MEDTRONIC PERCEPT[™] PC NEUROSTIMULATOR WITH BRAINSENSE[™] TECHNOLOGY

Included in this media kit are materials to help inform your local media, patients and physicians of the latest technological advancement in Deep Brain Stimulation (DBS) therapy.



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Introducing Percept[™] PC Neurostimulator with BrainSense[™] Technology

Medtronic received the Food and Drug Administration (FDA) approval for Percept[™] PC neurostimulator.

- The first and only DBS system in the U.S. with groundbreaking BrainSense[™] technology that allows clinicians to capture a patient's brain signals,^{*} enabling more data-driven, personalized treatment for patients with neurologic disorders, such as Parkinson's disease (PD), essential tremor and epilepsy.
- Brings forth several leading-edge innovations, such as BrainSense[™] technology and 3T and 1.5T MRI eligibility, in a modern, ergonomic, easy-to-use solution that clinicians and patients want.
- Approved in the U.S. for the treatment of symptoms associated with PD, essential tremor, primary dystonia^{**}, epilepsy, and obsessive-compulsive disorder (OCD^{**}).

* Signals may not be present or measurable in all patients. Clinical benefits of brain sensing have not been established.
** Humanitarian Device: The effectiveness of these devices for the treatment of dystonia and obsessive-compulsive disorder has not been demonstrated.

Press Release



Percept[™] PC Neurostimulator with BrainSense[™] Technology



Percept™ PC Neurostimulator with Programmers Showing Stimulation



Patient Programmer Showing Events



Percept™ PC Neurostimulator Animation Video



ABOUT DBS

- Deep Brain Stimulation (DBS) uses a small, pacemaker-like device, placed under the skin of the chest or abdomen, to send electronic signals to an area in the brain that controls movement.
- DBS may help control movement symptoms associated with PD, essential tremor, dystonia^{*}, and focal (partial) onset seizures associated with epilepsy.
- When medications aren't as effective as they used to be for PD and symptoms make everyday life a challenge, DBS may help.

AN UNRIVALED COMMITMENT TO DBS AT EVERY STEP OF THE JOURNEY



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BLUE MAN ANIMATION



BEFORE AND AFTER/ ON-OFF VIDEOS



Patient is receiving DBS therapy with an Activa™ PC neurostimulator

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

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.

 Activa systems (1.5T) Percept PC System (1.5 and 3T)

RIGOROUS DBS RESEARCH. REAL RESULTS.

Medtronic supports research to advance scientific and clinical knowledge related to our products and therapies. Today, clinical evidence has become increasingly more important in helping foster change that advances medicine.

SUMMARY OF KEY FINDINGS WITH MEDTRONIC DBS SYSTEMS

Refer to product labeling for full details

Parkinson's disease:

- DBS (STN) patients with recent onset of motor complications achieved a 20% statistically significant improvement in time with good mobility and no troublesome dyskinesia (2.1 hours from baseline) compared to 2% (0.2 hours) with BMT alone at 24-month follow-up.^{1,2}
- Brain State research conducted with an implanted Activa[™] PC+S^{*}
 Research conducted in-office suggests that local field potential or LFP power measurements at select frequencies correlate with symptoms of PD and treatments for PD. Refer to <u>Scientific</u> <u>Compendium: Research on Brain Sensing</u> for further details.

Essential tremor:

• Activities of daily living (ADL) showed statistically significant improvement in 7 scales for essential tremor patients.²



COMPENDIUM HIGHLIGHTS



CLINICAL COMPENDIUM FOR MOVEMENT DISORDERS



CLINICAL COMPENDIUM FOR EPILEPSY



SCIENTIFIC COMPENDIUM: RESEARCH ON BRAIN SENSING

Epilepsy:

- During a 3-month blinded comparison phase, DBS significantly reduced patients' most severe seizures, complex partial seizures, and the incidence of epilepsy-related injury.^{3,4}
- Long-term safety and effectiveness for DBS Therapy for Epilepsy was established through 2–7 years.⁴⁻⁷
- At 7-years, patients experienced a median 75% reduction in seizure frequency from baseline, as assessed with open-label ongoing therapy.⁴

Important Safety Information

A prescription is required. Not everyone who receives DBS Therapy will receive the same results. DBS Therapy requires brain surgery which can have serious and sometimes fatal complications. Once implanted, DBS complications may require additional surgery. Medtronic DBS Therapy may cause new or worsening neurological or psychiatric symptoms. Patients should always discuss the potential risks and benefits of the therapy with a physician.

LINK TO PUBLICATION FOR PARKINSON'S DISEASE





SPOKESPERSONS



MIKE DALY

Vice President and General Manager, Brain Modulation

Mike Daly serves Medtronic within the Restorative Therapies Group as Vice President and General Manager of the Brian Modulation Business.

