DBS™

Extension Kit for
Deep Brain Stimulation

Implant manual

Rx only
Model 7482A Extension (All dimensions are approximate.)
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System Description

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

Parkinson’s Control Therapy

The power source(s) for bilateral Activa Parkinson’s Control Therapy are one dual program Kinetra Model 7428 Neurostimulator or two single program Soletra Model 7426 Neurostimulators. The power source(s) generate electrical signals that are transmitted to the brain via either two Model 7482 Extensions, two Model 7482A Extensions, or two Model 7495 Extensions (Soletra only) and either two Model 3387 DBS Leads or two Model 3389 DBS Leads. These components comprise the implantable portion of the Activa System for bilateral Activa Parkinson’s Control Therapy.

Tremor Control Therapy

The power source for unilateral Activa Tremor Control Therapy is either one single program Soletra Model 7426 Neurostimulator or one single program Model 7424 Itrel II Neurostimulator. The power source generates electrical signals that are transmitted to the brain via either one Model 7495 Extension, one Model 7482A Extension, or one Model 7482 Extension and either one Model 3387 DBS Lead or one Model 3389 DBS Lead. These components comprise the implantable portion of the Activa System for unilateral Activa Tremor Control Therapy.

1 The dual-program Kinetra Model 7428 neurostimulator is not approved for Tremor Control Therapy since only unilateral stimulation is approved for Tremor Control Therapy.
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\(^1\)

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.

\(^1\) The Kinetra Model 7428 Neurostimulator is indicated for Activa Parkinson’s Control Therapy only.
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 transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area. Performing MRI with this equipment can cause tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis or death. Refer to the MRI guidelines manual packaged with this product for comprehensive safety information and instructions.

- 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 (Model 7426 and Model 7424 Neurostimulators only) described in the Model 3387/89 manual.
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.

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.

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 41 for more information.

Magnetic Resonance Imaging – Do not conduct an MRI examination on a patient with any implanted Activa System component until you read and fully understand all MRI information in this manual. Do not conduct an MRI examination at parameters other than those described in this guideline. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including coma, paralysis, or death. Refer to the MRI guidelines manual packaged with this product for comprehensive safety information and instructions.

Precautions

Physician Training

Implanting Physicians – Implanting physicians should be experienced in stereotactic and functional neurosurgery. Refer to “Physician Training Information” on page 41 in this manual for further information.

1 With all neurostimulators referenced in this manual, unexpected On/Off switching of the devices may occur when they are exposed to magnets and strong electromagnetic fields. See the Warnings and Precautions sections of this manual. With the Kinetra Model 7428, however, the magnet control circuit can be disabled by the clinician programmer software to avoid unexpected switching. If the magnet control circuit is disabled, patients will require a Model 7436 therapy controller to turn their therapy On or Off.
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 19 for further information.

Storage Temperature – Store the Model 7482A 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 Subthalamic 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. The patient’s disease symptoms will return if the device ceases to function.

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:
- Bilateral VIM stimulation
- 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 and Figure 3). 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 Kinetra Model 7428 Neurostimulator.

Figure 3. Wrap excess wire around the perimeter of the Soletra Model 7426 or Itrel II Model 7424 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 extension or 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 extension or 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.
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.

Setscrew Connections – Follow these guidelines when connecting the extension to the lead and neurostimulator.

- Do not use the hex wrench to connect the lead to the extension, which can result in over tightening. Use the torque wrench packaged with the extension.
- Do not use the torque wrench to connect the neurostimulator to the extension. This can result in undertightening, which may result in insufficient electrical contact within the connector block, and cause intermittent stimulation. Use the hex wrench packaged with the neurostimulator.
- After tightening the neurostimulator setscrews, verify that each leaf of the sealing rubber grommet is closed. If the grommet seal is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant site. In addition, fluid leakage into the setscrew connector block may result in changes to stimulation.

Torque Wrench – Discard the torque wrench after making all the connections. The wrench is a single-use-only item. Torque value of the wrench cannot be assured with multiple uses.

