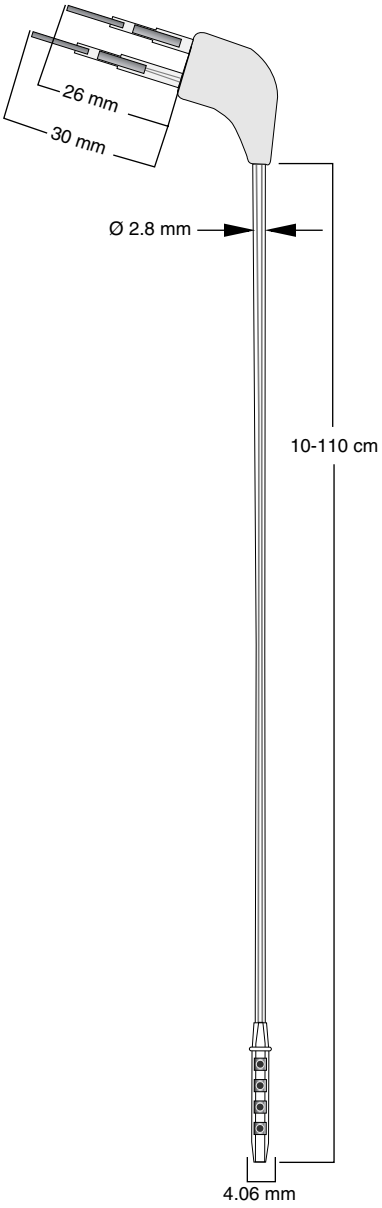
Medtronic

DBS™ 7482

Extension Kit for Deep Brain Stimulation

Implant manual

Rx Only



Model 7482 Extension (All dimensions are approximate.)

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Device Description

The Medtronic Model 7482 Extension has an in-line connector at its distal end and a dual-pin, four-contact plug at its proximal end. It is designed to connect a Medtronic Model 7426 Soletra or Model 7424 Itrel II[1] neurostimulator to a Medtronic Model 3387 or 3389 DBS lead (Figure 1).

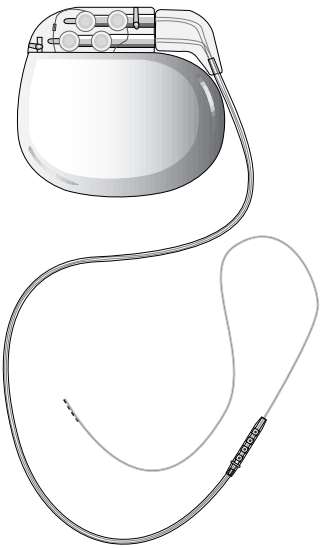

Figure 1. *Model 7482 Extension connected to a Medtronic neurostimulator and lead.*

System Description

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

Electrical signals are transmitted from either the Soletra Model 7426 or Itrel II Model 7424 Neurostimulator to targets in the brain via the Model 7482 or the Model 7495 DBS Extension and the Model 3387 or Model 3389 DBS Lead. The lead, extension, and neurostimulator comprise the implantable components of the Activa System.

The neurostimulator is comprised of electronic circuitry and a battery, which are hermetically sealed in a titanium case.

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

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: MRI and Activa Therapy" on page 37 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 the Model 3387/89 DBS Lead Manual in the section *Programming the Neurostimulator*. 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. Refer to “Patient Counseling Information” on page 32 for more information.

Precautions

Physician Training

Implanting Physicians – Implanting physicians should be experienced in stereotactic and functional neurosurgery. Refer to the “Physician Training Information” on page 31.

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 16 for further information.

Storage Temperature – Store the Model 7482 Extension 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). 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.

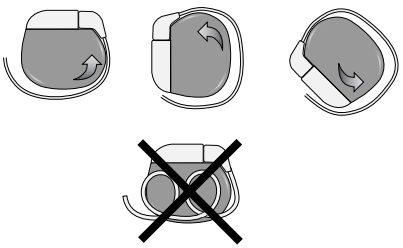

Figure 2. *Wrap excess wire around the perimeter of the neurostimulator.*

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

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, and refer to "Appendix: MRI and Activa Therapy" on page 37 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.

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, transcrananial 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.

Resterilization

The extension and accessories of the Model 7482 Extension Kit were sterilized with ethylene oxide before shipment. Inspect the sterile package for seal integrity and damage before opening and using the contents. If you are unsure of the components' sterility for any reason, they should be resterilized at the hospital site.

Note: If contamination is suspected because of a defective sterile package seal, extensions and accessories can be returned to Medtronic for replacement or they can be resterilized at the hospital. Replacements are otherwise subject to the terms of the Medtronic Limited Warranty (U.S. Customers). Medtronic does not accept returned leads or accessories for resterilization and return them to customers.

Due to variations in hospital sterilizers, precise instructions for sterilization or aeration cannot be given here. If further information is necessary regarding procedures to be used, contact the manufacturer of the sterilizer unit. Use biological indicators or other acceptable methods to validate the effectiveness of the hospital's sterilizer unit.

Medtronic cannot accept the responsibility for the hospital's resterilization of any components. If, however, the hospital decides to resterilize, usual and customary sterilization methods should be used.

