MiniStim PNS

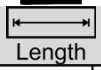
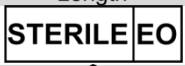
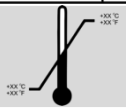
PIPG KIT

INSTRUCTIONS FOR USE

Caution: Federal law restricts this device to sale by or on the order of a physician.

Explanation of Symbols on Product or Package

Refer to the appropriate product for symbols that apply.

Symbol	English – EN
	Device reference identification
	Lot number
	Quantity of product included in package
	Consult instructions for use
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Store in a cool, dark, dry place
	Caution
	Warning
	MR Conditional
	MR Unsafe
	Use by
	Manufacturing date
	Manufacturer
	Device length
	Sterilization: ethylene-oxide gas
	Temperature limits

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Indications for Use

MiniStim PNS is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. MiniStim PNS is not intended to treat pain in the craniofacial region.

Package Contents

- pIPG – A neurostimulator to be inserted next to the target nerve.
- Introducer Assembly – A metal dilator and polymer introducer.
- Stylet – Stiff wire inserted into pIPG to aid in positioning (optional).

How To Use This Manual

This manual describes the MiniStim PNS, percutaneous Implanted Pulse Generator (pIPG) accessories, and the methods to optimally place and fixate the pIPG. It also provides important safety information, contraindications, warnings and precautions. Please refer to the MiniStim PNS Product Safety Guide for EMC related safety information.

Device Specifications

Table 1. MiniStim PNS pIPG Specifications.

Model Number	NRO4-07	NRO4-20	NRO4-38
			
pIPG(s):			
Length	7 cm	20 cm	38 cm
Diameter	1.35 mm	1.35 mm	1.35 mm
Electrode(s):			
Number	4	4	4
Shape	Cylindrical	Cylindrical	Cylindrical
Length	3 mm	3 mm	3 mm
Spacing	4 mm	4 mm	4 mm
Array Length	24 mm	24 mm	24 mm
Marker Band distance	7 cm	20 cm	38 cm
No. of Independent Channels:	1 Channel	1 Channel	1 Channel
Implant period	Perm.	Perm.	Perm.

Table 2. Material Specification for MiniStim PNS.

Component	Material	Tissue contact
pIPG		
Flexible circuit board	Polyimide	No
Flexible circuit trace	Copper	No
Encapsulation	Parylene C	No
Electrodes	Platinum-Iridium	Yes
Insulation	Polyurethane	Yes
pIPG Tip	Polyurethane	No
Adhesive	Epoxy	No
Needle	Stainless Steel	Yes
Introducer Assembly		Yes
Dilator	P Stainless Steel	Yes
Introducer	Yellow Hytrel	Yes
Stylet		
Handle	Polypropylene, Polycarbonate	Yes
Wire	Stainless Steel	Yes

Instructions for Implantation

(NRO4-07, NRO4-20, NRO4-38)

Implanting clinicians should be experienced in procedures that gain access to peripheral nerves, ultrasound and/or fluoroscopy, and MiniStim PNS product labeling.

Common Nerve Targets

Common peripheral nerves treated with MiniStim PNS include the occipital, suprascapular, axillary, brachial plexus, intercostal, ulnar, median, radial, cluneal, femoral cutaneous, ilioinguinal, lumbar, sacral, scrotal, pudendal, sciatic, genicular, peroneal, sural, saphenous, and tibial. The location of several of these nerve targets with the pIPG running parallel to the nerve target are shown in Figure 1 through 8.

