Medtronic

SOLETRA™ 7426

Neurostimulator for
Deep Brain Stimulation

Physician and Hospital Staff Manual

Rx Only

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Soletra™ Physician and Hospital Staff Manual

Model 7426

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Overview of Manual

This manual provides information on the Soletra neurostimulator, a component of the Activa System for deep brain stimulation. The manual describes some items to discuss with your patient, and explains how to register the patient's device. You will also find instructions for handling, storing, implanting, replacing, and explanting the neurostimulator. General resterilization guidelines are also provided for the new neurostimulator.

The manual is divided into the following sections:

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System Description

The Medtronic Activa System is an implantable, multiprogrammable quadripolar system that delivers electrical stimulation to selected areas of the brain.

The power source of the Activa System, the Model 7426 Soletra Neurostimulator, generates electrical signals that are transmitted to the brain. These signals are delivered from the neurostimulator to the brain via the Model 7482 DBS Extension or the Model 7495 Extension and either the Model 3387 DBS Lead or the Model 3389 DBS Lead. These components comprise the implantable portion of the Activa System.

The neurostimulator is comprised of electronic circuitry and a battery, which are hermetically sealed in a titanium case. The operation of the neurostimulator is supported by a physician programmer and control magnet.

For a complete list of model numbers and components compatible with the Soletra Neurostimulator, see the Activa System Components Sheet packaged with this manual in the neurostimulator shelf box.

Indications

Medtronic Activa Therapy includes Activa Parkinson's Control Therapy and Activa Tremor Control Therapy.

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.

Contraindications

Implantation of an Activa Brain Stimulation System is contraindicated for:

- Patients exposed to diathermy. Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

  Diathermy is further prohibited because it can also damage the neurostimulation system components resulting in loss of therapy, requiring additional surgery for system explantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned "on" or "off." Advise your patients to inform all their health care professionals that they should not be exposed to diathermy treatment.
- Patients who will be exposed to Magnetic Resonance Imaging (MRI) using a full body radio-frequency (RF) coil or a head transmit coil that extends over the chest area. Refer to "Appendix B: MRI and Activa Therapy" on page 72 for comprehensive safety information.
- Patients for whom test stimulation is unsuccessful.
- Patients who are unable to properly operate the brain stimulator.

Warnings

Coagulopathies – Use extreme care with lead implantation in patients with a heightened risk of intracranial hemorrhage. Physicians should consider underlying factors, such as previous neurological injury, or prescribed medications (anticoagulants), that may predispose a patient to the risk of bleeding.

Avoid Excessive Stimulation – There is a potential risk of brain tissue damage for stimulation parameter settings of high amplitudes and wide pulse widths.

The Activa System is capable of parameter settings out of the range of those used in the clinical studies. Suppression of symptoms should occur at amplitudes of 1 to 3.5 V, pulse widths of 60 to 120 µsec, and rates of 130 to 185 Hz. Higher amplitudes and pulse widths may indicate a system problem or less than optimal lead placement. Parameter values exceeding the recommended output settings should only be programmed with due consideration of the warnings concerning charge densities and charge imbalance described in "Programming Stimulation Parameters" on page 45.

If programming of stimulation parameters exceeds charge density limits, the following programmer warning appears: **WARNING: CHARGE DENSITY MAY BE HIGH ENOUGH TO CAUSE TISSUE DAMAGE. CONSULT TECH MANUAL. PRESS CLEAR TO CONTINUE.**

If a lead is implanted in the thalamus, the use of rates less than 30 pps may "drive" tremor, i.e., cause it to occur at the same frequency as the programmed frequency. For this reason, rates should not be programmed below 30 pps when the lead is implanted in the thalamus.

Case Damage – If the neurostimulator case is ruptured or pierced after implant due to outside forces, severe burns could result from exposure to battery chemicals.

Precautions

Placement of Lead-Extension Connector in Neck – 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 Screening Devices – Theft detectors found in retail stores, public libraries, etc., and airport/security screening devices may cause the stimulation power source of an implantable neurostimulation system to switch On or Off. It is also possible that sensitive patients, or those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation. For other indications, higher levels of stimulation have been described as uncomfortable ("jolting" or "shocking") by some patients as they pass through these devices. Refer to "Patient Counseling Information" on page 34 for more information.

