GET A SENSE OF WHAT'S POSSIBLE

SEE DBS FROM A NEW PERSPECTIVE

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

FOR DBS THERAPY

Medtronic

Further, Together

With the only commercially available sensing technology in deep brain stimulation (DBS), the Percept™ PC device ushers in a new era of DBS therapy for Parkinson's disease, essential tremor, dystonia,* obsessive-compulsive disorder (OCD),* and epilepsy.

Based on decades of commitment to DBS, Medtronic is redefining what's possible with the Percept™ PC device. It enables you to personalize therapy based on objective data and brings forth several leading-edge innovations in a modern, ergonomic, easy-to-use solution that you and your patients want.

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

BRAINSENSE™
TECHNOLOGY

3T
MR CONDITIONAL

SMART
BATTERY

ENGAGING,
INTUITIVE
PROGRAMMING

UNPRECEDENTED INSIGHTS — INSIDE AND OUTSIDE THE CLINIC

The Percept™ PC device features BrainSense™ technology, designed to capture brain signals (local field potential, or LFP) using the implanted DBS lead. These signals can be recorded simultaneously while delivering therapeutic stimulation, inside and outside the clinic.*

You can correlate these brain signals with stimulation and events capturing medication, symptoms, or side effects — to deliver personalized, data-driven treatment and adjust as patient needs evolve.**

The Percept™ PC device uses embedded software for patented processing and analysis of brain signals in real time. These signals are stored on the device and can be viewed using the intuitive clinician programmer. They can also be exported in JSON, a machine-readable format, for offline data processing.

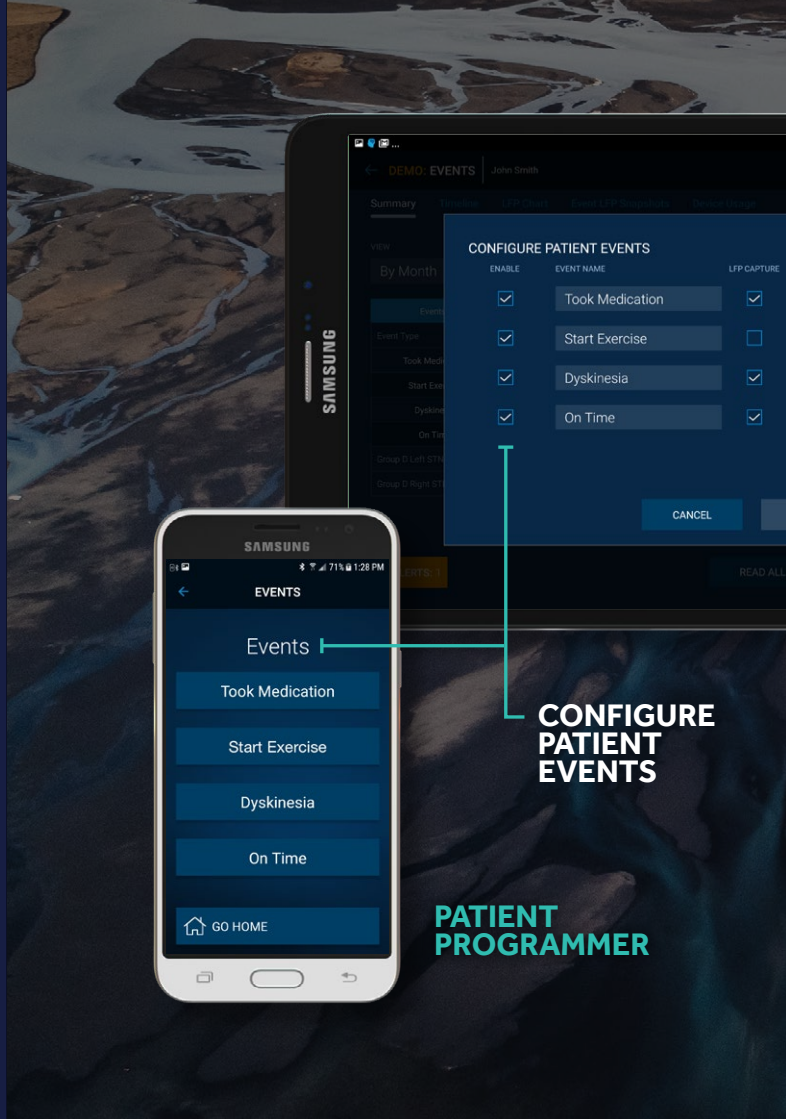
*Signals may not be present or measurable in all patients.
**Clinical benefits of brain sensing have not been established.