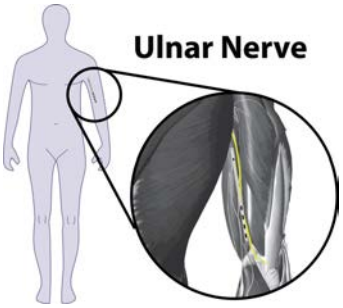


Figure 1

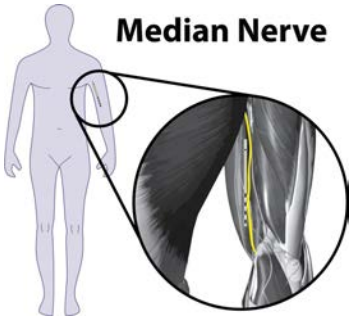


Figure 2

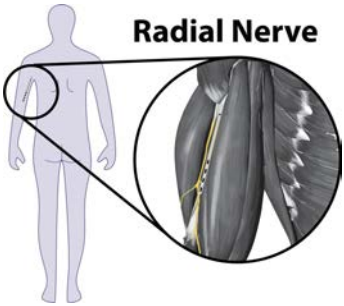


Figure 3

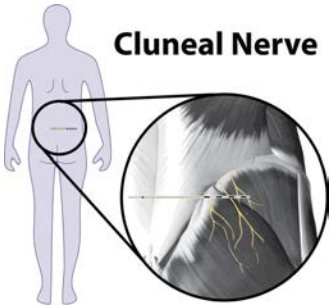
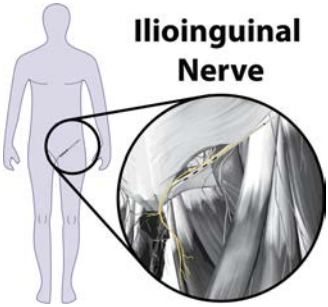


Figure 4



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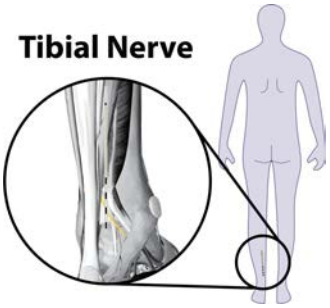
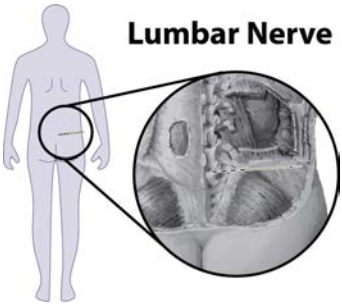


Figure 6



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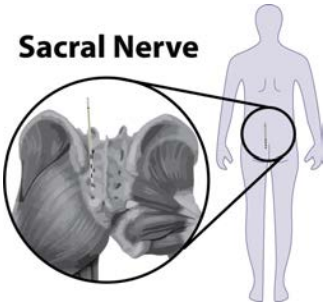


Figure 8

Preparing for Procedure

CAUTION:

To reduce the risk of pIPG damage that might result in intermittent or lost stimulation:

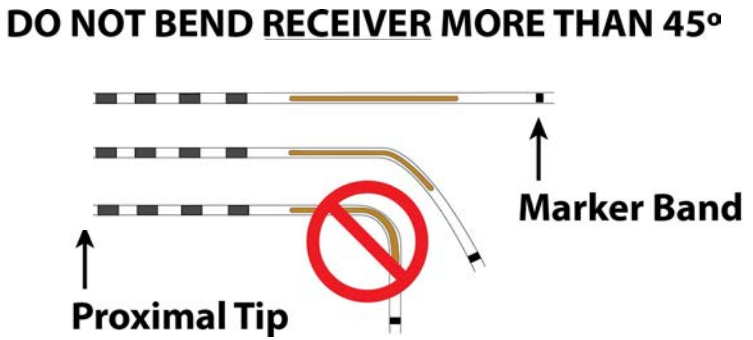
- Use only the Introducer supplied in the kit.
- Do not bend, kink, or stretch the pIPG.
- Do not use any instrument to handle the pIPG.
- Avoid excessive pressure on the pIPG.

Steps:

1. Verify all product expiration dates are valid.
2. Verify the package integrity and model number.
3. Set up ETx by following manufacturer's instructions for use. Check the battery charge level. If required, charge the ETx according to the instructions for use. Set ETx to the lowest power level.
4. The pIPG Kit is provided sterile. Do not use the product if package is damaged. Do not use product if the date has expired. Contact the manufacturer with any questions regarding expiration dates.

