



Physician Implant Manual

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NEVRO CORP.

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CE Mark effective on 4 May 2010

Nevro Corp. hereby declares that the Senza™ System is in compliance with the essential requirements and other relevant provisions of the R&TTE Directive (1999/5/EC).

IMPORTANT: Changes or modification to any component of the Nevro™ Spinal Cord Stimulation system, unless expressly approved by Nevro Corp., could void your authority to operate this product.

Explanation of symbols on the product or package labeling. Refer to the product for symbols that apply.

Symbols	Description
SN	Serial number
LOT	Batch code
	Date of Manufacture
	Manufacturer
	Caution
	Catalog number
 XX C XX F XX C XXX F	Temperature limitation (storage)
<div>STERILE</div> <div>EO</div>	Sterilized using ethylene oxide
	Use by
	Do not use if package is damaged
	Do not reuse
	Do not re-sterilize
	Keep dry
R _x ONLY	Physician only
	Consult Instructions for Use
	Non-sterile
	Non-ionizing radiation



Type B Applied Part



Type BF Applied Part



Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.



Conditional

MR Conditional



MR unsafe



CE Marking of Conformity



Authorized representative in the European Community

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Device Description

The Nevro™ Spinal Cord Stimulation (SCS) system is a neuromodulation system intended to treat chronic, intractable pain.

- **Leads:** The leads are a part of the Nevro™ SCS system and carries electrical stimulation to the nerve structures. There are two types of leads, percutaneous leads and surgical leads. The percutaneous leads have eight electrodes located near the distal end of each lead. The lead body is made of medical grade polyurethane with a stiffer proximal end to aid insertion into the connector of a lead extension or implantable pulse generator (IPG). The proximal end of the Surgical Lead has two legs each with 8 contacts. The proximal end of the Surgical Lead is identical to the proximal end of the Percutaneous Lead. The distal end of the lead is molded out of Silicone material and has 16 distal electrodes.
- **Implantable Pulse Generator (IPG):** The Nevro™ IPG is an implantable pulse generator that is programmable and rechargeable. The Nevro™ IPG delivers constant current stimulation through 1 or multiple leads.

Indications For Use

The Nevro™ SCS system is intended to aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following:

- Failed back surgery syndrome
- Intractable low back pain
- Leg pain

Contraindications

The Nevro™ SCS system should not be used if the patients:

- Are unable to operate the SCS system
- Are poor surgical risks

Patients contraindicated for permanent SCS therapy are those who:

- Have failed trial stimulation by failing to receive effective pain relief

Safety Information

Warnings

Pediatric Use - The safety and effectiveness of spinal cord stimulation has not been established for pediatric use.

Other Active Implanted Devices - Neuromodulation system may interfere with the programming of other active implantable devices (e.g. pacemaker, cardioverter defibrillator). If a patient requires more than one active implanted device, all of the involved physicians should discuss the potential interference between the devices prior to surgical procedures.

Patient Activities - Patients using therapy that generates paresthesia (tingling sensations caused by stimulation) may experience increased paresthesia when changing posture or making abrupt movements. Such patients should lower the amplitude or turn off the stimulation before making posture changes, such as stretching and moving their arms over their head. If unpleasant sensations occur, the IPG should be turned off. The Nevro™ SCS system's high frequency settings are designed not to generate paresthesia so patients should not experience unpleasant sensations caused by posture changes or movement.

Scuba Diving and Hyperbaric Chambers. Turn the device off prior to these activities. Patients should avoid scuba diving to depths below 35 meters and hyperbaric chambers with pressure above 4.5 ATM. The increased pressure may damage the neurostimulation system.

Heat From Charging – The charging coil may become warm while charging. The implanted patient may experience discomfort or burn if they charge while sleeping and do not use the provided charging belt. Instruct the patient to stop charging and contact a physician if the patient experiences discomfort or pain.

Diathermy Therapy - Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy on patients implanted with a neuromodulation 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. The neuromodulation system, whether it is turned on or off, may be damaged.

Magnetic Resonance Imaging (MRI) - Refer to the *Nevro Senza System 1.5T and 3T MRI Guidelines* for MRI-specific warnings and precautions on conducting a MRI scan on a patient with the Senza system. Scanning under different conditions may result in severe patient injury or device malfunction.

Electromagnetic Interference (EMI) - Most electrical devices and magnets that patients will encounter in a normal day are unlikely to affect the operation of the SCS system. However, some equipment may generate strong electromagnetic fields that can turn the IPG off or cause shocks or jolts. Patients should keep away from areas of EMI and turn off the IPG if they are in such an area. The following are examples of sources that can potentially generate strong EMI.

- Theft detectors or security screeners such as airport security screening devices.
 - Note: It is recommended that patients request assistance to bypass the device. If they must go through the device, the patient should turn off the IPG and go through the screener as quickly as possible.
- Power lines and power generators
- Arc welders

Precautions

Physician Training - The physicians providing the Nevro therapy should be experienced in the diagnosis and treatment of chronic pain and have proper surgical and clinical training.

