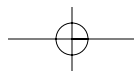


Activa® Dystonia Therapy

Activa Dystonia Therapy uses one or two surgically implanted medical devices, similar to cardiac pacemakers, to deliver electrical stimulation to precisely targeted areas within one or both sides of the brain. Stimulation of these areas appears to block the signals that cause the disabling symptoms of primary dystonia.



Activa® Dystonia Therapy: Product technical manual must be reviewed prior to use for detailed disclosure.

Indications: 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, or patients who are unable to properly operate the neurostimulator. Also, 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 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. 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