Cautions:

- Do not resterilize and use extensions or accessories after exposure to body tissues or fluids.
- Do not use radiation to resterilize any component. Do not steam autoclave the extension.

Subject to the foregoing, the following suggestions may be considered. Table 1 is a summary of the applicable resterilization options and restrictions. The paragraphs following the table provide additional information.

Table 1. *Resterilization Options and Restrictions.*

Component	**Sterilization Methods**[a]		
	Ethylene Oxide 55° C (130° F) Maximum	Autoclave 121° C (250° F) 15 psig 30 minutes	"Flash" Autoclave 132° C (270° F) 27 psig 5 minutes
Extension	YES	NO	NO
Tunneling Tools: Extension Passer, Carrier, and Obturator	YES	NO	NO
Other Accessories	YES	YES	YES

[a] Medtronic cannot accept responsibility for the hospital's resterilization of any components.

Ethylene oxide (ETO) is an acceptable method for resterilization when the leads and accessories are repackaged in an ethylene oxide-permeable package. The temperature during the process should not exceed 55° C (130° F). Allow for the maximum aeration of ETO residues before implanting the lead and using accessories.

Steam autoclaving may also be used as a sterilization method for components marked "YES" for autoclave in Table 1. A standard cycle of 30 minutes at 121° C (250° F) and 15 psig is recommended. If components are marked "YES" for "flash" autoclave, a standard cycle of 5 minutes at 132° C (270° F) and 27 psig is recommended. Do not use any method that is marked "NO" for a component.

Directions for Use

Suggested Implant Procedure

Following the test stimulation phase, the system may be implanted using the following applicable procedures. If extended test stimulation was done using an externalized percutaneous extension, remove it as follows. Otherwise, refer to “Creating a Neurostimulator Pocket” on page 19.

Removing the Percutaneous Extension

For each implanted lead:

1. Withdraw the external segment of the percutaneous extension approximately 1 cm (0.4 in.) from where it exits the skin (Figure 3).

△ **Caution:** Use gentle traction on percutaneous extension to avoid dislodging the lead.

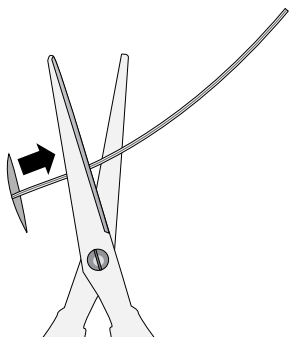

Figure 3. *Withdraw the external segment of the percutaneous extension.*

2. Sever and discard this section of extension.
3. Locate the lead’s percutaneous extension connector at the proximal end of the lead and make an incision to expose it. Allow room to hold the lead firmly to prevent dislodgement.

   Note: If an identifying mark was not made when the lead was implanted, probe the area with the fingers or use fluoroscopic observation.
4. Cut the suture and the connector boot over the setscrews to expose the setscrews (Figure 4).

△ **Caution:** Do not cut near lead when removing suture from percutaneous extension. Cutting lead’s insulation can result in loss of stimulation and lead failure.

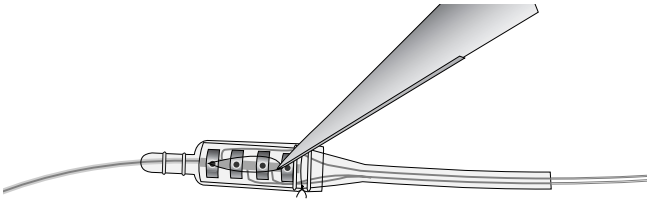

Figure 4. *Cut the suture and connector boot to expose setscrews.*

5. Using the hex wrench, loosen each of the four setscrews in the setscrew connector by turning the wrench counterclockwise (approximately one turn).
6. Gently remove the lead from the setscrew connector.

△ **Caution:** If resistance is felt when removing the lead from the percutaneous extension, loosen the setscrews slightly to ensure that they clear lead contacts. Avoid disengaging setscrews. Inspect lead contacts for damage (flattening or stretching of lead) if resistance was felt prior to removal.

7. Hold the setscrew connector and withdraw the percutaneous extension through the incision (Figure 5) and discard.

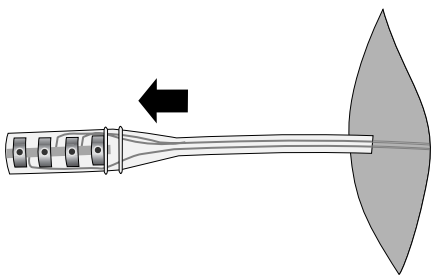

Figure 5. *Withdraw percutaneous extension.*

8. Remove the boot from the lead and discard the boot.
9. Repeat steps 1 through 8 for the other lead, if applicable.

Creating a Neurostimulator Pocket

1. Create a subcutaneous pocket for the neurostimulator using blunt dissection in the subclavicular region.

   Note: A neurostimulator should be located no more than 4 cm (1.5 in.) beneath the surface of the skin in subcutaneous tissue to ensure proper programming. The device must be placed parallel to the skin surface. The identification side of the neurostimulator must be visible.

