5492001 – Pulsante® SPG Microstimulator System Implant Manual

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1. WELCOME

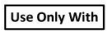
Welcome to the Pulsante® family! The instructions in this Manual are intended for physician implanters of the Pulsante® SPG Microstimulator. Please familiarize yourself with the Implant Manual, Programming Manual, and Patient Manual prior to using the Pulsante® SPG Microstimulator System.

2. INTENDED USE OF THE PULSANTE® SPG MICROSTIMULATOR SYSTEM

In the United States, the Pulsante® SPG Microstimulator System is intended to relieve the acute pain of cluster headache.

3. SYMBOLS

Symbols and definitions used for the Pulsante® SPG Microstimulator System:

	For Prescription Use Only
	Consult Operating Instructions
	Model Number
	Serial Number
	Lot Number
	Content
	Use Only With
	Peel Apart
	Warning/Precaution
	Storage and Transport Temperature Range
	Keep Dry
	Manufactured By

Do Not Do the following

Do not dispose devices in unsorted trash. Dispose devices per local country regulations for disposing electrical equipment

Do not use device if package is opened or damaged

Date of Manufacture

Use By Date

Symbols and definitions used only for the Pulsante® Microstimulator:

Electrode

Channel

Constant Current

Length

Max Implant Depth

Sterilized using Ethylene Oxide

Content of unopened, undamaged package is sterile

Single Use

The Pulsante® Microstimulator is MR Unsafe.

Symbols and definitions used only for the Pulsante® Remote Controller:

Non-Ionizing Radiation

Power ON/OFF button symbol

Up Button symbol

Down Button symbol

Applied Type B Equipment

USB connector symbol

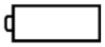
The Pulsante® Remote Controller is MR Unsafe. It will be hazardous in all MRI environments.

Press Up or Down Button symbol

Searching For Microstimulator antenna symbol

Recharge Remote symbol

Low Battery symbol



Depleted Battery symbol

Battery Charging symbol

Fully Charged Battery symbol

Alert Indicator symbol

Symbols and definitions used only for the Pulsante® Surgical Tools:

Single Use Only

Sterilized using Ethylene Oxide

Symbols and definitions used for the Pulsante® Programmer Software on Clinician Programmer:

Tilt Symbol indicates that the selected stimulation amplitude is not being delivered

Power ON/OFF button symbol

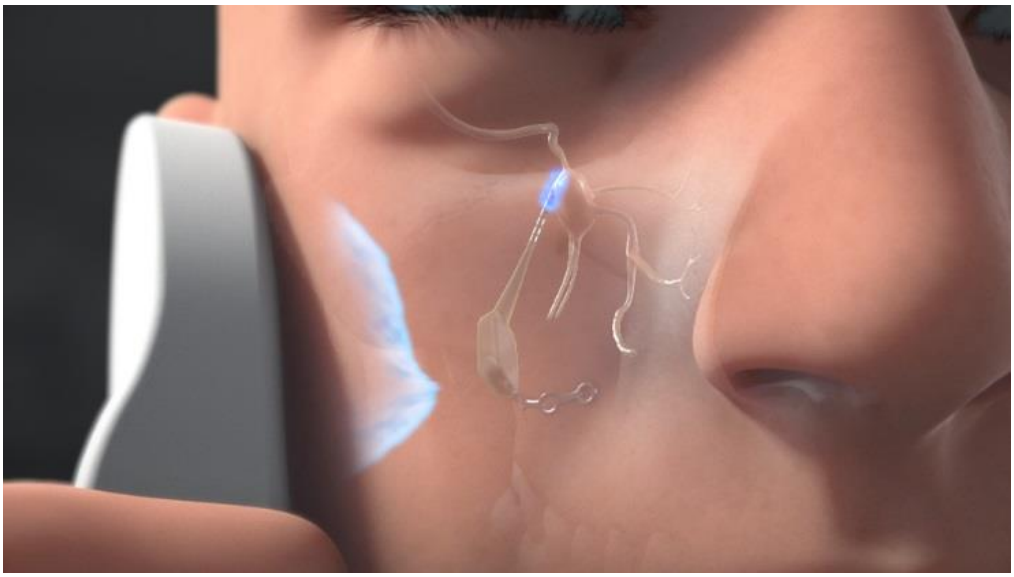
4. PATIENT IMPLANT IDENTIFICATION CARD

A Patient Implant Identification Card is packaged with the Microstimulator. Advise the patient to carry the identification card at all times. The identification card must be filled out with pertinent patient information prior to the patient being discharged from the implanting center.

5. PULSANTE® SPG MICROSTIMULATOR SYSTEM OVERVIEW

The rechargeable Pulsante® SPG Microstimulator System (the “System”) electrically stimulates the sphenopalatine ganglion (SPG) peripheral nerve structure (Figure 1). The rechargeable System includes a miniaturized Microstimulator, which is placed at the SPG through an incision in the patient’s gum. The Microstimulator has six electrodes, which are programmed by a trained clinician using the Programmer Software to customize therapy to the patients’ individual needs. The Microstimulator is then controlled and powered by a Remote Controller. The patient can use the Remote Controller to treat their headaches as needed. Periodically, the Remote Controller battery needs recharging using the Remote Controller Charger provided.

Figure 1: Location of the Implanted Pulsante® Microstimulator



The Pulsante® SPG Microstimulator System consists of the following:

Pulsante® SPG Microstimulator	A miniaturized implant with an integral lead, which has six stimulating electrodes placed near the sphenopalatine ganglion.
Pulsante® Surgical Tools	Surgical Tools used during implantation of the Microstimulator.
Pulsante® Remote Controller	A rechargeable handheld device used by the patient to activate and control the Microstimulator. The Remote Controller is also used by the physician to facilitate adjusting parameter settings in the Microstimulator.
Remote Controller Charger	The Charger is provided in the Remote Controller packaging and is used by the patient to charge the Remote Controller.
Pulsante® Programming Software	Software that allows the physician to test and program stimulation parameters into the Microstimulator and set the power in the Remote Controller. The Programming Software is provided on a Clinical Programmer.
Clinician Programmer	Medical-grade tablet that runs the Programming Software. It includes a Tablet Charger and Programming USB cable.

NOTE: The Microstimulator and Surgical Tools are provided sterile and are sterilized using Ethylene Oxide.