Precautions

Physician Training

Implanting Physicians – Implanting physicians should be experienced in stereotactic and functional neurosurgery. Refer to "Physician Training Information" on page 33 in this manual for further information.

Prescribing Physicians – Prescribing physicians should be experienced in the diagnosis and treatment of movement disorders and should be familiar with the use of the Activa System.

Storage and Sterilization

Resterilization Considerations – Refer to "Resterilization" on page 20 for further information.

Storage Temperature – Store the Model 7426 Neurostimulator between 0° F (-18° C) and 125° F (52° C). Temperatures outside this range can damage components.

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System and Therapy

Battery Longevity and Brain Target Selection – Stimulation settings for systems implanted in the internal Globus Pallidus (GPi) may be higher than stimulation settings for systems implanted in the Subthalmic Nucleus (STN). Consequently, systems implanted in the GPi may have shorter battery life than systems implanted in the STN.

Component Failures – The Activa System may unexpectedly cease to function due to battery depletion or other causes. These events, which can include electrical short or open circuits, conductor (wire) fracture, and insulation breaches, cannot be predicted.

Components – The use of non-Medtronic components with this system may result in damage to Medtronic components, loss of stimulation, or patient injury.

Inadvertent Programming – If more than one neurostimulator is implanted, then the potential for unintentional programming changes to the other neurostimulator exists. If two neurostimulators are implanted, they must be implanted at least 8 inches apart to minimize interference. Verify final programmed parameters by reviewing both devices at the conclusion of any programming session.

Lead Materials – The polyurethane tubing of the lead may release neurotoxic or carcinogenic compounds. Data are insufficient to assess the likelihood of these effects occurring in patients who receive the device.

Long-Term Safety and Effectiveness of Activa Therapy – The long-term safety and effectiveness of Activa Therapy has not been established.

Precautions

Programming Different Neurostimulator Models – The Model 7432 Physician Programmer must be turned off and turned back on before attempting to program a different neurostimulator model (for example, if programming a Soletra Model 7426 neurostimulator immediately after programming an Itrel II[1] Model 7424 neurostimulator). If the programmer is not turned off and on, the programmer will display "NO TELEMETRY, POSITION HEAD AND TRY AGAIN" and the software will not allow the different neurostimulator to be programmed.

Use in Specific Populations – The safety and effectiveness of this therapy has not been established for the following:

- Patients with neurological disease origins other than idiopathic Parkinson's disease or Essential Tremor
- Patients with a previous surgical ablation procedure
- Patients who are pregnant
- Patients under the age of 18 years
- Patients over the age of 75 years
- Patients with dementia
- Patients with coagulopathies
- Patients with moderate to severe depression

Implantation/Explantation

Body Fluids – Do not resterilize any system component after exposure to body fluids.

Component Disposal – If explanting an Activa System component, please remember the following guidelines:

- Do not incinerate or cremate the neurostimulator; explosion can result if a neurostimulator is subjected to incineration or cremation temperatures.

[1] The Itrel II Neurostimulator is used for Tremor Control Therapy only.

- Return all explanted components to Medtronic for analysis and safe disposal.

Connections – Wipe off any body fluids on the extension or lead contacts or connector before connecting. Contamination of connections can cause intermittent stimulation or shorts in the neurostimulation circuit.

Connector Block Setscrews – Limit counter-clockwise rotations of neurostimulator setscrews. Rotate enough to provide an unobstructed pathway for the extension connector pins. Too many counter-clockwise rotations may disengage the setscrew from the connector block.

Etched Identification – Place the neurostimulator away from bony structures and with the etched identification side facing outward, away from muscle tissue to minimize pain at the neurostimulator site. This also helps to minimize the possibility of skeletal muscle stimulation, which may be perceived by the patient as twitching or burning.