Handling the pIPG

The pIPG consists of electrodes, embedded receiver and electronics, and various positional marker bands. Handle the pIPG with care. Do not bend the pIPG. Bending can damage the device. The pIPG should be implanted straight for optimal performance and must be internalized completely within the body from the proximal tip to distal end of pIPG.



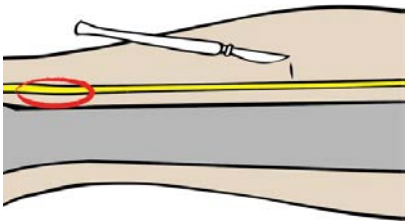
Implanting the pIPG

Notes:

- *ONLY use the introducer provided in the pIPG kit. Do not remove the dilator from the introducer assembly when placing in tissue.*
- *Use ultrasound or a nerve conduction to identify the location of the target nerve.*
- *Plan the entry site using measurements and skin markings far enough away from the target nerve so that the device will be fully implanted.*

Steps:

1. Prepare entry site using standard precautions and aseptic techniques.
2. Mark the area of the nerve on skin for planned trajectory of the pIPG.
3. Use a local anesthetic at the entry site.
4. Make a puncture incision before inserting introducer. (Figure 9).
5. Advance introducer through the incision. (Figures 10 to 11).
6. Remove dilator from the introducer leaving the introducer in place.
7. Advance pIPG through the introducer parallel with nerve. (Figure 12).



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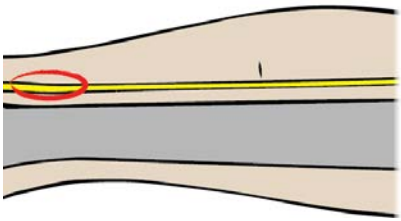


Figure 10

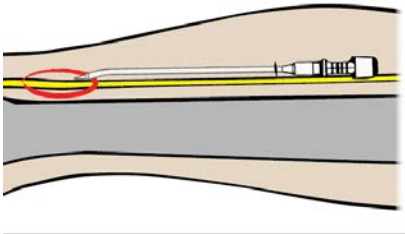


Figure 11

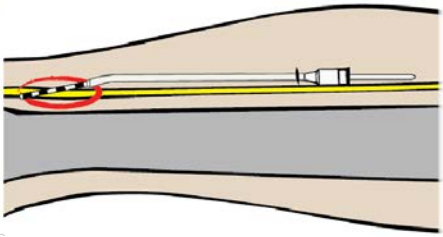


Figure 12

Testing pIPG Intraoperatively

To prevent possible unexpected stimulation (shocking sensations):

- Before placing the ETx over the pIPG, set the ETx to Program III (ETx will flash three times) at the lowest power level.
- Change power settings in small increments.
- ETx is pre-programmed with the following:

Program	Frequency (Hz)	Pulse Width (µs)	Amplitude (mA)
I	1500	50	0
II	500	200	0
III	60	200	0

- *Testing requires an ETx (packaged separately). Refer to ETx User Manual for use. Place ETx antenna directly over pIPG.*
- *Metal can **block** the signal from the ETx. Any metal instruments or accessories must be removed before intraoperative testing. The introducer sheath can be used throughout intraoperative testing.*

Steps:

1. Confirm that the electrodes are not obstructed by the introducer (i.e. - if pIPG is not advanced out of introducer by at least 3 cm retracted introducer 3 cm for electrodes to be in direct contact with tissue).
2. While holding the pIPG in place, completely withdraw the stylet (if applicable).
3. Place ETx in a sterile drape or fluoroscope bag over the region directly above the most proximal electrode on the pIPG (Figure 13). Increase power while asking the patient close-ended questions to identify threshold and appropriate relief.