2. Place the neurostimulator into the pocket to assure a proper fit and then remove it.

Tunneling Tools and Procedures

This section outlines tunneling from the lead incision site to the neurostimulator implant site to provide a path for the extension. The neurostimulator is typically placed in the subclavicular region although the implant location may vary depending upon the patient needs.

Tunneling tools supplied in the extension kit are the standard 38 cm length. The tunneling tools are also available separately in the standard length and in an extended length.

All tunneling tools are single use only.

Tools used for tunneling include (Figure 6):

- **The Extension Passer,** a hollow metal shunt that the obturator can slide through. The handle is attached to the proximal end of the passer and allows the obturator to snap in place for tunneling. The obturator can also be removed and an extension can be manually threaded through the passer.
- **The Obturator,** a narrow plastic cylinder with a sharp distal end that serves as the tunneling tip. The obturator slides through the extension passer and can be snapped in place into the extension passer's handle.
- **The Carrier,** an attachment like the obturator, but with two distal carrier ports for extension connectors.

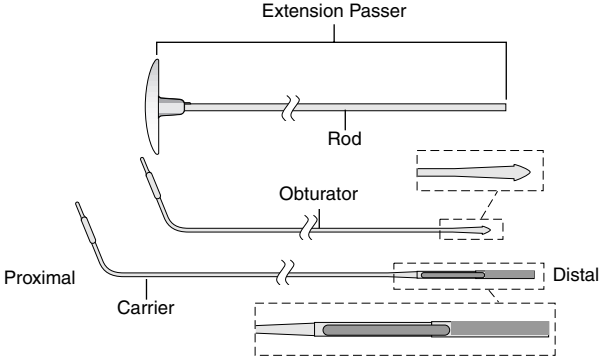

Figure 6. *Tunneling tools.*

Tunneling Preparation

1. If the obturator was removed from the passer, slide the proximal end of the obturator through the extension passer (Figure 7a).

   The pointed obturator tip will remain exposed at the distal end of the extension passer (Figure 7b).

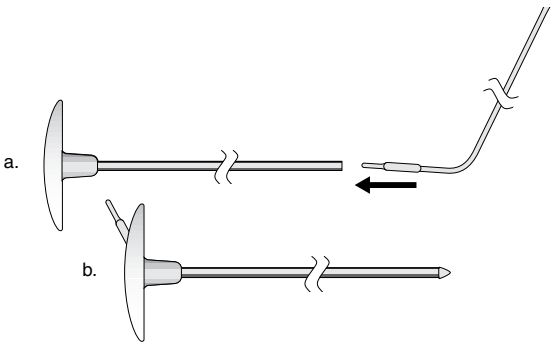

Figure 7. *Obturator slides through extension passer and snaps into the handle.*

2. Snap the proximal end of the obturator into the handle by folding the obturator down and pressing it into the groove in the handle (Figure 8).

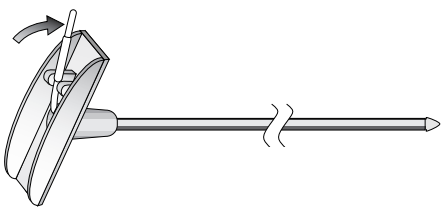

Figure 8. *Snap the obturator into the handle.*

3. Bend the extension passer as necessary to conform to the patient's body contour. Use caution not to kink the extension passer.

△ **Caution:** Do not bend the extension passer more than 90° at any one bend.

Suggested Tunneling Procedures

Following are two suggested tunneling procedures. Tunneling can be performed without or with a carrier.

Note: If the procedure is not done under general anesthetic, the anesthesiologist should administer the appropriate sedation to reduce patient discomfort during the tunneling portion of this procedure.

⚠ **Warning: Placement of Lead-Extension Connector in Neck –** The safety and effectiveness of neck placement of the connector between the lead and extension has not been established and has been associated with an increased incidence of lead fracture.

Tunneling Procedure without Carrier

1. Tunnel from the subgaleal pocket to an intermediate incision on either the top portion of the parietal bone or the mastoid area. Then tunnel from the intermediate incision to the neurostimulator pocket.

⚠ **Caution:** Use caution when approaching the pocket, proceed slowly to avoid additional trauma to the patient as resistance to tunneling suddenly ceases.

2. Make a secondary pocket at the intermediate incision site to contain the lead-extension so that the lead-extension connection does not lie directly below the incision.

   Note: Some surgeons who have experienced erosion at the lead-extension connection site on the skull have found that troughing the bone, or making a groove in the bone, helps lower the profile of the extension connection. This reduces the stress on the incision site and the skin and reduces the potential for erosion of the connector. Surgeons use a standard 5 mm round burr to make a trough in the shape and size of the connector boot used and approximately 3 mm in depth. Surgeons have reported that this step not only lowers the profile of the lead-extension connection, but also provides better stabilization so that the connection resists migrating downward into the neck area which can result in lead fractures.

   Note: Always tunnel from the lead site to the neurostimulator site. Do not tunnel in the opposite direction.

3. With the extension passer in place, remove the obturator by unsnapping the end that is attached to the handle and sliding the obturator out from the extension passer at the neurostimulator pocket (Figures 9a and 9b).

