Medtronic

Engineered to adapt

Percept™ family with BrainSense™ technology

Actual size

Engineered **to adapt**

The Percept™ family with exclusive BrainSense™ technology empowers you to adapt deep brain stimulation (DBS) therapy to your patients' evolving needs over time.†

Designed for the needs of today and tomorrow, the Percept™ family is:

Empowering patient freedom
with patient-first capabilities for flexibility and convenience.

Enabling personalization
with data-driven insights that allow you to adapt therapy to your patients' needs.

Designed for upgradability
Engineered to allow for future software updates designed for the Percept™ platform without a neurostimulator device exchange.

†The sensing feature of the Percept™ PC and Percept™ RC system is intended for use in patients receiving DBS where chronically recorded bioelectric data may provide useful, objective information regarding patient clinical status. The majority of patients with Parkinson's disease have an identifiable signal. Signal may not be present or measurable in patients treated for essential tremor, dystonia,* epilepsy or obsessive-compulsive disorder.*

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

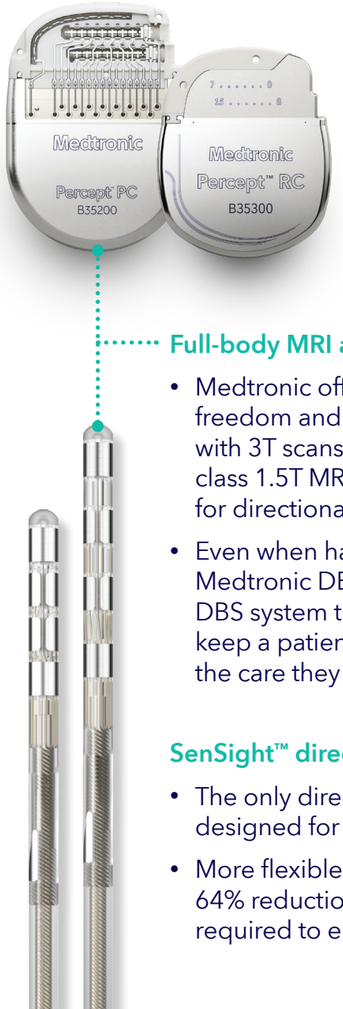
‡ MRI Under specific conditions. Refer to product labeling for full list of conditions: https://manuals.medtronic.com/manuals/mri/region

§When compared to the model 37085 and 37086 extensions

Meet the **Percept™ family**

The first complete DBS system with sensing, directionality, and advanced programming – now available in both recharge-free and rechargeable options.

Percept™ neurostimulators
- Small, ergonomic form factor
- The most advanced DBS technology available in two different models.



Full-body MRI access
- Medtronic offers greater freedom and scan access with 3T scans and best-in-class 1.5T MRI scan labeling[1-3] for directional leads‡
- Even when having an MRI, Medtronic DBS is the only DBS system that doesn't keep a patient from receiving the care they need‡[1-3]

SenSight™ directional leads
- The only directional DBS lead designed for sensing
- More flexible extensions – 64% reduction in the force required to elongate§

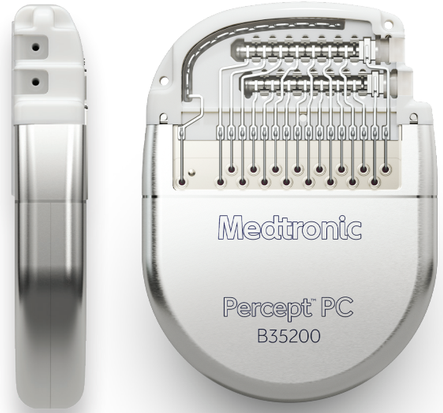
BrainSense™ technology
uses brain signals to provide a window into patients' conditions, in real time, over time.

OptiStim™ and ShapeLock™ controls
provide options to customize stimulation and amplitudes.

The most advanced DBS technology available in different models to meet unique patient needs

Percept™ PC neurostimulator

The recharge-free model blends ergonomic design with cutting-edge battery technology.



Actual size

Ergonomic design
Percept™ PC neurostimulator is designed for comfort.