Storage - Store the system components and accessories between the prescribed temperatures. Excessively hot or cold

temperatures may damage the components, particularly high heat. Devices should be kept in temperature regulated areas within the acceptable temperature range. Do not expose the components to liquids or excessive moisture.

- The storage temperature for the IPG should not exceed 0° C and 45° C (32° F and 113° F).
- The storage temperature for the Lead and Lead Extension should not exceed 0° C and 45° C (32° F and 113° F).
- The storage temperature for the Trial Stimulator and the Patient Remote Control should not exceed -20 to 60 °C (-4 to 140 °F).
- The storage temperature for the Charger should not exceed 0 to 45°C (32 to 113 °F).

Sterilization

- Prior to opening the sterile package, inspect the sterilization indicator and the sterile package.
- Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
- Do not use any component that shows signs of damage.
- Do not re-sterilize the package or the contents. There is risk of infection and device malfunction.
- Do not use if "Use by" date has passed.
- All implanted components are intended for single use only. Do not re-use.

Handling - Use care when handling the system components and accessories. Do not drop them or submerge them in water. Do not impact the system components against hard surfaces and avoid rough handling. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water or other rough handling, can permanently damage the components and accessories. Do not plug the charger into a power source near water.

Handling the Leads and Lead Extensions - Follow these guidelines when handling the Leads or Lead Extensions:

- Do not make sharp bends to the lead or lead extension.
- Do not tie suture directly to the lead or the lead extension.
- When placing a suture around the lead, use the provided lead anchors.
- Do not force the lead into the epidural space. Use the lead blank prior to inserting the lead.
- Create a stress relief loop to minimize tension on the lead.
- Do not stretch the lead.
- Do not use sharp instruments to handle the lead or lead extension.
- Wipe off any bodily fluids (e.g. blood) from the lead's proximal end before connecting it to any other component.
- Wipe off any bodily fluids (e.g. blood) from the lead stylet before inserting or reinserting it into the lead.
- When inserting the stylet into the lead, do not use excessive force.

Handling the IPG - Follow these guidelines when handling the IPG:

- Avoid rough handling of the IPG.
- Take care not to drop the IPG. If it has been dropped to a hard surface, do not use the device and send it back to Nevro Corp.

System Compatibility - Do not use any cables with the Trial Stimulator unless they are explicitly approved by Nevro Corp.

Devices in Hospital/Medical Environments - The following therapies or procedures should not be used on SCS patients:

- Diathermy
 - 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.

The use of following medical devices or procedures may damage the SCS system or turn the stimulation off. After usage of these devices or procedures, the IPG may need to be explanted as a result of permanent damage.

- **Electrocautery:** The IPG should not be exposed to electrocautery. If electrocautery is necessary with the IPG implanted, do not use monopolar cautery. If possible, use bipolar cautery instead.
- **External defibrillation:** The safety of discharge of an external defibrillator on patients implanted with an SCS system has not been established.
- **Lithotripsy or High-output ultrasonics:** Do not use these devices in patients with an implanted IPG. If lithotripsy must be used, do not use it near the IPG.
- **Radiation therapy:** If radiation therapy is needed near the IPG, shield the area over the IPG.
- **Ultrasonic scanning:** Do not use it over the IPG.

If the patient is required to undergo lithotripsy, high-output ultrasound, electrocautery, external defibrillation, radiation therapy, or ultrasonic scanning, follow these precautions.

- Turn off the IPG before the procedure.
- Use the devices as far away from the IPG as possible.
- Keep fields, such as current, radiation, or high-output ultrasonic beams, away from the IPG.
- Devices should be set to the lowest energy setting possible.
- After the therapy or procedure, check to see that the IPG is functioning properly by gradually increasing the IPG's stimulation to the desired level.

Post Operative Pain - In the days after the surgery, the patient may experience pain in the implant area as the incisions heal.

IPG Location - Advise the patient to not twist or rotate the IPG. If the IPG flips over in the body, the charger may not be able to charge the IPG. The patient's manipulation of the IPG in his or

her body may cause the skin over the IPG to become thinner over time.

Lead Movement – Patients should not make sudden and excessive bending, stretching, or twisting movements, particularly within the first weeks after the surgery. A lead can move from its original location during such movements, and stimulation may change as a result. In such cases, the patient may need to be reprogrammed or the lead may need to be repositioned through another operation.

Infection – Use proper infection control procedures. If the patient experiences persistent discomfort or excessive redness around the wound areas, the patient may need to be checked for infection. Infections related to the SCS may require the implanted components to be explanted. Do not use the charger if the incision is not healed. The charger and the charging belt are not sterile and should not be in contact with the incision.

