FASTER. SMARTER. MORE FLEXIBLE.

The next step in your patient’s smarter journey

HELP YOUR PATIENTS TAKE CHARGE

The 15-year Activa™ RC 16-contact Neurostimulator and SenSight™ Directional Lead system puts a more precise programming experience in your hands, and delivers a refreshed, wireless recharging experience with unmatched MRI access to your patients.
MISSION DRIVEN.
PATIENT FOCUSED.

With the complete Activa™ RC Neurostimulator and SenSight™ Directional Lead System your patients benefit from:

- The latest in DBS Lead technology
- 15 year battery Service Life & Warranty††
- 1.5 T Full Body MRI access†††

††Activa™ RC devices eligible for the service life extension and the supplemental limited warranty are those devices sold in the US that have been successfully interrogated with the Medtronic Activa Clinician Programmer prior to reaching End of Service (EOS). For additional information, contact rs.rtgwarranty@medtronic.com

†††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
SENSIGHT™
DIRECTIONAL
LEAD SYSTEM

26.7% Thinner*
SenSight™ extension body diameter with bootless connections to save you time

14.7% lower profile**
Burr Hole Device—for your patient’s comfort

1-3-3-1 electrode design
to more precisely direct the stimulation

0.5mm and 1.5mm electrode spacing options
to suit various targeting and patient needs

Completely insulated orientation markers
to guide directional programming. Automatic orientation of the lead is enabled by SureTune™ 4 software.

*Excluding the distal connector end, the extension body diameter is approximately 26.7% smaller than Medtronic extensions 37085 and 37086.

**As compared to Stimloc™ Burr Hole Device
The Activa™ RC Device can maintain a predictable recharge experience over 15 years.***

As part of our commitment to the Medtronic mission to DBS therapy, we have invested in post-market analysis and continuous device testing to validate our predictive models, and confidently extended device service life from 9 to 15 years.***

Even under a variety of use conditions, The Activa™ RC battery capacity fade is limited over time so as not to negatively impact the patient recharge experience.

**PROVEN BATTERY PERFORMANCE.**

Activa™ RC predicted recharge intervals for movement disorder patients. Percentiles correspond to patient groups that need different energy levels. Recharge interval corresponds to the maximum time allowed between recharge events. In practice more frequent recharge behavior might be seen.

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A SMARTER CHARGING EXPERIENCE IS IN THEIR HANDS.

It’s time to give your patients more flexibility. With faster feedback, and a coupling area that’s designed for a more consistent connection, patients may find it easier to charge while on the go. And with speed and temperature features that are customizable to each patient’s preference — they’ll be ready for an experience that fits their lifestyle — without holding them back.

- Larger coupling area
- More consistent connection
- Full charge in less time†

†Patients who had long charge times with 37651 Medtronic Implantable Neurostimulator Recharger (due to tilt, implant depth, and other challenges) have the opportunity to experience improvement with the wireless recharger.
**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.

**CONTRAINDICATIONS:**
Medtronic DBS Therapy is contraindicated (not allowed) for patients who are unable to properly operate the neurostimulator and 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 the patient has an implanted Soletra™ Model 7426 Neurostimulator, Kinetra™ Model 7428 Neurostimulator, Activa™ 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 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 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 adapter).
- 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). New onset or worsening depression, suicidal ideations, suicide attempts, and suicide have been reported.

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 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.

**PRECAUTIONS:**
- Loss of coordination in activities such as swimming may occur. 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, asympatric cistern 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.

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. Safety and effectiveness of Medtronic DBS Therapy for Tremor has not been established for bilateral stimulation or for patients over 80 years of age.

USA Rx only  Rev 03/20

SureTune™ 4 Software

**Intended Use:** The SureTune™ 4 Software is intended to assist medical professionals in planning programming of deep brain stimulation by visualizing the Volume of Neuronal Ablation (VNA) relative to patient anatomy. **Warning:** SureTune™ 4 Software does not replace clinical judgment.

Medical professionals must review the product technical manuals prior to use for detailed disclosure including Indications, Safety, and Warnings. For more information, call Medtronic at [1-800-328-0810](tel:1-800-328-0810) or visit Medtronic’s website at medtronic.com/SureTune

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