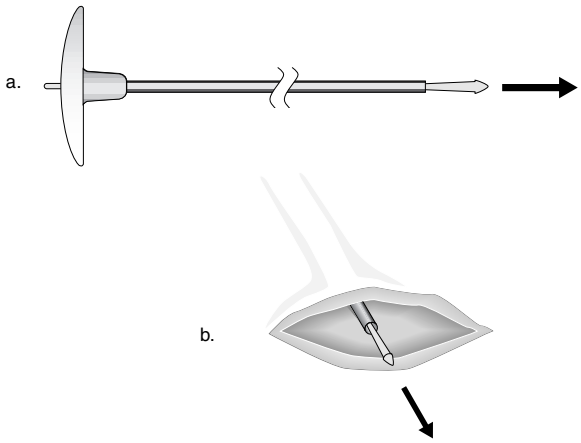

Figure 9. *Remove the obturator from the extension passer.*

4. Carefully insert the lead end of the extension into the extension passer and slide it through until it exits at the handle or until fully encompassed by the extension passer (Figure 10).

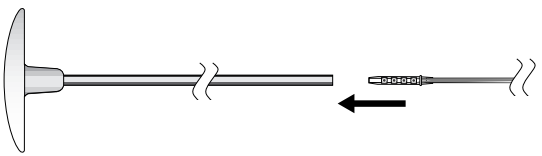

Figure 10. *Slide the extension into the extension passer.*

5. Remove the extension passer from the tunnel.

Tunneling Procedure with Carrier

1. Tunnel from the subgaleal pocket to an intermediate incision on either the top portion of the parietal bone or the mastoid area. Then tunnel from the intermediate incision to the neurostimulator pocket.

△ **Caution:** Use caution when approaching the pocket, proceed slowly to avoid additional trauma to the patient as resistance to tunneling suddenly ceases.

2. Make a secondary pocket at the intermediate incision site to contain the lead-extension so that the lead-extension connection does not lie directly below the incision.

Note: Some surgeons who have experienced erosion at the lead-extension connection site on the skull have found that troughing the bone, or making a groove in the bone, helps lower the profile of the extension connection. This reduces the stress on the incision site and the skin and reduces the potential for erosion of the connector. Surgeons use a standard 5 mm round burr to make a trough in the shape and size of the connector boot used and approximately 3 mm in depth. Surgeons have reported that this step not only lowers the profile of the lead-extension connection, but also provides better stabilization so that the connection resists migrating downward into the neck area which can result in lead fractures.

Note: Always tunnel from the lead site to the neurostimulator site. Do not tunnel in the opposite direction.

3. With the extension passer in place, remove the obturator by unsnapping the end that is attached to the handle and sliding the obturator out from the extension passer at the neurostimulator site (Figures 11a and 11b).

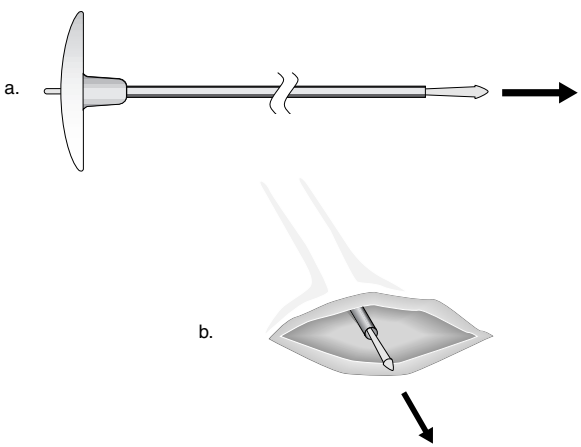

Figure 11. *Remove the obturator from the extension passer.*

4. Slide the carrier into the extension passer until it exits at the handle (Figure 12a). Snap the proximal end of the carrier into the handle. A single carrier port should remain exposed at the distal end of the extension passer (Figure 12b).

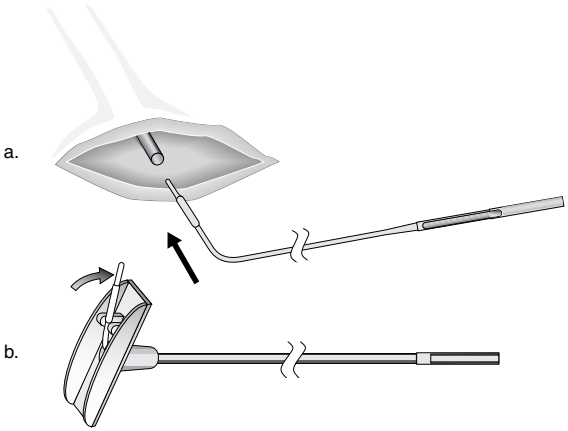

Figure 12. *Slide the carrier into the extension passer and snap the proximal end into the handle.*

5. Carefully insert the lead end of the extension into the carrier port until it snaps into place (Figure 13).

△ **Caution:** Use care when inserting the extension body into the carrier port. Rough handling can damage extension insulation.