Operating Temperature - The operating temperature range for the Patient Remote Control is 10 to 40 °C (50 to 104 °F). The operating temperature range for the Trial Stimulator is 10 to 38 °C (50 to 100 °F). While the Charger is plugged into the wall and charging itself, the operating temperature range for the Charging System is 10 to 40 °C (50 to 104 °F). While the Charger is charging the IPG, the operating temperature is 10 to 30 °C (50 to 86 °F).

Caring for the Trial Stimulator, Remote Control, and Charging System - These components can be cleaned by rubbing the surfaces without undue pressure with soft cloth dampened with water, isopropyl alcohol or mild detergent. The remaining residue should be removed by wiping the surfaces with a dry cloth. Do not use abrasive cleansers for cleaning. Do not allow moisture to get inside the components.

Operation of Vehicles (e.g., driving) or Machinery - Patients using therapy that generates paresthesia (tingling sensations caused by stimulation) should not operate motorized vehicles such as automobiles or potentially dangerous machinery and

equipment with the stimulation on when using paresthesia-causing programs. Stimulation must be turned off first in such cases. For these patients, any sudden stimulation changes may distract patients from proper operation of the vehicle, machinery, or equipment. Nevro™ SCS system's high frequency settings are designed not to generate paresthesia and its use does not restrict operation of moving vehicles.

Cell Phones - The impact of cell phones on the neuromodulation system is unknown at this time.

IPG Failure - If the patient's IPG does not provide therapy even after complete charging of the IPG or replacement of the batteries in the Patient Remote Control, turn off the IPG and contact Nevro Corp. When frequency of recharging becomes too inconvenient for your patient, the IPG may need to be replaced. Contact Nevro Corp.

Device Disposal - Do not dispose the IPG, Patient Remote Control or Charger in fire. The battery in these devices can explode in fire. The IPG should be explanted in the case of cremation. All explanted IPGs should be returned to Nevro Corp. Do not dispose of electrical components, including batteries, in the unsorted municipal waste stream. Dispose of electrical components, including batteries, according to local regulations.

FCC Statements: Senza IPG, Trial Stimulator and Patient Remote -

Senza IPG FCC ID: XKYIPG1000

Trial Stimulator FCC ID: XKYEXTS1000

Patient Remote FCC ID: XKYPTRD1000

Note:

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. If this equipment causes interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna.
- Increase the separation between the equipment and the antenna.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
- This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.
- Modification to the unit, unless expressly approved by Nevro Corp., could void your authority to operate this product.

FCC Statements: Programmer Wand -

Programmer Wand FCC ID:XKYWAND1000

Note:

- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. The equipment may cause interference to radio reception if it is not installed and used in accordance with the instruction manual. If this equipment causes interference to radio reception, the user may need to correct the interference.
- This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.
- Modification to the unit, unless expressly approved by Nevro Corp., could void your authority to operate this product.

Adverse Effects

Implantation of an SCS system involves potential risks. Such potential risks include, but is not limited to, the following:

- Changes in stimulation may occur over time. This may be caused by loose electrical connections, lead migration, lead failure, or cellular changes around the electrodes.
- System failure, which may be caused by lead breakage and hardware malfunctions.
- Allergic or immune response to implanted materials.
- Implant migration.
- Skin erosion.
- Surgical procedure risks, such as persistent pain at the implant site, infection, leakage of cerebrospinal fluid, seroma, hematoma, epidural hemorrhage, and paralysis.
- Radicular chest wall stimulation.
- Weakness, clumsiness, numbness, or pain below the level of implantation.

Technical Specifications

The following table contains technical specifications for the Charger.

AC input for the charger:	
Parameter	Specification
Frequency	50 to 60Hz
Voltage	100 to 240 VAC
Input Current	0.2A max

Additional technical information, including the Guidance and Manufacturer's Declarations on electromagnetic emissions and immunity, is available. To request this information, please contact Nevro Corp.

Patient Identification

Please ensure that the patient receives a completed temporary identification card following surgery.

Instructions for Use

Guidelines for Trial-phase Implantation

This section details the recommended procedures for trial-phase implantation of lead(s).

Temporary vs. Permanent Trials

- Physicians may elect to perform a trial in one of two ways, temporary or permanent. Nevro devices can be used with either method.
- In a **temporary trial**, the lead is placed in the patient, and the proximal end is externalized and connected to the Trial Stimulator. When the trial is over, the lead is removed from the patient. Subsequently, when a permanent system is implanted, the patient receives a new lead and IPG.
 - To perform a temporary trial, use the directions in the following sections in the order below:
 1. Pre-op Instructions
 2. Lead Placement
 3. Performing Intra-operative Testing
 4. Preparing for Temporary Trial
 5. Connecting the Lead or Extension to the Trial Stimulator
- In a **permanent trial**, the lead is placed in the patient and then fully implanted. The lead is attached to a lead extension, which is externalized and connected to the Trial Stimulator. With this approach, the implanted lead remains sterile. When a permanent system is implanted, the extension is discarded and the implanted lead is connected to an IPG. Depending on the patient body and the lead length that was used, a new lead extension may be necessary to connect the lead to the selected IPG site.
 - To perform a permanent trial, use the directions in the following sections in the order below:
 1. Pre-op Instructions
 2. Lead Placement
 3. Performing Intra-operative Testing
 4. Anchoring the Lead

