Medtronic News

Medtronic Receives CE Mark Approval for SenSight™ Directional Lead System for DBS Therapy

This First-of-its-Kind Directional Lead Combines the Benefits of Directionalitywith the Power of Sensing

DUBLIN, March 22, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the CE (Conformité Européenne) Mark for the SenSight™ directional lead system for Deep Brain Stimulation (DBS) therapy as treatment of symptoms associated with movement disorders and epilepsy. DBS is a therapy in which a small pacemaker-like device sends electrical signals through very thin wires, known as "leads," to a targeted area in the brain related to symptoms. The SenSight directional DBS lead system works seamlessly with certain Medtronic neurostimulators, including the recently-approved Percept™ PC neurostimulator. This system will enhance detection of local field potentials (LFPs) and offers directional stimulation to provide individualized and patient-specific data plus additional programming features to tailor therapy for patients.

"This is the only directional lead with built-in sensing capabilities," saidJens Volkmann, M.D., Ph.D., FEAN, chairman and professor of neurology in the University Clinic of Würzburg. "The challenge of DBS is to provide stimulation to a very small brain region only at times, when fluctuating symptoms require treatment. This new technology holds promise for a truly personalized therapy, which we can adapt using the objective data from each patient to inform programming in 'space and time.'"

With collaboration and insights from clinicians, Medtronic engineers have designed every component of the SenSight system to meet customer and patient needs and work seamlessly with the Percept PC neurostimulator to enhance detection of local field potentials (LFPs), which are 1 million times smaller than DBS stimulation pulses.[1]

"The new lead system and supporting technology has been designed with the patient, neurosurgeon and programming neurologist in mind," said Professor Stéphan Chabardès, M.D., Ph.D., Grenoble Alpes University Hospital. "What may seem like small changes to materials, design and technology will actually result in meaningful improvements in things like precisely delivering stimulation to each individual patient, streamlining the surgical procedure, and capturing objective data for more efficient, informed programming."

SenSight directional lead systems were first implanted at the University Clinic of Würzburg and Grenoble Alpes University Hospital, by multi-disciplinary teams on March 17 and 18, and a full launch inWestern Europe will immediately follow today's announcement. The product is currently under review by the U.S. Food and Drug Administration.

"Medtronic has been driving innovation in DBS therapy for more than 25 years and the approval of the SenSight directional lead system in the EU is our latest contribution to the quest for improved patient experiences and clinical outcomes," said Mike Daly, vice president and general manager of Brain Modulation within the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic. "Our commitment to evolving DBS therapy is unwavering and we look forward to introducing additional advancements in 2021 and beyond."

About Medtronic DBS Therapy

DBS therapy is currently approved in many locations around the world, includingthe United States and Europe, for the treatment of recent and longer-standing Parkinson's disease, essential tremor, primary dystonia, the disabling symptoms of epilepsy and treatment-resistant obsessive-compulsive disorder.

Medtronic was the first inthe United States to offer full-body MR Conditional DBS systems for patients to have safe scans anywhere on the body under certain conditions. Since 1987, more than 175,000 Medtronic DBS devices have been implanted worldwide for movement disorders and other indications.

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 90,000 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.

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.

[1.] Neumann WJ, Staub F, Horn A, et al. Deep brain recordings using an implanted pulse generator in Parkinson's disease. *Neuromodulation*. 2016;19(1):20-24.

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