micron medical

# MOVENTIS PNS

# pIPG RECEIVER KIT

# INSTRUCTIONS FOR USE

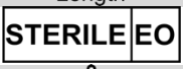
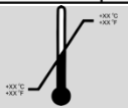
Caution: Federal law restricts this device to sale by or on the order of a physician.

MOVENTIS pIPG RECEIVER KIT

NRO4-STM-07, NRO4-STM-20, NRO4-STM-38

# 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 |

# TABLE OF CONTENTS

**EXPLANATION OF SYMBOLS ON PRODUCT OR PACKAGE ..... 2**

INDICATIONS FOR USE ..... 4

**HOW TO USE THIS MANUAL ..... 4**

**DEVICE SPECIFICATIONS ..... 4**

**INSTRUCTIONS FOR IMPLANTATION ..... 5**

COMMON NERVE TARGETS ..... 6

PREPARING FOR PROCEDURE ..... 7

HANDLING THE PIPG ..... 7

IMPLANTING A PIPG ..... 8

TESTING PIPG INTRAOPERATIVELY ..... 9

FIXATING PIPG ..... 10

TRIMMING EXCESS TUBING ..... 11

EXPLANT PROCEDURE ..... 11

DEVICE DISPOSAL ..... 11

**SAFETY INFORMATION ..... 12**

CONTRAINDICATIONS ..... 12

WARNINGS ..... 13

PRECAUTIONS ..... 18

ADVERSE EVENT SUMMARY ..... 20

**MRI SAFETY INFORMATION ..... 21**

**CONTACT INFORMATION ..... 22**

## INDICATIONS FOR USE

Moventis 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. Moventis 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(s) – Stiff wire inserted into pIPG to aid in steering and positioning.

## HOW TO USE THIS MANUAL

This manual describes the Moventis 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 Moventis PNS Product Safety Guide for EMC related safety information.

## DEVICE SPECIFICATIONS

**Table 1. Moventis pIPG Specifications.**

| Model Number | NRO4-07 | NRO4-20 | NRO4-38 |
|---|---|---|---|
| |  |  |  |
| pIPG(s): | | | |
| Length | 45 cm | 45 cm | 45 cm |
| Diameter | 1.35 mm | 1.35 mm | 1.35 mm |

| Model Number | NRO4-07 | NRO4-20 | NRO4-38 |
|---|---|---|---|
| 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 the Moventis PNS.**

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

# INSTRUCTIONS FOR IMPLANTATION

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

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

## COMMON NERVE TARGETS

Common peripheral nerves treated with Moventis PNS include the occipital, suprascapular, axillary, brachial plexus, intercostal, ulnar, median, radial, cluneal, femoral cutaneous, ilioinguinal, sacral, scrotal, pudendal, sciatic, genicular, peroneal, sural, saphenous, and tibial. The location of several of these nerve targets with the Moventis pIPG running parallel to the nerve target are shown in Figure 1 through 7.