5. Connecting an Extension to the Lead
6. Percutaneous Tunneling of the Extension
7. Closing the Incision Sites
8. Connecting the Lead or Extension to the Trial Stimulator

Pre-op Instructions

- Before opening the packages, verify the use-by date and the description of the component, such as length and type.
- Do not use any component that shows signs of damage.
- NOTE:
 - Confirm that the Trial Stimulator has batteries. When inserting batteries into the Trial Stimulator, match the positive (+) end of the battery to the positive (+) symbol inside the battery compartment.
 - Turn off the Trial Stimulator before taking out the batteries.
 - The Trial Stimulator's battery compartment must remain closed unless you are actively replacing batteries.

Percutaneous Lead Placement

- Prep the skin and drape the patient in a usual sterile fashion.
- Confirm pre-operative antibiotic prophylaxis if deemed appropriate.
- Inject a local anesthetic at the desired needle insertion site.
- Insert the needle at an angle of 45° or less into the posterior ligamentous complex at the desired vertebral level using fluoroscopic guidance.
- Remove the needle-stylet from the needle canula and confirm entry into the epidural space using standard methods such as loss of resistance. Verify needle location using fluoroscopy.
- In order to advance the lead easier, insert the lead blank through the needle and then withdraw it. Use fluoroscopic guidance.

- A stylet is pre-loaded into the lead. Prior to inserting the lead into the needle, ensure that the stylet is fully inserted and extended to the tip of the lead to ensure optimal steering of the lead.
- With the stylet in the lead, slowly insert the lead into the epidural space.
- Advance the lead to the appropriate vertebral level using fluoroscopic guidance. Rotate the stylet as necessary to steer the lead.
- NOTE:
 - Needles not provided by Nevro Corp. may damage Nevro™ leads.
 - Inserting the lead while the needle is at an angle of greater than 45° may increase difficulty in placing the lead or damage the lead.
 - If you are inserting a second lead, insert the second needle in such a way that doesn't damage the first lead.
 - If sedation or Monitored Anesthesia Care is used, it is recommended that the patient remain communicative during needle and lead placement to help mitigate any risk of neural injury.

Surgical Lead Placement

Refer to the Surgical Lead Manual

Performing Intra-operative Testing

- After the lead is in the desired location, you are ready to attach the OR Cable to the lead.
- If two leads are used, the leads may be marked using a sterile surgical marker, to specify which lead is on the patient's left and which is on the patient's right.
- Open the connector box of the OR Cable by pushing the two tabs away from each other. Insert the proximal end of the lead (or the lead extension) into the connector box.
- When the most proximal contact of the lead is in the first notch in of the connector box, close the connector box by pushing the two tabs towards each other.

- The OR Cable is usually not long enough to reach outside the sterile field, so an OR Cable Extension may need to be attached using an OR Cable Extension Connector. The OR Cable Extension is designed for temporary connection to the OR Cable to facilitate stimulation testing outside of the sterile field.
- Ensure that the Trial Stimulator is off.
- Connect the OR Cable or the OR Cable Extension to the Trial Stimulator.
- Conduct intra-operative testing to evaluate impedance of the system and appropriate lead position.
- Turn off the Trial Stimulator and disconnect the lead from the OR Cable.
- At this point, you can opt to do a temporary lead trial or a permanent lead trial.
- CAUTION:
 - Do not immerse the OR cable connector or plug in water or other liquids. Wipe fluids (e.g. blood) off the exposed lead connections to ensure that it is dry.
 - The OR Cable Assembly is intended for one-time only use. Do not re-sterilize.
 - Always turn the Trial Stimulator off before connecting or disconnecting the Cable Assemblies.
 - Do not pull on the OR cable while it is connected to the lead or the lead extender.

Preparing for Temporary Trial

- Using minimal force, carefully withdraw the insertion needle while holding the lead.
- Using minimal force, carefully withdraw the stylet while holding the lead.
- After removing the needle and the stylet, it is recommended that you confirm the location of the lead using fluoroscopy.
- Secure the lead to the skin using sterile tape or suturing to the skin. If you are suturing the lead to the skin, use a non-absorbable suture and the supplied anchoring device. Tying sutures directly to the lead can damage the lead.

- Note: Percutaneous Leads are suggested for temporary trial use when implantation of a surgical lead for permanent stimulation is planned. Refer to the Surgical Lead Manual for details on surgical lead placement.

