Medtronic

YOUR ACTIVA® THERAPY

With a Soletra™ Neurostimulator

Patient Manual
Rx Only

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FAMILY MEMBERS OR CAREGIVERS

Please remember the following:

- Read this patient manual thoroughly so you can assist the patient living with Activa Therapy.
- **Always tell any medical personnel that the patient has an implanted brain stimulator and tell them where it is located.** If medical personnel have any questions, they should contact Medtronic at 1-800-510-6735.
- Have the name and telephone number of the patient's doctor at hand if you have any questions or problems. Also, keep the telephone number of Medtronic's Patient Services Department (1-800-510-6735) in case you or medical or dental personnel have any questions. In the case of a medical emergency, always dial 911.

A COMPANY DEDICATED TO PATIENTS

Medtronic was founded in 1949 by Earl Bakken, a graduate student in electrical engineering, and his brother-in-law, Palmer J. Hermundslie. Today Medtronic is the world leader in medical technology, pioneering therapies that restore health, extend life, and alleviate pain.

From its modest beginnings in a 600-square-foot Minneapolis garage, we have transformed Medtronic into a worldwide company that serves customers in more than 120 countries. Each year, millions of patients are treated with Medtronic products and therapies. We invest almost $500 million each year in research and development, working closely with the world's leading physicians and scientists to enhance our current products and therapies, and to

develop new ones. Although we are a large company, individual patients and their needs are still the driving force behind what we do and how we do it.

Our goal is to improve the quality of your life. This booklet is one small way we try to help.

Welcome to the Medtronic family. We wish you well.

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1 GLOSSARY

Amplitude – Amplitude is the strength of stimulation for your specific therapy. The amplitude is measured in volts. The amplitude setting is one of several that can be adjusted by your doctor in the office or clinic using the physician programmer to improve your Parkinson's disease symptoms.

Battery – A part of the neurostimulator that provides the power for your brain stimulation system. The neurostimulator battery needs to be changed every 3-5 years, on average.

Computerized Axial Tomography (CT or CAT) Scans – A test that can see inside the brain and other parts of the body, into areas that cannot be seen with regular x-ray.

Contraindications – A medical term meaning that a procedure, device, or drug, etc. should always be avoided because the risk is greater than any possible benefit.

Electromagnetic Interference (EMI) – Electrical or magnetic energy that is strong enough to interfere with or disrupt your therapy.

Essential Tremor – A movement disorder in which the only symptom is rhythmic shaking produced by muscle contractions. The tremor often occurs in the hands, head, legs, trunk, or voice.

Fluoroscopy – An x-ray procedure that makes it possible to see internal organs in motion.

Levodopa – The main medication used for the treatment of Parkinson's disease.

Magnetic Resonance Imaging (MRI) – A type of scan using magnetic fields that provides detailed pictures of your anatomy.

"On Time" – The time period when you are receiving relief from your Parkinson's disease symptoms.

"On Time" with Dyskinesia – The time period when you are receiving relief from your Parkinson's disease symptoms, but have uncontrolled movements caused by Parkinson's disease medications.

Parkinson's Disease – A movement disorder with four typical symptoms: tremor (involuntary rhythmic shaking), rigidity (stiffness of the limbs), bradykinesia/akinesia (slowness of movement/no movement), and postural instability (problems with balance or coordination). Parkinson's disease is caused by loss of a chemical in the brain called dopamine.

Physician Programmer – A small computer that is used to program the Activa System. The doctor can change the therapy settings using this programmer.

Stimulation – The delivery of electrical signals to the brain cells. The electrical signals may block some of the incorrect messages

processed by the brain in the areas that control movement.

Test Stimulation – The time period during the Activa System implant procedure where brain stimulation is evaluated to determine how well it controls your symptoms.

Ultrasound – The use of high frequency sound waves for diagnostic or therapeutic purposes.

2 PRESCRIBING INFORMATION

Physicians prescribe Medtronic Activa Therapy based on the information provided in this section. This medical and technical information is explained for patients in the following sections of this manual:

- Purpose of the Device on page 43
- When the Device Should Not be Used on page 49
- General Warnings on page 64
- Electromagnetic Interference on page 32
- Quick Look-up Table for Interference from Equipment on page 111

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.
- 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 the Model 3387/89 DBS Lead Manual. 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.

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. For more information, refer to "Theft Detectors and Security Gates" on page 93.

Precautions

Physician Training

Implanting Physicians – Implanting physicians should be experienced in stereotactic and functional neurosurgery.

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" in the Model 3387/89 DBS Lead Implant Manual for further information.

Storage Temperature – Store the DBS Lead between -30° F (-34° C) and 135° F (57° C). Temperatures outside this range can damage components.

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.

Magnet-Controlled Amplitude (Model 7424 Itrel II Neurostimulator only) – For Activa Therapy, always program Mag Amp, or Magnet-Controlled Amplitude, to the same value as the normal amplitude setting. If no Mag Amp value is programmed, the amplitude will decrease to zero when Mag Amp is activated, resulting in no stimulation whether the device is On or Off.

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 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.
- 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 2.1). 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.

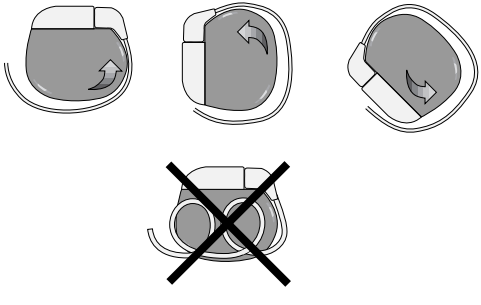

Figure 2.1 Wrap excess wire around the perimeter of the neurostimulator.

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 following sections for guidelines on the interaction of electromagnetic interference and an implanted Activa System.

Magnetic Resonance Imaging

To the patient: Conducting an MRI on patients with an implanted neurostimulation system can potentially cause injury. Before undergoing MRI be sure your physician reads the MRI safety information appendix in the physician

manuals for the Activa Therapy System or contacts Medtronic at 1-800-510-6735 for complete MRI safety information.