Prior to joining Medtronic, Mike was the Vice President and General Manager for the Australia/ New Zealand region at C.R. Bard. In this role, he oversaw all divisions, businesses, and operations, successfully accelerating growth rates and consistently delivering over plan each year. During his tenure there, he also had general management responsibilities for Southeast Asia, Taiwan, India and Korea.

Prior to this, he spent 16 years with Boston Scientific where he served as the Vice President and Managing Director covering various regions in Australia, New Zealand, Asia, South Africa and Canada.

Mike holds a Bachelor of Science degree in Business Administration from Robert Morris University in Pennsylvania. He and his family reside in Minneapolis, Minnesota.



STEVE GOETZ

Engineering Director, Technology, Strategy, Business Development at Medtronic

Steve has over 20 years of experience in various research and development roles with Medtronic Neuromodulation, contributing to development of products in the spinal cord stimulation, implantable pump, and deep brain stimulation therapies. Over the past 8 years, he has focused brain modulation exclusively, first as chief engineer for deep brain stimulation and most recently directing the product and technology portfolio for the therapy. He completed a master's degree in electrical engineering from the University of Minnesota, with an undergraduate degree in the same field from Rose-Hulman Institute of Technology.



WILFRED VAN ZUILEN

Vice President Restorative Therapies Group, Europe, Middle East & Africa

Wilfred van Zuilen, is responsible for leading the Restorative Therapies Group comprising the Spine, Brain, Pain and Specialties Therapies in Europe, Middle East & Africa. He has been a leader of the business unit since February 1, 2017.

Prior to his current appointment, Wilfred held the position of Vice President, Advanced Surgical Technologies (AST) Europe, MITG, from 2013 until January 2017. He was responsible for defining, implementing and executing the Strategic Imperatives in the Stapling, Energy and Haemostats businesses.

Wilfred has more than 20 years' experience in the Healthcare industry in a number of various positions in Novartis, Edwards Lifesciences and Medtronic. Wilfred started in Medtronic (US Surgical) in 1998 as Sales Rep Cardiovascular Benelux introducing the Paragon coronary stents. After the acquisition by Covidien, he assumed increasing responsibility in the Dutch subsidiary and he was promoted to General Manager for MITG in 2004. After the division in 2006 of the commercial franchises, he held several Area Vice President positions in Surgical Solutions before he was promoted to his role of Vice President AST Europe, Surgical Solutions in 2013.

Wilfred holds a bachelor's degree in Business Economics from Erasmus University in Rotterdam.

Wilfred lives with his wife Femke and their two sons, Martijn and Floris, in Woerden, The Netherlands.

References:

- 1 Schuepbach WMM, Rau J, Knudsen K, et al. Neurostimulation for Parkinson's disease with early motor complications. N Engl J Med. February 14, 2013; 368:610-622.
- 2. Medtronic DBS Therapy for Parkinson's Disease and Essential Tremor Clinical Summary, 2015.
- 3. Fisher RS et al. Electrical stimulation of the anterior nucleus of thalamus for treatment of refractory epilepsy. Epilepsia. 2010 May: 51(5):899 908.
- 4 Medtronic. Medtronic DBS Therapy for Epilepsy Clinical Summary. 2018-10-15. M959283A001 Rev C.
- 5 Salanova V et al. Long-term efficacy and safety of thalamic stimulation for drug-resistant partial epilepsy. Neurology. 2015 Mar10; 84(10):1017 25.
- 6 Sandok E et al. Long term outcomes of the SANTE Trial: 7-Year Follow-Up. American Epilepsy Society Annual Meeting. 2016 Abst. 1.298.
- 7 Tröster AI et al. Memory and mood outcomes after anterior thalamic stimulation for refractory partial epilepsy. Seizure. 2017 Feb; 45: 133 141.

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

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 SoletraTM Model 7426 Neurostimulator, KinetraTM Model 7428 Neurostimulator, ActivaTM 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 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.

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 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. For Obsessive-Compulsive Disorder, the safety and probable benefit of this therapy has not been established for patients without partial-onset seizures, patients with augulopathies, 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 second line medications with augmentation, who have not attempted to complete an adequate trial of Giognitive behavior therapy (CBT), who are pregnant, who are under the age of 18 years, and who don thave 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 sympt

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MEDIA CONTACTS

David T. Young Public Relations 1 (774) 284-2746

Medtronic

710 Medtronic Parkway NE Minneapolis, MN 55432-5604 USA Tel: 1 (763) 514-4000 Fax: 1 (763) 514-4879

Toll-Free: 1(800) 510-6735 to speak to Medtronic Patient Services (Support for patients is available M-F 8 AM - 5 PM CT)

medtronic.com/DBS

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