Medtronic News

FDA Approves First-of-its-Kind SenSight™ Directional Lead System for DBS Therapy

The SenSight™ Directional Lead System Was Designed to Enable Precision, Personalization and Enhanced Patient Comfort

DUBLIN, June 7, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the U.S. Food and Drug Administration (FDA) approval and first U.S. implants of the SenSight™ Directional Lead System used for Deep Brain Stimulation (DBS) therapy. SenSight is the first-of-its-kind DBS directional lead that combines the benefits of directionality with the power of sensing, allowing physicians to deliver precise, patient-specific DBS therapy for the treatment of some symptoms associated with movement disorders like Parkinson's disease, dystonia and essential tremor, and medically refractory epilepsy.

"Until now, sensing capability and directional leads have not been available in the same DBS system, so we have had to choose one technology or the other, based on the predicted needs of each patient," said Kelly D. Foote, M.D., professor of neurosurgery at University of Florida. "Now, by coupling this new directional lead with a pulse generator capable of brain sensing, we are excited to be able to offer our patients the synergistic benefits of both technologies. Furthermore, the ability to continuously record brain activity while affected patients go about their daily lives is a powerful research tool that is rapidly improving our understanding of these brain circuitry disorders that diminish the lives of so many people."

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 of certain neurological disorders. A few weeks after surgery, the neurologist will wirelessly adjust the neurostimulator setting to best control symptoms while minimizing potential side effects in a process known as "programming."

For the SenSight directional lead system, Medtronic reimagined how a lead system could be designed, with the patient, neurosurgeon, and programming neurologist in mind. Deliberate choices related to materials and design were made to enhance comfort for patients, allow for more precise stimulation, and streamline the surgical procedure—all while being able to capture objective data for more efficient, informed programming.

SenSight is the first directional, sensing-enabled lead designed to enhance the detection of local field potentials (LFPs), which are brain signals that correlate with the severity of Parkinson's disease symptoms and are 1 million times smaller than DBS stimulation pulses[1]. When paired with the Percept™ PC device, SenSight expands on BrainSense™ technology, enabling clinicians to capture and record enhanced, directional LFP information from the implanted lead. When physicians can detect LFPs, they can correlate these brain signals with stimulation and events capturing medication, symptoms, or side effects to deliver personalized, data-driven therapy and adjust this therapy as patient needs evolve.

"We are learning from studies across the globe as well as daily patient care that knowing the absolute best location to implant a lead can provide both very efficient and efficacious stimulation," said Leonardo Almeida, M.D., assistant professor of neurology at University of Florida. "The more we continue to learn about signals from different diseases and where they are located in relation to where we usually target an implant, the more healthcare teams will be able to refine targeting and accurately plan electrode positioning for each specific patient."

SenSight directional lead systems were first implanted at theUniversity of Florida, by multi-disciplinary teams in early June, and a full launch in the U.S. will immediately follow today's announcement. The product also recently received CE Mark and fully launched in Western Europe in March of 2021.

"We are excited to see the clinical benefits that the new SenSight directional lead system will provide to patients and physicians

in the U.S.," said Mike Daly, vice president and general manager of Brain Modulation within the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic. "For over 25 years, Medtronic has driven discoveries and advancements in DBS therapy and we look forward to continuing to deliver meaningful innovation to the movement disorder and epilepsy patient communities."

About Medtronic DBS Therapy

DBS therapy is currently approved in many locations around the world, including the 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 in the 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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