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.
- 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.

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.

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 1-800-510-6735.

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.

3 DESCRIPTIVE INFORMATION

Purpose of the Device

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

Refer to "Prescribing Information" on page 15 of this manual for indications for use.

Parkinson's Control Therapy

Activa Parkinson's Control Therapy delivers electrical stimulation to areas in your brain to help treat advanced Parkinson's disease. Electrical stimulation can be delivered to both sides of your brain to help relieve symptoms on both sides of your body. You may be a candidate for this therapy if your symptoms respond to levodopa, but levodopa and/or other medications have become less effective or ineffective. Activa Therapy increases "on" time, decreases "on" time with

dyskinesias, and improves the symptoms of Parkinson's disease in some patients. Individual results with Activa Therapy vary. The specific benefit of this therapy for an individual patient cannot be predicted.

Tremor Control Therapy

Activa Tremor Control Therapy delivers electrical stimulation to an area in your brain to help treat Essential Tremor or tremor associated with Parkinson's disease. It is used to treat tremor in one arm of your body. The system is used in patients who are diagnosed with Essential Tremor or Parkinsonian tremor not adequately controlled by medications and where the tremor is disabling.

Description of the Device

The brain stimulation system is implanted inside your body. A control magnet is used to turn the therapy on and off. The Activa System is made up of three major parts:

- The **lead** is made of four wires contained in a plastic tube. It carries the stimulation signal to the four electrodes (platinum rings) that deliver stimulation to the brain tissue. About four inches of the lead is implanted inside the brain. The rest of the lead (about 15 inches) is implanted under the skin of the scalp. Whether you have one or two leads depends upon your medical condition.
- The **extension** is made of four wires contained in a tube that connects the lead to the neurostimulator. The extension is connected to the end of the lead, just behind the ear (or where your doctor decides is the best placement). The

extension is then tunneled under the skin of the neck down to the upper chest area to connect to the neurostimulator. For each lead, you will have one extension.

- The **neurostimulator (battery)** is about 2.5 inches long, 2 inches high, and 0.5 inches thick. It contains a battery that is the power source of your system. The neurostimulator controls the stimulation. It is implanted just under the skin in the upper chest area.

Depending upon your medical condition, you may have one or two systems implanted (Figure 3.1).

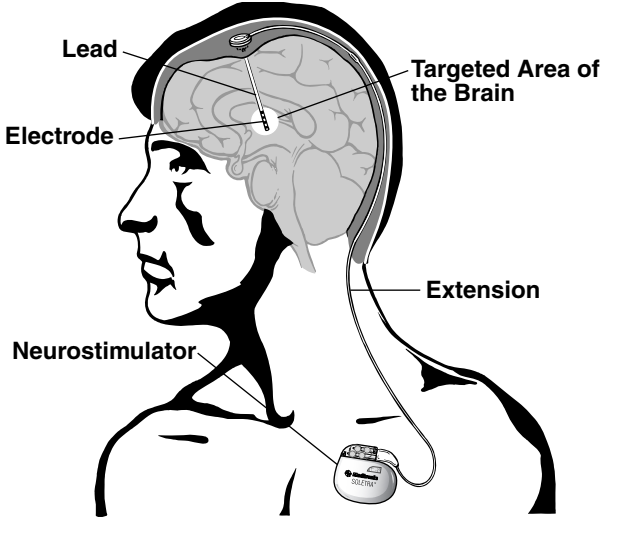

Figure 3.1 Parts of the brain stimulation system implanted inside your body.

How Does Your Brain Stimulation System Work?

Some of your symptoms are caused by abnormal messages sent by your brain. Your brain stimulation system delivers mild electrical stimulation to an area in the brain that controls movement. Stimulation blocks some of the messages as they travel to and from the brain. This may relieve the symptoms of your disease.

Your therapy helps control symptoms. **It is not a cure.** When you turn on the brain stimulation system, it will deliver stimulation that may decrease your symptoms. Symptoms will return when the system is turned off.

When the Device Should Not be Used (Contraindications)

An Activa Brain Stimulation System should not be used for:

- Patients who will be exposed to diathermy (deep heat treatment). Inform anyone treating you that you CANNOT have any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) anywhere on your body because you have an implanted neurostimulation system. Energy from diathermy can be transferred through your implanted system, can cause tissue damage and can result in severe injury or death.

  Diathermy can also damage parts of your neurostimulation system. This can result in loss of therapy from your neurostimulation system, and may require

additional surgery to remove or replace parts of your implanted device. Injury or damage can occur during diathermy treatment whether your neurostimulation system is turned "on" or "off."

- 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.
- Patients for whom test stimulation is unsuccessful.
- Patients who are unable to properly operate the neurostimulator.

Risks

Risks of the Activa Therapy can include risks of surgery, side effects, or device complications.

Risks of Surgery

Implanting the neurostimulator system carries the same risks associated with any other brain surgery. Risks may include:

- Paralysis, coma, and/or death
- Bleeding inside the brain (stroke)
- Leakage of fluid surrounding the brain
- Seizures
- Infection
- Allergic response to implanted materials
- Temporary or permanent neurologic complications
- Confusion or attention problems

- Pain at the surgery sites
- Headache

Possible Side Effects

Side effects of brain stimulation may include the following:

- Tingling sensation (paresthesia)
- Temporary worsening of the patient's disease symptoms
- Speech problems like whispering (dysarthria), and trouble forming words (dysphasia)
- Vision problems (double vision)
- Dizziness or lightheadedness (disequilibrium)
- Facial and limb muscle weakness or partial paralysis (paresis)
- Abnormal, involuntary movements (chorea, dystonia, dyskinesia)

- Movement problems or reduced coordination
- Jolting or shocking sensation
- Numbness (hypoesthesia)

Possible Device Complications

- There may be pain, lack of healing, or infection where the brain stimulation system parts are implanted.
- The brain's stimulation system parts may wear through your skin which can cause an infection or scarring.
- The lead or lead/extension connector may move. You may need surgery to re-adjust the location.
- Activa Therapy could stop because of mechanical or electrical problems. Either of these would require surgery. The neurostimulator battery needs to be changed every 3-5 years, on average.