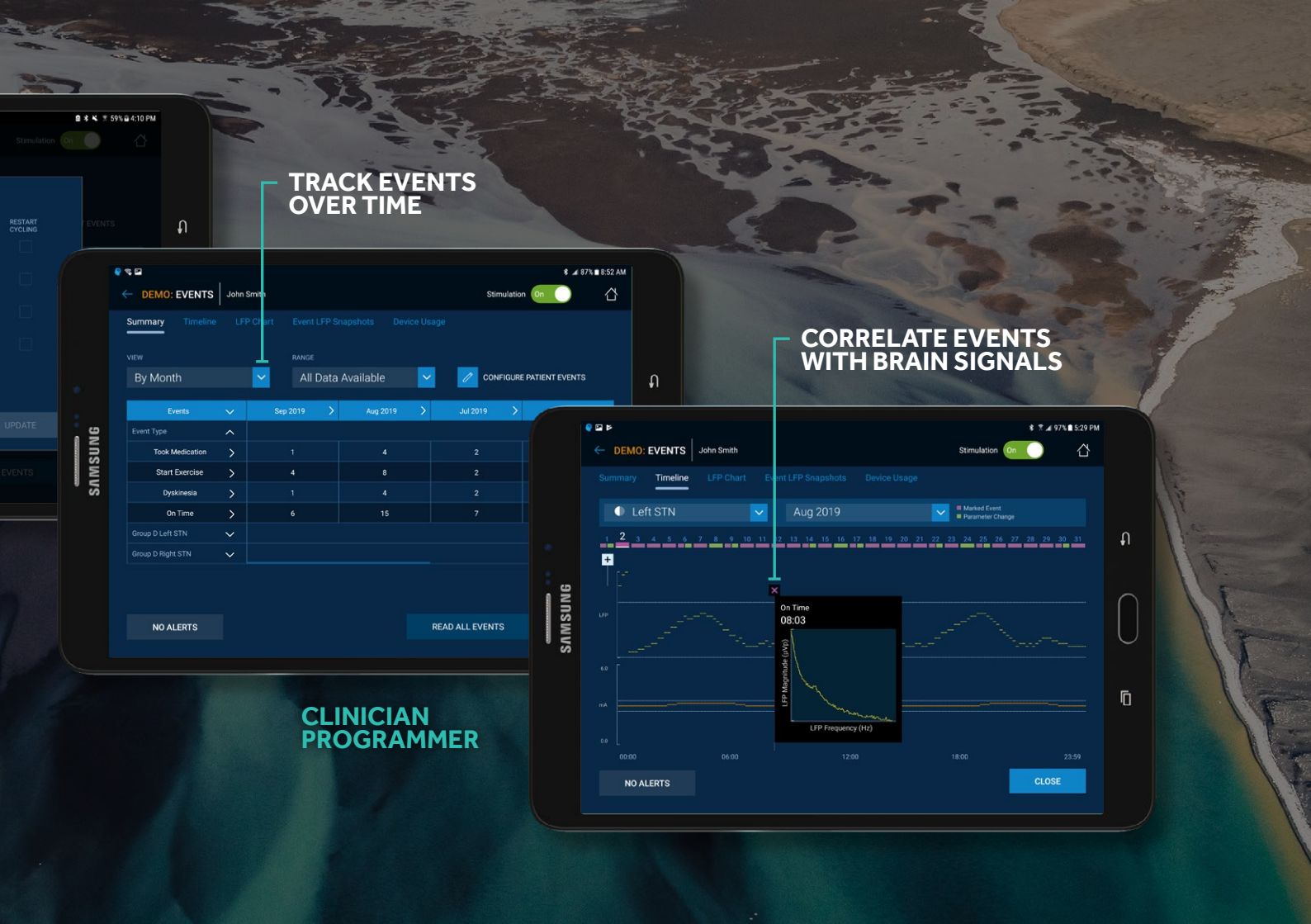
BRAINSENSE™ TECHNOLOGY IS INFORMED BY 10+ YEARS OF SENSING RESEARCH

EMPOWER YOUR PATIENTS

You can configure up to four custom events — such as medication adherence, side effects, and experiencing on/off state — that your patients can conveniently capture digitally using the intuitive patient programmer.

