What if you could do more in the operating room?

Perform procedures with more efficiency, more certainty, and more precision? What if you had quick access to the vital information you need, when and where you needed it? That’s the vision of Medtronic Surgical Synergy™. With proprietary technologies, surgical tools, device implants, and therapy expertise that form the foundation for the next generation of surgical innovation—you’ll be poised to take the next step in surgical performance. And working to raise the standard of care, from planning to programming.
1. PLAN
Experience streamlined workflows designed around your DBS procedure in our most advanced planning software applications: StealthDBS™, StealthViz™ and cloud-based convenience with StealthConnect™.

2. ACCESS
Procedural solutions that offer proven performance.
- MidasRex™ Drill System
- PlasmaBlade™ dissection device
- EasyDrill™ Perforator

3. IMPLANT
Intraoperative imaging that provides additional data to make informed decisions around lead placement—with potentially fewer MER passes and decreased OR time—for improved efficiency and faster procedures.¹

4. VERIFY
Confidence—with the combined power and visual feedback of StealthDBS and the O-arm™—assurance that the surgical goal was achieved.

5. PROGRAM
The Medtronic Clinician programmer, with Activa A610 application—maximize your post-surgical practice with an intuitive, visual interface designed to optimize the programming session.

For over 25 years, we’ve built upon our legacy of DBS innovation—to create a better experience for you and your patients. And with Medtronic Surgical Synergy™, we’re providing data for more informed decisions around procedural planning, lead placement, and verification—to make the experience easier and more streamlined.

Together, we’re furthering our Unrivaled Commitment to DBS. Not only are we driving to improve accuracy and efficiency, but address the barriers to neurocranial surgery—by developing technology that could make procedures faster and less intimidating for patients. With our dedicated partnership, and support at every step of the DBS journey, you can be confident that the work you are doing today, will truly make a difference for your patients.

¹Single center study. Study included Parkinson’s Disease patients only.
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 essential (idiopathic or reflexive) 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 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 tunnel coil that extends outside the body if they have an implanted Solera™ Model 7426 Neurostimulator, Kineta™ Model 7428 Neurostimulator, Activa™ SC Model 37822 Neurostimulator, or Model 64003 or 64062 pocket adapter.

Warnings and Precautions: 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 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 damage or injury. Th却 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 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 injury, including coma, paralysis, or death, or that may cause device damage, include neurostimulator implant location other than pectoral and familial regions; unsupervised MRI parameters; partial system ‘abandoned systems’; inadvertent neurostimulator model numbers; and broken conductor wires (in the lead, extension or pocket adapter). The safety of electroconvulsive therapy (ECT) in patients receiving DBS Therapy has not been established. Tunneling the extension too superficially or too deeply may result in nerve or vascular injury or tunneling through unintended anatomy. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. 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 less DBS therapy. For Epilepsy, cessation, reduction, or cessation 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. Patients using an exchangeable 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. Loss of coordination in activities such as swimming may occur. Depression, suicidal ideations and suicide have been reported in patients receiving Medtronic DBS Therapy for Movement Disorders and Epilepsy, 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 symptoms appropriately. Patients should be monitored for memory impairment and may be admitted. 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.

Adverse Events: Adverse events related to the therapy, device, or procedure may include intracranial hemorrhage, cerebral infection, CSF leak, pneumocephalus, seizures, surgical site complications (including pain, infection, dehiscence, erosion, seroma, and hematoma), meningitis, encephalitis, brain abscess, cerebral edema, aspetic cyst formation, device complications (including lead fracture and device migration) that may require revision or explant, extension fibrosis, tightening or loosening, 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, shaking or jittering sensation, ineffective therapy and weight gain or loss.

Safety and effectiveness has not been established for patients with previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression, or patients who are pregnant. Parkinson’s disease and essential tremor: safety and effectiveness has not been established for patients under 18 years or patients with neurological disease other than idiopathic Parkinson’s disease or Essential Tremor. Essential tremor: safety and effectiveness has not been established for bilateral stimulation or for patients over 80 years of age. Dystonia age of implant is suggested to be that at which brain growth is approximately 90% complete or above. 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 this 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 for 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.

Medtronic DBS Therapy is not for everyone. DBS Therapy requires brain surgery which can have serious and sometimes fatal complications. Other complications can occur and may require additional surgery. DBS Therapy may cause new or worsening neurological or psychiatric symptoms. For additional safety information, please refer to Indications, Safety and Warnings at medtron.com

References


medtronic.com