Figure 2: Pulsante® Remote Controller

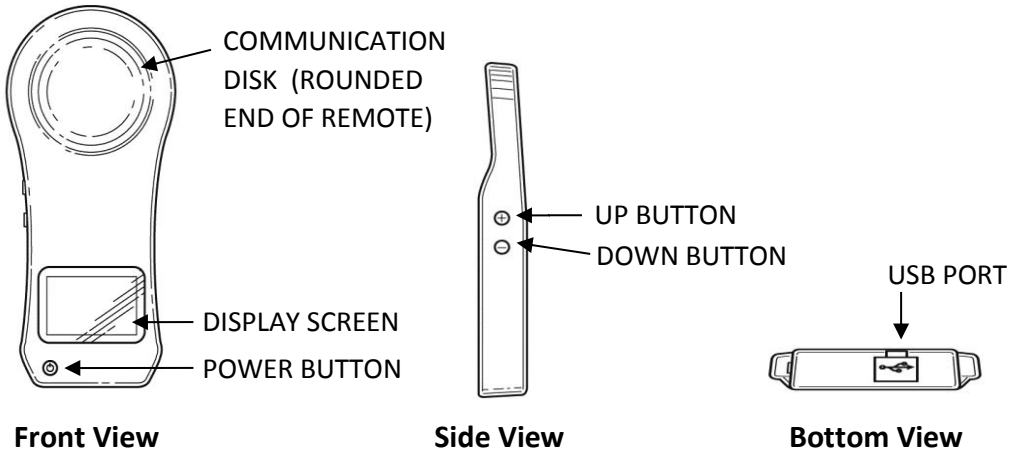
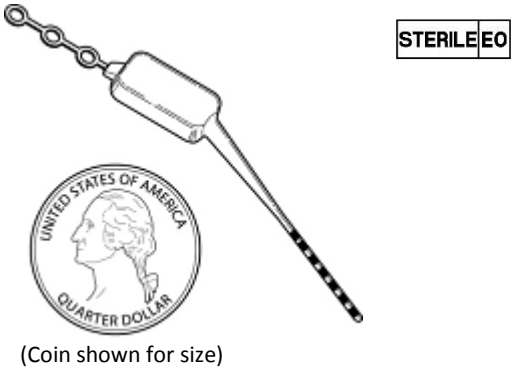


Figure 3: Pulsante® Microstimulator



(Coin shown for size)

Figure 4: Remote Controller Charger

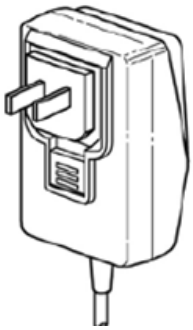


Figure 5: Pulsante® Programming Software on Clinician Programmer

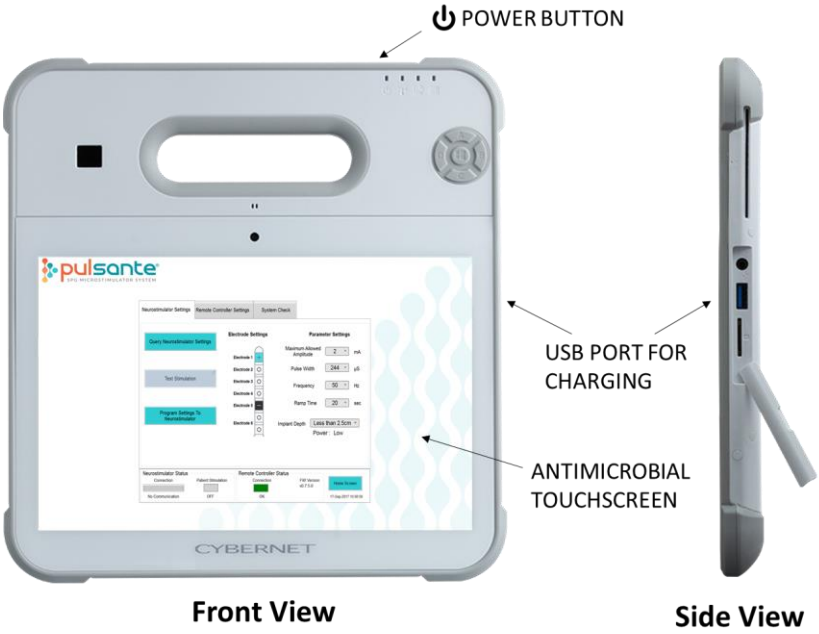


Figure 6: Surgical Introducers 100 & 110

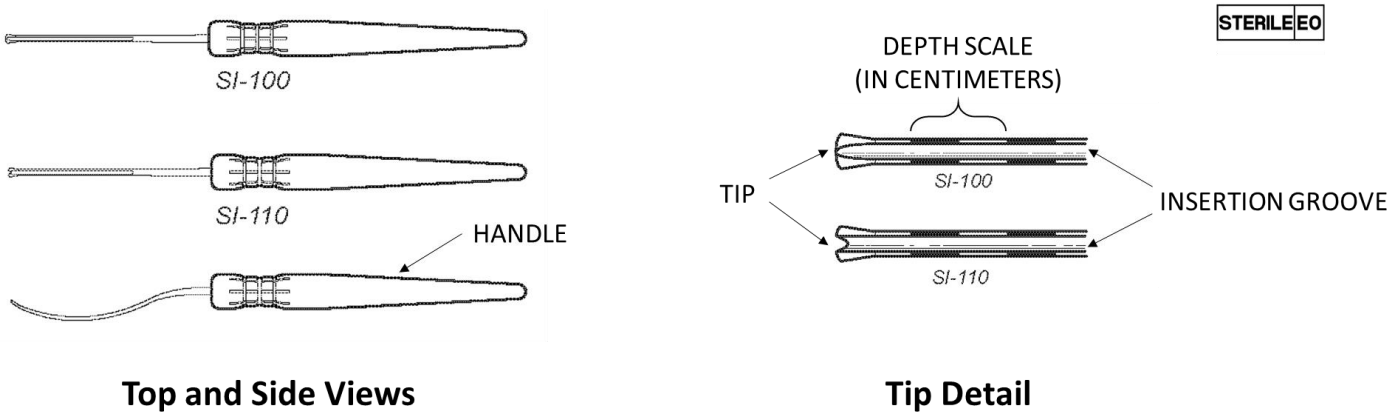
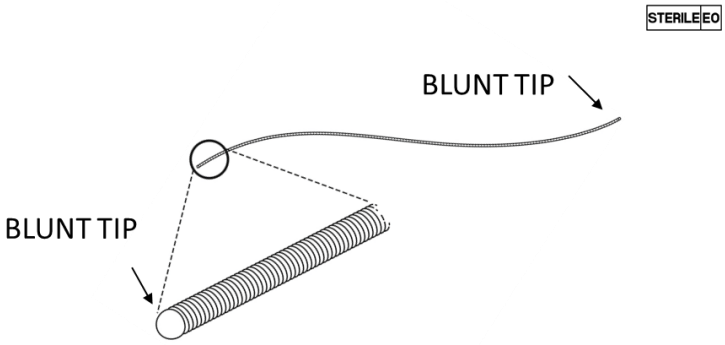


Figure 7: Lead Blank



6. IMPLANT PROCEDURE OVERVIEW

Pre-Operative

Pre-operative facial bone/paranasal sinus Computed Tomography (CT) scan or Magnetic Resonance Imaging (MRI) may be used for surgical planning and to estimate the appropriate Microstimulator length for a specific patient. Ensure the patient meets the indications for use.

Intra-Operative

Expose the superior-lateral surface of the zygomaticomaxillary buttress region. Advance the Surgical Introducer from the superior-lateral buttress to the pterygopalatine fossa along the posterior maxilla. The Surgical Introducer may be used to estimate the appropriate Microstimulator length by using the centimeter scale on the medial surfaces of the Surgical Introducer.