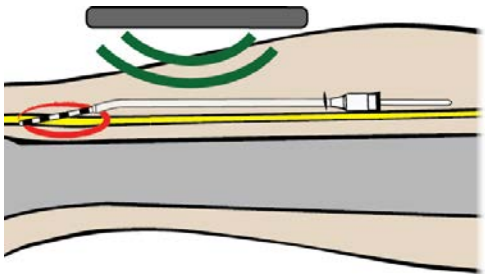


Figure 13

4. If appropriate relief is not achieved, adjust pIPG position. In patient's chart, document device position that provided appropriate relief. Record power level settings and patient responses.
5. Patients will be instructed to utilize a power level setting at 90% of the responsive setting noted during the procedure for therapeutic relief.

Fixating the pIPG

Steps:

1. Place suture through tubing of pIPG body with 2-0 non-absorbable suture material (silk or other types of braided polyester mesh).
2. Use the suture needle to penetrate the empty tubing portion of the pIPG and attach the pIPG to surrounding tissue (Figure 14).
3. After fixating, ensure that pIPG has not moved and the pIPG is securely fixated to tissue with the receiver portion as straight as possible. If the device has moved, reestablish coverage using the ETx to ensure that appropriate coverage persists.
4. Close the incision using sterile skin closures and dressings.

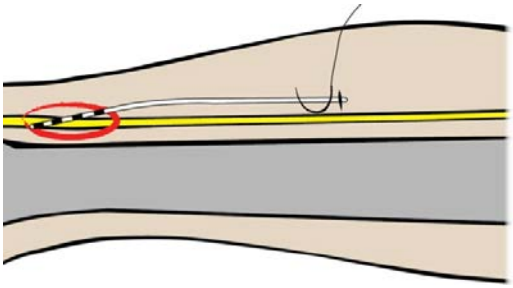


Figure 14

Trimming Excess Tubing

Before removing any excess tubing from the pIPG, confirm that the stylet (if applicable) has been removed.

Steps:

1. Use sterile scissors to cut excess tubing off only proximal of maker band on the pIPG (Figure 15).
2. Close the incision using sterile skin closures and dressings.

Figure 15

Explant Procedure

pIPG tissue encapsulation is expected approximately 14 days post-implant. If pIPG must be explanted, follow procedures as specified by the clinician.

Steps:

1. Examine the incision site for signs of infection.
2. Using sterile technique, prepare and drape the site in typical fashion.
3. Inject original incision of the pIPG with local anesthesia.
4. Remove sutures and make an incision over or near the original incision, taking care not to cut the pIPG. Using forceps, hook the pIPG and gently draw it above the skin.
5. Grasp the protruding pIPG and gently pull the device out of the body in the direction opposite to how it was implanted and continue pulling until the entire device is removed including the electrodes.
6. Examine pIPG to ensure it is intact. If the pIPG is fractured, then further surgical exploration may be required.
7. Close the incision site using standard techniques and apply wound dressing as appropriate.

Device Disposal

Explanted devices are not to be re-sterilized or re-implanted. Dispose of the used pIPG according to local laws and regulations.

SAFETY INFORMATION

Contraindications

- **Poor surgical risks –** MiniStim PNS should not be used on patients who are poor surgical risks, have multiple illnesses, active infections or who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.
- **Pregnancy –** Safety and effectiveness of MiniStim PNS for use during

pregnancy and nursing have not been established.

- **Inability to operate MiniStim PNS –** MiniStim PNS should not be used on patients unable to operate the device.
- **Exposure to shortwave, microwave, or ultrasound diathermy –** Diathermy should not be operated within the vicinity of a patient implanted with a pIPG or when wearing the external transmitter (ETx). The energy from diathermy can be transferred through the pIPG or ETx and cause tissue damage, resulting in potential injury.
- **Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy –** Users who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with MiniStim PNS. The energy in high-level areas can be transferred through the pIPG and cause tissue damage, resulting in injury. Examples of environments having high level non-ionizing radiation includes radio or cell phone transmission stations, facilities using radiofrequency heat sealers or induction heaters, electric power infrastructure-controlled environments (i.e. step down transformers or high voltage power lines).
- **Implanted cardiac systems –** Patients who have implanted cardiac systems should not use MiniStim PNS. Electrical pulses from the device may interact with the sensing operation of an implanted cardiac system, causing inappropriate responses.