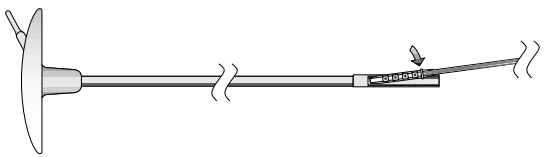

Figure 13. *Gently place the lead end of the extension into the carrier.*

6. Pull the extension passer, with the extension and carrier attached, through the tunneled path to where the lead lies anchored.
7. Completely remove the extension passer and carrier from the body.
8. Remove the lead end of the extension from the carrier.

Making the Lead-Extension Connection

Two different boot styles are provided, winged and cylindrical.

1. Push the boot over the proximal end of the lead.
2. Insert the lead fully into the setscrew connector junction socket. The four metal connector bands on the lead should be aligned under the four setscrews (Figure 14).

Caution: Wipe off any remaining body fluids from the surface of the lead contacts and extension connector.

Note: Sterile water may be used as a lubricant for ease of inserting the lead and as an aid in viewing the lead through the setscrew connector.

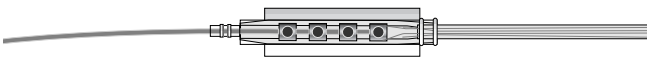

Figure 14. *Lead visible in viewing area (winged boot shown).*

3. Tighten each of the four setscrews with the hex wrench clockwise until resistance is felt (Figure 15). Continue tightening to a maximum of 1/4 turn. The setscrews must contact the lead connector sleeves for proper electrical connection.

Cautions:

- Do not overtighten the setscrews because overtightening could permanently damage the lead connector sleeves.
- Do not pull the lead body taut when implanted. The extension is available in different lengths. Select an extension length that allows connection without tension.

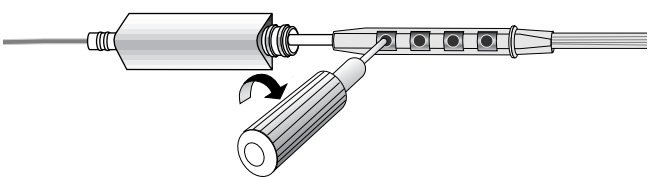

Figure 15. *Tighten setscrews (winged boot shown).*

Caution: Do not overtighten setscrews. Excessive torque on setscrews may damage the lead contacts.

4. Push the boot back over the lead-extension connection.

   Note: Sterile water may be used as a lubricant for ease of placing the boot.

5. Secure the connection with nonabsorbable sutures around both grooved ends of the boot (Figure 16).

Caution: Do not tie a suture directly to the extension or the lead body.

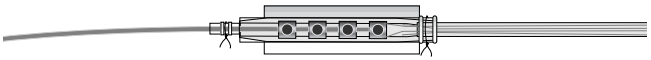

Figure 16. *Suture around suture grooves.*

Note: Gently pull excess extension length toward the implant pocket. The connection should lie straight in the subcutaneous plane with the lead and extension curving gently away.

6. If using a winged boot, make sure the flat side of the boot lies against the skull.
7. If using the cylindrical boot, suture it to the underlying tissue to minimize the possibility of migration. Place this suture in the suture groove at the proximal end of the boot covering the lead-extension connection. Loop this suture through the underlying tissue to stabilize the connection.
8. Close and dress the wound.

Making the Extension-Neurostimulator Connection

To make the connection between the extension and the neurostimulator:

1. Check the neurostimulator connector block and determine if any setscrews obstruct the socket. If necessary, partially back out the setscrews.
   a. To back out a setscrew, insert the hex wrench through the pre-pierced hole in the rubber grommet and turn the setscrew counterclockwise only until the socket is unobstructed.

⚠ **Caution:** Limit counterclockwise rotations of the setscrews. Rotate enough to provide an unobstructed pathway for extension connector pins. Too many rotations may disengage the setscrew from the neurostimulator connector block.

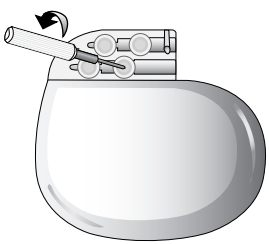

Figure 17. *Insert hex wrench in rubber grommet and turn setscrew counterclockwise to back out setscrew.*

   b. Wipe off any body fluids from the extension connector pins and connector block.

c. Check that the encapsulated diagram on the extension matches the diagram on the neurostimulator. Insert the extension connector pins into the neurostimulator sockets until fully seated within the neurostimulator connector block (Figure 18).

Note: If inserting the extension pins is still difficult, use sterile water as a lubricant.

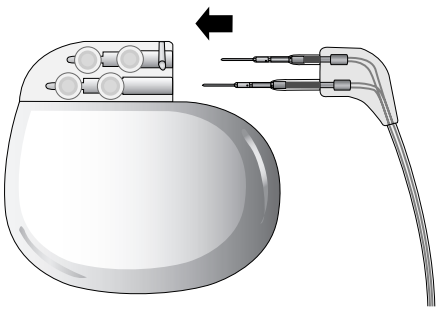

Figure 18. *Insert extension connector pins into neurostimulator socket.*

2. Once the extension connector pins are fully inserted in the neurostimulator sockets, do the following for each of the four setscrews:
   a. Insert the hex wrench through the rubber grommet to engage the setscrew.
   b. Tighten the setscrew by turning the hex wrench clockwise until resistance is felt (Figure 19).
   c. Continue tightening **for a maximum of 1/4 turn**. The setscrews must touch the extension connector pins for proper electrical connection.

