Medtronic News

Medtronic Launches New Clinician Programmer for Deep Brain Stimulation Therapy

FDA Approved, DBS Clinician Programmer Optimizes the Programming Experience By Addressing Day-to-Day Clinical Management Challenges

DUBLIN - June 13, 2018 - Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced that the U.S. Food and Drug Administration (FDA) recently approved its state-of-the art Deep Brain Stimulation (DBS) Clinician Programmer and Activa(TM)Programming Application, which followed closely on the recent achievement of CE Mark this past March. The ActivaProgramming Application has been uniquely designed with the input of over a hundred clinicians from around the world and is managed on the Samsung Galaxy Tab S2 tablet interface. This modern, familiar tool will enhance the clinical programming experience, streamline workflows and provide actionable information to support neurologists and neurosurgeons in their treatment of patients that use the market leading, Medtronic Activa DBS system as therapy for neurological diseases such as Parkinson's disease and Dystonia1.

Globally, approximately 125,000 Medtronic Activadevices are implanted, and this programmer will have an immediate impact to the programming interactions that are a critical part of post-implant care for thousands of patients. The programmer will also enable the upgrade of Activa rechargeable implantable neurostimulators service life to 15 years2, giving patients an additional 6 years until their next device replacement.

"After using the Medtronic Clinician Programmer for the first time, I am impressed with the thoughtfulness put into the user interface," said Dr. Mohammad Maarouf, associate professor, head of the Department of Stereotaxy and Functional Neurosurgery, Cologne Merheim Medical Center, University of Witten/Herdecke, Germany. "Its intuitive, visual interface and task-based workflow makes daily use easier, saving me time to focus on what's most important-my patients."

The Medtronic DBS Clinician Programmer is also approved for use with Medtronic Activa DBS systems that treat medically refractory epilepsy, a therapy that will be launched later this year in the U.S.

"This marks a new era of innovation from the only partner with a 25-year DBS legacy, and paves the way to our vision of the future of DBS with a fully integrated system from planning to programming," said Mike Daly, vice president and general manager of the Brain Modulation business, which is part of the Restorative Therapies Group at Medtronic. "Additionally, this launch serves as evidence of our dedication to the Medtronic Mission and our DBS patients, with the extension of the device longevity of the ActivaRC rechargeable neurostimulator. Now patients can benefit from 6 extra years of therapy between surgeries, giving them even more time to do the things they love."

The European launch of the Medtronic DBS Clinician Programmer is underway, with the U.S. launch expected to take place before the end of July 2018.

For more information on how Deep Brain Stimulation (DBS) Programmer and Activa Programming Application work together, visit MedtronicDBSTherapy's YouTube channel.

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 as adjunctive treatment for several neurological disorders. Medtronic DBS systems are the first and only approved for full-body MRI scans under specific conditions in the United States. Since 1997, more than 150,000 Medtronic DBS devices have been implanted worldwide for movement disorders and other indications.

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 Humanitarian Device Exemption (HDE) approvals in the United States, the therapy can also be used to treat chronic intractable primary dystonia and severe, treatment-resistant obsessive-compulsive disorder.

The FDA-approved indication for epilepsy is as follows: Bilateral anterior thalamic nucleus stimulation using the Medtronic DBS System for Epilepsy is indicated as adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications. The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness in patients who averaged six or more seizures per month over the three most recent months (with no more than 30 days between seizures) and has not been evaluated in patients with less frequent seizures.

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 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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1 Dystonia is approved under Humanitarian Device Exemption (HDE) in the U.S.
2 Activa(TM) RC devices eligible for the service life extension are those that have been successfully interrogated with the Medtronic Tablet Clinician Programmer prior to reaching End of Service (EOS).

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