- Your body may have an allergic reaction to the brain stimulation system. Your body could also reject the system (as a foreign body).
- There is the possibility of tissue damage resulting from the programming parameters or a malfunction of one of the parts of the brain stimulation system.

Benefits

For Patients with Parkinson's Disease

Activa Therapy delivers electrical stimulation to areas in the brain to help treat patients with advanced Parkinson's disease. Electrical stimulation can be delivered to both sides of the brain to help relieve symptoms on both sides of the body.

Activa Therapy may be beneficial in:

- Increasing your "on" time,

- Decreasing your "on" time with dyskinesias and,
- Improving your symptoms of Parkinson's disease.

Your therapy helps control symptoms. **It is not a cure.** When you turn on the brain stimulation system, it will deliver stimulation that may decrease your symptoms.

For Patients with Essential Tremor or Parkinsonian Tremor

Activa Therapy delivers electrical stimulation to areas in the brain to help treat patients with Essential Tremor and tremor associated with Parkinson's disease. Electrical stimulation is delivered to one side of your brain to help relieve symptoms on one side of your body.

Your therapy helps control your tremor. It is not a cure. When you turn on the brain stimulation system, it will deliver stimulation

that may decrease your tremor. Your tremor will return when the system is turned off.

What to Expect From Your Implant Procedure

Provided below is general information about how the Activa Brain Stimulation System will be implanted. Your doctor can provide you with more specific information about your implant procedure.

Before Surgery

The evening before surgery, you may be instructed to stop taking all of your medications. This is so the effect of Activa Therapy on your symptoms can best be determined. You will be admitted to the hospital either the night before or the morning of your surgery. You may have your head shaved prior to surgery to help prevent infection.

The Day of Surgery

Your surgery may consist of these steps:

1. A metal frame will be attached to your head. The frame is a special instrument that allows your surgeon to find the correct path to the target site in your brain.

2. Pictures of your brain will be taken using MRI (magnetic resonance imaging) and/or computer-aided tomography (CAT) scans. This will allow your surgeon to determine the area in your brain where the leads will be placed.

3. You will then go to the operating room where a small hole will be drilled in your skull for each system. You will receive local anesthesia before this procedure. This hole is needed to place the lead in your brain. Later in the surgery, a hole cap will be placed over this hole.

4. Your surgeon will test stimulate areas of your brain to determine the best placement for the lead. You will be awake, but lightly sedated. This is so you can help determine, along with your doctor, when your symptoms are best controlled. Your doctor may move your arms or legs, or ask you to tap your fingers, move your hands, or pretend to drink from an ceramic cup. This will help your doctor to determine if the Activa System is controlling symptoms like rigidity, slowness of movement, and tremor.

5. When the best target in the brain is located, the lead is then passed into the brain. The control of your symptoms will be checked again. The lead's position is then held in place with a hole cap in the hole in your skull.

6. The metal frame is then removed from your head. If you do not have the extension and the neurostimulator implanted right away, you will typically be allowed to go home in approximately 24 to 48 hours. Your doctor will decide the length of your hospital stay.

7. When you have the extension and neurostimulator implanted, you will be sedated and asleep. Refer to Figure 3.2 and Figure 3.3 to see the implanted components of the Activa Brain Stimulation System. You will typically be allowed to go home in approximately 24 to 48 hours. Your doctor will decide the length of your hospital stay.

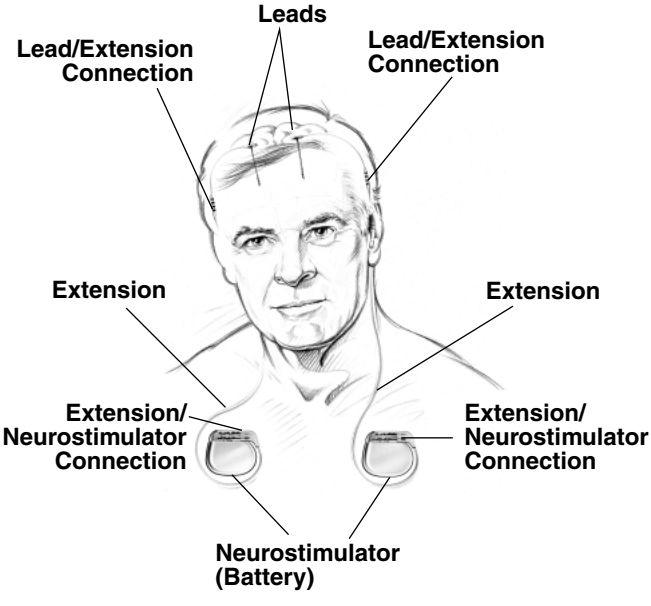

Figure 3.2 The Implanted Activa Brain Stimulation System.

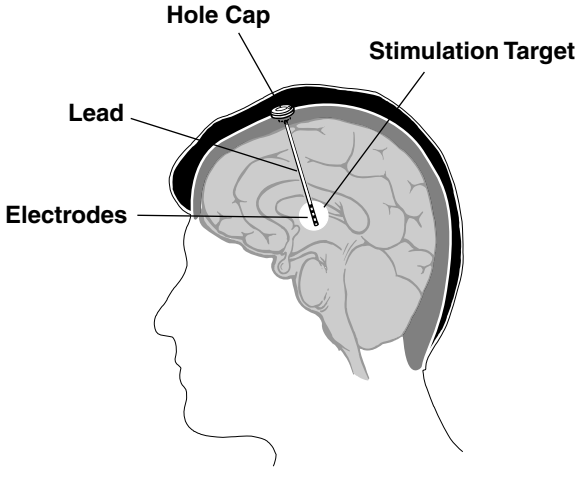

Figure 3.3 The Location of the Lead in Your Brain.