Anchoring the Lead

- After assuring appropriate anesthesia, make a longitudinal incision around the needle and use a combination of sharp and blunt dissection to access the supraspinous ligament.
- Using minimal force, carefully withdraw the insertion needle while holding the lead.
- Using minimal force, carefully withdraw the stylet while holding the lead.
- After removing the needle and the stylet, it is recommended that you confirm the location of the lead using fluoroscopy.
- Place suture(s) over the anchor.
 - For a silicone anchor:
At least two sutures are needed. One is needed to tie the lead anchor to the lead, and another is needed to attach the lead anchor and lead to the patient's tissue.
 1. Slide the lead anchor over the lead and to the supraspinous ligament.
 2. Use a non-absorbable suture to tie the lead anchor to the lead. Tie the suture around a groove on the lead anchor to prevent the lead from sliding.
 3. Suture the lead anchor to the supraspinous ligament or deep fascial tissue. Run the suture through the eyelets on the lead anchor or around the bumps or grooves of the lead anchor. Make sure the suture is firm enough to hold the anchor to the tissue.
 - For an active anchor:
At least one suture is needed. It is needed to attach the lead anchor to the tissue.
 1. Slide the lead anchor over the lead and to the supraspinous ligament.

2. Use non-absorbable suture(s) to attach the lead anchor to the patient's tissue. Suture the lead anchor to the supraspinous ligament or deep fascial tissue. Run the suture through the eyelets on the lead anchor or around the grooves of the lead anchor. Make sure the suture is firm enough to hold the lead to the tissue.
 3. Use the supplied torque wrench to tighten the anchor to the lead. Tighten the torque wrench in clockwise direction until the audible click is heard.
- **CAUTION:**
 - Tying sutures directly on the lead can damage the lead. Always use one of the provided lead anchors.
 - Do not use polypropylene sutures as they may damage the lead anchor.
 - Do not use a hemostat on the lead body. This may damage the lead insulation.
 - It is recommended that the surgeon uses bipolar cautery for hemostasis around the epidural needles. Energy from monopolar cauterization could theoretically conduct down the needle to the epidural space and damage the neural structures.
 - If the lead does not fully insert into the active anchor, loosen the anchor by turning the torque wrench counter-clockwise and then re-insert the lead.

Connecting an Extension to the Lead

- Wipe fluids (e.g. blood) from the proximal end of the lead. Then fully insert the proximal end of the lead into the lead extension's connector.
- Do an impedance check.
- Fully insert the torque wrench into the setscrew.
- Rotate the torque wrench handle to turn the lead extension connector's setscrew clockwise until it clicks. Clicking indicates that it is fully tightened.

- **NOTE:**
 - Ensure that the set screw is not removed from the connector.
 - If the lead does not fully insert into the lead extension's connector, check to see whether the setscrew is impeding the progress of the lead. If it is, use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-insert the lead.
 - If the setscrew does not tighten smoothly, try the following:
 1. Use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-tighten by turning it clockwise.
 2. Check to see that the lead is fully inserted into the lead extension's connector before tightening.
 - The wrench is torque-limited and cannot be over tightened if you use the handle.
 - Use only a Nevro™ torque wrench to ensure that the proper torque is applied to the setscrews.

Percutaneous Tunneling of the Extension

- Assemble the tunneling tool by screwing in one of the tips on the end of the shaft. Make sure the straw is on the shaft prior to screwing in the tip.
- Plan the desired route of the tunnel and mark the route and the destination point at least 10-15cm from the incision.
- Give appropriate local anesthetic along the tunneling route.
- Create a small incision at the planned exit site.
- Insert the tunneling tool from the exit site and create a subcutaneous tunnel from the exit site to the lead incision site until the straw can be seen.
- Hold the tunneling tip firmly and then unscrew and remove the tunneling tip. Take care not to drop the tunneling tip.

- Remove the tunneling tool while leaving the straw in the tunnel.
- Insert the proximal end of the lead extension(s) through the straw.
- Push the lead extension(s) until they come out of the straw's other end.
- Gently pull the extension(s) to get as much of the extension(s) that you need through the straw, and then withdraw the straw from the exit site. It is recommended that a strain relief loop is left in the dorsal wound.
- Make sure that the lead location has not changed.

Closing the Incision Sites

- At the lead insertion site, use blunt dissection to create a pocket large enough to place excess lead. Coil excess lead into small loops and place them in the pocket.
- Gently pull on the lead extension from the exit site to remove excess slack.
- Close the incision at the lead insertion site.
- A small suture may be used to close the incision at the exit site. Do not tighten a suture around the lead or lead extension.
- Create a stress relief loop outside the body and tape it to the skin.
- Appropriate sterile dressings must be applied to the site where the lead or lead extension exits the body.

Connecting the Lead or Extension to the Trial Stimulator

- Appropriate sterile dressings must be applied to the site where the lead or lead extension exits the body. Tape the lead securely to the skin.
- Connect the lead or lead extension to the OR Cable.
- Create a loop of the OR Cable for strain relief and then tape the OR Cable to the skin.
- Connect the OR Cable to the Trial Stimulator.

Guidelines for Permanent Implantation

This section details the recommended procedures for permanent implant-phase.