- The **thinnest** PC on the market‡4–6

Designed to last
The Percept™ PC device has a projected mean longevity >5 years for median energy-user† and features smart battery technology offering real-time estimation of battery longevity,§ to keep your patients informed.

Designed to adapt
BrainSense™ technology and advanced programming capabilities let you personalize therapy to your patients' evolving needs over time.

Broad indication coverage
Indicated for: PD, ET, epilepsy, dystonia*, OCD*

†For median energy use in DBS for patients with Parkinson's disease.
‡As compared to Boston Scientific Vercise Genus™* P16. MP92328632-05 REV-A. As compared to St Jude Medical Infinity™* 7. IPG. ARTEN600150429 - B.
§Based on current actual battery level and therapy settings from last seven days.
***Humanitarian device:** The effectiveness of these devices for the treatment of dystonia and obsessive-compulsive disorder has not been demonstrated.

Introducing

Percept™ RC neurostimulator

Meet the **newest member** of the Percept™ family. Percept™ RC offers patients a rechargeable neurostimulator specifically designed to be:

Actual size

Small

Patient comfort
The smallest, thinnest, dual-channel DBS device available.Ω

Smart

Rapid recharging
Patients can charge under normal conditions (from 10% to 90% full) in less than an hour.††

Greater than 99% capacity at 15 years with weekly recharge, it is designed to offer a more consistent recharge experience over time.

Adaptive

Designed to adapt
BrainSense™ technology and advanced programming capabilities allow you to personalize therapy to your patients' evolving needs over time.

Broad indication coverage
Indicated for: PD, ET, epilepsy, dystonia*

ΩAs compared to Boston Scientific Vercise Genus™* R16 and Vercise Genus™* P16. MP92328632-05 REV-A. As compared to St Jude Medical Infinity™* 5/7 IPG. ARTEN600150429 - B.
††For implant depths of up to 2.0cm.

BrainSense™ technology allows you to adapt to patient needs over time **with data-driven insights**

BrainSense™ technology supports clinical decision-making

BrainSense™ technology offers data-driven insights into a patient's condition, inside and outside the clinic, enabling you to adapt DBS therapy to patients' evolving needs.

- Only the Percept™ family offers the BrainSense™ suite of tools. That means you'll have decision-making support to select and optimize programming configurations and maximize therapeutic results over time.

Future-ready software so **you're ready for what's next**

Engineered to allow for future software updates so that patients may have access to additional features designed for the Percept™ platform without a neurostimulator device exchange.

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 dystonia and obsessive-compulsive disorder has not been demonstrated.

The Percept™ family of neurostimulators offers exclusive BrainSense™ technology.

Originator to innovator Medtronic is your dedicated and proven partner in DBS therapy

For over 30 years, we have helped more than 180,000[7] people with our innovative and life-changing therapy. Driven by our passion to deliver the best outcomes, we are continuously advancing DBS therapy with innovation that adapts to the evolving needs of patients.

References

1. ImageReady™ MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems – 92195369-01, accessed on 10/4/2023
2. MRI Procedure Information for Abbott Medical™† MR Conditional Deep Brain Stimulation Systems – ARTEN600090482 A, accessed on 10/4/2023
3. MRI guidelines for Medtronic deep brain stimulation systems 37601 37602 37603 37612 B35200 B35300 – M929535A_a_092 https://manuals.medtronic.com/manuals/mri/region
4. Implantable Pulse Generator Infinity™ IPG Clinician's Manual ARTEN600149416 A - St Jude Medical (US Version), accessed on 10/4/23
5. Percept™ PC B35200 Neurostimulator with BrainSense™ Technology–Implant Manual M982261A015 REV A–Medtronic
6. Vercise™ Deep Brain Stimulation Systems, Surgical Implant Manual. MP92328632-05 REV A, accessed 10/4/23
7. Medtronic data on file

Brief Statement: 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 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 implanted cardiac devices (e.g., pacemaker, defibrillator), external defibrillation/cardioversion, 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, essential tremor, dystonia, or epilepsy 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, essential tremor, dystonia, or epilepsy 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 five years duration or whose YBOCS score is less than 30, who have not completed a minimum of three 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:** 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. Authorized by Federal law for use as an adjunct to medications and as 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 the devices for this use has not been demonstrated.

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