△ **Caution:** Do not overtighten the setscrews or permanent damage to the setscrews and/or sockets could result. Verify that each leaf of the sealing rubber grommet has closed.

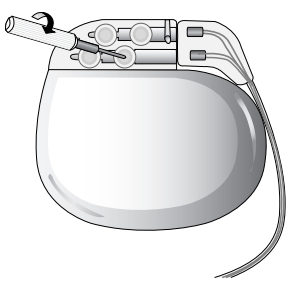

Figure 19. *Fully seat connector to block and insert hex wrench to engage setscrew.*

Note: The sealing rings within the neurostimulator connector block are designed to form a seal with the extension connector pins. No sealant or sutures are required.

3. Place the neurostimulator into the subcutaneous pocket (Figure 20). Position the neurostimulator so that no sharp bends occur along the extension or lead (Figure 21).

△ **Caution:** 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, and to minimize possibility of skeletal muscle stimulation, which may be perceived by the patient as twitching or burning.

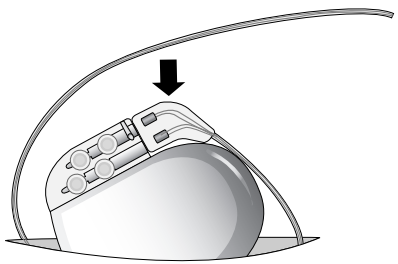

Figure 20. *Implant neurostimulator.*

△ **Caution:** Do not loop or coil the extension on top of the neurostimulator's etched identification side. Wrap any excess extension wire around the perimeter of the neurostimulator (Figure 21). This avoids any increase in subcutaneous pocket depth, minimizes potential damage during replacement surgery, and minimizes potential kinking of the extension wire.

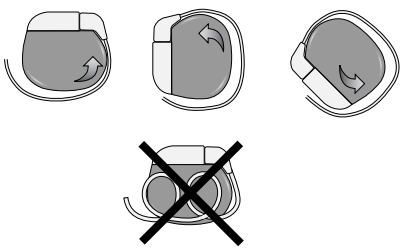

Figure 21. *Wrap excess wire around the perimeter of the neurostimulator.*

4. Secure the neurostimulator in the subcutaneous pocket, using the suture holes in the connector block to secure it to the muscle fascia. (Figure 22).

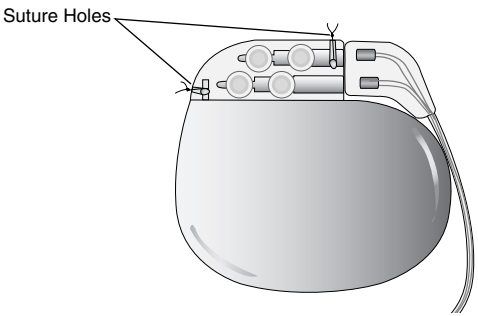

Figure 22. *Suture hole locations on neurostimulator connector block.*

5. Close and dress the incision.
6. Complete the registration form and mail it to Medtronic, Inc.

Physician Training Information

Prescribing physicians should have expertise in the medical treatment of patients with movement disorders. Implanting physicians should have expertise with functional stereotactic neurosurgical treatment of movement disorders. Such expertise should include knowledge of the anatomical and neurophysiological characteristics of the targeted nucleus, surgical and /or implantation techniques for the Activa System, operational and functional characteristics of the Activa System, and experience in the continued management of patients by stimulation parameter adjustment. Physicians may contact Medtronic before prescribing or implanting an Activa System for the first time and request a referral to a physician experienced in the use of Activa Therapy.

All Activa System programming should be by or under the supervision of a physician or other experienced medical personnel familiar with the use of the programming software and equipment. Physicians should be thoroughly familiar with Activa System supporting material, including:

- All product labeling, and
- Education and training materials.

Patient Counseling Information

Before surgery, the patient and family should be advised of the known risks of the surgical procedure and the therapy, as discussed in other sections of this manual, as well as the potential benefits. After the Activa System is implanted, the patient should also be advised to read the patient manual included in the neurostimulator package.

Theft Detectors and Screening Devices

Patients should be advised to use care when approaching security arches or gates (such as those found in airports, libraries, and some department stores) because these devices can turn on or turn off their neurostimulator. If an airport security wand is used, they should ask the security personnel to avoid placing the wand over the neurostimulator.

When approaching these devices, patients should do the following:

1. If security personnel are present, show them the neurostimulator identification card and request a hand search.
2. If patients must pass through the security device, they should approach the center of the device and walk normally (Figure 23).
   a. If two security gates are present, they should walk through the middle, keeping as far away as possible from each gate.
   b. If one gate is present, they should 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.