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

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, power tools) 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 Medtronic at 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.

**Clinical Studies and Adverse Events**

The clinical use of the Kinetra Model 7428 Neurostimulator is supported by the Medtronic Parkinson’s disease clinical studies using the Itrel II Model 7424 Neurostimulator. For results of the Parkinson’s disease clinical trials and a complete list of adverse events reported during the Parkinson’s disease clinical trials, refer to the Activa Clinical Summary packaged with this product.

Because safety and effectiveness of the Activa Parkinson’s Control therapy was established using bilateral Itrel II neurostimulators, clinical results and adverse event rates associated with a single dual-program Kinetra neurostimulator may not be identical.

**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 7482A 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, extensions, 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.
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.

### 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.

Ethylene oxide (ETO) is an acceptable method for resterilization when the leads, extensions, and accessories are repackaged in an ethylene oxide-permeable package. The temperature during the process should not exceed 130°F (55°C). Allow for the maximum aeration of ETO residues before implanting the lead or extension 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 250°F (121°C) and 15 psig is recommended. If components are marked “YES” for “flash” autoclave, a standard cycle of 5 minutes at 270°F (132°C) and 27 psig is recommended. Do not use any method that is marked “NO” for a component.

### Table 1. Resterilization Options and Restrictions.

<table>
<thead>
<tr>
<th>Component</th>
<th>Sterilization Methods</th>
<th>Ethylene Oxide</th>
<th>Autoclave</th>
<th>“Flash” Autoclave</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>130°F (55°C)</td>
<td>250°F (121°C)</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maximum 15 psig (103 kPa)</td>
<td>30 minutes</td>
<td>5 minutes</td>
</tr>
<tr>
<td>Extension</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Extension Passer Handle, Carrier, and Obturators</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Extension Passer, Thumbscrew (Packaged in Extension Passer Handle), and Other Accessories</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>

Medtronic cannot accept responsibility for the hospital’s resterilization of any components.

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

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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 22.

Removing the Percutaneous Extension

For each implanted lead:

1. Withdraw the external segment of the percutaneous extension approximately 0.4 in. (1 cm) from where it exits the skin (Figure 4).

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

   ![Figure 4. Withdraw the external segment of the percutaneous extension.](image)

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 5).

   △ 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.
5. Using the torque 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 6) and discard.

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 1.5 in. (4 cm) 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 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.

All tunneling tools are single use only.

Tools used for tunneling include (Figure 7):

- **The Extension Passer Handle with Thumbscrew**, attaches to the proximal end of the passer allowing the obturator and carrier to snap in place for tunneling. The handle is detachable to allow removal of the extension passer from either the lead site or the neurostimulator site.

- **The Extension Passer**, a hollow metal shunt that the obturator can slide through. The obturator can also be removed and an extension can be manually threaded through the passer.

- **The Obturators**, narrow plastic cylinders with distal ends that serve as the tunneling tips. The obturator slides through the extension passer and can be snapped in place into the extension passer handle. Three obturators with different shaped distal tips are included in the extension kit:
  - **The Cone Tip** requires the least amount of force to tunnel.
  - **The Wedge Tip** requires more force to tunnel.
  - **The Blunt Tip** requires the most force to tunnel.

- **The Carrier**, an attachment like the obturator, but with two distal carrier ports for extension connectors. Either one or two extension connectors can be attached and pulled through the tunnel created by the tools.

![Figure 7. Tunneling tools.](image)

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Tunneling Preparation

1. Attach the tunneling tool handle to the proximal end of the extension passer:
   a. Align the drop-shaped proximal end of the extension passer with the drop-shaped connection on the handle (Figure 8).

   ![Figure 8. Align the handle and extension passer.](image)

   b. Push the handle onto the extension passer until the mark on the extension passer is flush with the handle (Figure 9).

   ![Figure 9. Attach the handle to the extension passer.](image)

   c. Tighten the thumbscrew located on the handle.

