TREATMENT AS UNIQUE AS YOU

PERCEPT™ PC NEUROSTIMULATOR
WITH **BRAINSENSE™** TECHNOLOGY

FOR DBS THERAPY

Medtronic

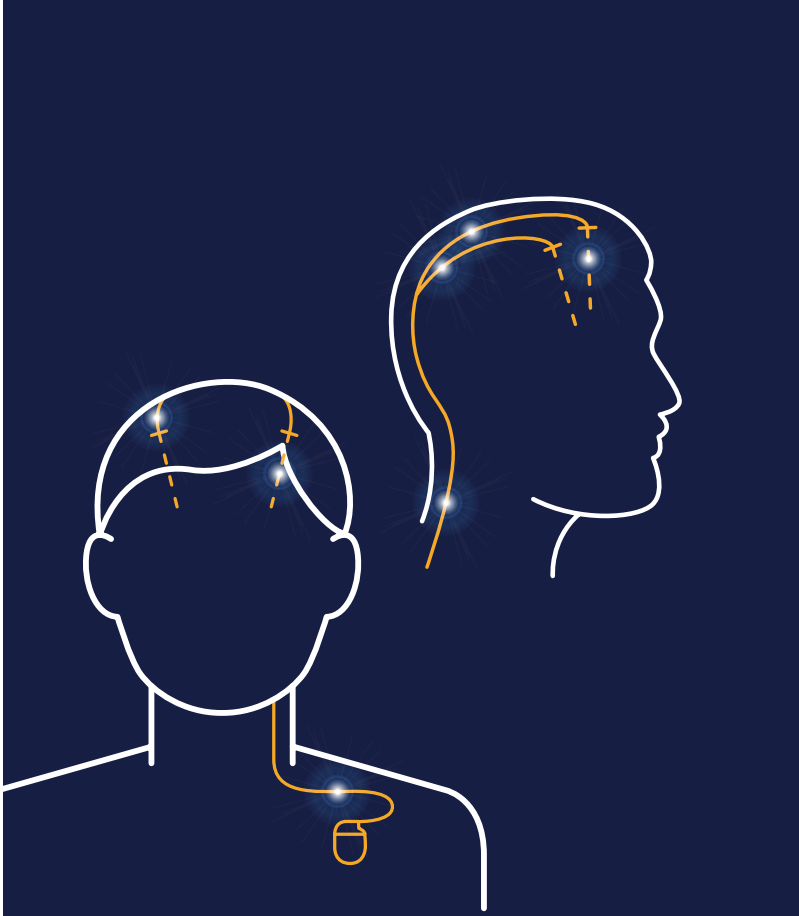
LIVING WELL WITH DBS THERAPY

Medtronic is dedicated to helping people live their best lives. And for decades we've partnered with doctors to help alleviate pain, restore health, and extend life. Our new deep brain stimulation (DBS) device continues that mission.

For many people with Parkinson's disease, essential tremor, dystonia*, obsessive compulsive disorder* (OCD), or epilepsy, DBS may make a difference when even small tasks have become challenging. **DBS has helped some people stay independent and enabled them to keep doing the activities they love.**

DBS uses a small pacemaker-like device, placed under the skin of the chest, to send electrical signals through very thin wires (leads) to an area in the brain related to the symptoms of your condition.

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



Essential tremor indication is unilateral only

PERSONALIZE YOUR THERAPY — GET A SENSE OF WHAT'S POSSIBLE

BRAINSENSE™ TECHNOLOGY

Our new device, the Percept™ PC neurostimulator, features BrainSense™ technology. This innovative technology captures brain signal data direct from your implanted leads. It then stores the data, so your physician can access it.*

Using this data, your physician may adjust your settings — personalizing your therapy for the best possible outcome. **

As new features are added to the technology, you may not need to get a new device. They can simply be applied to your neurostimulator through software on your physician's clinician programmer. This can enable you to continue to receive the latest innovations from Medtronic.

DIGITAL DIARY

The neurostimulator is used with an intuitive patient programmer that enables you to track your events, such as when you took medication. It can eliminate the need to carry a notebook or diary.