Pre-op instructions

- Before opening the packages, verify the use-by date and the description of the component, such as length and type.
- Do not use any component that shows signs of damage.
- Ensure that the IPG is charged prior to implant

If the patient was given a temporary trial

- NOTE: At the end of a temporary trial, remove the temporary trial lead(s) as described below and follow the “IPG Implantation” section below. The leads will typically be removed before a patient comes in for the permanent implant.
- Removing the temporary trial lead(s):
 - Clip sutures if they were used to secure the lead(s) in place.
 - Remove the lead(s) and discard.
- Place lead(s) by following previous sections for:
 1. Pre-op Instructions
 2. Lead Placement
 3. Performing Intra-operative Testing
 4. Anchoring the Lead
- Prepare the IPG implant site and tunnel the lead to the IPG site by following the instructions below:
 - Prepare the skin and drape in the usual sterile fashion.
 - Anesthetize the site for the IPG pocket.
 - Identify a desired IPG implant site. Use the IPG template to estimate the size of the pocket. Mark the IPG implant site and make an incision that would be adequate to insert the IPG.
 - Create a subcutaneous pocket using blunt dissection. The pocket should be no larger than the IPG and no deeper than a depth of 2 cm from the skin.
 - NOTE:

1. For optimal charging, the IPG must be no more than 2 cm from the surface of the skin.
 2. Deep tunneling is not recommended.
 - Assemble the tunneling tool by screwing in one of the tips on the end of the shaft. Make sure the straw is on the shaft.
 - Mark the desired tunneling route.
 - Give appropriate local anesthetic along the tunneling route.
 - If necessary, gently bend the shaft of the tunneling tool to conform to the patient's anatomy.
 - Create a subcutaneous tunnel between the IPG implant site and the lead anchor site. Insert the tunneling tool until the tip of the straw is out of the tunnel.
 - Hold the tunneling tip firmly and then unscrew and remove the tunneling tip. Take care not to drop the tunneling tip.
 - Remove the tunneling tool's tip. Remove the tunneling tool, while leaving the straw in the tunnel.
 - If deemed necessary, use a lead extension. (Refer to the previous section on "Connecting an Extension to the Lead")
 - Insert the proximal end of the lead(s) or lead extension(s) through the straw.
 - Push the lead(s) or lead extension(s) until they come out of the straw's other end.
 - Gently pull the lead to get as much of the lead that you desire through the straw, and then carefully withdraw the straw. It is recommended that a strain relief loop is left in the anchoring incision.
 - Make sure that the lead location has not changed.
- Follow the instruction on ***IPG Implantation*** below.

If the patient was given a Permanent trial

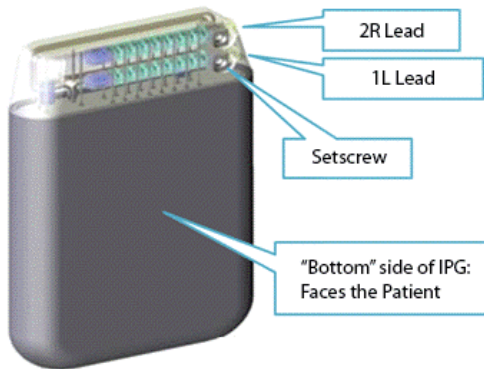
- NOTE: At the end of a permanent trial, remove the lead extension(s) as described below and follow the “IPG Implantation” section below.
- Removing the lead extension(s):
 - Prepare the skin and prep the patient in the usual sterile fashion. It is recommended to prep the midline incision in the sterile field and leave the extension site outside the sterile field so that it can be removed by an OR assistant.
 - Open the midline incision.
 - Cut the lead extension at the connector at the lead insertion site. Confirm that you are cutting the lead extension, not the lead.
 - Use the torque wrench to loosen the setscrew in the lead extension connector. Disconnect the head of the lead extension.
 - Remove the lead extension by pulling on the portion of the lead extension that is already externalized. This will be done outside the sterile field.
 - Discard the head of the lead extension.
- Prepare the IPG implant site and tunnel the lead to the IPG site by following the instructions below:
 - With consideration for patient comfort, identify a desired IPG implant site away from the exit site for the lead extension used for the trial.
 - Anesthetize the site for the IPG pocket
 - Mark the IPG implant site and make an incision equal to the IPG’s width.
 - Create a subcutaneous pocket using blunt dissection. The pocket should be no larger than the IPG and no deeper than a depth of 2 cm from the skin.
 - NOTE:
 1. For optimal charging, the IPG must be no more than 2 cm from the surface of the skin.
 2. Deep tunneling is not recommended.

