Medtronic News

Medtronic receives FDA approval for Inceptiv™ closed-loop spinal cord stimulator

Closed-loop sensing capability instantly and automatically adjusts therapy while treating chronic pain

DUBLIN, April 26, 2024 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced that the U.S. Food and Drug Administration (FDA) has approved the Inceptiv™ closed-loop rechargeable spinal cord stimulator (SCS) for the treatment of chronic pain. Inceptiv is the first Medtronic SCS device to offer a closed-loop feature that senses biological signals along the spinal cord and automatically adjusts stimulation in real time, keeping therapy in harmony with the motions of daily life.

"Pain is intensely personal, and stimulation therapy should meet the needs of every patient, moment to moment," said Dr. Krishnan Chakravarthy, M.D., Ph.D., Director of Innovative Pain Treatment Solutions and Surgery Center, VA San Diego Healthcare, and Chairman of the Empower You Chronic Pain Foundation. "Inceptiv listens to what the body is saying and, more quickly than you can blink, it seamlessly adjusts. This represents an important leap forward for the treatment of chronic pain."

Traditional fixed-output SCS devices deliver constant, mild electrical impulses that disrupt pain signals before they reach the brain. As patients go about their daily lives, certain movements such as laughing, bending, or sneezing may result in brief moments of uncomfortable overstimulation. This in turn may lead some patients to turn down their device's stimulation output, resulting in a suboptimal therapy experience.

By contrast, Inceptiv SCS senses biological signals and consistently maintains the physician's prescribed stimulation that is tailored to a patient's needs. Specialized circuitry and a proprietary algorithm detect ECAPs (Evoked Compound Action Potentials), signals generated by the spinal cord in response to electrical stimuli. ECAPs are a direct measure of how much nerve tissue is activated in the spinal cord and can be used to inform real-time adjustments to stimulation. Inceptiv SCS senses the body's response to stimulation† 50 times per second and instantly increases or decreases stimulation to maintain prescribed settings as determined by the physician.

The Inceptiv system delivers additional advantages beyond its closed-loop capability. Inceptiv offers unparalleled access to diagnostic imaging, with 1.5T and 3T full-body MRI access with no power or impedance restrictions.‡ It is the only FDA-approved closed-loop spinal cord stimulator that offers full-body 3T MRI access. Up to 84% of SCS-implanted patients are expected to need at least one MRI within five years of implant.[1] It is the world's smallest and thinnest fully implantable SCS device, designed for patient comfort. In addition, Inceptiv SCS allows the option of multiple types of waveforms, including Medtronic's proprietary DTM™ SCS therapy, which demonstrated an 84% responder rate at 12 months in a large, multicenter randomized controlled trial (RCT).[2,3] Patients with Inceptiv SCS can also access CareGuidePro™, a mobile application and web portal that serves as a virtual guide throughout their Medtronic spinal cord stimulation therapy journey.

"A new era for spinal cord stimulation technology is beginning, and with Inceptiv SCS, Medtronic is at the forefront," said David Carr, vice president and general manager, Pain Interventions within the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic. "For patients dealing with chronic pain, every day is a struggle. They deserve personalized and effective relief, without compromising future access to MRI. They deserve the comfort that the smallest and thinnest device on the market can provide. We are proud to offer the most cutting-edge solution available today with Inceptiv SCS."

Medtronic will initiate the U.S. market launch of Inceptiv in the coming weeks. The system previously earned approvals for sale in Europe and in Japan. For more information, visit Medtronic.com/Inceptiv.

† Sensing signals may not be measurable in all cases

‡ Under certain conditions. Refer to product labeling for full list of conditions.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin,Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com, and follow Medtronic on LinkedIn.

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] Desai, Mehul J., et al. "The rate of magnetic resonance imaging in patients with spinal cord stimulation." Spine, vol. 40, no. 9, 2015, https://doi.org/10.1097/brs.0000000000000805.

[2] Fishman, M, Cordner, H, Justiz, R, Provenzano, D, Merrell, C, Shah, B, et al. Twelve-Month results from multicenter, open-label, randomized controlled clinical trial comparing differential target multiplexed spinal cord stimulation and traditional spinal cord stimulation in subjects with chronic intractable back pain and leg pain. Pain Pract. 2021; 21: 912– 923

[3] DTM™ SCS outcomes demonstrated using open-loop SCS

Contacts:

Jeff Trauring	Ryan Weispfenning
Public Relations	Investor Relations
+1-763-505-0159	+1-763-505-4626

SOURCE Medtronic plc

Additional assets available online: Photos (1) Video (1)

https://news.medtronic.com/2024-04-26-Medtronic-receives-FDA-approval-for-Inceptiv-TM-closed-loop-spinal-cord-stimulator