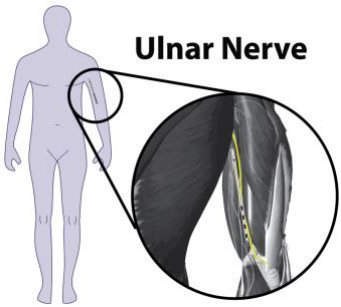



**Figure 1**

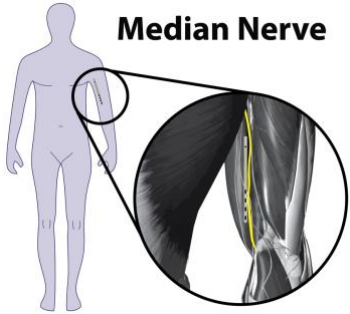



**Figure 2**

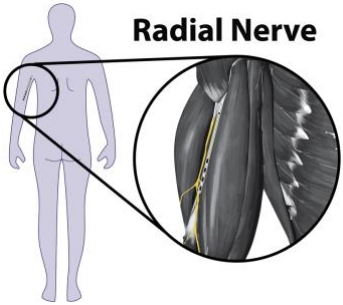



**Figure 3**

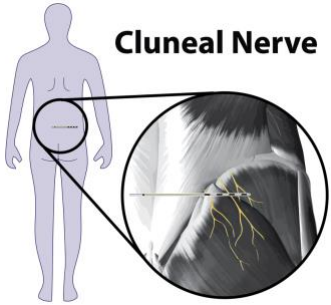



**Figure 4**

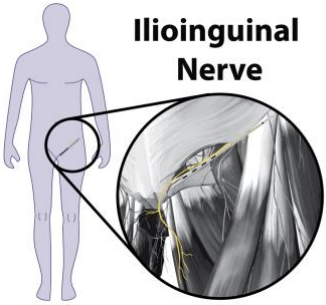



**Figure 5**

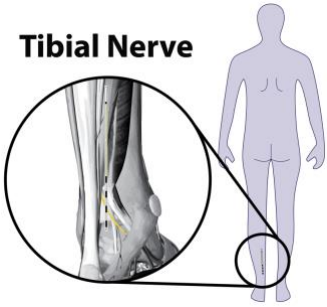



**Figure 6**

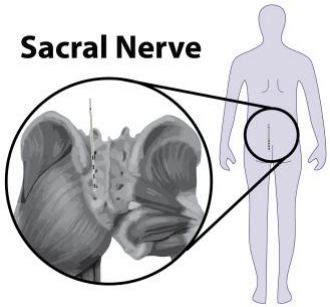



**Figure 7**

## PREPARING FOR PROCEDURE

### ⚠ CAUTION:

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

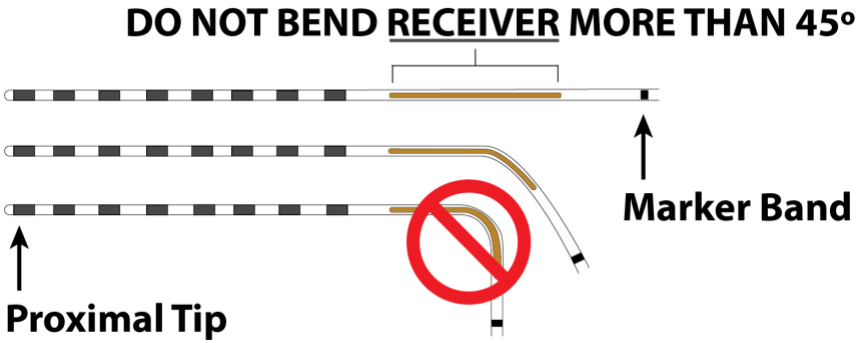
- Use only the Introducer supplied in the pIPG Receiver Kit.
- Do not bend, kink, or stretch the pIPG or stylet.
- Do not use any instrument to handle the pIPG.
- Avoid excessive pressure on the pIPG.

***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 manufacturer's instructions for use. Set ETx to lowest power level.
4. pIPG Receiver Kit is provided sterile. Do not use the product if the package is damaged. Do not use the product if the date has expired. Contact Micron for any questions regarding packaging and expiration dates.

## HANDLING THE PIPG

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




## IMPLANTING A PIPG

***Notes:***

- *Use ONLY the introducer provided in the pIPG receiver kit. Do not remove the dilator from the introducer assembly when placing in tissue.*
- *Use ultrasound or a nerve conduction technique to identify the location of the target nerve.*
- *Plan entry site using measurements and skin marking so it is far enough away from the target nerve 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 8).
5. Advance introducer through the incision. (Figures 9 to 10).
6. Remove dilator from the introducer leaving the introducer in place.
7. Advance pIPG through the introducer parallel with nerve. (Figure 11).