2. If desired, select a different obturator than the one inserted in the extension passer. Remove the inserted obturator by sliding it out from the extension passer at the obturator distal tip. Slide the proximal end of the selected obturator through the extension passer (Figure 10a).

   The obturator distal tip will remain exposed at the distal end of the extension passer (Figure 10b).
3. 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 11).

4. 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 three suggested tunneling procedures. For single extension procedures, tunneling can be performed without or with a carrier. For dual-extension procedures the carrier must be used.

Notes:
- 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.
- Position the thumbscrew on the handle away from the patient during insertion and removal. This will facilitate handle removal and assist in preventing twisting of the extensions.
Tunneling Procedure: Single Extension without Carrier

1. Select the tunneling direction:
   a. **If tunneling from the lead site to the neurostimulator pocket**, 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.
   b. **If tunneling from the neurostimulator pocket to the lead site**, tunnel from the neurostimulator 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 subgaleal pocket.

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.

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 obturator distal tip (Figures 12a and 12b).

   **Warning:** 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.

   **Caution:** Use caution when approaching the pocket—proceed slowly to avoid additional trauma to the patient as resistance to tunneling suddenly ceases.
4. Carefully insert the lead end of the extension into the extension passer at the neurostimulator pocket and slide it through until it exits at the opposite end or until fully encompassed by the extension passer.

⚠️ Caution: Use care when inserting the extension body into the extension passer. Rough handling can damage extension insulation.

5. Remove the extension passer from the tunnel. If necessary, detach the handle from the proximal end of the extension passer.

Tunneling Procedure: Single Extension with Carrier

1. Select the tunneling direction:
   a. If tunneling from the lead site to the neurostimulator pocket, 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.
   b. If tunneling from the neurostimulator pocket to the lead site, tunnel from the neurostimulator 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 subgaleal 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.

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 obturator distal tip (Figures 13a and 13b).

![Figure 13. Remove the obturator from the extension passer.](image)

4. Insert the carrier into the extension passer (Figure 14):
   a. If tunneling from the lead site to the neurostimulator pocket, slide the carrier into the extension passer until it exits at the handle (Figure 14a). Snap the proximal end of the carrier into the handle (Figure 14b). A single carrier port should remain exposed at the distal end of the extension passer.
   b. If tunneling from the neurostimulator pocket to the lead site, remove the handle from the proximal end of the extension passer and slide the carrier into the proximal end of the extension passer until it exits at the distal end (Figure 14a). A single carrier port should remain exposed at the proximal end of the extension passer.
Figure 14. 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 15).

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

Figure 15. 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.

Tunneling Procedure: Two Extensions for Dual-Lead System

1. Repeat steps 1-3 from the instructions for tunneling a single extension with the carrier beginning on page 27.
2. Insert the carrier into the extension passer (Figure 14a):
   a. If tunneling from the lead site to the neurostimulator pocket, slide the carrier into the extension passer until it exits at the handle. Both carrier ports should remain exposed at the distal end of the extension passer.
   b. If tunneling from the neurostimulator pocket to the lead site, remove the handle from the proximal end of the extension passer and slide the carrier into the proximal end of the extension passer until it exits at the distal end. Both carrier ports should remain exposed at the proximal end of the extension passer.

3. Carefully insert the lead end of the first extension into port 1, the proximal carrier port (Figure 16).

4. With the first extension attached to the carrier, gently pull the proximal end of the carrier further into the extension passer until port 1 is fully encompassed within the extension passer (Figure 17).

5. If tunneling from the lead site to the neurostimulator pocket, snap the proximal end of the carrier into the handle (Figure 18).

Δ Caution: Use care when inserting the extension body into the carrier port. Rough handling can damage extension insulation.
6. Carefully snap the lead end of the second extension into distal carrier port 2 (Figure 19).

