The first-of-its-kind SenSight™ Directional Lead System

The benefits of directionality plus the power of sensing

With your collaboration and insights, we've designed every component of our DBS directional lead system – including the lead, the burr hole device, the extension, and everything in between. It's the first DBS directional lead system with 3T and 1.5T MR Conditional* eligibility.

Built with proprietary materials, components, and processes, the SenSight™ directional lead and Sensight™ Extension work seamlessly with the Percept™ PC Neurostimulator to enhance detection of local field potentials (LFPs), which are 1 million times smaller than DBS stimulation pulses.[1]

SenSight™ directional lead

1.5mm and 0.5mm spacing

Image enlarged to show detail.

*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. Neumann WJ, Staub F, Horn A, et al. Deep brain recordings using an implanted pulse generator in Parkinson's disease. *Neuromodulation*. 2016;19(1):20–24.

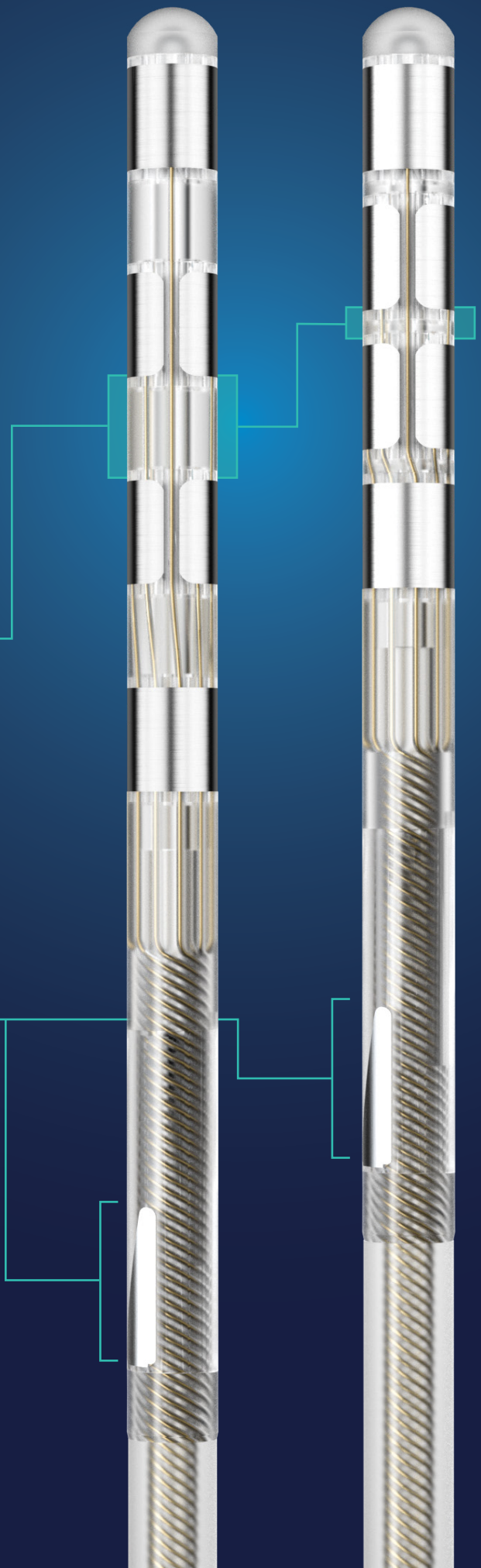
Medtronic

SenSight™ directional leads

1-3-3-1 electrode configuration
to more precisely direct the stimulation

1.5mm and 0.5mm electrode spacing options to suit various targeting and patient needs

Completely insulated orientation markers to guide directional programming. Automatic orientation of the lead is enabled by SureTune™ 4 software.



Images enlarged to show detail.
*Leads and extensions with markers are identified with model numbers ending in M. The extension also has a marker near the proximal end (not pictured).
†Excluding the distal connector end, the extension body diameter is approximately 26.7% smaller than Medtronic extensions 37085 and 37086.
‡As compared to the Stimloc™ burr hole device.
**Based on a study in an animal model, the SenSight™ directional lead system provided on average a 57% lead tip stability improvement compared to Medtronic's legacy lead system. Animal data may not be indicative of clinical performance.
***When compared to the Model 37085 and 37086 extensions.

SenSight™ directional lead — proximal end features

Proximal end of lead inserted into extension

Laser-etched markers on the proximal end for identification of left and right leads with bilateral implants

Laser-etched insertion line on the lead body, which provides visual confirmation of complete insertion — providing confidence in the connection

SenSight™ extension

Single set screw connection on a non-active contact to minimize steps and protect therapeutic delivery

Left and right laser-etched markers and radiopaque marker
Laser-etched markers on the proximal end (not shown) and distal end for bilateral implants, for identification of left and right extensions. Extensions with the laser-etched markers also include a radiopaque marker visible under CT, fluoroscopy, X-ray, and O-arm™ Imaging System, for distinguishing with bilateral implants*

SenSight™ burr hole device

14.7% lower profile‡ — for your patient's comfort

57% improved lead tip stabilization**

Clip designed with vertically elongated securing mechanism with ribs to increase the surface area holding force and minimize lead rotation once secured

Flexible — designed to be placed in any orientation and conform to the patient's skull

SenSight™ burr hole device: base, support clip, and cover

26.7% thinner†
SenSight™ extension body diameter with bootless connections to save you time

More flexible
64% reduction
in the force required to elongate***

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

Medtronic DBS Therapy for Parkinson's Disease, Tremor, Dystonia, 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 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.

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.

PRECAUTIONS: Loss of coordination in activities such as swimming may occur. 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 procedures, dementia, coagulopathies, or moderate to severe depression, or for patients 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.

***Humanitarian Device (Dystonia):** 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.

USA Rx only Rev 02/21

SureTune™ 4 Software

Intended Use: The SureTune™ 4 Software is intended to assist medical professionals in planning programming of deep brain stimulation by visualizing the Volume of Neuronal Activation (VNA) relative to patient anatomy. **Warning:** SureTune™ 4 Software does not replace clinical judgment.

Medical professionals must review the product technical manuals prior to use for detailed disclosure including Indications, Safety, and Warnings. For more information, call Medtronic at (1-800)-328-0810 or visit Medtronic's website at medtronic.com/SureTune

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