WARNINGS

Electromagnetic interference (EMI) – EMI is a field of energy that can be generated by certain equipment found in home, work, medical or public environments. Strong EMI signals have the ability to cause interference with MiniStim PNS operation. Most electrical devices and magnets encountered in a normal day will not affect the operation of MiniStim PNS. However, strong sources of EMI could result in the following:

- Serious patient injury from heating of implanted device or damage to surrounding tissue;
- System damage resulting in a change in MiniStim PNS operation;
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation. Some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device

or cause a patient direct injury. In rare cases, as a result of the unexpected changes in stimulation, patients have injured themselves.

If you suspect that equipment is interfering with device function:

- Immediately move away from the equipment or object;
- Remove the ETx from the vicinity of the patient.

Electromagnetic equipment/environments – The product is suitable for use in home environments and public areas. Avoidance of high electromagnetic equipment environments is highly encouraged. Examples of equipment and/or environments include the following:

- High-power amateur transmitters, citizen band (CB) radio or Ham radio used for recreation, communication, and wireless experimentation;
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics;
- Industrial electric induction furnace/heater or electric arc furnace/heater used for melting metals and plastics;
- High-voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area);

Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area);

- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area);
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or other electronic equipment;
- Radio telemetry equipment used for tracking location of vehicles, equipment or animals.

Adjacent to or Stacked with Equipment – Use of this equipment adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communications Equipment – Portable RF communications equipment (including external antennas) should be used no closer than 30 cm (12 inches) to any part of the System. Otherwise, degradation of the performance of this equipment could result.

Active Implantable or Body Worn Medical Devices – Safety has not been established for using MiniStim PNS with other active implantable or body worn medical devices. These devices include other neurostimulation systems, insulin pumps, automated external defibrillators (AED), cochlear implants, and wearable medical sensors. Malfunction and/or damage could occur to either system that could result in harm to the patient or other people nearby.

Radiofrequency (RF) ablation – Safety has not been established for radiofrequency (RF) ablation in patients with a pIPG. RF ablation may cause induced electrical currents that result in heating and tissue damage. Do not use RF ablation anywhere near the pIPG. If RF ablation is used, ensure that ablation is not performed over or near the pIPG.

Magnetic resonance imaging (MRI) – **MiniStim PNS is MR Unsafe.** The strong magnetic field of the MR system could attract or otherwise damage the device, and cause harm to the patient or damage to the MR system. **The ETx is MR Unsafe; ensure that the ETx does not enter the MR room.** The strong magnetic field of the MR system could attract or otherwise damage the ETx, and in the process cause serious harm to the patient or other people or damage to the MR system.

Machinery or heavy equipment – Machinery and heavy equipment (including vehicles) should not be operated while using MiniStim PNS. Malfunction could result in loss of body control, body function, or a feeling that could render the patient incapable of controlling the device.

Bone growth stimulators – Safety has not been established for bone growth stimulators in the vicinity of MiniStim PNS. Use of a bone growth stimulator may result in damage to the device or harm to the patient.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients with a pIPG. Induced electrical currents can cause heating that may result in tissue damage.

Dental drills and ultrasonic probes – Safety has not been established for dental drills or ultrasonic probes within the vicinity of the pIPG. Use of

dental drills or ultrasonic probes may result in damage to the device or harm to the patient.

Electrolysis – Safety has not been established for electrolysis within the vicinity of the pIPG. Use of electrolysis may result in damage to the device or harm to the patient.

