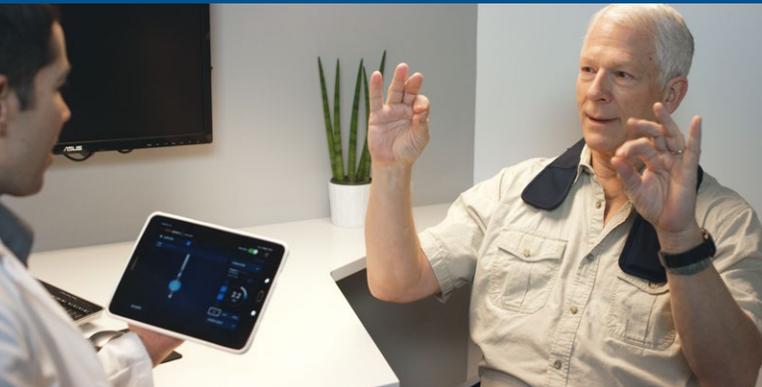


Whether you're considering deep-brain stimulation (DBS) therapy, or you're already using it, you're smart to be careful about whom you trust with your health. As a global leader in medical technology, we continually seek ways to improve the lives of patients — and that's why you can be assured our DBS technology is backed by decades of research, innovation, and experience.



Medtronic DBS Therapy for Parkinson's Disease, Tremor, Dystonia, and Epilepsy: Patients should always discuss the potential risks and benefits with a physician.

Medtronic DBS systems are MR Conditional which means they are marked to indicate they are safe in the MR environment as long as certain conditions are met. Read and fully understand the MRI Guidelines for Medtronic deep brain stimulation systems before conducting the MRI examination. Always obtain the latest MRI guidelines at www.medtronic.com/mri or contact Medtronic at (1-800)-328-0810 for a copy. Also review current MRI manufacturer labeling before conducting the MRI.

Indications:

Medtronic DBS Therapy for Parkinson's Disease: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson's Disease is indicated for adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson's disease of at least 4 years' duration that are not adequately controlled with medication, including motor complications of recent onset (from 4 months to 3 years) or motor complications of longer-standing duration.

Medtronic DBS Therapy for Tremor: Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) using Medtronic DBS Therapy for Tremor is indicated for the suppression of tremor in the upper extremity. The system is intended for patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

Medtronic DBS Therapy for Dystonia*: Unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Dystonia is indicated as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients seven years of age or above.

Medtronic Reclaim™ DBS Therapy for Obsessive-Compulsive Disorder*: Bilateral stimulation of the anterior limb of the internal capsule, AIC, using Medtronic Reclaim™ DBS Therapy is indicated as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs).

Medtronic DBS Therapy for Epilepsy: Bilateral stimulation of the anterior nucleus of the thalamus (ANT) using the Medtronic DBS System for Epilepsy is indicated as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications.

The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures.

Contraindications/Warnings/Precautions: Use of a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area is contraindicated for patients with the following implanted DBS systems or system components: Soletra™ Model 7426 Neurostimulator; Kinetra™ Model 7428 Neurostimulator; Activa™ SC Model 37602 Neurostimulator; and Model 64001 and Model 64002 pocket adaptors. Tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death, can occur if a contraindicated MRI scan is performed on a patient with these DBS systems. Other conditions that may cause excessive heating at the lead electrodes which can result in serious injury or death, or that may cause device damage, include: neurostimulator implant location other than pectoral and abdominal regions; unapproved MRI parameters; partial system explants ("abandoned systems"); misidentification of neurostimulator model numbers; and broken conductor wires (in the lead, extension or pocket adaptor). Active scan time >30 minutes within a 90 minute window, elevated core body temperature due to fever or use of blankets, or patient position within the MRI bore other than prone or supine, may cause excessive tissue heating. Leaving therapy on during the scan could increase the potential for uncomfortable, unintended stimulation. Failure to cap a lead-only system may result in unintended stimulation during the scan. External control devices such as the patient programmer, recharger, external neurostimulator and clinician programmer, are MR Unsafe and not allowed in the MRI scanner (magnet) room.

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

USA Rx only Rev 08/18

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Rx only. Refer to product instruction manual/
package insert for instructions, warnings,
precautions and contraindications. © 2019
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UC20200534 EN 08.2019

THE MEDTRONIC DIFFERENCE

Bringing decades
of experience
in improving lives
through DBS therapy



Medtronic
Further, Together

LEADERS IN HELPING DBS PATIENTS LEAD FULLER LIVES

Our DBS technology was designed to relieve some of the symptoms of movement-related disorders. We started developing DBS therapy in 1987 and continue to be the leader in this area with more than **150,000** Medtronic DBS devices implanted in patients worldwide.