After Surgery

Healing stage

Your doctor will decide when to turn on your neurostimulator. It may be turned on immediately or after healing is complete (about four weeks).

First programming

Your doctor (or nurse) will use a computer called a physician programmer to turn on your neurostimulator. This programming session sets the stimulation to best control your symptoms and may take several hours. You may have to return to the clinic a few times to have the stimulation adjusted in order to achieve the best symptom control for you, especially during the first few months after implant.

Changes in Therapy

There may be changes in the level of your symptom suppression over time. These changes may include:

- Less relief or no symptom relief
- Loss of effective stimulation

In many cases, your doctor can correct these changes by programming the brain stimulation system again. However, surgery may be required to reposition or replace the lead, replace the system, or remove the system.

Because your disease changes with time, your condition may improve, may worsen, or may remain unchanged with stimulation.

General Warnings

Also refer to "When the Device Should Not be Used (Contraindications)" on page 49 and "About Electromagnetic Interference (EMI)" on page 92 for more safety information.

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

Excessive Stimulation – There is the possibility of brain tissue damage from high stimulation settings or a malfunction of one of the parts of the neurostimulator.

Medications that Slow Blood Clotting – If you are a candidate for implant surgery and are taking medications that slow clotting of the blood [anticoagulants (e.g., aspirin, coumadin)], inform your doctor. These medications increase the risk of bleeding during surgery.

General Precautions

Battery Longevity and Brain Target Selection – Systems implanted in the Globus Pallidus (GPi) may have shorter battery life than systems implanted in the Subthalamic Nucleus (STN).

Component Failures – The brain stimulation system may unexpectedly stop working due to the battery wearing out or other causes.

Lead Materials – Over time, there is some risk that the lead could break down. If this would happen, the breakdown materials are known to cause nerve damage or cancer in animals. The chance of these effects occurring in patients who receive the device are not yet known.

Magnetic Resonance Imaging – If you are using your neurostimulator to control tremor and need to have a magnetic resonance

imaging (MRI) scan, inform your doctor. Image quality during MRI scans may be reduced, because the tremor may return when the neurostimulator is turned off. Refer to "When the Device Should Not be Used (Contraindications)" on page 49 and "Interference Likely – Medical and Dental Environment" on page 102 for information on MRI.

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.

Pushing or Twisting the Implanted Parts of Your System – Avoid pushing or twisting the implanted parts of your system, such as the neurostimulator. This can damage the system or cause skin erosion. This may require surgery.

Use in Specific Populations – The safety and effectiveness of this therapy is not known for:

- Patients with neurological disease origins other than Parkinson's disease or Essential Tremor
- Patients with a previous surgical ablation procedure (e.g. pallidotomy, thalamotomy)
- Patients who are pregnant
- Patients younger than 18 years
- Patients older than 75 years (Parkinson's Control Therapy)
- Patients older than 80 years (Tremor Control Therapy)
- Patients with dementia
- Patients at high risk for bleeding (e.g. coagulopathies)

- Patients with moderate to severe depression

Electromagnetic Interference (EMI)

Electromagnetic Interference is a field of energy (electrical, magnetic, or both) made by equipment found in the home, work, medical or public environments that is strong enough to interfere with your neurostimulator. Electromagnetic Interference could cause:

- **Serious Injury or Death,** resulting from heating of the implanted system components, which can damage surrounding tissue. See "When the Device Should Not be Used (Contraindications)" on page 49 and "About Electromagnetic Interference (EMI)" on page 92.

- **System Damage,** requiring surgical replacement; or result in a loss of, or change in, symptom control.
- **Changes in your Neurostimulator Function,** causing it to switch ON or OFF, or reset to factory settings which may result in loss of stimulation, return of symptoms, and require reprogramming by your doctor.
- **Unexpected Changes In Stimulation,** causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as "shocking" or "jolting."

If you think that equipment is interfering with your neurostimulator function, you should do the following:

1. Move away from the equipment or object.

2. If possible, turn off the equipment or object.
3. If necessary, use the control magnet to return your neurostimulator to the desired on or off state.
4. Inform the equipment owner/operator of what happened.

If the above actions do not correct the effects of the interference, or if you think that your therapy is not effective after exposure to EMI, you should contact your doctor.

Refer to "Electromagnetic Interference" on page 92, for information on sources of Electromagnetic Interference and their effect on you and your brain stimulation system.

Living with Your Activa Therapy: What You Should Know

The following guidelines about your brain stimulation system will help to ensure that you receive the safest and most effective treatment.

- **Always tell any medical personnel that you have an implanted brain stimulation system and tell them where it is located.** If they have any questions, they should contact Medtronic at 1-800-510-6735.
- If you experience any unusual symptoms that you think may be related to your neurostimulator, contact your doctor.
- If you have a family member or caregiver, ask them to read this manual along with you. There may be situations where you need their assistance.

- Go to all follow-up appointments. This will ensure that you get the best care.
- When the neurostimulator is turned off, your symptoms will return. Some symptoms return quickly. Other symptoms may take longer to return.

When to Call Your Doctor

Call your doctor if any of the following situations occur:

- You experience pain, redness, or swelling along the scalp, neck, or chest where the stimulation system is implanted.
- You are not receiving enough relief from your symptoms.
- You are not receiving any relief from your symptoms and it appears that the neurostimulator is turned on.
- You feel uncomfortable or painful sensations during stimulation. First, turn

off the neurostimulator, then call your doctor.

- You cannot turn on or turn off the neurostimulator.
- You experience unexpected changes in your symptoms.
- You experience any unusual symptoms that you think may be caused by electromagnetic interference (e.g., theft detectors).
- You lose your control magnet.

Recovering at Home

After your surgery, your doctor or nurse will give you instructions about care at home. These instructions often include information about the healing process after surgery, medication to take, and when to return to your daily activities.

Healing

It takes several weeks to heal from surgery. You will feel some discomfort from the incision sites. You will feel some discomfort or pain at the neurostimulator sites during the healing process. If you notice unusual symptoms, contact your doctor.