Electrocautery – If electrocautery tools are used near the pIPG then the insulation can be damaged. The pIPG may fail or conduct induced currents. Induced electrical currents can cause heating that results in tissue damage. If electrocautery is used, the following precautions must be followed:

- If unipolar cautery is necessary:
  - Only low-voltage modes should be used;
  - The lowest possible power setting should be used;
  - Current path (ground plate) should be kept far away from pIPG;
  - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm that the pIPG is working as intended.

Computed Tomography (CT) Scanning – Safety has not been established for CT scanning of patients with a pIPG. X-rays from the scan could cause unintended shocks or malfunctions of the pIPG. The CT operator should use CT scout views to determine if implanted medical devices are present and their location relative to the programmed scan range. For CT procedures in which the device is in or immediately adjacent to the programmed scan range, the operator should:

- Remove the ETx from the CT scan range.
- Minimize X-ray exposure to the implanted device by:
  - Use lowest possible X-ray current consistent with obtaining the required image quality;
  - Make sure X-ray beams do not dwell over device for more than a few seconds.

After CT scanning directly over the implanted device:

- Place ETx and turn on stimulation.
- Check that indicator lights are operating as expected.
- Shut off ETx if suspect the device is not functioning properly.

High-output ultrasonics/lithotripsy – Safety has not been established for high-output ultrasonics or lithotripsy for MiniStim PNS. Use of lithotripsy

may result in damage to the device or harm to the patient.

Radiofrequency Identification (RFID) Emitters - Theft detectors, electronic article surveillance (EAS) systems, and radiofrequency identification systems – Tests performed with simulated RFID emitter systems have demonstrated that MiniStim PNS is not affected by separation distances between the device and RFID emitters of less than 10 ft. More powerful RFID emitters might cause an effect at farther distances. RFID emitters can be hidden or portable and not obvious to the patient. A RFID emitter may temporarily interrupt stimulation or cause elevated levels of stimulation. It is recommended that if a patient feels a change in stimulation near a potential RFID emitter, they move away from the area and remove the ETx from the body. When possible, it is best to avoid RFID emitters or remove the ETx while passing near RFID emitters. Patients with a pIPG should inform the attendant who may be able to assist them in bypassing any RFID emitter. If unavoidable, the patient should walk through the RFID emitter and promptly move away from the area. Patients should not lean on scanners or linger in the area of RFID emitters.

Device fracture – If pIPG insulation is ruptured or pierced due to extensive forces, unexpected changes in stimulation could result.

Laser procedures – Safety has not been established for lasers within the vicinity of MiniStim PNS. Use of lasers may result in damage to the device or harm to the patient.

Radiation therapy – Safety has not been established for high radiation sources such as cobalt 60 or gamma radiation when implanted with MiniStim PNS. Use of radiation therapy could cause damage to the device or harm to the patient.

Transcutaneous electrical nerve stimulation – Safety has not been established for use of transcutaneous electrical nerve stimulation (TENS) when implanted with MiniStim PNS. Use of TENS could cause the device to turn off or intermittent/increased stimulation.

Other medical procedures – EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)

- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep the magnet away from the pIPG site. Magnetic fields will generally not affect the pIPG.

ETx Skin Contact – Do not place ETx directly on skin. Direct skin contact may cause irritation and/or sensitivity. The ETx should be placed overtop a thin layer of clothing.

Painful Stimulation – If the patient experiences painful stimulation, the power on the ETx should be decreased immediately and/or removed from the patient's body.

Aircraft Usage – Safety has not been established for use of MiniStim PNS on aircrafts. Use of MiniStim PNS on a commercial aircraft may result in damage to the device or harm to the patient.

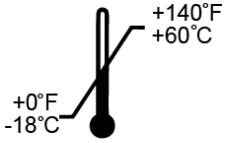
Precautions

Physician training – Prescribing clinicians should be experienced in the diagnosis and treatment of peripheral pain and should be familiar with using MiniStim PNS. Implanting clinicians should be experienced and review the procedures described in Instructions for Use.