The Microstimulator is available in four lengths:

- Short - Approximately 3.6cm in length
- Medium - Approximately 4.4cm in length
- Long - Approximately 5.2cm in length
- Extra-Long - Approximately 6.0cm in length

Use the Lead Blank to create a path for the Microstimulator Lead. Next, remove the Lead Blank and insert the Microstimulator Lead. Advance the Microstimulator lead into the pterygopalatine fossa

using the Surgical Introducer (SI-100 or SI-110) as a guide. Remove the Surgical Introducers leaving the lead in the fossa. Anchor the Microstimulator Body to the anterior zygomatic process of the maxilla using the Bone Fixation Plate and at least two bone screws.

NOTE: Bone screws are not supplied by Autonomic Technologies.

7. PULSANTE® SPG MICROSTIMULATOR SYSTEM CONTRAINDICATIONS

The Pulsante® SPG Microstimulator System should not be used in patients who have an opening to the pterygopalatine fossa of less than 1.2mm or have had metal implants or facial surgery in an area that would prevent proper placement of the Microstimulator.

8. WARNINGS & PRECAUTIONS

WARNINGS

Carefully read all instructions prior to use. Observe all warnings and precautions noted in this Manual.

Implantation

Only physicians with sufficient skill and expertise in the surgical anatomy of the midface, anterior skull base, pterygopalatine fossa and infratemporal fossa should perform this procedure. Additionally, only physicians with sufficient skill and expertise in trans-oral surgical techniques, including proper sterile techniques, should perform this procedure. The surgery is performed under anesthesia, which has its accompanying risks. Infection may result from the implantation procedure or the implanted device.

Use only specified Pulsante® devices and accessories, specifically the Microstimulator, Remote Controller, Charger, Surgical Tools and Programmer Software.

Electrostatic Discharge

The integral Microstimulator lead electrodes provide a low-impedance pathway to the Microstimulator electronics. It is recommended that all healthcare personnel handling the Microstimulator avoid directly touching the electrodes. Placing the Microstimulator within physiologic saline (only), as described in the Implant Procedure section, is recommended before handling the Microstimulator.

Diathermy

Diathermy is the use of high-frequency electromagnetic currents as a form of physical therapy in surgical procedures. Do Not undergo shortwave diathermy, microwave diathermy, or therapeutic diathermy. Diathermy may cause damage to the tissue near your Microstimulator. Patients should be advised to contact their doctor before undergoing diathermy.

Magnetic Resonance Imaging (MRI)

The Pulsante® System is MRI Unsafe. Patients should be advised to contact their doctor before undergoing MRI.

Chronic SPG Stimulation

The effects of chronic SPG stimulation on peripheral nerve structures are not known. In addition, the effect of chronic SPG stimulation on cognitive function is not known. Patients should be advised to contact their doctor if they experience any unusual symptoms that they think may be related to the Microstimulator. If you decide that the System is not providing the therapy needed, it may be left implanted and not used for stimulation or will require additional surgery to be explanted.

Procedures of the Pterygopalatine Fossa

The SPG is located within a space behind your nose called the pterygopalatine fossa. This is where part of your Microstimulator is implanted. The effects of other procedures on the Microstimulator in this area are not known. Permanent damage to the Microstimulator may result from these procedures. Procedures in this area include intra-nasal thermocoagulation and procedures to the SPG, maxillary branch of the trigeminal nerve, vidian nerve or other neurovascular structures. NOTE: Inform your doctor of the implanted Microstimulator before undergoing any procedure in the pterygopalatine fossa.

Electrocautery / Electrosurgery

The use of electrocautery or electrosurgery may cause damage to the Microstimulator, particularly if used in close proximity to the Microstimulator electrodes. To ensure proper functionality, interrogate the Microstimulator and perform an electrode impedance test.

Electrical Therapies and Diagnostic Imaging

The effects of certain electrical therapies and diagnostic imaging on the Microstimulator are not well understood. If you require such treatment, your doctor should consult Autonomic Technologies for current information on how electrical therapies and diagnostic imaging could affect your device. Electrical therapies and diagnostic imaging include, but are not limited to: nuclear imaging (for example, PET Scans), brachytherapy, therapeutic radiation stereotactic radiosurgery, electroconvulsive therapy, lithotripsy, therapeutic ultrasound, transcranial magnetic stimulation, bone growth stimulators, and electrolysis. Do Not use your Remote Controller to apply therapy while undergoing any electrical therapy or diagnostic imaging procedure.

Explosive or Flammable Gases

Do Not use your Remote Controller in an environment where explosive or flammable gases are present.

Other Patient-Controlled Medical Devices

Do Not place the Remote Controller over other implantable devices (for example, pacemaker, defibrillator, another neurostimulator). The Remote Controller may accidentally change the operation of another device. Do not place another device’s transmitter over the Microstimulator. It may accidentally disrupt the operation of the Microstimulator.

Exposure to Moisture

Do Not use your Remote Controller to activate your Microstimulator while showering, swimming, or during other activities where the Remote Controller may get wet. The Remote Controller is not waterproof and should be kept dry to avoid damage.

PRECAUTIONS

Pulsante® SPG Microstimulator System Failure

Although it is unlikely, the System may unexpectedly malfunction, as does any implantable electronic device. Autonomic Technologies has completed extensive testing under worst-case conditions to develop and manufacture high-quality devices. However, malfunctions may be caused by things that cannot be predicted and may result in the device not working and the need for additional surgery. If a malfunction occurs, then your Remote Controller may not be able to wirelessly connect with your Microstimulator or your Microstimulator may not deliver therapy.

Lack of Therapy

The communication between the Remote Controller and the Microstimulator is based on many factors, including orientation and distance between the two devices. Swelling near the incision and/or

implant location may prevent communication between the Remote Controller and the implanted Microstimulator, and therapy may not be possible. If the distance between the devices is greater than 2.5cm, the Remote Controller may not be able to communicate with the Microstimulator. If it is difficult to establish communication with the Microstimulator, re-evaluate the implant depth specified in the Programming Software.

Lead Tip Migration

The Microstimulator Lead may migrate from its initial implant location. Lead migration may result in changes in SPG Microstimulator System effectiveness and the need for additional surgical procedures. To help minimize the chance of lead migration, care should be taken not to put excess pressure on the implant location, especially in the immediate post-operative period. For example, oxygen masks should be avoided in favor of intranasal oxygen.

Prior Surgical Procedures

Prior surgical procedures of the mid-face or anterior skull base may affect the proper implantation of the Microstimulator. In addition, any metallic objects implanted in the mid-face may cause interference with the SPG Microstimulator System. Physicians should assess these patients prior to implanting the Microstimulator to determine if the proper implantation and usage of the SPG Microstimulator System can be accomplished. Tooth fillings will not interfere with the System.

Post-Implant Medical Tests and Procedures

Medical procedures, devices or tests may damage or alter the SPG Microstimulator System. The following procedures or tests should only be performed and the following devices should only be used if the benefits outweigh the risks: facial nerve blocks (e.g., infra-orbital or maxillary), orthodontic or dental procedures (e.g., tooth extractions or bridge implants), cosmetic procedures (e.g., lipectomy, face lift, radiothermoplasty, laser skin removal, resurfacing or dermal fillers), and electrohydraulic lithotripters.