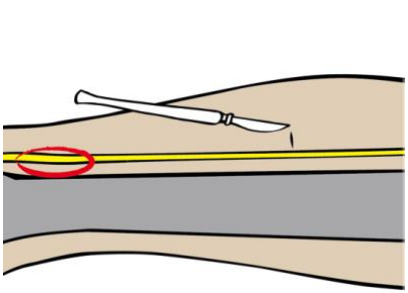


**Figure 8**

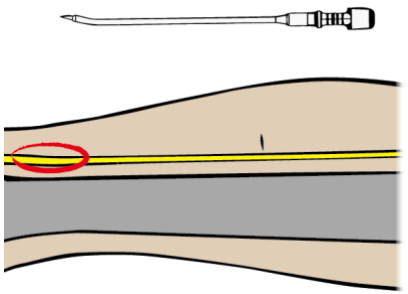


**Figure 9**

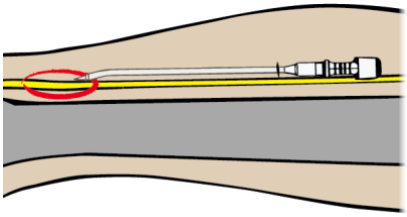


**Figure 10**

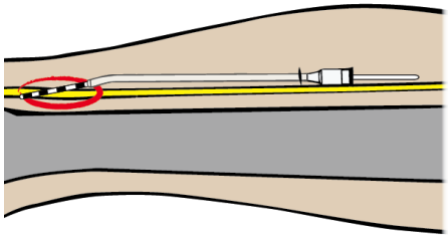


**Figure 11**

## TESTING PIPG INTRAOPERATIVELY

To prevent possible unexpected stimulation (jolting or shocking sensations):

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

| Program | Frequency (Hz) | Pulse Width (µs) |
|---|---|---|
| I | 1500 | 50 |
| II | 500 | 200 |
| III | 60 | 200 |

- *Testing requires an ETx (packaged separately). Refer to ETx User Manual for use. Place ETx directly over pIPG.*
- *Metal can **block** waveform from 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.
3. Place ETx in a sterile drape or fluoroscope bag over the region directly above the most proximal implanted electrode on pIPG (see Figure 12).
4. Increase power while asking the patient close-ended questions to identify threshold and appropriate relief.

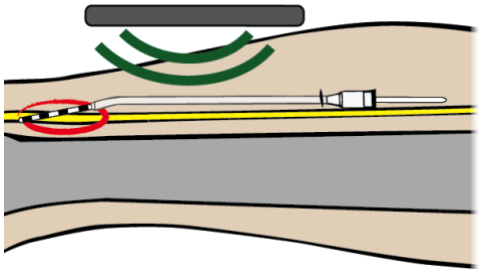


**Figure 12**

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

## FIXATING 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) (see Figure 13).
2. Use suture needle to penetrate pIPG body and secure the pIPG to the facia (See Figure 14).
3. After fixating, ensure that pIPG has not moved and the pIPG is securely fixated as straight as possible to tissue. 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.

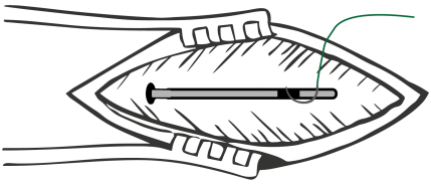


**Figure 13**

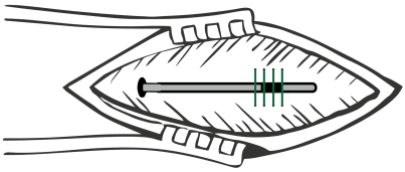


**Figure 14**

## TRIMMING EXCESS TUBING

Before cutting excess tubing from pIPG, confirm the stylet has been removed.

***Steps:***

1. Use sterile scissors to cut excess tubing off only proximal of maker band on the implanted pIPG. Ensure that you cut off distal of the device marker band (see 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 from the skin, 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 pIPG is fractured, then further surgical exploration may be required to remove any remaining parts.
7. Close the incision site using standard techniques such as suture 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. Alternatively, contact Micron Medical Corporation for information on returning the devices for safe disposal.