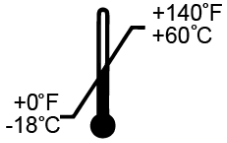
Keep the ETx dry – ETx is not waterproof. Keep it dry to avoid damage. Do not use the ETx when engaging in water activities.

Storage temperatures – MiniStim PNS should be kept within the storage temperatures listed on the product packaging. Exceeding the storage temperature could cause harm to you or the component. Please contact the manufacturer if a storage temperature is surpassed.

pIPG Storage Temperature



ETx Storage Temperature



Clean the ETx – Clean the ETx with a damp cloth when needed to prevent dust and grime. Mild household cleaners will not damage the device.

Handle the ETx with care – The ETx is a sensitive electronic device. Avoid dropping the device onto hard surfaces. Keep the ETx out of the reach of children and pets.

Medical tests and procedures – Before undergoing medical tests or procedures, contact the clinician to determine if the procedure could cause damage to MiniStim PNS.

Physician instructions – Always follow instructions of clinician. Failure to do so may cause the therapy to be less effective in providing relief.

Use ETx as directed – Use ETx only as discussed in the User Manual. Using the ETx in any other manner could result in harm.

Do not dismantle the ETx – Do not dismantle or tamper with ETx, as it could result in harm. If device is not working properly, contact the clinician.

Flammable or Explosive Environments – Do not use the ETx in flammable or explosive environments as it could result in harm.

Use of another patient's ETx - Never use another patient's ETx. Use of another patient's ETx could result in overstimulation.

Activities requiring excessive twisting or stretching – Avoid activities that potentially can put undue stress on the device. Activities that including sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause the pIPG to fracture or migrate. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Scuba diving or hyperbaric chambers – Do not dive below 13 meters (45 feet) of water or enter hyperbaric chambers above 1.5 atmospheres absolute (ATA). These conditions can damage the device. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with the clinician.

Skydiving, skiing, or hiking in the mountains – High altitude should not affect MiniStim PNS. However, take care to not put undue stress on the

pIPG. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the device. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Unexpected changes in stimulation – Electromagnetic interference, changes in posture, and other activities can cause unintended stimulation. Some patients have described this as a jolting or shocking sensation. You should reduce your power to the lowest setting and turn OFF your ETx before engaging in activities that could become unsafe. Discuss these activities with your clinician.

Adverse Event Summary

Implantation of a pIPG procedure risks include the following:

- Allergic or immune system response to implanted material.
- Infection.
- Hemorrhage or hematoma.

Therapeutic use of the MiniStim PNS incurs the following risks:

- Undesired change in stimulation.
- Migration, erosion, or fracture resulting in loss of therapeutic effect.
- Electromagnetic interference leading to change in performance.
- Loss of therapeutic effect despite a functioning system.

Adverse events that could occur with the MiniStim PNS:

- Migration, resulting in altered therapy that may be uncomfortable.
- Device fracture, resulting in loss of stimulation.
- Infection, resulting in tissue sensitivity, redness and swelling.

Adverse effects of stimulation are usually mild and go away when stimulation is turned off. Patients should be contact their clinician immediately if they experience any problem or a change in stimulation.

MRI SAFETY INFORMATION

MiniStim PNS is MR Unsafe and must not be allowed in the MR system room. MiniStim PNS components are labeled as follows:

MR Unsafe Components

- pIPG (NRO4-07, NRO4-20, NRO4-38)
- External Transmitter (ETx)
- Charger
- Introducer
- Stylet

DO NOT have an MRI while the pIPG is implanted or with any accessory in the room. pIPG and the accessories are MR Unsafe.

Failure to adhere to the specific requirements described in this manual can result in tissue damage, severe injury, or death. Please use the contact information found on the last page of this manual for additional information.

CONTACT INFORMATION

Manufacturer

MiniStim LLC

1900 Glades Road, Ste 500
Boca Raton, Florida 33431
United States
Telephone: +1.888.691.0585
Fax: +1.888.691.0585
Internet: www.ministim.com

31-00014-3 Published November 2022