The following procedures or tests should only be performed and the following devices should only be used after talking to a doctor: facial nerve blocks (for example, infra-orbital or maxillary), orthodontic or dental procedures, and cosmetic procedures.

Therapeutic Radiation

Therapeutic radiation may damage the electronic circuitry of the System. Sources of therapeutic radiation include, but are not limited to: therapeutic x-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted device should be shielded with lead.

Implantable and External Devices

The interaction between the SPG Microstimulator System and other medical devices, including pacemakers, defibrillators, neurostimulators, hearing aids and other implantable and external devices, has not been characterized. If the patient requires such devices, the physician should consult Autonomic Technologies for current information concerning the compatibility of such devices.

Cardiac Defibrillation/Cardioversion

The effect of internal or external defibrillation or cardioversion on the implanted Microstimulator is not known. If a patient undergoes defibrillation, they should see their doctor to confirm their Microstimulator settings before using their Remote Controller.

Electromagnetic Interference (EMI)

Certain commercial electrical equipment (for example, arc welders, induction furnaces, resistance welders), communication equipment (for example, microwave programmers, linear induction motors, linear power amplifiers, high-power amateur transmitters, and cellular phones), and high-voltage

power lines may generate sufficient EMI to cause paresthesia (a sensation of tingling, pricking or numbness in the face) or interfere with the System. If a patient is uncomfortable or unable to apply therapy when near such equipment, the patient should move away from the area of EMI. The system has been designed to fail safely so strong EMI could prompt the Remote Controller to turn off.

Interaction with Electronic Systems

How the System interacts with other electronic devices including RFID systems (particularly within the 121 kHz to 130 kHz range) is not fully understood. Patients should not use the Remote Controller close to other electronic devices, particularly keyless entry FOBs or near automobile electronics. The strong electromagnetic fields from the remote controller can disrupt electronic systems that are close by.

Interaction with Metallic or Magnetic Objects

Using the System close to metal or magnetic objects (for example, heavy metal jewelry, metal headphones, magnetic earrings) may prevent your Remote Controller from communicating properly with your Microstimulator, especially if that metal object is between the Remote Controller and the patient's cheek. If the patient is unable to apply therapy when you are near such objects, have the patient move away from the object and try again. Metallic objects in the mouth (for example, a metal retainer) may get warm if they are not removed prior to applying therapy. For clarification, the Remote Controller is safe to use with tooth fillings.

Handling of the Pulsante® Remote Controller

Use care when handling your Remote Controller. The Remote Controller is a sensitive electronic device that may be damaged by rough handling, including dropping on the ground or being crushed. Store the Remote Controller in a cool, dry place. Excess heat can reduce the battery life of the Remote Controller considerably (for example, patients should not leave the Remote Controller in a car or under direct sunlight for long periods of time).

Charging the Pulsante® Remote Controller

Only use the Charger provided in the Remote Controller packaging to charge the Remote Controller. Use of non-Pulsante® charging equipment to charge the Remote Controller can damage the Remote Controller.

Scuba Diving or Hyperbaric Chambers

Patients should not dive below 30 meters (98 feet) of water or enter hyperbaric chambers above 4.0 atmospheres absolute (ATA), as greater pressures may damage your Microstimulator. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their physician. Also, patients should leave the Remote Controller in a cool, dry play—they should not use the Remote Controller while swimming or diving.

Excess Pressure or Trauma

Patients should avoid putting excess pressure on the Microstimulator and avoid trauma to that area. Playing certain contact sports (for example, boxing) may damage the System or change how well it works with their headaches. If a patient experiences excess pressure or trauma to the area around your Microstimulator, they should contact their physician.

Pregnancy

The safety and effectiveness of this therapy have not been established for pregnancy, unborn fetus, or delivery.

Pediatric

The safety and effectiveness of this therapy have not been established for patients under the age of 18.

9. RISKS AND SIDE EFFECTS

Please discuss the risks and benefits with your doctor to determine if the device is right for you. Risks of neurostimulation therapy can include surgical risks, possible side effects, or device complications. Your doctor can provide more information about these and other potential risks. Please follow your doctor's instructions after surgery to minimize surgical risk.

Similar to other oral procedures, most patients will experience some or all of the following effects post-surgery and most effects resolve within 60 days:

- Sensory and/or motor dysfunction, including numbness, other sensations, and/or facial paresis (slight or incomplete paralysis)
- Post-operative pain, swelling and/or tenderness at the surgery site

Other risks of surgery may include:

- Seroma/Hematoma (a collection of serum/blood in the body)
- Abcess
- Bruising
- Permanent numbness and other sensations
- Dry eye and tearing
- Trismus (lockjaw)
- Itching
- Pain in the area of the implant
- Infection
- Bleeding
- Facial asymmetry
- Allergic response to implanted materials
- Headache
- Penetration of the sinus wall
- Increased severity/frequency of cluster headaches
- Post-operative nausea or emesis (vomiting)
- Nose bleed
- Ear or nasal fullness/rhinorrhea (nasal discharge)
- Taste alteration

Possible side effects of SPG stimulation include:

- Discomfort or pain during stimulation associated with paresthesia (a sensation of tingling, pricking or numbness in the face)
- Runny nose
- Dry eye and tearing
- Conjunctivitis
- Headache

Device complications may include:

- Microstimulator migration or misplacement potentially leading to explant and/or re-implant
- Inability of the Remote Controller to connect with the Microstimulator
- Device malfunction
- Skin and/or bone erosion around the Microstimulator implant site

10. PACKAGING, STORAGE AND HANDLING

Pulsante® SPG Microstimulator

- The Microstimulator is provided sterile. The Microstimulator is sterilized using ethylene oxide.
- Do not excessively bend the Microstimulator Lead or Bone Fixation Plate. Excessive bending may damage the integrity of the Microstimulator and may affect device performance.
- Do not attempt to reuse or re-sterilize the Microstimulator. The Microstimulator is intended for single use only.
- Do not use the Microstimulator if the current date is beyond the labeled “Use by” date.
- Do not use the Microstimulator if the packaging or its contents are damaged or have been previously opened.
- Do not store the Microstimulator packaging where it may be exposed to water or other liquids, as moisture may damage the seal integrity of the package materials.
- Store the Microstimulator between –10°C (–14°F) and +55°C (+131°F); temperatures outside of this range may damage components.

Pulsante® Surgical Tools

- The Surgical Tools are provided sterile. The Surgical Tools are sterilized using ethylene oxide.
- Do not attempt to reuse or re-sterilize the Surgical Tools after surgical use. The Surgical Tools are intended for single use only.
- Do not use the Surgical Tools if the packaging or its contents are damaged or have been previously opened.
- Do not store the Surgical Tools’ packaging where it may be exposed to water or moisture.