Excess Extension Wire – Do not place any excess extension wire on top of the neurostimulator's front side (printed side). Wrap any excess extension wire around the perimeter (Figure 1). This avoids any increase in subcutaneous pocket depth, helps minimize potential damage during neurostimulator replacement surgery, and helps minimize potential kinking of the extension wire.

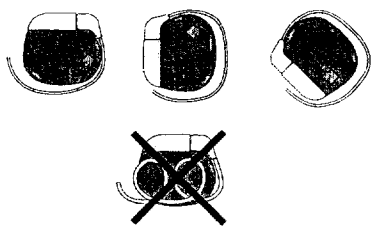

Figure 1. *Wrap excess wire around the perimeter of the neurostimulator.*

Precautions

Handling Components – Handle the implanted components of this system with extreme care. These components may be nicked, cut, or damaged by excessive traction or sharp instruments and may require surgical replacement.

- Do not bend, kink, or stretch the lead body whether or not the stylet is in place. Do not bend or kink the tungsten stylet.
- Do not tie a suture directly to the lead body. Use the burr hole cap and ring provided by Medtronic to secure the lead in place.
- When handling the lead with forceps, use only a rubber-tipped bayonet forceps.

Hex Wrench – Do not overtighten setscrews when using the hex wrench. Excessive torque on setscrews may damage lead contacts. Verify that the sealing grommet has closed on the neurostimulator.

Implant Considerations – Do not implant a component of the system when:

- The storage package has been pierced or altered; or if the component shows signs of damage; or
- The "Use By" date has expired, because this can adversely affect storage package sterility.

Multiple Implants – The long-term safety associated with leads left in place without use, replacement of leads, multiple implants into the target structure, and lead explant is unknown.

Percutaneous Extension Setscrew Connector – If resistance is still felt when removing lead from the percutaneous extension setscrew connector, loosen the setscrews slightly to ensure that they clear the lead contacts. Avoid disengaging the setscrews. Inspect the lead contacts for damage (flattening or stretching of the lead) if resistance was felt prior to removal.

Percutaneous Extension Severing – When severing the percutaneous extension, use gentle traction on the extension to avoid dislodging the lead.

Percutaneous Extension Suture Removal – Do not cut near the lead when removing sutures from the percutaneous extension. Cutting the lead's insulation can result in loss of stimulation and the lead's failure.

Sutures – Do not draw the suture too tightly because damage may occur to either the connector boot or the lead.

Electromagnetic Interference (EMI)

Electromagnetic interference is a field (electrical, magnetic or a combination of both) that is generated by various medical or environmental devices. These medical and environmental (home, occupational, and other) devices may generate enough interference to change the parameters of a neurostimulator; turn a neurostimulator off and on, or cause a neurostimulator to surge, shock, or jolt the patient.

In addition, it is possible for the extension, lead, or both to "pick up" electromagnetic interference and deliver an excess voltage, which can in turn deliver an excessive amount of heat to the brain. Refer to the sections that follow for guidelines on the interaction of electromagnetic interference and an implanted Activa System.

Magnetic Resonance Imaging

Based on tests to date, some MRI procedures can be performed safely with an implanted Activa System. MRI systems used to safely perform MRI include MRI systems operating at 1.5 Tesla (specific MRI machines include Siemens Magnetom 1.5T VISION, Picker International 1.5T Edge, and GE Signa 1.5T Echospeed). The safety of other MRI machines used with implanted Activa Systems is not known.

- Use only a transmit and receive type RF head coil to minimize the exposure of the lead/neurostimulator system to the MRI RF fields. Do not use a whole body RF coil.

Precautions

- Select imaging parameters to perform MRI at a specific absorption rate (SAR) that does not exceed 0.4 W/kg in the head.
- Carefully weigh any decision to perform magnetic resonance imaging (MRI) scans on patients who require the neurostimulator to control tremor. Image quality during MRI scans may be reduced, because the tremor may return when the brain stimulator is turned off.

