidisciplinary teams can work flexibly. SureTune3 is currently not approved in the United States.

Data on SureTune3 were presented today by Professor Jens Volkmann, MD, PhD, FEAN, chairman and professor of neurology in the University Clinic of Würzburg at the World Society for Stereotactic and Functional Neurosurgery Meeting currently ongoing in Berlin, Germany. At the congress, he explained how SureTune3 is helping his team with patient management. "With SureTune3, I can integrate all patient data - both planning and procedure - which allows for more personalized management of each case," said Prof. Volkmann. "The improved software allows me to accurately visualize each DBS patient's stimulation settings." Using this approach, clinical programming experience, patient-specific visualization of simulated volume of neural activation and stereotactic planning will form an integrated workflow. Prof. Volkmann also presented research using SureTune3 which may provide further insight into how individual neural activation maps may be used.

Medtronic DBS therapy has CE Mark approval for Parkinson's Disease, Dystonia, Essential Tremor, OCD and Epilepsy and is the only DBS complete portfolio that, under specific conditions, is full body MR conditional and can be left on during an MRI scan.2

"The latest innovations to our SureTune software take the Medtronic DBS solution to the next level: beyond our former innovations of MR conditional devices and beyond the standard visualization of the stimulation field," said Brett Wall, senior vice president and president of the Brain Therapies division, which is part of the Restorative Therapies Group at Medtronic. "Medtronic has been leading the way in DBS therapy for more than 30 years and we will continue to explore and develop new innovations for both the patients and physicians who rely on them."

About Medtronic DBS Therapy

DBS therapy uses a surgically implanted medical device, similar to a cardiac pacemaker, to deliver electrical stimulation to precisely targeted areas of the brain to reduce some of the most disabling motor symptoms associated with Parkinson's disease, including shaking, stiffness and movement difficulties. Medtronic DBS complete portfolio is the first approved for full-body MRI scans under specific conditions.2 Since 1997, more than 150,000 Medtronic DBS devices have been implanted worldwide.

DBS therapy is currently approved in many locations around the world, including the United States and Europe, for the treatment of the disabling symptoms of essential tremor and recent and longer-standing Parkinson's disease. Under a Humanitarian Device Exemption (HDE) in the United States, the therapy can also be used to treat chronic intractable primary dystonia. In Europe, Canada and Australia, DBS therapy is licensed for the treatment of refractory epilepsy. DBS therapy is also approved for the treatment of severe, treatment-resistant obsessive- compulsive disorder in the European Union and Australia, and in the United States under an HDE.

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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1. Parkinson's Disease Foundation: "Who has Parkinson's?" Available at: http://www.pdf.org/parkinson_statistics. Accessed June 21, 2017.

2. Medtronic: MRI guidelines for Medtronic deep brain stimulation systems. Available at: http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@neuro/documents/documents/contrib_228155.pdf. Accessed June 21, 2017.

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