Pulsante® Remote Controller

- Do not sterilize the Remote Controller.
- Do not store the Remote Controller where it may be exposed to water or other liquids, as moisture may damage the integrity of the package materials or damage the Remote Controller.
- Do not use the Remote Controller if the packaging or the Remote Controller look damaged.
- The Remote Controller is a sensitive electronic device that may be damaged by rough handling, including dropping on the ground or being crushed.
- The Remote Controller can be safely stored and operated between 5°C and 40°C. The Remote Controller can be transported between 20°C and +70°C. Temperatures outside of this range may reduce battery life.
- Do not connect the USB Port to any other electrical device other than the Charger provided with the Remote Controller or the Programming USB cable provided with the Programmer Software.
- The Remote Controller may feel warm when providing therapy. If the patient experiences discomfort, recommend moving the Remote Controller away from the face slightly and avoid contact with skin.
- The Remote Controller should not come into contact with skin that is cut or bleeding.

Clinician Programmer

- Do not sterilize the Clinician Programmer.
- Do not store the Clinician Programmer where it may be exposed to water or other liquids, as moisture may damage the integrity of the package materials or damage the Clinician Programmer.
- Do not use the Clinician Programmer if the packaging or the Clinician Programmer look damaged.

- The Clinician Programmer can be safely stored and operated between 5°C and 40°C. The Clinician Programmer can be transported between 20°C and +70°C. Temperatures outside of this range may reduce battery life.
- Do not connect the USB Port to any other electrical device other than the Tablet Charger or Programming USB cable provided with the Clinician Programmer.

11. OPERATOR'S INSTRUCTIONS: HOW TO IMPLANT THE MICROSTIMULATOR

A. Personnel Training

Physicians performing the Microstimulator implant should be experienced in the surgical anatomy of the mid-face, anterior skull base, pterygopalatine fossa and infratemporal fossa. Physicians should be trained on the use of all components of the Pulsante® SPG Microstimulator System and the contents of this Manual before initiating the procedure.

B. Planning for Surgery

Implant laterality is selected based on the patient's predominant side of headache pain. Choose an appropriate Microstimulator size based on the laterality. Using a pre-operative facial bone/paranasal sinus Computed Tomography (CT) scan to complete a 3D rendering of the surgical anatomy and subsequent surface measurement can provide an estimate of the appropriate Microstimulator length. Alternatively, you can estimate the appropriate Microstimulator length during the implant procedure by using the scale on the Surgical Introducers as detailed in Section F below. The Microstimulator is provided in four lengths, excluding the integral Bone Fixation Plate:

- Short - Approximately 3.6 cm in length
- Medium - Approximately 4.4 cm in length
- Long - Approximately 5.2 cm in length
- Extra-Long - Approximately 6.0 cm in length

The following items are supplied by Autonomic Technologies:

- Microstimulator
- Surgical Tools
- Remote Controller with Remote Controller Charger
- Programmer Software on a Clinician Programmer with Tablet Charger and Programming USB cable

The following accessories are not supplied by Autonomic Technologies and will need to be available at the implanting facility:

- Craniomaxillofacial surgical equipment, specifically including:
  - Midface periosteal elevator
  - Craniomaxillofacial bone kit including self-tapping bone screws (1.8 mm diameter and 4mm length) and the associated driver
- Sterile wand cover/ultrasound probe cover, or other sterile cover as appropriate for intra-operative use of the Remote Controller
- Sterile plastic basin with sterile saline
- Imaging equipment, such as fluoroscopy.

Observe all oral pre-operative standard-of-care procedures.

C. Preparing Devices

Assess the tips of the Surgical Introducers to determine which one(s) will be used for the procedure.

Prior to placing the Microstimulator, place the Microstimulator in physiologic saline inside a sterile plastic basin away from a metal surface with the Microstimulator Lead completely submerged. Complete an interrogation of the Microstimulator and perform an electrode impedance test to ensure proper functionality as detailed in Section 11, Part H.

Next, bend the Microstimulator Bone Fixation Plate appropriately to the surgical anatomy by holding the body with your fingers and using a tool. The Bone Fixation Plate bend should reflect the following target Microstimulator placement:

- The Microstimulator body should lie flat against the posterior maxilla bone, medial to the zygoma.
- The Microstimulator lead should be positioned within the superior medial pterygopalatine fossa (PPF) using a lead trajectory that is inferior to superior within the PPF. This position and trajectory should ensure that at least one electrode is in close proximity to the SPG.
- The Microstimulator Bone Fixation Plate should be positioned sub-periosteally over the anterior zygomatic process of the maxilla.

D. Make an Incision

Using standard oral surgical techniques make a 1.0-1.5cm incision located 3–5 mm superior to the mucogingival junction above the maxillary first or second molar and carried through the maxillary periosteum (Figure 8).

Figure 8: Incision Location

E. Dissect to Target Anatomy

Elevate the maxillary periosteum superiorly and laterally to accommodate the Microstimulator's Bone Fixation Plate and to expose the edge of the zygomaticomaxillary buttress (Figure 9 and Figure 10). Limiting the amount of periosteal elevation may improve post-surgical side effects from the implantation procedure.

Figure 9: Initial Dissection

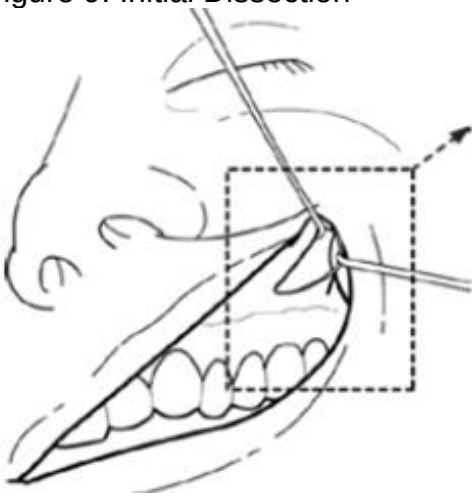
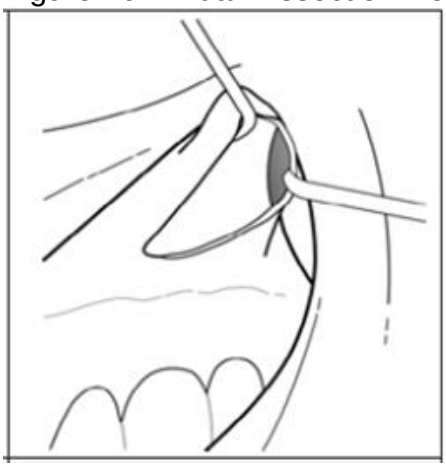


Figure 10: Initial Dissection Detail



Using fluoroscopy or other visualization, advance the Surgical Introducer from the posterior-lateral edge of the zygomaticomaxillary buttress towards the pterygopalatine fossa (PPF) using gentle pressure (Figure 9). The Surgical Introducer is advanced along the posterior maxilla until the distal tip of the Surgical Introducer is within the pterygomaxillary fissure, or just within the PPF.

Care should be taken to avoid injury to the infra-orbital nerve during the procedure.

Surgical Introducers 100 and 110 differ in the design of the distal tip. Both tips are designed to maintain contact with the posterior maxilla during the procedure. However, model 110 is designed to promote guidance of the Microstimulator Lead into the PPF, if needed.