Your doctor can see the events you've been logging at your next appointment via the clinician's programmer. This information may help your doctor deliver treatment that's as unique as you.

*Signal may not be present or measurable in all patients.
**Clinical benefits of brain sensing have not been established.

DBS CLINICIAN PROGRAMMER

DBS PATIENT PROGRAMMER

ENGINEERED FOR YOUR COMFORT

Percept™ PC neurostimulator is designed to provide you with more comfort.

SLEEK, CURVED DESIGN

20%
SMALLER THAN PREVIOUS-GENERATION ACTIVA™ PC*

20%
THINNER THAN PREVIOUS-GENERATION ACTIVA™ PC**

*In overall device volume
**Refers to case thickness

DESIGNED TO LAST LONGER — AND KEEP YOU INFORMED

The Percept™ PC neurostimulator is smaller and features a battery that lasts longer.*

You can check how much battery life is left on your device at any time, so you and your doctor will know when to schedule an appointment to replace your neurostimulator. The battery information is available on the easy-to-use patient programmer as well as on your clinician's programmer.

REAL-TIME ESTIMATION OF BATTERY LIFE**

>5 YEARS
BATTERY LIFE***

*When compared to the previous generation Activa™ PC device
**Based on current actual battery level and therapy settings from last seven days
***For median energy use in DBS for patients with Parkinson's disease, with moderate (up to 2 months per year) BrainSense™ technology usage

YOU DESERVE OPTIONS — NOW AND IN THE FUTURE

Medtronic is committed to ensuring you have safe access to cutting-edge diagnostic imaging technology. That includes MRI. MRI is short for magnetic resonance imaging, and it's a non-invasive way to examine organs, tissues, and the skeletal system. MRI is used to diagnose causes of common medical conditions of the heart, brain, and spine. You may need an MRI in the future. **Percept™ PC neurostimulator is the first and only device to have full-body MR Conditional* access anywhere on the body for both 1.5T and 3T MRI scans.**

Approximately **7 out of 10** DBS-eligible patients with movement disorders may need an MRI within **10 years** of receiving their device.[1]

*Medtronic DBS systems are MR Conditional and safe in the MR environment as long as certain conditions are met. If the conditions are not met, a significant risk is tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death. Refer to the MRI Guidelines for Medtronic Deep Brain Stimulation Systems for a complete list of conditions: http://professional.medtronic.com/mri.

1. Falowski S, Safriel Y, Ryan MP, Hargens L. The rate of magnetic resonance imaging in patients with deep brain stimulation. *Stereotact Funct Neurosurg*. 2016; 94(3):147-153.

EXPANDED ACCESS TO MRI — NOW EVEN EASIER

Getting an MRI is now even easier for you. Simply check your patient programmer for compatibility and put the device into MRI mode. Because your patient device can perform a check before your scan, you may not need to schedule a doctor visit, and **you may even be able to leave your stimulation on during the MRI scan**.

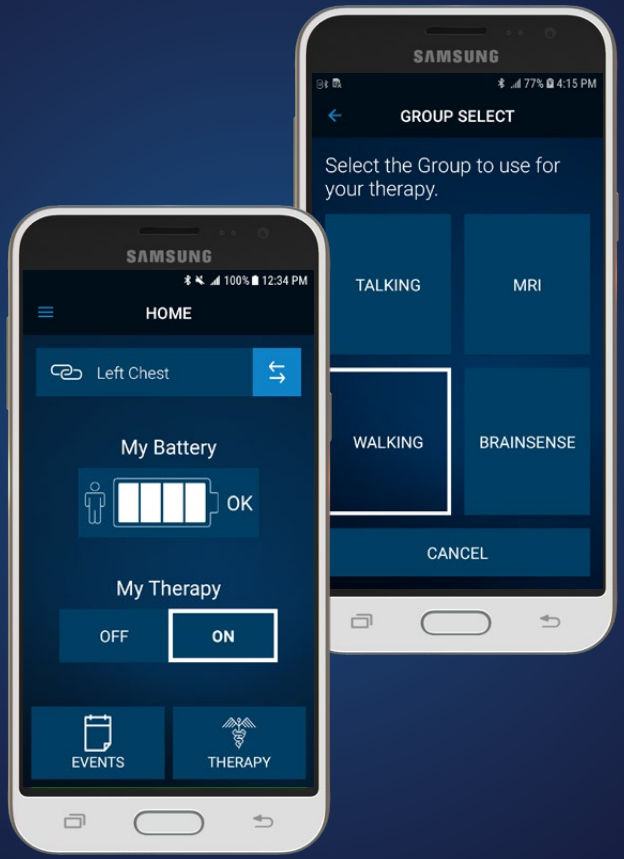
SIMPLE. PERSONAL. SMART.