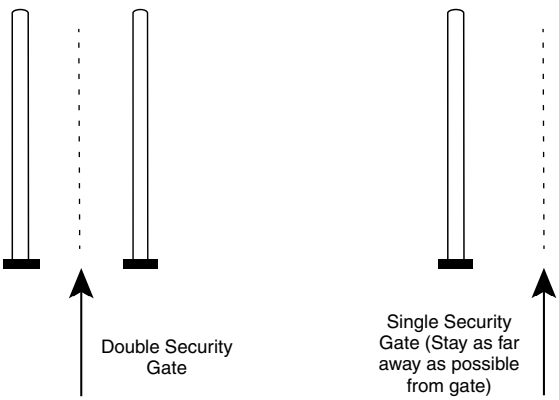

Figure 23. *Approaching security gates*

4. If patients suspect that their neurostimulator was turned off, they should make sure someone is able to turn on the system again. (This person could be the patient, if their medical condition allows it. It could also be a family member or clinician who has been taught how to use the system.)

Component Manipulation by Patient

Advise your patient to avoid manipulating the implanted system components (e.g., the neurostimulator, the burr hole site). This can result in component damage.

Specifications

Model 7482 Extension

Length	10-110 cm
Standard	40 cm
Distal (lead end)	
Connector	Quadripolar, In-Line
Conductor wire diameter	0.1 mm
Lead entrance diameter	1.47 mm
Conductor wire material	MP35N
Conductor wire insulation	Fluoroplymer
Extension Insulation	Siloxane Coated Silicone Rubber
Stiffener	Polyethylene Terephthalate
Set Screws	Titanium
Connector Blocks	Stainless Steel
Proximal (neurostimulator end)	
Connector	Quadripolar
Contact diameters	1.6 mm 2.7 mm
Contact material	Stainless Steel
Contact insulation	Siloxane Coated Silicone Rubber and Polyurethane
Label	Polyethylene Terephthalate
Resistance:	<52 Ω (25 cm) <67 Ω (40 cm) <78 Ω (51 cm) <93 Ω (66 cm) <122 Ω (95 cm)

Notes:

- To determine the resistance level for extension lengths not listed above, take the desired length in centimeters and add 27. This provides the resistance level in Ohms. For example, take the 40 cm length and add 27 to obtain a resistance level of 67 Ohms.The electrical resistance of leads and extensions is proportional to their length. Very long extensions have an increased resistance that may limit pulse amplitude at the electrodes.
- Each material composing the extension has been selected for biocompatibility through laboratory testing, animal testing, and clinical experience. The extension and accessories contained in the extension kits are intended for **Single Use Only**.
- All dimensions are approximate.

How Supplied

The Model 7482 Extension Kit consists of the following items:

- One Model 7482 Extension with setscrews
- One set of tunneling tools: extension passer with inserted obturator, and carrier
- One hex wrench
- Two additional hex screws
- Four connector boots
- Product literature

The contents of the inner package are **STERILE**.

Special Notice

Medtronic Model 7482 DBS Extensions (the “Extensions”) are implanted in the extremely hostile environment of the human body. Extensions may fail to function for a variety of reasons including, but not limited to, medical complications, body rejection phenomena, breakage, or failure by breakage or by breach of their insulation covering. In addition, extensions and tools may easily be damaged by improper handling or use. For tools, Medtronic disclaims all warranties, both express or implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Medtronic shall not be liable to any person or entity for any medical expenses or any direct, incidental, or consequential damages caused by any defect, failure or malfunction of any tool, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind Medtronic to any representation or warranty with respect to tools.

Appendix: MRI and Activa Therapy

Activa Therapy Clinical Experience

Due to the variability of clinical MRI systems, the safety of patients or the functioning of devices exposed to MRI systems cannot be unequivocally ensured. However, 39 patients in the Medtronic-sponsored clinical study with an implanted Activa System have safely undergone 1.5 Tesla MRI procedures. These patients were implanted with the Itrel II Model 7424 Neurostimulator, the Model 7495 Extension, and the Model 3387/3389 DBS Lead. For comparison purposes, the Activa System comprising the Soletra Model 7426 Neurostimulator, the 7495/7482 Extension, and the 3387/89 DBS lead is expected to have similar outcomes.

- 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.

To validate the in-vitro information regarding safety and efficacy, patient medical records were reviewed at four North American centers that participated in the Medtronic-sponsored clinical investigations of Activa therapies. These centers had 39 patients who underwent a total of 55 MRI procedures with implanted components of the Activa System. At least one neurostimulator was in place for 27 of these procedures.

The MRI procedures were used to verify lead implant within the target (40 procedures); to assess other medical conditions (7 procedures); to localize the brain target contralateral to an implanted lead or to replace a lead (8 procedures). There were no reported adverse events associated with MRI procedures used in conjunction with the implanted Activa lead, regardless of implantation of extensions and neurostimulators.

Risks of MRI and Activa Therapy Safety Results

The potential risks of performing MRI on patients with implanted neurostimulation systems and the specific safety information related to the Activa System include:

- Magnetic field interactions and mechanical forces
- Heating effects around the neurostimulator or lead electrodes from Electromagnetic Interference (EMI)
- Inadvertent reed switch activation from magnetic fields
- Neurostimulator damage
- Image distortion and artifacts

Magnetic Field Interactions and Mechanical Forces

Potential Risk: The neurostimulator may experience mechanical forces within or near the static magnetic field of the MRI system due to small amounts of magnetic material contained in the neurostimulator. This may cause the neurostimulator to move within the implant pocket and/or may place mechanical stress on tissues and/or the lead. Compromised tissues (such as recently sutured tissue) may be susceptible to further injury from these forces. Patients may feel a tugging sensation at the site of the neurostimulator implant.