![Figure 19. Place second extension into port 2.](image)

7. Pull the extension passer and carrier, with both extensions attached, through the tunneled path to where the leads are anchored. Make sure not to twist the extensions.
8. Remove the second extension from carrier port 2.
9. If necessary, unsnap the carrier from the handle.
10. Push the carrier forward to expose carrier port 1 at the distal end. Remove the first extension.

### Making the Lead-Extension Connection

Two different boot styles are provided, winged and cylindrical.

For each lead:

1. Push the clear boot over the proximal end of the lead in a single-lead system or over the first lead in a dual-lead system.
2. Push the white radiopaque boot over the proximal end of the second lead in a dual-lead system.
   
   **Note:** For dual-lead systems, the radiopaque boot will distinguish the first lead-extension from the second lead-extension.

   ![Caution: Wipe off any remaining body fluids from the surface of the lead contacts and extension connector.](image)

3. Hold the extension securely in your fingers. Insert the lead. The four metal connector bands on the lead should be aligned under the four setscrews (Figure 20).
   
   **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.
4. Using the torque wrench provided, tighten each of the four setscrews by turning the setscrews clockwise in the setscrew sockets (Figure 21). Hold the extension firmly on the sides of each setscrew socket while tightening the setscrew. Tighten until the torque wrench clicks once.

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

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

6. Secure the connection with nonabsorbable sutures around both grooved ends of the boot (Figure 22).

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

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### Caution:
- To prevent over tightening the extension setscrews, **do not** use the neurostimulator hex wrench. Excessive torque on setscrews may damage lead contacts.
- Discard the torque wrench after making all connections. The wrench is a single-use-only item. Torque value of the wrench cannot be assured with multiple uses.
- 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.

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**Figure 20.** Insert the lead into the setscrew connector.

**Figure 21.** Tighten the setscrews holding the extension firmly on the sides of each setscrew socket (winged boot shown).

**Figure 22.** Suture around suture grooves (winged boot shown).
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.

7. If using a winged boot, make sure the flat side of the boot lies against the skull.

8. 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 (periostium) to stabilize the connection.

9. Close and dress the wound.

Making a Single 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 (Figure 23).

   ![Figure 23](image)
   
   **Figure 23.** 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 neurostimulator 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 24).
Note: If inserting the extension pins is still difficult, use sterile water as a lubricant.

*Figure 24. 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. Using the hex wrench included in the neurostimulator package, tighten the setscrew by turning the hex wrench clockwise until resistance is felt (Figure 25).
   c. Continue tightening for a maximum of 1/4 turn. The setscrews must touch the extension connector pins for proper electrical connection.

⚠️ Cautions:
- To prevent undertightening on the neurostimulator setscrews, do not use the torque wrench from the extension kit. Undertightening may result in insufficient electrical contact within the connector block, which may cause intermittent stimulation.
- Do not overtighten the setscrews or permanent damage to the setscrews and/or sockets could result.
- Be sure the hex wrench is fully inserted to prevent damage to the setscrew.
- Verify that each leaf of the sealing rubber grommet has closed after the wrench is withdrawn. If the grommet seal is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant site. In addition, fluid leakage into the setscrew connector block may result in changes to stimulation.
Figure 25. 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 26). Position the neurostimulator so that no sharp bends occur along the extension or lead (Figure 27).

⚠ 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.

⚠ 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 27). This avoids any increase in subcutaneous pocket depth, minimizes potential damage during replacement surgery, and minimizes potential kinking of the extension wire.
Figure 27. 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 28).

Figure 28. Suture hole locations on neurostimulator connector block.

5. Close and dress the incision.

6. Complete the registration form and mail it to Medtronic, Inc.

Making the Extension-Neurostimulator Connection for a Dual-Program System

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 (Figure 29).

   Note: With the Kinetra Model 7428 Neurostimulator, four setscrews are located on top of the connector module, two for each extension. Two setscrews are oriented at a 90° angle and two are oriented at a 45° angle.
Figure 29. 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 neurostimulator connector block.
c. Check that the encapsulated diagram on the extension matches the diagram on the neurostimulator.
d. Insert the Extension 1 connector pins fully into Socket I. Socket I corresponds to electrodes 0-3 on Lead I (Figure 30).
e. Insert the Extension 2 connector pins fully into Socket II. Socket II corresponds to electrodes 4-7 on Lead II (Figure 30).

