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Medtronic receives landmark FDA approval for Asleep Deep Brain Stimulation surgery

First ever FDA approval provides more options to meet patients' personalized needs, including those with Parkinson's disease

Medtronic plc, a global leader in healthcare technology, has received U.S. Food and Drug Administration (FDA) approval of Asleep Deep Brain Stimulation (DBS) surgery for people with Parkinson's and people with essential tremor. Medtronic is the first and only company to receive FDA approval to offer DBS surgery while a patient is asleep (under general anesthesia) or awake.

"This is a significant advancement in our surgical offering, providing another safe and effective option for patients considering DBS," said Amaza Reitmeier, vice president and general manager, Brain Modulation within the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic. "This approval underscores our dedication to continuous innovation to address the needs of patients and healthcare providers."

Several studies have published safety and efficacy data on Asleep DBS and compared the two different DBS modalities: Asleep DBS and Awake DBS. Clinical data confirms people with Parkinson's Disease achieve a comparable improvement in certain motor symptoms whether having Asleep DBS or Awake DBS surgery[1-2]. Recent studies also show Asleep DBS procedures maintain patient safety and may foster surgery efficiencies, shortening procedure time compared to Awake DBS[1-4].

"Asleep DBS offers a safe, comfortable and less stressful experience for patients who are apprehensive about the surgery," said Francisco Ponce, M.D., neurosurgeon and chief of stereotactic and functional neurosurgery at The Barrow Neurological Institute. "Whether performed asleep or awake, DBS is proven to reduce motor symptoms in movement disorders like Parkinson's."

DBS uses a surgically implanted medical device, similar to a cardiac pacemaker. Medtronic Percept™ neurostimulators transmit electrical signals via slender wires to specific brain targets affected by debilitating neurological disorders. The Medtronic Percept™ family of neurostimulators is the first and only DBS system with sensing, directionality, and advanced programming. Medtronic's DBS system with BrainSense™ technology captures and records brain signals, equipping healthcare providers with valuable data and insights needed to tailor therapy to patients' individual needs.

Since 1987, Medtronic has served over 180 thousand people with movement disorders and other indications in more than 70 countries with its life-changing DBS therapy[5].

Patients should discuss DBS therapy and surgical options with their healthcare provider to determine what best serves their individual treatment needs and preferences.

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 more than 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, visit www.Medtronic.com and follow us 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 U.S. Securities and Exchange Commission. Actual results may differ materially from anticipated results.

References

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