Summary of Test Results: Implanted leads and extensions should not experience magnetic field-related mechanical forces since they are made from non magnetic material. Based on MRI safety testing conducted using an MRI system with a static magnetic field of 1.5 Tesla, patient-equivalent phantoms and various device configurations, the magnetic forces acting on the Activa neurostimulator are less than the force of gravity.

Heating Effects

Potential Risk: As with many biomedical implants (e.g. joint replacements, spinal fixation rods, etc.), heating associated with MRI may occur in the Activa System. Tissue damage is a risk because of the potential for temperature rise in the system.

Summary of Test Results: To date, no clinically significant heating has been reported in patients with Activa Systems in the Medtronic-sponsored clinical investigations. Clinically significant heating of up to 15° C was observed in a patient-equivalent phantom during testing in a 1.5 Tesla MRI. To minimize heating the recommendations in “MRI Operation/Settings” on page 40 must be followed.

Inadvertent Reed Switch Activation/Electromagnetic Interference (EMI)

Potential Risk: The magnetic fields of the MRI may activate the magnetic reed switch within the neurostimulator. This may cause the neurostimulator to switch between On and Off (in addition, the Model 7424 Itrel II Neurostimulator may also switch between normal and Mag Amp modes). The MRI gradient and/or RF fields could cause extraneous electrical current to be induced through the lead/extension that the patient may feel.

Summary of Test Results: MRI testing using a 1.5 Tesla MRI System and a patient-equivalent phantom show that the neurostimulator reed switch may be activated by the MRI resulting in on/off switching of the neurostimulator (or also for Itrel II, changing between Normal and Mag Amp modes). In the Medtronic-sponsored clinical trial, there were no reports of shocking or jolting resulting from induced voltages on the lead system.

Neurostimulator Damage

Potential Risk: Induced voltages on the lead/extension system could damage the electronic circuitry and result in a nonfunctioning neurostimulator, requiring replacement. Induced voltages could also cause the neurostimulator to lose its programmed parameter values, which would require subsequent reprogramming. In addition, the neurostimulator could lose its serial number, which cannot be reprogrammed by the physician programmer but does not affect therapeutic use of the neurostimulator.

Summary of Test Results: Medtronic-sponsored in-vitro testing using a 1.5 Tesla MRI system (GE Signa 1.5T) did not result in damage or reprogramming to the Activa neurostimulator or associated leads and extensions.

Image Distortion and Artifacts

Potential Risk: The neurostimulator and lead/extension may distort the MRI image or cause artifacts that may block viewing of tissue located near them.

Summary of Test Results: MRI testing using a 1.5 Tesla MRI System and a patient-equivalent phantom show that there may be substantial image distortion or artifacts near the DBS lead system and neurostimulator. Proper selection of various imaging parameters, while not exceeding the recommendations in “MRI Operation/ Settings” on page 40, will help reduce image distortion or artifacts.

MRI Guidelines

Pre-MRI Preparation

- Because of the need to change the operating parameters for the Activa System, an appropriate health care professional with access to a Medtronic neurological physician programmer should assist and prepare the patient with this device for the MRI procedure.
- If the neurostimulator has already been implanted, record the patient’s current therapeutic settings, set the neurostimulator amplitude to 0 volts (normal and magnet amplitude for the Model 7424 neurostimulator) and turn the neurostimulator output to Off.
- Disconnect all external leads (screening cables) from any percutaneous extensions. Any parts of the percutaneous extensions that exit the body should be wrapped in a thermally and electrically insulating material of approximately 0.5-inch thickness or greater. These coils/leads should be kept out of contact with the patient’s skin to avoid the risk of thermal burns from RF energy.
- Instruct the patient to alert the MRI system operator of any problems (heating, shocks, etc) so the operator can terminate the MRI procedure if needed.

Caution: An MRI procedure should not be performed in a patient with an Activa System that has a broken lead wire because tissue damage may result from localized heating at the break. If a broken lead wire is suspected, lead impedance should be checked on all electrodes in unipolar mode. If any electrode impedance is > 2000 ohms and battery current is <10 μA, then an x-ray should be obtained prior to an MRI to verify the presence of a broken wire.

Implant Recommendations

- Implant the minimum length lead and extension possible to minimize induced RF voltage in the lead system.
- Avoid, if possible, implanting the neurostimulator in the abdomen. This requires the use of longer length leads/ extensions that can increase the amplitude intensity of the induced RF voltage on the lead system.

MRI Operation/Settings

- Use only MRI systems operating at a static magnetic field strength of 1.5 Tesla.
- 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 perform continuous verbal and visual monitoring of the patient throughout the MRI procedure.
- Discontinue the MRI if the patient experiences any pain or discomfort, or if you observe heating or other problems with the implanted components.

Post-MRI Recommendations Operation/Settings

- Verify the neurostimulator is functional.
- Reprogram the stimulation parameters to pre-MRI values.

Medtronic

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