- Do not apply excessive force to the Surgical Introducer when advancing along the posterior maxilla. Puncture of the sinus wall can occur.
- Do not advance the Surgical Introducer beyond the pterygopalatine fossa. Patient injury or poor outcomes may result from further advancement of the Surgical Introducer.
- NOTE: Surgical Introducer placement at the pterygomaxillary fissure or just within the PPF may be confirmed using standard intra-operative imaging (e.g., fluoroscopy).

Figure 11: Inserting the Surgical Introducer

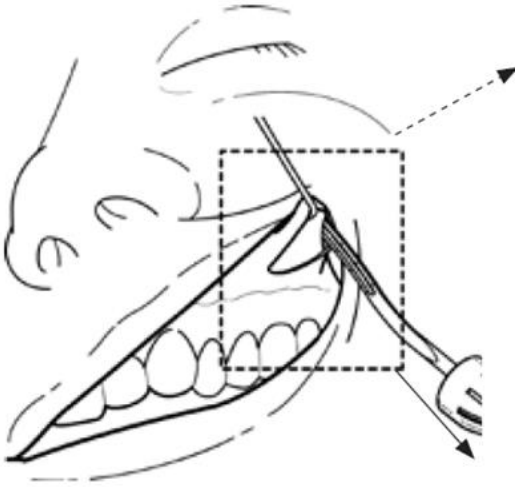


Figure 12: Close-Up View of the Surgical Introducer Inserted

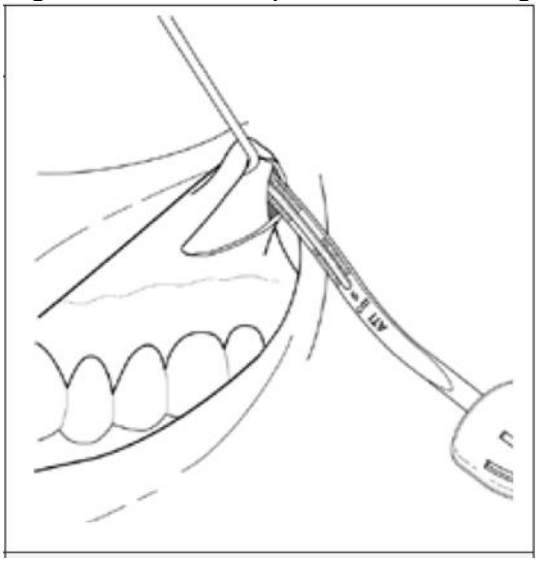
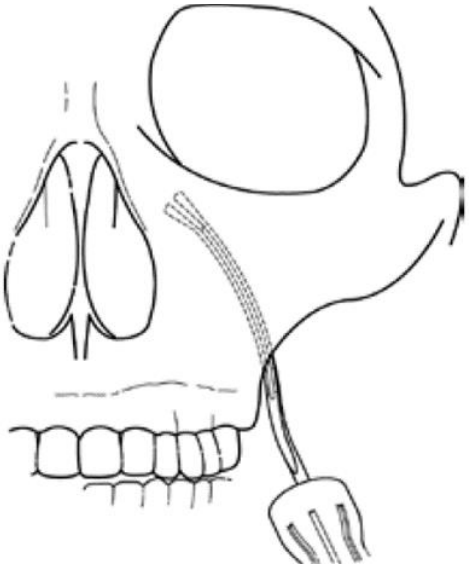


Figure 13: Example Anterior-Posterior Fluoroscopy Image of Surgical Introducer Placement



If the Microstimulator size was not chosen beforehand, then it can be chosen during the procedure. To do so, estimate the appropriate Microstimulator length by using the centimeter scale on the medial surface of the Surgical Introducers (Figure 6 and Figure 12) once it is positioned correctly at the pterygomaxillary fissure or within the PPF (Figure 13). This can be done by reading the distance from the start of the scale on the proximal portion of the Surgical Introducer to the posterior-lateral edge of the zygomaticomaxillary buttress, and subtracting the distance from 6.0 cm. Each solid/clear segment of the Surgical Introducer scale represents 0.5 cm.

EXAMPLE: The distance from the proximal portion of the scale to the buttress is three solid/clear segments (1.5 cm). The estimated Microstimulator length is then 4.5cm, which is the equivalent of 6.0cm less 1.5cm (Figure 12). In this example, the physician may choose the medium size of Microstimulator. The Microstimulator length does not include the integral Bone Fixation Plate.

The distal tip of the Surgical Introducer, when placed properly, is located at the pterygomaxillary fissure or just within the pterygopalatine fossa. The Lead Blank is used to create an implant path beyond the tip of the Surgical Introducer within the pterygopalatine fossa for the Microstimulator Lead. Surgical Introducers include an Insertion Groove (Figure 6) along the medial surface. Track the Lead Blank along the Insertion Groove on the Surgical Introducer (Figure 14). Using gentle pressure, advance the Lead Blank along the Insertion Groove beyond the distal tip of the Surgical Introducer into the pterygopalatine fossa (Figure 15). The Lead Blank has a spherical tip and a flexible shaft that can be used to create an implant path within the soft tissue of the pterygopalatine fossa. An inferior to superior implant path or trajectory (Figure 15), starting at the inferior portion of the PPF and progressing superiorly and medially within the PPF may be associated with better therapy. Implant trajectories that are more lateral to medial within the PPF are associated with reduced outcomes compared to inferior to superior trajectories. The Lead Blank is approximately the same diameter as the Microstimulator Lead.

Figure 14: Advancing the Lead Blank in the Surgical Introducer Insertion Groove

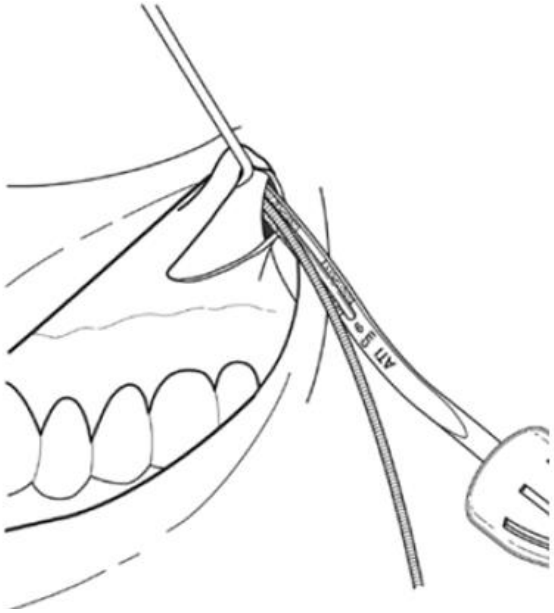
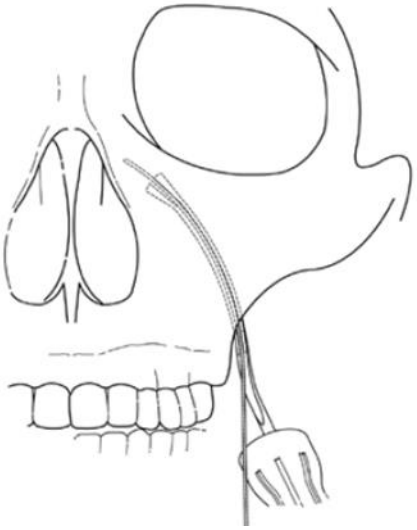


Figure 15: Example Fluoroscopy View of the Lead Blank Extended Beyond the Surgical Introducer Within the Pterygopalatine Fossa



- Do not apply excessive force to the Lead Blank when advancing into the pterygopalatine fossa.
- Do not advance the Lead Blank beyond the pterygopalatine fossa. Patient injury or poor outcomes may result from further advancement of the Lead Blank.
- Care should be taken to confirm that the distal tip of the Lead Blank has not entered the inferior orbital fissure or nasal cavity.
- NOTE: Surgical Introducer and Lead Blank placement may be confirmed using standard intra-operative imaging (e.g., fluoroscopy).