Medication

Always follow your doctor's instructions for taking medication.

Daily Activities and Exercise

During your recovery, follow your doctor's instructions. On the advice of your doctor, you should be able to return to your normal lifestyle after a period of healing.

Returning to your daily activities should make you feel better, not worse. Ask your doctor about activities that include bending of your neck, raising your arms over your shoulders, or strenuous activities like lifting heavy objects.

Use care when you choose any activities that may result in accidents or falls. Sudden jerky movements may cause the leads to move. Falls may damage parts of the implanted system. Surgery may be needed to repair or replace the brain stimulation system parts.

4 OPERATING INFORMATION

Using Your Control Magnet

A control magnet is used to turn your neurostimulator on and off. When the therapy is turned on:

- Patients with tremor (caused by Essential Tremor or Parkinson's disease), may feel a brief tingling sensation, and relief from symptoms is seen almost immediately.
- Patients with other symptoms of Parkinson's disease often do not feel any sensation, and the full effect of the therapy may not be immediate.

There may be a slight possibility of a "jolting" or "shocking" sensation when the therapy is turned on.

Turning Your Neurostimulator On or Off

To start (and stop) therapy, you will place your control magnet over your neurostimulator for one to two seconds (Figure 4.2). Your doctor or nurse will show you how to position the magnet over your neurostimulator. Use the control magnet as explained to you by your doctor or nurse. Instructions are also given on the next few pages.

Before using your control magnet, read the entire procedure below and examine figures 4.2-4.4 on the following pages.

Note: Family members or caregivers should be able to turn the neurostimulator on and off using the magnet.

1. Grasp the magnet with the flat end away from you (Figure 4.1).

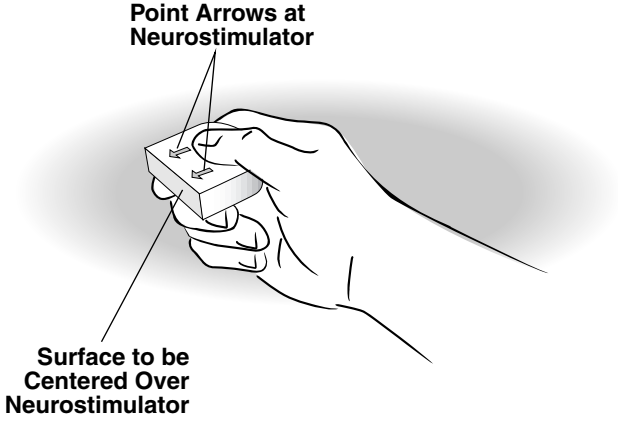

Figure 4.1 Grasp magnet with flat end away from you.

2. Press the flat end of the magnet directly over the length of your neurostimulator (Figure 4.2). Position the magnet so that the arrows are toward your body (Figure 4.3).

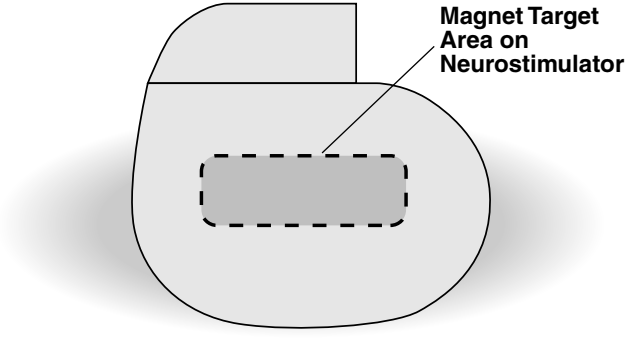

Figure 4.2 Magnet centered over neurostimulator.

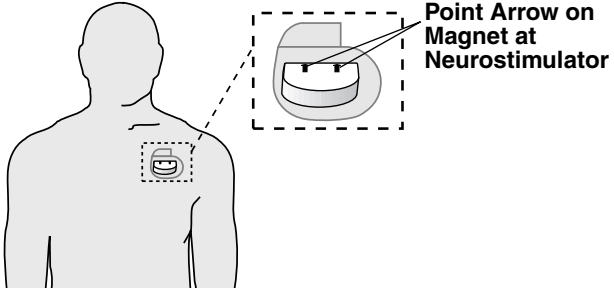

Figure 4.3 Position magnet over neurostimulator and hold in position for one to two seconds.

3. Hold the magnet steady in place for one to two seconds and then remove it.

Note: If you have trouble turning your neurostimulator on or off, try changing the position of the magnet. Picture your neurostimulator as the face of a clock. Then place the magnet in the one o'clock position as shown in Figure 4.4. If the one o'clock position does not work try the four o'clock position.

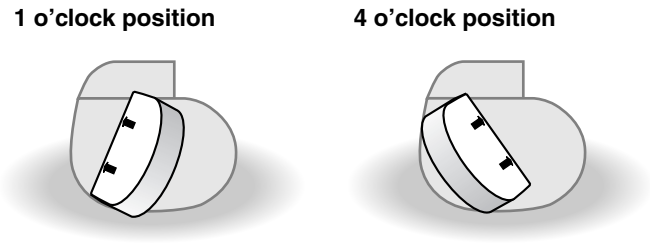

Figure 4.4 You may need to position the magnet at the 1 o'clock or 4 o'clock position.

If you have tried repositioning the magnet, but your symptoms do not decrease at the time they normally do, contact your doctor.

Carrying Your Magnet

Your control magnet is a very strong magnet.

Cautions:

- When carrying your control magnet in a pocket or purse, make sure the magnet is on the other side of your body from where the neurostimulator is placed. The control magnet may come close enough to the neurostimulator to turn your therapy on and off when you don't expect it.
- Keep your control magnet away from children.

Storing Your Magnet

The magnetic field of the control magnet can affect other items such as watches, credit cards, and computer discs. These items can be easily protected by keeping the control magnet away from them, as described below:

Keep more than 2 inches away. Store the control magnet more than two inches away from a wristwatch, pocket watch, and clock. The control magnet can stop them from working.

