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Medtronic earns FDA approval for expanded deep brain stimulation labeling for Dystonia

Now supported with effectiveness evidence, Medtronic DBS is the first and only U.S. FDA approved system to treat Dystonia symptoms

Medtronic plc, a global leader in healthcare technology, has received U.S. Food and Drug Administration (FDA) approval of its expanded Dystonia clinical labeling for Medtronic Deep Brain Stimulation (DBS). This approval reflects a shift from Humanitarian Device Exemption (HDE) status to full effectiveness labeling supported by clinical evidence, marking an important milestone for patients and clinicians.

Dystonia is the third most common movement disorder affecting as many as 250,000 people in the U.S., and no cures and no treatments exist to reverse the course of the disorder.[1] Dystonia is characterized by involuntary muscle contractions that force certain parts of the body into repetitive, twisting movements or painful postures that may interfere with everyday functions like walking, sleeping, eating, and talking.

For more than 20 years, Medtronic has advanced care for people with Dystonia, pioneering DBS for Dystonia since 2003 as a humanitarian use device (HUD) under an HDE. The labeling approval includes management of chronic, intractable primary dystonia, including generalized dystonia, segmental dystonia of the head and neck, and cervical dystonia for adults and for primary generalized dystonia in patients ages 12 or older. The expanded clinical labeling also provides physicians and patients with stronger evidence, clearer treatment pathways, and more predictable access.

“Medtronic DBS therapy provides people with Dystonia a safe and effective non-destructive treatment that physicians can tailor with BrainSense™ technology, offering recharge and recharge-free options and the broadest conditional MRI access,” said Ashwini Sharan, chief medical officer, Medtronic Neuromodulation, which is part of the Medtronic Neuroscience Portfolio. “The clinical data show meaningful improvements in dystonia symptoms and quality of life in adult patients. DBS improved motor, disability, and severity scores across both groups, and reduced pain in adult patients – outcomes that can be truly life-changing.”

Since 1987, Medtronic has served more than 200,000 patients with movement disorders and other indications in more than 70 countries with its life-changing DBS therapy[2]. The expanded Dystonia clinical labeling builds upon decades of partnership with clinicians, ongoing investment in evidence generation, and Medtronic’s commitment to improving outcomes for people living with complex movement disorders.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, 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.

Medtronic DBS therapy is approved for five indications: Parkinson's disease, essential tremor, dystonia, obsessive-compulsive disorder* (OCD), and epilepsy. Indications vary by product. Refer to product labeling for details.

***Humanitarian device**: The effectiveness of these devices for the treatment of obsessive-compulsive disorder has not been demonstrated.

References

1. American Association of Neurological Surgeons. Dystonia. April 15, 2024. Accessed November 25, 2025. Available at: www.aans.org/patients/conditions-treatments/dystonia
2. Medtronic data on file.

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