- Assemble the tunneling tool by screwing in one of the tips on the end of the shaft. Make sure the straw is on the shaft.
- Mark the desired tunneling route.
- Give appropriate local anesthetic along the tunneling route.
- If necessary, gently bend the shaft of the tunneling tool to conform to the patient's anatomy.
- Create a subcutaneous tunnel between the IPG implant site and the lead anchor site. Insert the tunneling tool until the tip of the straw is out of the tunnel.
- Hold the tunneling tip firmly and then unscrew and remove the tunneling tip. Take care not to drop the tunneling tip.
- Remove the tunneling tool's tip. Remove the tunneling tool, while leaving the straw in the tunnel.
- If deemed necessary, use a lead extension. (Refer to the previous section on "Connecting an Extension to the Lead")
- Insert the proximal end of the lead(s) or lead extension(s) through the straw.
- Push the lead(s) or lead extension(s) until they come out of the straw's other end.
- Gently pull the lead to get as much of the lead or lead extension that you desire through the straw, and then carefully withdraw the straw. It is recommended that a strain relief loop is left in the anchoring incision.
- Make sure that the lead location has not changed.
- Follow the instruction on ***IPG Implantation*** below.

IPG Implantation

- Wipe the proximal end of the lead(s) or lead extension(s).

- Left lead or lead extension connects to IPG port 1L.
Right lead or lead extension connects to IPG port 2R.



- **NOTE:**
 - When using one lead, start by placing the port plug in the 2R port of the IPG. Then insert the lead into IPG port 1L. It is recommended not to tighten the setscrew until the lead is secure in the 1L port
 - When using two leads, connect the left lead or lead extension to IPG port 1L. Then, connect the right lead or lead extension to IPG port 2R.
- Place the lead or lead extension fully into the header. The "stop" at the end can be seen and felt.
- Look at the side of the IPG header after the lead or lead extension is fully inserted. When the lead contacts are between the terminal blocks, the lead will appear reflective and silver in terms of color. This means that the lead or lead extension is not fully inserted into the IPG header. When the lead contacts are in their correct position, the polyurethane insulation of the lead or lead extension can be seen and the silver colored lead contacts will seem to disappear.
- **NOTE:** When the lead or lead extension is properly inserted, the retention ring will be located under the setscrew. The retention ring looks like a wide contact, but it is much stronger and is designed to hold the lead or lead extension in place.
- Check the impedance of the system to verify that the lead or lead extension is fully inserted and making good contact within the header. If any of the contacts have

unusually high impedance, re-insert the lead or lead extension into the header.

- When the lead impedance shows normal readings and it has been visually verified that the lead or lead extension is fully inserted into the header, proceed to tightening the setscrew.
- Carefully insert the torque wrench through the septum in the IPG header and fully into the setscrew socket. The torque wrench will be exactly perpendicular to the broad side of the IPG when properly aligned.
- Turn the torque wrench's handle clockwise until it clicks. Clicking indicates that it is fully tightened.
- NOTE:
 - Ensure that the set screw is not removed from the header.
 - If the lead or lead extension does not fully insert into the IPG header, check to see whether the setscrew is not impeding the progress of the lead or lead extension. If it is, use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-insert the lead or lead extension.
 - If the setscrew does not tighten smoothly, try the following:
 1. Use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-tighten by turning it clockwise.
 2. Check to see that the lead or lead extension is fully inserted into the IPG header before tightening.
 - The wrench is torque-limited and cannot be over tightened if you use the handle.
 - The lead or lead extension could be damaged if the setscrew is tightened without being fully inserted.
 - Use only a Nevro™ torque wrench to ensure that the proper torque is applied to the setscrews.

- If the connector plug is used in 2R port, it is still necessary to tighten the setscrew as described for the 2R port.
- Place the IPG in the subcutaneous pocket with "This Side Up" facing towards the skin.
- If there is excess lead, either wrap it in large coils under the can or place the excess lead in a pocket separate from the IPG.
- It is recommended that non-absorbable sutures are placed through the suture holes in the IPG header and attached to the patient. This prevents the IPG from moving.
- Close all wounds and apply dressings in the usual surgical manner.

IPG Explant or Replacement

- Turn off the IPG.
- Surgically open the IPG pocket and withdraw the device.
- Unscrew the connector setscrews to release and disconnect the leads or extenders.
- For replacement, connect a new IPG to the leads or extenders. To terminate therapy, surgically remove the implanted lead system.
- NOTE:
 - Be careful not to cut the lead(s) or extender(s) when making an incision to remove the IPG.

Using the Nevro™ System

Trial Stimulator

Basic Operation

- NOTE: When the buttons on the Trial Stimulator are not pressed for longer than 1 minute, the Trial Stimulator will "lock". Only the red button, which turns the stimulation off, is operable when the Trial Stimulator is in the locked mode.
- Unlocking the Trial Stimulator: To unlock, press and hold both the '+' and '-' buttons simultaneously on the Trial Stimulator for longer than 2 seconds. Trial

Stimulator will beep once for 1 second when it is unlocked.

- Turning Stimulation OFF: Push the red button to turn stimulation OFF. This button only turns stimulation OFF. It does not turn stimulation ON. This button will work even if the Trial Stimulator is “locked”.
- Turning Stimulation ON: Press ‘+’ button.
- Changing Stimulation Amplitude: Press ‘+’ button to increase stimulation. Press ‘-’ button to decrease stimulation.