# SAFETY INFORMATION

## CONTRAINDICATIONS

- **Poor surgical risks –** Moventis 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 Moventis PNS for use during pregnancy and nursing have not been established.
- **Inability to operate Moventis PNS –** Moventis PNS should not be used on patients who are unable to operate Moventis PNS.
- **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 Moventis 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 Moventis 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 Moventis PNS operation. Most electrical devices and magnets encountered in a normal day will not affect the operation of Moventis PNS. However, strong sources of EMI could result in the following:

- Serious patient injury from heating of implanted device and damage to surrounding tissue;
- System damage, resulting in a loss of, or change in Moventis 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 radiators or 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 because 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 Moventis 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)** – **Moventis PNS is MR Unsafe.** Since Moventis PNS is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the device, and in the process cause serious harm to the patient or other people or damage to the MR system.

**ETx component is MR Unsafe; ensure that the ETx does not enter the MR system room.** Since the ETx is MR Unsafe, 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 Moventis 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 stimulator systems within the vicinity of Moventis 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 who have peripheral nerve pIPGs. 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 Moventis PNS 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 Moventis PNS. 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.

When electrocautery is necessary, these precautions must be followed:

- The ETx should be taken off.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
    - Only low-voltage modes should be used;
    - The lowest possible power setting should be used;

- The current path (ground plate) should be kept as far away as possible 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:
  - Using the lowest possible X-ray current consistent with obtaining the required image quality;
  - Making sure X-ray beams do not dwell over the device for more than a few seconds.

After CT scanning directly over the implanted device:

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

**High-output ultrasonics / lithotripsy** – Safety has not been established for high-output ultrasonics or lithotripsy when implanted with Moventis 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 have been performed with an array of simulated RFID emitter systems, and have demonstrated that Moventis PNS (pIPG and ETx) are not affected by separation distances between Moventis PNS and the RFID emitter of less than 3 m (~10 ft.). More powerful RFID Emitters might cause effect at farther distances. RFID emitters can be hidden or portable and not obvious to the patient. Any 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 promptly 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 the 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 Moventis 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 Moventis 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 Moventis 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 Moventis PNS on aircrafts. Use of Moventis PNS on a commercial aircraft may result in damage to the device or harm to the patient.

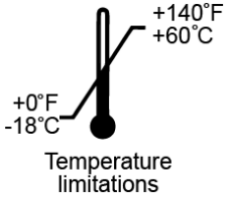
## PRECAUTIONS

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

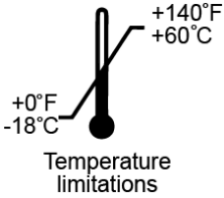
**Keep the ETx dry –** ETx is not waterproof. Keep it dry to avoid damage. Do not use the ETx when engaging in water activities.

**Storage temperatures –** Moventis 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 –** 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 the patient or to Moventis PNS.

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

**Use the 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. Tampering with the device could result in harm. If the device is not working properly, contact the clinician for help.

**Flammable or Explosive Environments –** Do not use the ETx in flammable or explosive environments. Using the ETx in one of these environments 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 Moventis 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 Moventis PNS incurs the following risks:

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

Adverse events that could occur with the Moventis PNS:

- Migration, resulting in altered stimulation 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 instructed to contact their clinician immediately if they experience any problem or if they experience a change in stimulation. Over time there could be changes in the level of pain control.

# MRI SAFETY INFORMATION

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


**MR Unsafe Components**

- pIPG (NRO4-07, NRO4-20, NRO4-38)
- External Transmitter (MNRO-915-1A)
- Battery Charger
- Introducers
- Stylets

**DO NOT** have an MRI while the pIPG is implanted or with any accessory components in the room. pIPG and the accessory components 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

Micron Medical Corporation
606 Banyan Trail
Boca Raton, Florida 33431
United States
Telephone: +1.888.691.0585
Fax: +1.888.691.0585
Internet: www.microndevices.com

31-00014-6 Published August 2020