Keep more than 6 inches away. The magnetic field of the control magnet may damage the information on some magnetic items. To prevent damage, keep the magnet more than 6 inches away from the following items:

- Items with a magnetic strip such as bank cards and credit cards.
- Magnetic media such as video and audio cassette tapes and computer disks.
- Home electric items such as personal computers, VCRs, televisions, or cameras.

Expected Battery Life

When you visit the clinic or doctor, the energy level of the battery in your neurostimulator will be checked. The length of time the battery will last depends on your programmed settings and the amount of time you use your neurostimulator.

Typically your battery will last three to five years. However, depending on your neurostimulator settings the battery may last as few as one and a half years or as long as seven years. Your doctor can give you an estimate.

To extend the life of your battery, turn off your neurostimulator if you do not need therapy.

As the energy in the battery is reduced, the therapy may not be as effective. This is normal. If you feel this kind of change, ask your doctor to check the battery. No surgery

is required for your doctor to check your battery.

The battery is a permanent part of the neurostimulator. To replace the battery, your doctor must replace the neurostimulator. This is a minor surgical procedure typically done using a local anesthetic. It does not require the use of a head frame.

Instructions on Disposing of Your Device

If your implanted system is ever explanted, your physician will dispose of your device for you.

The neurostimulator must be removed before a body is cremated. The cremation process can cause the battery to explode.

Your Patient Identification Card

A patient identification card (Figure 4.5) identifies you as having an implanted medical device. This card also provides basic information about your neurostimulator and lists your doctor's name and telephone number. The information is important for others to know, should you need to bypass a security system, or in case of a medical emergency. Keep this card with you at all times.

You will receive a temporary card during your hospital stay. Several weeks after your surgery you will receive a plastic-coated card.

If you change your address or doctor's information, contact Medtronic. Include the current information and indicate the changes. You may either call 1-800-510-6735 with the information or send the information to:

Medtronic Neurological and Spinal
Device Registration
P.O. Box 59262
710 Medtronic Parkway
Minneapolis, MN 55459-9896

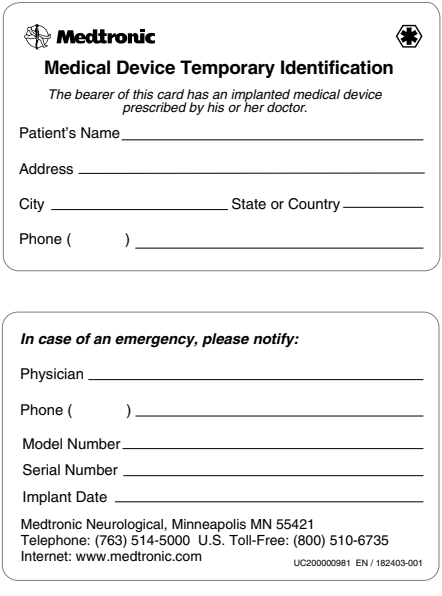

Figure 4.5 Patient Identification Card.

5 TROUBLESHOOTING

Note: If your problem is not solved after several attempts, or if your problem is not described here, contact your doctor.

What should I do if I have trouble turning on my Activa Therapy or if I can't tell if it's turned on?

Your doctor can advise you as to how long it takes to feel the effects of the therapy. This time can be different from patient to patient. It also depends upon your medical condition.

After you have waited the appropriate amount of time after turning on your therapy, use your control magnet and try again. Be sure you hold your magnet directly over the neurostimulator. Also, try rotating the magnet to the 1 o'clock or 4 o'clock position (refer to Figure 4.4 on page 81).

If your symptoms are making it difficult for you to use your magnet:

1. Place the magnet on a stationary object like a bookshelf or countertop, or on a metal surface like the side of a refrigerator.
2. Move your body so that the magnet is centered over your neurostimulator for one or two seconds, and step away.

If you still cannot turn on your therapy, call your doctor.

What should I do if I think that my neurostimulator has turned off accidentally?

Turn your neurostimulator back on using your control magnet and the instructions provided in the section, "Turning On and Turning Off Activa Therapy" on page 108. If this is happening often, review the section "About Electromagnetic Interference (EMI)"

on page 92 and try to identify the source of the problem.

6 ELECTROMAGNETIC INTERFERENCE

About Electromagnetic Interference (EMI)

Electromagnetic interference is a field (electrical, magnetic or a combination of both) that is generated by various equipment found in medical, work, and home environments. This equipment can create enough interference to do the following;

- Turn your neurostimulator off or on
- Cause stimulation that can result in an uncomfortable sensation
- Reset your neurostimulator to factory settings, which will require reprogramming by your doctor

Your neurostimulator is designed to protect against most EMI. However, strong

electromagnetic fields and permanent magnets can interfere with your system.

Specific warnings regarding possible effects from EMI are provided in the section "Electromagnetic Interference (EMI)" on page 68.

Even when the therapy is turned off, interference can affect the lead(s). If you suspect EMI, move away from the source of the EMI. If possible, turn off the suspected source of EMI. Then use your control magnet to turn your therapy on or off.

Theft Detectors and Security Gates

Caution: Walking through some theft detectors or security gates can cause an increase in stimulation or additional stimulation. It could also turn on or turn off your neurostimulator.

Use care when approaching security arches or gates (such as those found in airports, libraries, and some department stores). If an airport security wand is used, ask the security personnel to avoid placing the wand over your neurostimulator.

When approaching these devices, do the following:

1. If security personnel are present, show them your neurostimulator identification card and request a hand search.
2. If you must pass through the security device, approach the center of the device and walk normally.
    a. If two security gates are present, walk through the middle, keeping as far away as possible from each gate.
    b. If one gate is present, walk as far away as possible from it.

Note: Some theft detectors may not be visible.