Use of MRI could possibly result in movement, heating, or damage to the implanted Activa System. The MRI image around the implanted lead may be distorted and shadowed. Induced voltages in the neurostimulator and/or lead may occur, possibly causing uncomfortable ("jolting" or "shocking") levels of stimulation. Clinicians should carefully weigh the decision to use MRI in patients with an implanted Activa System, and should refer to "Appendix B: MRI and Activa Therapy" on page 72 for comprehensive safety information.

Medical Environment

Most routine diagnostic procedures, such as fluoroscopy and x-rays, are not expected to affect system operation. However, because of higher energy levels, sources such as transmitting antennas found on various diagnostic and therapeutic equipment may interfere with the Activa System.

Effects on Other Medical Devices – The Activa System may affect the operation of other implanted devices, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable pacemaker and/or defibrillator therapy, careful programming of each system may be necessary to optimize the patient's benefit from each device.

Electrocautery – Electrocautery can damage the lead, the extension, or both. It can also cause temporary suppression of neurostimulator output and/or reprogramming of the neurostimulator. If use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the neurostimulator, extension, and lead as possible, and use of bipolar electrocautery is recommended.

External Defibrillators – If a patient requires external defibrillation, the first consideration should be patient survival. Safety for use of external defibrillatory discharges on patients with neurostimulation systems has not been established. External defibrillation may damage a neurostimulator.

If external defibrillation is necessary, follow these precautions to minimize current flowing through the neurostimulator and lead system:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the implanted neurostimulator-lead system.
- Use the lowest clinically appropriate energy output (watt seconds).
- Confirm neurostimulation system function following any external defibrillation.

High Radiation Sources – High radiation sources, such as cobalt 60 or gamma radiation, should not be directed at the neurostimulator. If a patient requires radiation therapy in the vicinity of the neurostimulator, place lead shielding over the device to prevent radiation damage.

Precautions

Lithotripsy – Use of high output ultrasonic devices, such as an electrohydraulic lithotriptor, is not recommended for patients with an implanted neurostimulation system. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the neurostimulator circuitry. If lithotripsy must be used, do not focus the beam near the neurostimulator.

Psychotherapeutic Procedures – The safety of psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroshock therapy, transcranial magnetic stimulation) has not been established.

Home or Occupational Environment

Home Appliances – Home appliances that are in good working order and properly grounded do not usually produce enough electromagnetic interference (EMI) to interfere with neurostimulator operation. However, items with magnets (e.g., stereo speakers, refrigerators, freezers) may cause the neurostimulator to switch On or Off.

Occupational Environments – Commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave transmitters, linear power amplifiers, high-power amateur transmitters), and high voltage power lines may generate enough electromagnetic interference (EMI) to interfere with neurostimulator operation if approached too closely.

Patient Activities/Environmental Precautions – Patients should exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. Close proximity to high levels of electromagnetic interference (EMI) may cause a neurostimulator to switch On or Off. The system also may unexpectedly cease to function due to battery depletion or other causes. For these reasons, the patient should be advised about any activities that would be potentially unsafe if their symptoms unexpectedly return. For additional information about devices which generate electromagnetic interference, call 1-800-707-0933.

Patient Magnet – The magnet provided to the patient for device activation and deactivation may damage televisions, computer disks, computer monitors, credit cards, and other items affected by strong magnetic fields.

Radio Frequency Sources – Analog and digital cellular phones, AM/FM radios, cordless phones, and conventional wired telephones may contain permanent magnets. To prevent undesired turning On or Off of the stimulation, these devices should be kept at least 4 inches away from the implanted neurostimulator.

Therapeutic Magnets – Therapeutic magnets (for example, those found in bracelets, back braces, shoe inserts and mattress pads) can cause inadvertent on or off activations of the neurostimulator. Therefore, patients should be advised not to use them.

Adverse Events

For a complete list of adverse events reported during the Parkinson's disease and tremor clinical trials, refer to the *Activa Clinical Summary* packaged with this product.

Clinical Studies

For results of the Parkinson's disease and tremor clinical trials, refer to the *Activa Clinical Summary* packaged with this product.

Individualization of Treatment

For information about individualization of treatment, refer to the *Activa Clinical Summary* packaged with this product.