Today, Medtronic DBS therapy is indicated for the following conditions:

- Parkinson's disease
- Essential tremor
- Epilepsy
- Dystonia*
- Obsessive-compulsive disorder (OCD)**

LEADERS IN MRI ACCESSIBILITY FOR DBS PATIENTS

Approximately seven out of ten DBS-eligible patients with movement disorders may need an MRI within ten years of receiving their device.¹ That's why we developed the first full-body MR Conditional DBS system*** — which gives you access to this important diagnostic imaging tool.

Access to scans anywhere on the body

Other DBS systems are limited to head-only MRI or worse, no MRI at all. Our full-body MR Conditional DBS systems means it's safe to have scans anywhere on the body with some of our devices under certain conditions. (Including the requirement that your system must contain only Medtronic components. Systems comprised of components from multiple manufacturers are not MRI safe.)

Uninterrupted therapy

Unlike other manufacturers, some of our devices can remain on during MRI, when programmed to certain settings, so your DBS therapy will not be interrupted. This may also improve MRI image quality, if it reduces movement symptoms related to your movement disorder.

*Humanitarian Device - Authorized by Federal Law as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients seven years of age or above. The effectiveness of the devices for treating these conditions has not been demonstrated.

**Humanitarian Device: Authorized by Federal (U.S.A.) law for use as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The effectiveness of this device for this use has not been demonstrated.

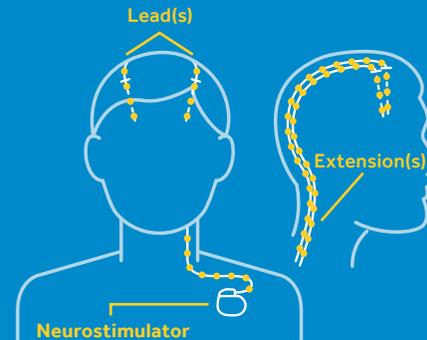
***Medtronic DBS systems are MR Conditional, which means they are safe for MRI scans only under certain conditions. If the conditions are not met, the MRI could cause tissue heating, especially at the implanted lead(s) in the brain, which may result in serious and permanent injury or death. Before having an MRI, always talk with the doctor who manages your DBS Therapy to determine your eligibility and discuss potential benefits and risks of MRI. For further information, please call Medtronic at 1-800-328-0810.

¹ Falowski, S, Safriel Y, Ryan, M et al. The Rate of Magnetic Resonance Imaging in Patients with Deep Brain Stimulation. *Stereotactic and Functional Neurosurgery*. 2016; 94:147-153.

ONLY MEDTRONIC HAS DECADES OF DBS THERAPY EXPERIENCE.

A COMPLETE SYSTEM THAT BRINGS COMPLETE BENEFITS

Medtronic DBS Therapy is a system that works together to deliver therapy to control your symptoms. This includes lead(s), extension(s), and the device (neurostimulator) itself.



It is important that all components — including a new battery — are always from Medtronic.

With a complete Medtronic system, you get:

- **Warranty coverage:** With a full Medtronic system, you can have peace of mind knowing your warranty will remain intact. Replacing your Medtronic battery with a battery from a different manufacturer will void the warranty.
- **World-class support:** While we want to ensure you are getting the most out of your therapy, Medtronic cannot provide support for patients who no longer have full Medtronic systems.
- **A system backed by safety and clinical evidence:** Your safety is our priority, which is why Medtronic DBS Therapy is backed by decades of research and the highest level of clinical evidence. Medtronic leads and extensions paired with non-Medtronic batteries do not have the same level of evidence to ensure safety.
- **Access to MRI Scans anywhere on the body:** For you to safely receive an MRI scan, you must have a complete Medtronic DBS system.

ONGOING SUPPORT FOR EVERY STEP OF YOUR DBS JOURNEY

Still deciding if DBS is right for you?

We can connect you to people who have DBS, nurses who specialize in it, and other resources such as brochures, videos, and more. Visit medtronic.com/DBS or ask your local Medtronic representative for information.

Already have DBS and have some questions?

Our representatives are located all over the United States so you're never far from someone who can help. Contact your local representative or call our Patient Services Team at 800-510-6735 between 8 a.m. and 5 p.m. Central time.

Let us know how we can help you.