3. Proceed through the security device. Do not linger near the device.

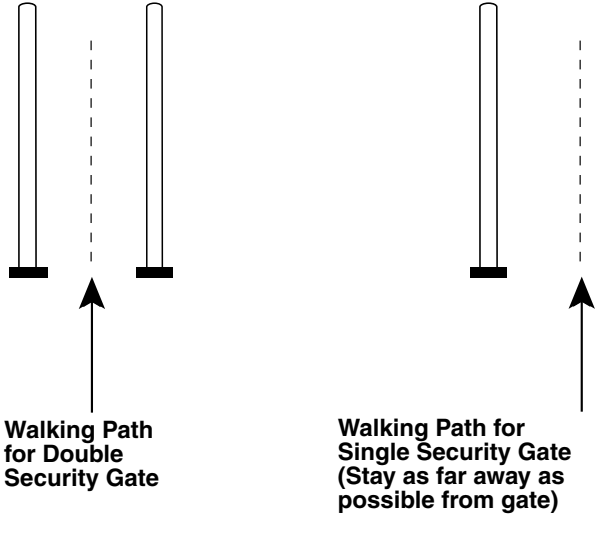

Figure 6.1 Walking Through Security Gates

4. If you suspect that your neurostimulator was turned off, make sure someone is able to turn on your system again. (The

person could be you, if your medical condition allows it. Or, it could be someone who has been taught how to use the system.)

Home and Work Environments

Most home appliances and office equipment will not affect your therapy, if they are installed properly and in good working order.

Interference Likely – Home and Work Environment

Avoid the following equipment or environments. EMI from the following may affect or damage the neurostimulator.

- Antenna of a citizen band or ham radio
- Electric arc or resistance welding equipment
- Electric induction heaters used in industry to bend plastic

- Electric steel furnaces, for example, the blast furnaces found in steel mills, not the furnaces found in your home.
- Power lines
- Television and radio transmitting towers
- Electric substations and power generators
- Therapeutic magnets, if placed close to neurostimulator

Possible Interference – Home and Work Environment

Some household items have small, strong magnets. You can use these items if you keep a distance that is expected for normal use of the item. Some examples are described below. If you notice that your therapy is affected by being too near to an item, move away from it. If EMI has started or stopped your therapy, use the control magnet to return your therapy to its original state.

- You can open and shut a **refrigerator or freezer door**. However, do not lean against the magnetic strip inside a refrigerator or freezer door.
- You can listen with a **standard, cordless or cellular telephone handset**, but do not pass or lay the **earpiece** over the neurostimulator because you may turn it on or off.
- You can be near **stereo speakers** and **radios for the home or the car**. However, do not lift or carry them so that they are close to or touching the part of your body where the neurostimulator is located.
- You can use a **sewing machine** or **salon hair dryer**. However, keep your neurostimulator away from the motors (such as when leaning over these items).

- You can use an **induction range (or smooth top range)**. However, keep your neurostimulator away from the burners.
- You can use **power tools** when the motor is kept away from the neurostimulator. Do not lean against the tool. Use caution when using power tools that may be unsafe if your symptoms would return.

Safe from Interference – Home and Work Environment

The following items should not interfere with your neurostimulator when they are properly installed and in good working order:

- Microwave ovens
- Appliances like washing machines, dryers, electric stoves, toasters, blenders, electric can openers, and food processors
- Electric blankets and heating pads
- Hand-held items like hair dryers, shavers, remote controls, and pagers
- Home security systems
- Personal computers, electric typewriters, copiers, and FAX machines
- Televisions, AM and FM radios, and stereos
- Vacuum cleaners and electric brooms

Medical and Dental Environments

Tell medical and dental personnel that you have a neurostimulation system which works similar to a pacemaker. (Both systems create amounts of electricity.)

Most routine diagnostic procedures, such as **fluoroscopy** and **x-ray** do not affect the system. And, some procedures can be done when precautions are taken. However, interference from some medical procedures can:

- Damage a component of your system requiring surgery to replace it; or
- Affect your brain stimulation system, for example, turning your neurostimulator on or off; or
- Cause harm to you, for example, heating a system component enough that it can cause tissue damage.

Interference Likely – Medical and Dental Environment

The following procedures can damage the neurostimulator or cause harm to you:

Avoid the following procedures:

- **Diathermy** (deep heat treatment).

Note: Additional safety information about diathermy is located in the front of this manual. Refer to "When the Device Should Not be Used (Contraindications)" on page 49.

If any of the procedures listed below are required, please inform your treating doctor that you have an implanted neurostimulator. Your doctor should contract Medtronic at 1-800-510-6735 for more information:

- **Magnetic Resonance Imaging (MRI).** Some types 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.

- **Cautery or Electrocautery** (stops the bleeding of blood vessels. It is used during most surgeries.)
- **External defibrillation** (strong electrical shock that slows a fast heartbeat)
- **Lithotripsy** (the crushing of stones using electricity. These stones are usually in the gallbladder or urinary tract.)
- **Radiation therapy** (often used in cancer treatment). This may be done if the focus of the therapy is away from the neurostimulator.

- **Psychotherapeutic Procedures.** The safety of psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroshock therapy, transcranial magnetic stimulation) is not known.

Possible Interference – Medical and Dental Environment

The following procedures can be done when the therapy is turned off and when the medical equipment is not directly over your neurostimulator. If the equipment is placed over your neurostimulator, it may be turned on accidently, or it can be permanently damaged which will require surgery.

- **Dental drills and ultrasonic probes** (used to clean teeth)
- **Electrolysis** (removes unwanted hair)

Note: Additional safety information about therapeutic ultrasound is located in the front

of this manual. Refer to "When the Device Should Not be Used (Contraindications)" on page 49.

The following procedures and devices require safeguards:

- **Implantable device that senses electrical signals** such as a **pacemaker** or **defibrillator** (medical device placed inside the body to regulate the heart rate). Tell the cardiac doctor that you have a neurostimulator.
- **Mammography** (x-ray of breast tissue). When an x-ray requires tight pressure around the neurostimulator, such as during mammography, tell the person using the equipment that the brain stimulation system should not be squeezed tightly. Too much pressure can permanently damage the system which will require replacement surgery.

