Electrical stimulation of the brain has been used since 1987 to treat movement disorders. Today, more than 20,000 people worldwide have been treated with the Medtronic deep brain stimulation technology called Activa® Therapy for Essential Tremor, advanced Parkinson’s disease, or dystonia.

- **1987**
  The medication levodopa (L-dopa) becomes generally available to treat Parkinson’s disease. By the late 1970s, neurologists realize that with long-term use, L-dopa can lose its effectiveness and can contribute to disability in Parkinson’s patients.

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- **1980s**
  Neurosurgeons begin implanting stimulating electrodes to treat movement disorders. Scientific papers published throughout the decade describe brain stimulation’s results in various patients.

- **1950s**
  Lesioning procedures are commonly used to correct movement disorders. During this procedure, a neurosurgeon temporarily inserts an electrode into a patient’s brain to pinpoint the origin of the symptom. That small area of the brain is then destroyed. This irreversible procedure is called thalamotomy or pallidotomy, according to the area of the brain being destroyed.

- **1960s and 1970s**
  While performing surgical lesions to correct movement disorders, neurosurgeons theorize that tremor may be significantly controlled by implanting an electrode.

- **1987**
  French neurosurgeon Prof. Alim-Louis Benabid and team in Grenoble, France, implant a thalamic stimulation system to control disabling tremor, and begin a pilot study.

- **February 1995**
  Medtronic brain stimulation therapy available commercially in Europe, Canada and Australia for Essential Tremor and tremor in Parkinson’s disease.

- **August 1992**
  First patients enroll in European multicenter clinical study for tremor that includes more than 100 patients.

- **April 1998**
  Medtronic Activa® Parkinson’s Control Therapy available commercially in Europe, Canada and Australia for advanced Parkinson’s disease motor symptoms.

- **Fall 1995**
  First patients enroll in the Medtronic 18-center, global clinical study of stimulation of the brain’s subthalamic nucleus or globus pallidus to control advanced Parkinson’s symptoms. Study includes more than 150 patients in the United States, Europe, Canada and Australia.

- **January 2002**
  Medtronic Activa® Parkinson’s Control Therapy available commercially in the United States for advanced Parkinson’s disease motor symptoms.

- **March 2003**
  Medtronic Activa® Dystonia Therapy FDA approved under Humanitarian Device Exemption (HDE), a special U.S. designation for devices that treat rare diseases.
Indications:

**Parkinson's Control Therapy:** Bilateral stimulation of the internal globus pallidus (GPI) or the subthalamic nucleus (STN) using Medtronic® Activa® Parkinson's Control Therapy 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.

**Tremor Control Therapy:** Unilateral thalamic stimulation by the Medtronic® Activa® Tremor Control System 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. The safety or effectiveness of this therapy has not been established for bilateral stimulation.

**Dystonia Therapy:** Unilateral or bilateral stimulation of the internal globus pallidus (GPI) or the subthalamic nucleus (STN) by the Medtronic Activa System is indicated as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and segmental dystonia, hemidystonia, and cervical dystonia (torticollis), for individuals 7 years of age and older.

Contraindications: Contraindications include patients who will be exposed to MRI using a full body radio-frequency (RF) coil or a head transmit coil that extends over the chest area, patients who are unable to properly operate the neurostimulator, or for Parkinson's disease and Essential Tremor, patients for whom test stimulation is unsuccessful. Additionally, 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 tissue damage and can result in severe injury or death. Diathermy can damage parts of the neurostimulation 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. Do not place the lead-extension connector in the soft tissues of the neck. Placement in this location has been associated with 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 Activa System, clinicians should carefully weigh the decision to use MRI in patients with an implanted Activa 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. Severe burns could result if the neurostimulator case is ruptured or pierced. The Activa 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 or Essential Tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; or for patients who are pregnant, under 18 years, over 75 years of age (Parkinson's Control Therapy) or over 80 years of age (Tremor Control Therapy). For patients with Dystonia, age of implant is suggested to be that at which brain growth is approximately 90% complete or above. Additionally, the abrupt cessation of stimulation for any reason should be avoided as it may cause a return of disease symptoms. In some cases, symptoms may return with an 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.

Humanitarian Device: Authorized by Federal Law for the use as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and segmental dystonia, hemidystonia, and cervical dystonia (torticollis), for individuals 7 years of age and older.

Rx only