Understanding the Lead or Cable Detection feature:

- The Trial Stimulator can check whether the lead(s) or cable(s) are able to delivery therapy.
- If the Trial Stimulator is unable to deliver therapy, stimulation is disabled and an audio alert is sounded until it is acknowledged by the user by turning off stimulation or re-enabling stimulation.
- One possible cause of the alert is one or more loose connections between the various components (Trial Stimulator, OR cable, lead extension, lead). Other possible causes of the alert include a ‘high impedance’ state due to a variety of other conditions.
- If the state is due to a loose connection, the patient may be able to clear the alert by rechecking the connections. Otherwise, intervention by the physician or a company representative may be required.
- The checking is done by the Trial Stimulator every 1 minute. This feature may be turned ON or OFF.

Plugging the OR Cables Into the Trial Stimulator

- Ensure that the Trial Stimulator is OFF.
- Check the color of the sticker at the end of the OR Cable.
- Plug in the OR Cable into Trial Stimulator’s port that matches the color of the OR cable’s sticker.

Replacing the Trial Stimulator Batteries

- When the Battery Indicator (at the top left corner of the Trial Stimulator) is flashing, there is less than 10

minutes remaining before the Trial Stimulator's batteries need to be replaced.

- When the Low Battery Indicator light is ON, the batteries need to be replaced.
- The Trial Stimulator uses 2 Tadiran lithium batteries.
 - DO NOT USE alkaline batteries.
 - DO NOT USE the alkaline batteries provided for the Patient Remote Control.
 - ONLY USE BATTERIES SUPPLIED BY NEVRO CORP. FOR THE TRIAL STIMULATOR.
- NOTE:
- Store batteries in a cool, dry place.
- The battery compartment must remain closed unless you are actively replacing batteries.
- If pressing the buttons on the Patient Remote Control does not perform their intended purposes, the batteries may need to be replaced in the Trial Stimulator or Patient Remote Control.

Rechargeable IPG Overview

- The Nevro™ spinal cord stimulator is rechargeable. Nevro recommends a recharge schedule that fits the patient's schedule and lifestyle while maintaining sufficient charge to deliver a desired level of stimulation.
- The rechargeable implant battery should provide at least 10 years of service on typical high frequency stimulation settings.¹ If lower power stimulation parameters are used to deliver therapy, the battery should provide service for a longer period of time. At typical low frequency stimulation settings, the implant battery should provide 25 years of service or more. As is to be expected with all rechargeable batteries, over time, patients may experience shorter intervals between recharging. The implant will need replacement when stimulation can no longer be maintained with routine charging.

¹Nevro Report RD0032 Rev 1

IPG Battery Status

- When the Patient Remote Control communicates with the IPG, the battery status is sent to the Patient Remote Control, displaying up to 4 bars in the battery status display. 4 bars mean that the IPG is fully charged. When the battery status display has 2 or less bars, the IPG's batteries need charging. If it has 1 bar, the IPG should be recharged as soon as possible. Failure to recharge will lead to loss of stimulation, and the IPG will need to be charged for approximately 3 hours before reactivation.
- Note: If the Patient Remote Control is unable to communicate with the IPG, indicated by 3 beeps from the Remote, the lack of communication may be due to a low battery. Instruct the patient to recharge the IPG and then try using the Patient Remote Control again.
- The charger can also be used to turn the IPG's stimulation OFF. This is done by turning the charger ON (by pushing the arrow button), placing the charger coil over the implant and pressing the red button on the charger.

Refer to the Patient Manual for detailed instructions on the Trial Stimulator, Patient Remote Control, and Charging system.

Important Information

- Trial Stimulator
 - Always turn off the Trial Stimulator before taking out the batteries.
 - The Trial Stimulator's battery compartment must remain closed unless you are actively replacing batteries.
- IPG
 - If the IPG is not responding to remote control commands or not providing therapy, check whether the IPG is adequately charged and whether the remote control and the charger are functioning properly.

- **Charger**
 - Do not charge while sleeping. This may result in a burn.
 - While charging, the charger may become warm. It should be handled with care.
 - Failure to use the charging belt may result in a burn. If pain or discomfort is felt, cease charging and contact Nevro Corp.
 - Do not charge the IPG while the charger is plugged into the outlet.
 - Use only the Power Adapter supplied by Nevro Corp.
- **Patient Remote Control**
 - **Device Linking:** A Patient Remote Control can link and communicate with only one stimulator at a time.
 - If the Patient Remote Control does not seem to be working, use it closer to the IPG or replace the batteries. The Patient Remote Control communicates with the IPG through a radio frequency (RF) telemetry link from a distance of up to 1.5 meters.
 - When replacing the Patient Remote Control batteries, confirm that the new batteries are AA alkaline batteries. When inserting new batteries, match the positive (+) end of the battery to the positive (+) symbol inside the battery compartment.

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This image shows a single page of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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NEVRO CORP.

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