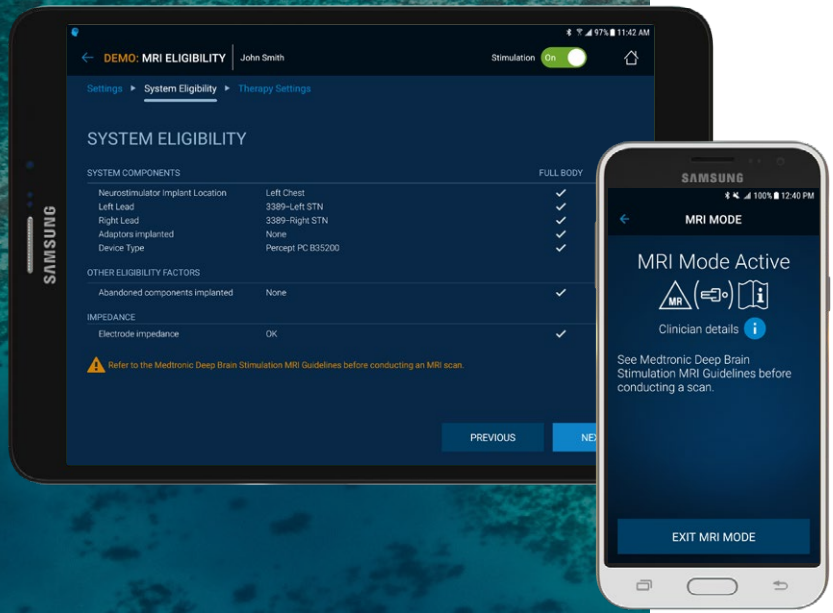
You can then view the events they've marked at their next visit right on your clinician programmer. These details can help you identify trends, and you have the option of correlating the events with brain signals.





CLINICIAN
PROGRAMMER

THE ONLY 3T AND 1.5T MR CONDITIONAL* DBS SYSTEM

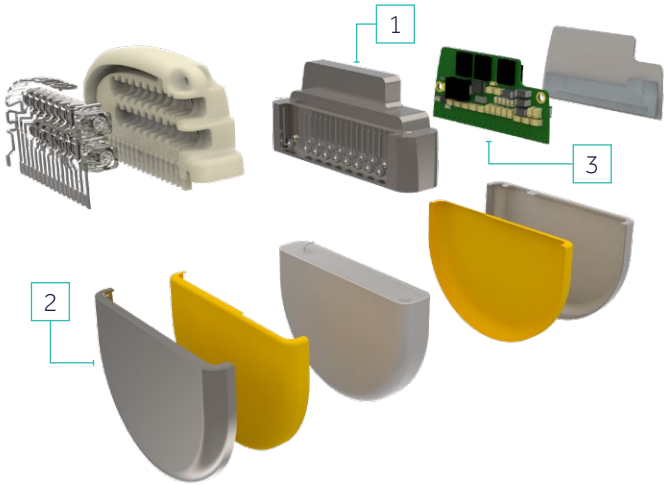


The Percept™ PC device adds full-body 3T MRI eligibility for DBS patients, so they may benefit from the cutting-edge medical imaging when they need it. Plus, using a bipolar therapy group allows therapy to be ON during an MRI scan.

Now clinicians can use **MRI Eligibility** workflow on the clinician programmer to check MRI eligibility, generate an eligibility report, and place a patient's device into the appropriate state for an MRI exam.

Patients can use **MRI Mode** on their patient programmer for a streamlined path to conditionally safe MRI scans, without needing to visit the clinician managing their DBS therapy.

*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.



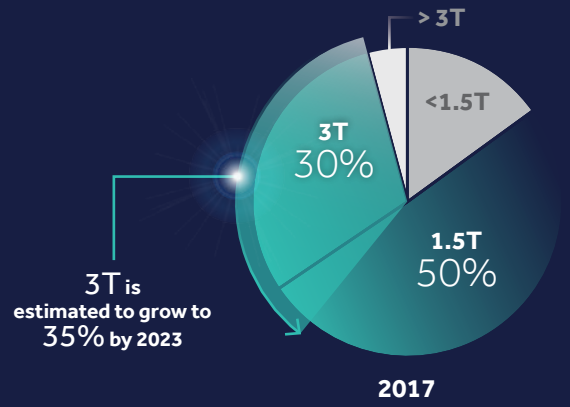
1 **Filtered feedthrough technology** mitigates radiofrequency (RF) energy from entering and damaging the device.