If the Microstimulator size was chosen intra-operatively, then perform an impendence test and bend the bone plate as detailed in Section C above. With the Surgical Introducer in place, and the distal tip located at the pterygomaxillary fissure or just within the pterygopalatine fossa (after the Lead Blank has been used to create an implant path), advance the Microstimulator along the Insertion Groove on the Surgical Introducer. Using gentle pressure, advance the Microstimulator beyond the distal tip of the Surgical Introducer into the pterygopalatine fossa. Care should be taken to advance the Microstimulator in the same lead path or trajectory created by the Lead Blank. This inferior to superior trajectory with a final distal lead location of the superior medial PPF may be associated with better therapy. Lead trajectories that are more lateral to medial or final distal lead location other than the superior medial PPF may result in the inability to effectively stimulate the SPG by not having one or more electrodes in close proximity to the SPG. Care should be taken to understand the surgical anatomy fully prior to surgery.

Once the distal tip of the Microstimulator Lead is placed within the pterygopalatine fossa in very close proximity to the sphenopalatine ganglion, slowly retract the Surgical Introducer, leaving the Microstimulator inserted in the anatomy. Gently hold the Bone Fixation Plate against the superior lateral zygomaticomaxillary buttress and slowly retract the Surgical Introducer.

NOTE: Microstimulator placement may be confirmed using standard intra-operative imaging (e.g., fluoroscopy).

F. Adjust Placement as Needed

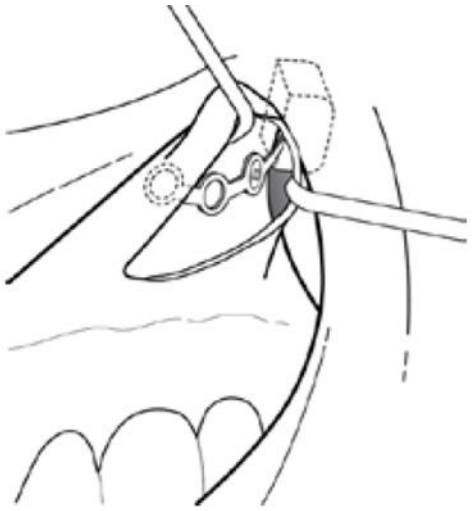
To refine placement, small adjustments may be made to the electrode position in the fossa with respect to the vidian canal and foramen rotundum. Make any needed adjustments by grasping the Microstimulator body or bone plate to advance or retract the lead in the fossa. Intraoperative images are taken to confirm final placement of the Microstimulator in the appropriate location.

G. Attach the Microstimulator

Use the Bone Fixation Plate and at least two 1.8 mm craniomaxillofacial bone screws (not provided by Autonomic Technologies) to anchor the Microstimulator to the anterior zygomatic process of the maxilla, which contains thick, dense bone (Figure 16). Care should be taken to confirm that the distal lead has not entered the inferior orbital fissure or nasal cavity.

NOTE: The Microstimulator should be placed such that the flat portion of the Microstimulator Body and Bone Fixation Plate are facing the maxillary bone.
NOTE: Confirm the Microstimulator's distal lead position using fluoroscopy or X-ray.
NOTE: Fix the Microstimulator to thick, dense bone to avoid potential dislodgement.
NOTE: Take care to avoid displacement of the Microstimulator while bending the Bone Fixation Plate.
NOTE: The Bone Fixation Plate can also accept a rescue screw, if needed, of up to 1.8 mm in diameter.
NOTE: Implant the microstimulator at least 1.2cm from the skin surface to ensure the ability to use all available power setting during therapy.

Figure 16: Anchoring the Microstimulator



H. Intra-Operative Functionality Testing

To confirm proper Microstimulator functionality, perform an implant impedance test. To do so, hold the sterile-sleeved Remote Controller to the Patient's cheek above the implant or instruct a Scrub Tech to do so. Next, use the Programming Software to wirelessly connect the Remote Controller to the Microstimulator (or instruct a Scrub Tech to do so). Select the impedance test

option in the Programming Software. If the Programming Software confirms that the impedance test is successful, then the procedure may proceed. If the test is not successful, then select a higher implant depth and repeat the test. If the Microstimulator does not respond to repeated testing, then a new Mircrostimulator must be used. Refer to the Pulsante® Programming Manual for information on proper use of the Programmer Software and Remote Controller.

NOTE: If you encounter any issues during intra-operative testing, refer to the Troubleshooting Section of the Pulsante® Programming Manual for further guidance.

I. Surgical Closure

Close the incision using standard oral surgery techniques. Should a clinician decide to remove the Microstimulator in the future, it can be removed using standard procedures to open the incision and remove the bone screws from the Microstimulator Bone Fixation Plate.

J. Post-Operative Care

Observe all standard oral post-operative standard-of-care procedures.

12. DISPOSAL

Remote Controller

Please send any non-functional Remote Controllers to Autonomic Technologies for analysis (ATI contact information is provided at the back of this manual). Do not throw away the Remote Controller in the trash.

Microstimulator

In the event that an Microstimulator is explanted, please return the device to Autonomic Technologies for analysis. Do not throw away the Microstimulator in the trash.

Surgical Tools

The Surgical Tools are intended for single use only. After use, please dispose of the Surgical Tools using standard Operating Room disposal procedures.

13. TECHNICAL DESCRIPTION AND SPECIFICATIONS

USA-Federal Communications Commission (FCC)

The following is communication regulation information on the Pulsante SPG microstimulator system comprises of Neurostimulator NS-100 and Remote Controller RC-300.

FCC ID of the system: 2APE8-RC300

Labeling Note: FCC ID information can be retrieved by pressing and holding the Remote Controller RC-300 power button for 10seconds.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
This product does not contain any user serviceable components. Any unauthorized product changes or modifications will invalidate warranty and all applicable regulatory certifications and approvals, including authority to operate this device.

FCC Part 15 Digital Emissions Compliance We, Autonomic Technologies, Inc, declare under our sole responsibility that this product complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

WARNING: 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. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful 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 or relocate the receiving antenna. Increase the separation between the equipment and receiver. Connect the equipment into an outlet on a circuit different from the one the receiver is connected to.

Consult the dealer or an experienced radio/TV technician for help. The user may find the following booklet prepared by the Federal Communications Commission helpful: The Interference Handbook. This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402. Stock No.004-000-00345-4.

