Medtronic

FACT SHEET

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Medtronic Deep Brain Stimulation (DBS) Therapy for Advanced Parkinson's Disease

Overview

Medtronic DBS Therapy is an FDA-approved treatment clinically demonstrated to reduce some of the most disabling motor symptoms associated with Parkinson's disease. Developed by Medtronic in collaboration with clinicians and researchers from around the world starting in the 1980s, the therapy was approved by the FDA for the treatment of advanced Parkinson's disease in 2002. Medtronic DBS Therapy has benefited more than 100,000 patients worldwide.

Medtronic DBS Therapy uses a surgically implanted medical device, similar to a cardiac pacemaker, to deliver electrical stimulation to precisely targeted areas of the brain to reduce some of the most disabling motor symptoms associated with Parkinson's disease, including shaking, stiffness and movement difficulties. In addition, Medtronic DBS Therapy stimulation settings can be adjusted in response to individuals' Parkinson's symptoms, and the system can be turned off or removed. Removal would require surgery.

Benefits of Medtronic DBS Therapy

Medtronic DBS Therapy, in addition to medication, offers many clinically demonstrated benefits, which include:

Quality of Life/Motor Function Improvements[1]

- Five additional hours of good movement control each day compared to medication alone
- 21 percent improvement in Parkinson's disease related quality of life compared to medication alone at six months
- 28 percent improvement in the activities of daily living at six months compared to medication alone. These include bathing, dressing, writing clearly and drinking from a glass.
- Improvement in overall motor function, including shaking, stiffness and movement difficulties from Parkinson's disease (15 percent with Medtronic DBS Therapy vs. 2 percent with medication alone)

Significantly Reduced Medication Use[1]

- Significant reduction in the amount of medication needed to treat Parkinson's disease

- By reducing the need for levodopa, DBS Therapy simplifies a patient's medication schedule

Long-Term Safety and Effectiveness[1]

- Established long-term safety and effectiveness of Medtronic DBS Therapy for advanced Parkinson's disease through 36 months
- The long-term data will further support the already extensive access and insurance coverage for the therapy

Risks

DBS Therapy requires brain surgery. Risks of brain surgery may include serious complications such as coma, bleeding inside the brain, seizures and infection. Some of these may be fatal. Once implanted, the system may become infected, parts may wear through skin, and the lead or lead/extension connector may move. Medtronic DBS Therapy could stop suddenly because of mechanical or electrical problems. Any of these situations may require additional surgery or cause symptoms to return.

Medtronic DBS Therapy may cause worsening of some motor symptoms associated with movement disorders, and may cause speech and language impairments. Stimulation parameters may be adjusted to minimize side effects and attain maximum symptom control. In patients receiving Medtronic DBS Therapy, depression, suicidal thoughts and suicide have been reported. Occurrence of "fall" has also been reported in patients with Parkinson's disease.

Who Should Consider Medtronic DBS Therapy for Parkinson's Disease

Medtronic DBS Therapy may be a treatment option for people who have Parkinson's disease and:

- Have responded well to the medication levodopa;
- Still receive benefit from medication, but notice that it's becoming less effective or causing intolerable side effects; and,
- Require multiple medications, higher dosages, or more frequent doses to manage symptoms.
- Are 18 years or older

When to Consider Medtronic DBS Therapy for Parkinson's Disease

As soon as medications begin to lose their effectiveness, it may be time to consider Medtronic DBS Therapy; the "window of opportunity" closes when symptoms no longer respond to medications. In order to obtain maximum benefits from Medtronic DBS Therapy, individuals with Parkinson's disease should talk to a neurologist or neurosurgeon about the optimal time in the window of opportunity when DBS Therapy might be the most effective and how long the window of opportunity will be open.

About the Procedure

The surgery to implant the device takes several hours and is divided into two parts: the procedure to implant the lead(s); and the procedure to implant the neurostimulator(s) and extension(s). The duration of each procedure and the specific steps involved vary by patient and neurosurgeon. Some neurosurgeons complete both procedures during a

single surgery; others complete each procedure in separate surgeries.

- Bilateral stimulation is used in the treatment of Parkinson's disease. Bilateral stimulation requires two leads and two extensions – one set for each side of the brain – but can be delivered with one or two neurostimulators. For patients requiring bilateral stimulation, the choice between one or two neurostimulators is influenced by physician and patient preference.
- Medtronic DBS Therapy requires the involvement of a multidisciplinary team of clinicians. A neurologist is involved in advising patients with movement disorders about their treatment options, including Medtronic DBS Therapy. Supported by a neurologist and sometimes a neurophysiologist, a specially trained neurosurgeon performs the DBS system implant procedure. After surgery, a neurologist or another clinician is involved in programming and adjusting the stimulation parameters to maximize symptom control and minimize side effects. Programmable stimulation parameters include: frequency, amplitude and pulse width.
- People receiving Medtronic DBS Therapy can use a hand-held patient programmer to control the stimulator within the parameters set by the physician.

Resources

The therapy is not for everyone. Not everyone will receive the same results. For further information, call Medtronic at (800) 328-0810 or visit Medtronic's website at http://www.medtronic.com/patients/parkinsons-disease/index.htm.

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References:

[1] Medtronic DBS Therapy for Parkinson Disease and Essential Tremor Clinical Summary, 2013

Important Safety Information

Medtronic DBS Therapy for Parkinson's Disease: Patients should always discuss the potential risks and benefits with a physician.

Indications: 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 of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication.

Contraindications: Contraindications include patients who will be exposed to MRI 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, patients who are unable to properly operate the neurostimulator, or for patients for whom test stimulation is unsuccessful. Diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy's energy can be transferred through the implanted system (or any of the separate implanted components), which can cause neurostimulation system or tissue damage and can result in severe injury or death. Transcranial Magnetic Stimulation (TMS) is contraindicated for patients with an implanted DBS System.

Warnings/ Precautions/Adverse Events: There is a potential risk of tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with a heightened risk of intracranial hemorrhage. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. 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. Although some MRI procedures can be performed safely with an implanted DBS System, clinicians should carefully weigh the decision to use MRI in patients with an implanted DBS System. MRI can cause induced voltages in the neurostimulator and/or lead possibly causing uncomfortable, jolting, or shocking levels of stimulation. MRI image quality may be reduced for patients who require the neurostimulator to control tremor, because the tremor may return when the neurostimulator is turned off.

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. Safety and effectiveness has not been established for patients with neurological disease other than Parkinson's disease, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; patients who are pregnant; and patients under 18 years. Depression, suicidal ideations and suicide have been reported in patients receiving Medtronic DBS Therapy for Movement Disorders, although no direct cause and effect relationship has been established.

Abrupt cessation of stimulation may cause a return of disease symptoms in some cases with intensity greater than was experienced prior to system implant ("rebound" effect). Adverse events related to the therapy, device, or procedure can include: stimulation not effective, cognitive disorders, pain, dyskinesia, dystonia, speech disorders including dysarthria, infection, paresthesia, intracranial hemorrhage, electromagnetic interference, cardiovascular events, visual disturbances, sensory disturbances, device migration, paresis/asthenia, abnormal gait, incoordination, headaches, lead repositioning, thinking abnormal, device explant, hemiplegia, lead fracture, seizures, respiratory events, and shocking or jolting stimulation. Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist.

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