The Pocket Adaptor Tip Cards are to be used for educational purposes only. Please refer to the Pocket Adaptor Kit Implant Manual for complete instructions, warnings and cautions.

Pocket Adaptor Model 74001 (1×4) and Model 74002 (2×4) are intended to be implanted with a new replacement 16-electrode neurostimulator in the same pocket used for the explanted neurostimulator.

Note: Implanting in the same neurostimulator pocket allows for a single-incision procedure.

The RestoreUltra® (Model 37712) neurostimulator is shown on the following procedure cards.

The following neurostimulators are also compatible with the Pocket Adaptors although the orientation of the sockets on the header block is different:

• RestoreAdvanced® (Model 37713)
• PrimeAdvanced® (Model 37702)
• Restore® (Model 37711)
• RestorePrime® (Model 37701)

Compatible Quadripolar Extensions

<table>
<thead>
<tr>
<th>Quadripolar extension model number</th>
<th>Model 74001 (1×4)</th>
<th>Model 74002 (2×4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7471\textsuperscript{a}</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7472\textsuperscript{a}</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7489</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>7495</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>7495 LZ</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>7496</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>7498\textsuperscript{a}</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\textsuperscript{a} The Models 7471 and 7472 extensions are bifurcated on the proximal end.
\textsuperscript{b} The Model 7498 extension is bifurcated on the distal end.

Warning: Evaluate the suitability of a Pocket Adaptor for patients with an implanted Model 7498 extension. The extension is bifurcated on the distal end, connecting 2 leads in parallel. If one lead should break, an impedance measurement may yield a result in the normal range because of the presence of the second lead. Thus, open circuits may be difficult to detect, which can increase the potential for risks related to MRI.
Caution: Only use a 2x4 Pocket Adaptor for systems using the Model 7471 or the Model 7472 bifurcated extension. Using two 1x4 Pocket Adaptors with these bifurcated extensions will cause electrode numbering to be mismatched when programming and cause some neurostimulator features to be inoperable.

1. Retract the explanted neurostimulator set screws.

2. Remove only Extension 2 from Socket II (back) of the explanted neurostimulator.

3. Insert Extension 2 into Connector Port 2 (bottom) of the adaptor.

4. Remove Extension 1 from Socket I (front) of the explanted neurostimulator.

5. Insert Extension 1 into Connector Port 1 (top) of the adaptor.

6. Tighten all adaptor setscrews.
Slowly advance the adaptor connection into Socket I (top) of the neurostimulator.

Insert the plug into Socket II (bottom) of the neurostimulator.

Tighten all neurostimulator setscrews.

Place the neurostimulator, adaptor, and coiled wires (placed behind the adaptor) into the subcutaneous pocket.  

**Note:** Ensure there are no sharp bends in the wires and the wires are not between the devices.

Program the lead and electrode configuration (see Programming tab) and perform a system integrity check to ensure that lead configuration is set up appropriately and implanted leads and extensions are functional.
Retract the explanted neurostimulator set screws.

Remove the extension from the neurostimulator.

Insert the extension into the adaptor.

Tighten the adaptor setscrews.

Slowly advance the adaptor connection into Socket I (top) of the neurostimulator.

Insert the plug into Socket II (bottom) of the neurostimulator.
To be used with all pocket adaptor procedures

Pocket Placement

Procedure

Tighten all neurostimulator setscrews.

Place the neurostimulator, adaptor, and coiled wires (placed behind the adaptor) into the subcutaneous pocket.

Note: Ensure there are no sharp bends in the wires and the wires are not between the devices.

Program the lead and electrode configuration (see Programming tab) and perform a system integrity check to ensure that lead configuration is set up appropriately and implanted leads and extensions are functional.
Retract the explanted neurostimulator set screws.

Remove only Extension 2 from Socket II (back) of the explanted neurostimulator.

Insert Extension 2 into one of the adaptors.

Slowly advance the first adaptor connection into Socket II (bottom) of the new neurostimulator.

Remove Extension 1 from Socket I (front) of the explanted neurostimulator.

Insert Extension 1 into the other adaptor.

Caution: Only use a 2×4 Pocket Adaptor for systems using the Model 7471 or the Model 7472 bifurcated extension. Using two 1×4 Pocket Adaptors with these bifurcated extensions will cause electrode numbering to be mismatched when programming and cause some neurostimulator features to be inoperable.
Procedure #3
Two 1×4 Pocket Adaptors with 2 extensions (4 electrodes each)

1. Advance the second adaptor connection into Socket I (top) of the new neurostimulator.

2. Tighten all adaptor setscrews (both adaptors).

3. Tighten all neurostimulator setscrews.

4. Place the neurostimulator, adaptors, and coiled wires (placed behind the adaptors) into the subcutaneous pocket.

   **Note:** Ensure there are no sharp bends in the wires and the wires are not between the devices.

5. Program the lead and electrode configuration (see Programming tab) and perform a system integrity check to ensure that lead configuration is set up appropriately and implanted leads and extensions are functional.
<table>
<thead>
<tr>
<th>Pocket Adaptor</th>
<th>Neurostimulator socket and corresponding electrodes</th>
<th>Lead Configuration(^{a,b})</th>
</tr>
</thead>
</table>
| One 2×4        | • If Socket I is used, the default electrode numbering is as follows and requires no renumbering:  
  — Lead I: 0-3  
  — Lead II: 4-7  
  • If Socket II is used, the electrodes require renumbering to the following:  
  — Lead I: 8-11  
  — Lead II: 12-15 | 2×4 |
| One 1×4        | • If Socket I is used, the default electrode numbering is 0-3 and requires no renumbering.  
  • If Socket II is used, the electrodes require renumbering to 8-11. | 1×4 |
| Two 1×4s       | • Socket I default electrode numbering for Lead I is 0-3 and requires no renumbering.  
  • Socket II electrodes for Lead II require renumbering to 8-11. | 2×4 |

\(^a\) This is the configuration to select in the Lead Configuration screen of the N’Vision® clinician programmer.  
\(^b\) If additional leads are added to the system, the lead configuration will be different from what is given in this column.
NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

Brief Summary: Product manuals must be reviewed prior to use for detailed disclosure.

Indications: Implantable neurostimulation systems – A Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) system as an aid in the management of chronic, intractable pain of the trunk and/or limbs—including unilateral or bilateral pain associated with the following conditions:
- Failed Back Syndrome (FBS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia

Contraindications: Diathermy – Do not use shortwave diathermy, microwave 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 cause tissue damage at the locations of the implanted electrodes, resulting in severe injury or death.

Warnings: Sources of strong electromagnetic interference (eg, defibrillation, diathermy, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the neurostimulation system, resulting in serious patient injury or death. These and other sources of EMI can also result in system damage, operational changes to the neurostimulator or unexpected changes in stimulation. Rupture or piercing of the neurostimulator can result in severe burns. An implanted cardiac device (eg, pacemaker, defibrillator) may damage a neurostimulator, and the electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device.

Precautions: The safety and effectiveness of this therapy has not been established for pediatric use (patients under the age of 18), pregnancy, unborn fetus, or delivery. Patients should be detoxified from narcotics prior to lead placement. Clinicians and patients should follow programming guidelines and precautions provided in product manuals. Patients should avoid activities that may put undue stress on the implanted neurostimulation system components. Patients should not scuba dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmosphere absolute (ATA). Electromagnetic interference, postural changes, and other activities may cause shocking or jolting.

Adverse Events: Adverse events may include: undesirable change in stimulation described by some patients as uncomfortable, jolting or shocking; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, eosin, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, and surgical risks.

For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic’s website at www.medtronic.com.

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