The DBS patient programmer is enhanced so you can more easily and conveniently manage your therapy.

EASY-TO-ADJUST STIMULATION OPTIONS

You may also be able to adjust therapy throughout your day with options programmed by your doctor.

Your doctor can create preset stimulation for up to four types of groups — such as walking, sleeping, and talking. Simply choose which preset stimulation you want for the activity you're doing.



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

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 use in 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 DBS Therapy for Obsessive-Compulsive Disorder*: The Medtronic Reclaim™ DBS Therapy is indicated for bilateral stimulation of the anterior limb of the internal capsule, AIC, 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: Medtronic DBS Therapy is contraindicated (not allowed) for patients who are unable to properly operate the neurostimulator and, for Parkinson's disease and Essential Tremor, patients for whom test stimulation is unsuccessful. The following procedures are contraindicated for patients with DBS systems: diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy), which can cause neurostimulation system or tissue damage and can result in severe injury or death; Transcranial Magnetic Stimulation (TMS); and certain MRI procedures using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area if they have an implanted Soletra™ Model 7426 Neurostimulator, Kinetra™ Model 7428 Neurostimulator, Activa™ SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

Warnings: There is a potential risk of brain tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths and, for Parkinson's disease and Essential Tremor, a potential risk to drive tremor (cause tremor to occur at the same frequency as the programmed frequency) using low frequency settings. Extreme care should be used with lead implantation in patients with an increased risk of intracranial hemorrhage. Sources of electromagnetic interference (EMI) may cause device damage or patient injury. Theft detectors and security screening devices may cause stimulation to switch ON or OFF and may cause some patients to experience a momentary increase in perceived stimulation. The DBS System may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious and permanent injury including coma, paralysis, 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). The safety of electroconvulsive therapy (ECT) in patients receiving DBS Therapy has not been established. Abrupt cessation of stimulation should be avoided as it may cause a return of disease symptoms, in some cases with intensity greater than was experienced prior to system implant ("rebound" effect). Onset of status dystonicus, which may be life-threatening, may occur in dystonia patients during ongoing or loss of DBS therapy.

For Epilepsy, cessation, reduction, or initiation of stimulation may potentially lead to an increase in seizure frequency, severity, and new types of seizures. For Epilepsy, symptoms may return with an intensity greater than was experienced prior to system implant, including the potential for status epilepticus. For Parkinson's disease or essential tremor, new onset or worsening depression, suicidal ideation, suicide attempts, and suicide have been reported. For Dystonia or Epilepsy, depression, suicidal ideations and suicide have been reported, although no direct cause-and-effect relationship has been established. For Epilepsy, preoperatively, assess patients for depression and carefully balance this risk with the potential clinical benefit. Postoperatively, monitor patients closely for new or changing symptoms of depression and manage these systems appropriately. Patients should be monitored for memory impairment. Memory impairment has been reported in patients receiving Medtronic DBS Therapy for Epilepsy, although no direct-cause-and effect relationship has been established. The consequences of failing to monitor patients are unknown. When stimulation is adjusted, monitor patients for new or increased seizures, tingling sensation, change in mood, or confusion. For Obsessive-Compulsive Disorder, patients should be monitored for at least 30 minutes after a programming session for side effects, including: autonomic effects (e.g., facial flushing, facial muscle contractions, or increased heart rate), hypomania, increased disease symptoms, and sensations such as tingling, smell, or taste. For Obsessive-Compulsive Disorder, during treatment, patients should be monitored closely for increased depression, anxiety, suicidality, and worsening of obsessive-compulsive symptoms.

Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive or repetitive bending, twisting, or stretching can cause component fracture or dislodgement that may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Patients should avoid manipulating the implanted system components or burr hole site as this can result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site. Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA) as this could damage the neurostimulation system, before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their clinician.

Patients using a rechargeable neurostimulator for Parkinson's disease or essential tremor must not place the recharger over a medical device with which it is not compatible (eg, other neurostimulators, pacemaker, defibrillator, insulin pump). The recharger could accidentally change the operation of the medical device, which could result in a medical emergency. Patients should not use the recharger on an unhealed wound as the recharger system is not sterile and contact with the wound may cause an infection.

Warning For Obsessive-Compulsive Disorder:

Electroconvulsive Therapy (ECT) – The safety of ECT in patients who have an implanted deep brain stimulation (DBS) system has not been established. Induced electrical currents may interfere with the intended stimulation or damage the neurostimulation system components resulting in loss of therapeutic effect, clinically significant undesirable stimulation effects, additional surgery for system explantation and replacement, or neurological injury.

Precautions: Loss of coordination in activities such as swimming may occur. For Obsessive-Compulsive Disorder, the safety of somatic psychiatric therapies using equipment that generates electromagnetic interference (e.g., vagus nerve stimulation) has not been established. Patients using a rechargeable neurostimulator for Parkinson's disease or essential tremor should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist.

Adverse Events: Adverse events related to the therapy, device, or procedure can include intracranial hemorrhage, cerebral infarction, CSF leak, pneumocephalus, seizures, surgical site complications (including pain, infection, dehiscence, erosion, seroma, and hematoma), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device complications (including lead fracture and device migration) that may require revision or explant, extension fibrosis (tightening or bowstringing), new or exacerbation of neurological symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), psychiatric and behavioral disorders (including psychosis and abnormal thinking), cough, shocking or jolting sensation, ineffective therapy, and weight gain or loss.

For Parkinson's disease or essential tremor, safety and effectiveness has not been established for patients with neurological disease other than idiopathic Parkinson's disease or Essential Tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression, patients who are pregnant, or patients under 18 years. For Essential Tremor, safety and effectiveness has not been established for bilateral stimulation or for patients over 80 years of age. For Dystonia, safety of this device for use in the treatment of dystonia with or without other accompanying conditions (e.g., previous surgical ablation procedure, dementia, coagulopathies, or moderate to severe depression, or for patient who are pregnant) has not been established. Age of implant is suggested to be that at which brain growth is approximately 90% complete or above. For Epilepsy, the safety and effectiveness of this therapy has not been established for patients without partial-onset seizures, patients who are pregnant or nursing, patients under the age of 18 years, patients with coagulopathies, and patients older than 65 years. For Obsessive-Compulsive Disorder, the safety and probable benefit of this therapy has not been established for patients with: Tourette's syndrome, OCD with a subclassification of hoarding, previous surgical ablation (e.g., capsulotomy), dementia, coagulopathies or who are on anticoagulant therapy, neurological disorders, and other serious medical illness including cardiovascular disease, renal or hepatic failure, and diabetes mellitus. In addition, the safety and probable benefit has not been established for these patients: those whose diagnosis of OCD is documented to be less than 5 years duration or whose YBOCS score is less than 30, who have not completed a minimum of 3 adequate trials of first and/or second line medications with augmentation, who have not attempted to complete an adequate trial of cognitive behavior therapy (CBT), who are pregnant, who are under the age of 18 years, and who do not have comorbid depression and anxiety. Physicians should carefully consider the potential risks of implanting the Reclaim DBS System in patients with comorbid psychiatric disorders (e.g., bipolar, body dysmorphic, psychotic) as the Reclaim DBS System may aggravate the symptoms.

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

USA Rx only Rev 02/20

A global leader in medical technology, Medtronic continually seeks ways to improve the lives of patients. So you can be assured our DBS technology is backed by decades of research, innovation, and experience. We began developing DBS therapy in 1987, and our devices have been implanted in more than 175,000 patients worldwide.

Learn more about Percept™ PC neurostimulator with BrainSense™ technology at **medtronic.com/DBS**.

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