Safe from Interference – Medical and Dental Environment

The following medical procedures should not affect your therapy:

- **Computerized axial tomography (CT or CAT) scans.** (A special type of x-ray equipment that gives a cross-section view.)
- **Diagnostic ultrasound.** (An imaging technique which uses high-frequency sound waves)**.**
- **Diagnostic x-rays.** Diagnostic x-rays do not interfere with the system. However, tight pressure can affect the system, as described above in Mammography.

7 COMMON QUESTIONS

About the System and its Components

Will the neurostimulator show through my clothes?

Depending on your body build, the neurostimulator may be noticeable as a small bulge under the skin. However, your doctor will try to place the neurostimulator in a place that is most comfortable and cosmetically acceptable.

What does stimulation feel like?

You may not feel stimulation. You will experience the effects of stimulation when it reduces the symptoms of your medical condition. However, some people may feel a brief tingling sensation when the therapy is first turned on. Higher levels of stimulation

have been described as uncomfortable, "jolting" or "shocking" by some patients.

Does the brain stimulation system make any noise?

No.

Turning On and Turning Off Activa Therapy

What happens if the neurostimulator stops working?

Your symptoms will return. If you can't determine the possible cause and correct the problem, contact your doctor.

Will I be able to increase or decrease the strength of stimulation?

No. The strength of stimulation can only be changed by your doctor. Your doctor will make these changes for you.

Everyday Use of Your Therapy

Will I be able to resume my normal daily activities?

For the first few weeks after surgery, you should avoid strenuous activity, and arm movements over your shoulder, and excessive stretching of your neck. You may gradually want to try activities that were difficult before your surgery. Talk about this with your doctor first.

Can stimulation be used during pregnancy?

The safety of using Activa Therapy during pregnancy or delivery is not known. If you learn, or think, that you are pregnant, turn off your neurostimulator and call your doctor.

What should I do if the stimulation changes or becomes uncomfortable?

Turn off your neurostimulator and contact your doctor immediately. If needed, ask a family member or caregiver familiar with the use of the magnet and the device to help you.

8 QUICK LOOK-UP TABLE FOR INTERFERENCE FROM EQUIPMENT

Equipment in your daily environment could affect your system. Ways to minimize or prevent interference from happening, is discussed in the chapter "Troubleshooting" beginning on page 89. To help you quickly locate information about an item, use this table to find the page number containing details.

Table 8.1 Quick Look-up Table for Interference from Equipment[a]

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Airport security gates		✓		93
Arc welding equipment			✓	96
Blenders	✓			100
CAT (or CT) scan	✓			106
Cautery			✓	103
Cellular phones		✓		98
Computers, personal	✓			100
Copiers	✓			100
Defibrillation, external			✓	103
Defibrillation, implantable		✓		105
Dental Drills		✓		104

Table 8.1 Quick Look-up Table for Interference from Equipment[a]

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Dental ultrasonic probes		✓		104
Diagnostic ultrasonic	✓			106
Diathermy treatment			✓	49, 102
Dryers (clothes)	✓			100
Electric blankets	✓			100
Electric brooms	✓			100
Electric can openers	✓			100
Electric power generators			✓	97
Electric stoves	✓			100
Electric substations			✓	97
Electric typewriters	✓			100

Table 8.1 Quick Look-up Table for Interference from Equipment[a]

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Electrocautery			✓	103
FAX machines	✓			100
Fluoroscopy	✓			101
Food processors	✓			100
Freezer door		✓		98
Hair dryers, salon		✓		98
Hair dryers, hand-held	✓			100
Ham radio antenna			✓	96
Heating pads	✓			100
Home security system	✓			100
Induction furnace			✓	96
Induction heaters for industry			✓	96
Libraries, theft detectors		✓		93

Table 8.1 Quick Look-up Table for Interference from Equipment[a]

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Lithotripsy			✓	103
Magnets, therapeutic			✓	97
Magnetic Resonance Imaging		✓		49, 64, 102
Mammography		✓		105
Microwave ovens	✓			100
MRI		✓		49, 64, 102
Pacemaker		✓		105
Pagers	✓			100
Personal computers	✓			100
Power generators, electric			✓	97
Power lines			✓	97
Power tools		✓		99

Table 8.1 Quick Look-up Table for Interference from Equipment[a]

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Psychotherapeutic procedures			✓	104
Radiation therapy			✓	103
Radio, AM and FM	✓			100
Radio antenna, Ham			✓	96
Radio transmission towers			✓	97
Radio with large speakers		✓		98
Range, induction		✓		99
Refrigerator door		✓		98
Remote controls	✓			100
Security gates at airports and other public places		✓		93
Security systems for the home	✓			100

Table 8.1 Quick Look-up Table for Interference from Equipment[a]

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Sewing machine		✓		98
Shavers	✓			100
Smooth top oven ranges		✓		99
Steel furnaces			✓	97
Stereos	✓			98
Stereo speakers		✓		98
Stores, theft detectors		✓		93
Stove, electric	✓			100
Surgery that uses cautery			✓	103
Telephone handset, standard		✓		98
Telephones, cellular		✓		98
Television	✓			100

Table 8.1 Quick Look-up Table for Interference from Equipment[a]

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Television towers for transmitting			✓	97
Theft detectors		✓		93
Toasters	✓			100
Transmission towers for television and radio signals			✓	97
Typewriters	✓			100
Ultrasonic, diagnostic	✓			106
Ultrasonic, therapeutic			✓	49
Vacuum cleaners	✓			100
Washing machines	✓			100
X-ray, CAT scan	✓			106
X-ray, diagnostic	✓			106

Table 8.1 Quick Look-up Table for Interference from Equipment[a]

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
X-ray, mammography		✓		105

[a.] Assuming equipment is in proper working order.

9 ADDITIONAL INFORMATION

More About Activa Therapy

For additional information about Activa Therapy, use these resources:

- Medtronic web site: www.medtronic.com
- Contact Medtronic Patient Services 1-800-510-6735
- Contact your doctor

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