2 **Minimal ferrous material** reduces potential for unwanted device and lead movement caused by magnetic pull.

3 **Protection diodes** help prevent failure when exposed to electromagnetic interference.

The expanded MRI eligibility of the Percept™ PC device supports the most prevalent and fastest-growing MRI modalities.

Estimated North American MRI Systems Market:



BCC Research Report HLC078D: Medical Magnetic Resonance Imaging (MRI) Technologies and Global Markets (July 2018).

ENGINEERED FOR **PATIENT COMFORT**

Ergonomically designed, the Percept™ PC device offers enhanced comfort for patients.

20% **SMALLER* THAN ACTIVA™ PC DEVICE**

20% **THINNER** THAN ACTIVA™ PC DEVICE**

SLEEK, CURVED DESIGN

*In overall device volume
**Refers to case thickness

DESIGNED TO LAST LONGER — AND KEEP YOU INFORMED

The Percept™ PC device is smaller, yet offers improved longevity. This is due to a synergistic combination of a new proprietary battery composition, which allows for higher-energy-density packaging, and efficient low-power electronics.

The smart battery technology allows real-time prediction of remaining battery life,* so you and your patients can maximize available battery capacity and have elevated peace of mind while planning for device replacement.

>5 YEARS
BATTERY LIFE**

>15% INCREASE
IN PROJECTED LONGEVITY OVER 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
***For median energy use in DBS for patients with Parkinson's disease, with equivalent settings and no BrainSense™ technology usage

INSIGHTFUL. INTUITIVE. SECURE.

The DBS clinician programmer is now even more feature-rich and ready to streamline your programming session with the information you need, quickly and intuitively.

- High-contrast touchscreen interface
- Enhanced task-based workflows
- Intuitive, patient-specific customization options
- Expanded reporting and export functionality

DATA SECURITY
The clinician and patient programmers use multi-layer encryption and proprietary wireless telemetry in a worldwide-licensed frequency band to ensure information is exchanged in a secure, confidential manner.

SIMPLE.
PERSONAL.
SMART.

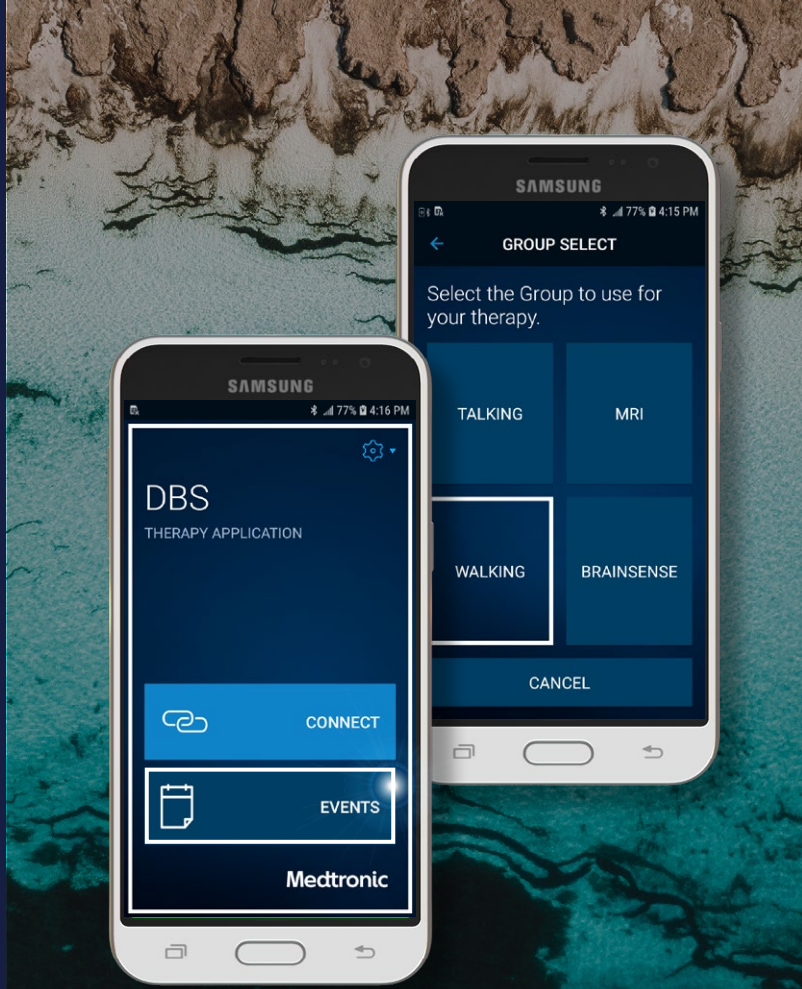
The DBS patient programmer is enhanced so patients can more easily and conveniently engage with their therapy.