Electromagnetic Compatibility

The use of cables other than those specified or sold by Autonomic Technologies may result in increased emissions or decreased electrical immunity of the system. The RF transmitter within the remote controller operates at 126 kHz +/- 3kHz, with Frequency Shift Keying (FSK), and the effective radiated power of less than 5mW. NOTE: The device remains safe under its typical electromagnetic interference environment. The Pulsante® SPG Microstimulator System complies with the international standard IEC 60601-1-2, Edition 4.0 2014-02 for Electromagnetic Compatibility (EMC). Use of this equipment should follow the Electromagnetic Compatibility (EMC) guidance below.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The Pulsante® SPG Microstimulator System is intended for use in the electromagnetic environment specified below. The customer or user of the Pulsante® SPG Microstimulator System should assure that it is used in such an environment.

EMMISSIONS/IMMUNITY TEST	TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions - CISPR 11	Not applicable	Class B, Group 2	The Pulsante® SPG Microstimulator System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted emissions - CISPR 11	Not applicable	Class B, Group 2	The Pulsante® SPG Microstimulator System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions - IEC 61000-3-2	Not applicable	Not applicable	
Voltage fluctuations / Flicker emissions - IEC 61000-3-3	Not applicable	Not applicable	
Electrostatic discharge (ESD) - IEC 61000-4-2	±8 kV contact ±15 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast - Transient burst - IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	
Surge - IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	
Voltage dips, short interruptions, and voltage variations on power supply input lines - IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	
	Note: UT is the a.c. mains voltage prior to application of the test level.		
Power frequency - 50/60 Hz magnetic field - IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical locations in a typical commercial or hospital environment.
Conducted RF - IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	The Portable and mobile RF communications equipment should be used no closer to any part of the Pulsante® SPG Microstimulator System, including cables, than the recommend separation distance calculated from the equation applicable to the frequency to the transmitter. Recommended separation distance $d = 1.167\sqrt{P}$ 150 kHz to 80 MHz $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating to the transmitter in Watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey (Note A),
Radiated RF - IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	

			should be less than the compliance level in each frequency range (Note B). Interference may occur in the vicinity of equipment marked with the following symbol. 
Note 1: At 80 MHz and 800 MHz. The higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Note A: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulsante® SPG Microstimulator System is used exceeds the applicable RF compliance level above, the Pulsante® SPG Microstimulator System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Pulsante® SPG Microstimulator System. Note B: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

The RC-300 of the Pulsante® SPG Microstimulator System is battery operated and the NS-100 is battery less active device works in conjunction with RC.

NOTE: The Pulsante® SPG Microstimulator System should not be used while stacked on or adjacent to other equipment. If stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used. Portable and mobile RF communications equipment can affect the System; the following separation distances are recommended.

Specifications for the Pulsante® Microstimulator:

STIMULATION PARAMETER	SPECIFICATION
Power Source	Resonate Inductive Coupling, no finite life
Channels	Six (6) Channels
Waveform Characteristics for Each Channel	Biphasic, constant current, charge balanced, rectangular pulse
Output Current	0-3.9 mA 0.05 mA steps (from 0.0-1.0 mA) 0.10 mA steps (from 1.0-3.9 mA), ± 20%
Signal Frequency	1-200 Hz 1 Hz steps (from 1-20 Hz), 5 Hz steps (from 20-40 Hz) 10 Hz steps (40-200 Hz), ± 20%
Pulse Width Per Phase	40-480 µsec steps: 40, 47, 55, 63, 71, 79, 87, 95, 103, 110, 118, 126, 134, 142, 150, 158, 166, 174, 181, 189, 197, 213, 229, 244, 260, 276, 292, 308, 323, 339, 355, 371, 386, 402, 418, 434, 450, 465, 480 µs ± 20%
Electrode Configuration	2 to 6 electrodes as anode, cathode or OFF
Leakage Current (No Output)	1 µA
Net DC Current	500 nA
PHYSICAL CHARACTERISTICS	SPECIFICATION
Sizes	Short (~3.6 cm) Medium (~4.4 cm), Long (~5.2 cm), Extra-Long (~6.0 cm)
Body	16 x 8 x 4 (Length x Width x Height) mm ± 20%
Lead	1.0 mm ± 10% in Diameter
Fixation Plate Bone Screws	Accepts standard bone screws 1.8 mm in Diameter
Bone Fixation Plate	17.4 x 3.7 x 0.5 (Length x Width x Thickness) mm ± 20%
Weight	~1.49 grams (Short) – ~1.52 grams (Extra-Long)
Volume	~515 mm3 (Short) – ~590 mm3 (Extra-Long)
Storage Temperature	-10 0C (-14 0F) and +55 0C (+131 0F)
MATERIALS	SPECIFICATION
Microstimulator Body and Lead	Polyurethane-silicone co-polymer (Material Contacts Human Tissue)
Electrodes	Platinum (90%) / Iridium (10%) (Material Contacts Human Tissue)
Bone Fixation Plate	Titanium, Grade 2 (Material Contacts Human Tissue)

Specifications for the Pulsante® Remote Controller:

PHYSICAL CHARACTERISTICS	SPECIFICATION
Remote Controller Size	17.7 x 7.9 x 2.4 (Height x Width x Thickness) cm ± 10%
Weight	10.3 oz ± 10%
Case Material	PC-ABS
Connector	Micro USB Port
Storage / Transport Temperature Range / Humidity	The Remote Controller can be safely stored between 5°C and 40°C. The Remote Controller can be transported between -20°C and +70°C. Temperatures outside of this range may reduce battery life. Humidity: 0% to 93% Relative humidity, non-condensing at 70°C.
Operating Temperature Range / Humidity	The Remote Controller can be safely operated between 5°C and 32°C. Humidity: 15% to 90% Relative humidity, non-condensing at 70°C.
ELECTRICAL CHARACTERISTICS	SPECIFICATION
Power	Built-in rechargeable lithium polymer battery
Battery Charge Life	Constant usage – 2 hours from full charge Non-operation – 3 months from full charge
Total Expected Life of Device	18 Months
Operating Frequencies	126 kHz ± 4 kHz
Communication Method	Radio Frequency (RF)

Specifications for the Pulsante® Remote Controller Charger:

PHYSICAL CHARACTERISTICS	SPECIFICATION
Remote Controller Charger Size	64 x 40.5 x 29 (Height x Width x Thickness) mm
Case Material	94V0 Polycarbonate
Connector	Micro USB
Length of Cord	1 Meter
Storage/Operating/Transport Temperature Range / Humidity	Storage Temperature: 0°C to 40°C Operating Temperature: -40°C to 80°C Humidity: 0% to 90% Relative Humidity
ELECTRICAL CHARACTERISTICS	SPECIFICATION
Input Voltage	100-240 VAC
Output Voltage	5VDC
Input Frequency	47 - 63 Hz
Output Current	1.2A
Output Power	6 Watts Max
Switching Frequency	66.5 kHz Typical

14. INFORMATION AND SUPPORT

Autonomic Technologies
355 Ravendale Drive, Mountain View, CA 94043 USA
www.pulsante.com