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

Figure 30. Insert extension connector pins into neurostimulator sockets.
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. Using the hex wrench included in the neurostimulator package, tighten the setscrew by turning the hex wrench clockwise until resistance is felt (Figure 31).
   c. Continue tightening for a maximum of 1/4 turn. The setscrews must touch the extension connector pins for proper electrical connection.

   Note: When tightening the setscrews, the hex wrench must be oriented at the same angle as the setscrews (Figure 31).

   △ Cautions:
   - To prevent undertightening on the neurostimulator setscrews, do not use the torque wrench from the extension kit. Undertightening may result in insufficient electrical contact within the connector block, which may cause intermittent stimulation.
   - Do not overtighten the setscrews or permanent damage to the setscrews and/or sockets could result.
   - Be sure the hex wrench is fully inserted to prevent damage to the setscrew.
   - Verify that each leaf of the sealing rubber grommet has closed after the wrench is withdrawn. If the grommet seal is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant site. In addition, fluid leakage into the setscrew connector block may result in changes to stimulation.

45° Angle  90° Angle

*Figure 31. 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 32). Position the neurostimulator so that no sharp bends occur along the extension or lead (Figure 32).

⚠️ **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.

⚠️ **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 33). This avoids any increase in subcutaneous pocket depth, minimizes potential damage during replacement surgery, and minimizes potential kinking of the extension wire.

*Figure 32. Implant neurostimulator.*

*Figure 33. 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 34).

![Figure 34. Suture hole locations on neurostimulator connector block.](image)

5. Close and dress the incision.

6. Complete the registration form and mail it to Medtronic, Inc.

**Note:** If only one lead is implanted at this time, perform the following steps using the accessories from the Model 3550-09 Accessory Kit:

- **1 Lead, 1 Extension**—Insert the neurostimulator connector plug into the unused socket of the neurostimulator connector block and tighten the setscrews (Figure 35).

![Figure 35. Insert connector plug into unused neurostimulator socket.](image)

- **1 Lead, 2 Extensions**—Slide the closed boot over the extension’s setscrew connector and secure with sutures (Figure 36).

![Figure 36. Slide closed boot over extension setscrew connector and suture.](image)
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 37).
   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 arch or gate. Do not touch, lean on or linger near the security arch or gate.
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.

*Figure 37. Approaching security gates.*
Specifications

Model 7482A Extension

Lengths 10 - 110 cm
Standard Lengths 25, 40, 51, 66, 95 cm

Distal (lead end)
- Connector: Quadripolar, In-Line
- Conductor wire diameter: 0.1 mm
- Lead entrance diameter: 1.47 mm
- Conductor wire material: Silver Core MP35N
- Extension Insulation: Siloxane Coated Silicone Rubber
- Set Screws: Titanium
- Connector Blocks: Stainless Steel
- Implant material in contact with human tissue: Siloxane Coated Silicone Rubber

Proximal (neurostimulator end)
- Connector: Quadripolar
- Contact diameters: 1.6 mm, 2.7 mm
- Contact material: Stainless Steel
- Contact insulation: Silicone Rubber and Polyurethane

Resistance (Max): 7 Ω for all lengths

Note: The extension and accessories contained in the extension kits are intended for Single Use Only.

How Supplied

The Model 7482A Extension Kit consists of the following items:
- One Model 7482A Extension with setscrews
- One set of tunneling tools:
  - extension passer with inserted obturator
  - obturators: blunt distal tip (1), cone distal tip (1), wedge distal tip (1)
  - extension passer handle with thumbscrew
  - 2x4 low-profile extension carrier
- One torque wrench
- Two additional hex screws
- Four connector boots
- Product literature

The contents of the inner package are STERILE.

1 All dimensions are approximate.