CUSTOM NAMES FOR THERAPY GROUPS

The patient programmer enables patients to easily correlate treatment and everyday activities. You can assign custom names to therapy groups, such as walking, sleeping, and talking, which patients can use to adjust therapy throughout their day as they switch activities.

CUSTOM EVENTS

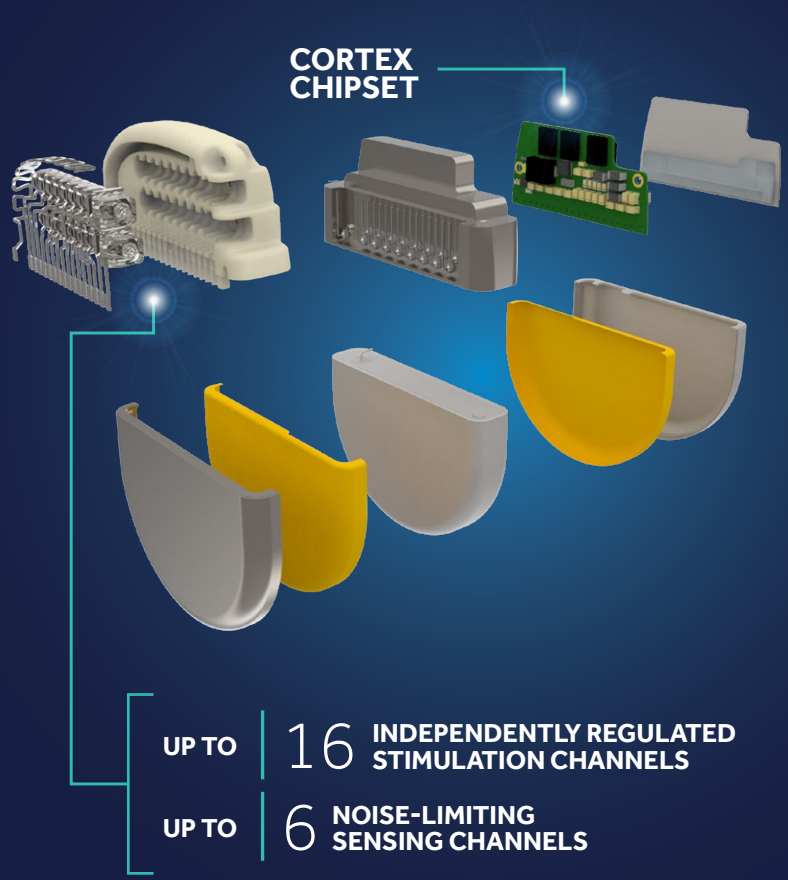
The patient programmer now integrates elements of a motor diary. You can configure up to four custom events to track digitally. A patient or caregiver can capture such an event using the patient programmer, and you can assess frequency and occurrence of these events during clinic visits.



DESIGNED FOR TODAY AND TOMORROW

The Percept™ PC device features our most advanced DBS technologies: proprietary cortex chipset, custom cutting-edge electronics, and embedded software for patented processing and analysis of brain signals.

The state-of-the-art Percept™ PC device is also **designed to facilitate expanded capabilities** in the future via software upgrades — **so you're prepared for what's next in DBS.**



Brief Statement: Medtronic DBS Therapy for Parkinson's Disease, Tremor, Dystonia, Obsessive-Compulsive Disorder, and Epilepsy

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Medtronic DBS Therapy for Parkinson's Disease, Tremor, Dystonia, Obsessive-Compulsive Disorder, and Epilepsy: Product labeling must be reviewed prior to use for detailed disclosure of risks.

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

USA Rx only Rev 02/20

LEARN MORE ABOUT PERCEPT™ PC NEUROSTIMULATOR WITH BRAINSENSE™ TECHNOLOGY AT MEDTRONIC.COM/PERCEPT

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