Nalu™ Medical, Inc.

NALU™ NEUROSTIMULATION SYSTEM

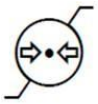
SURGICAL INSTRUCTIONS FOR USE

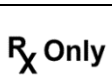
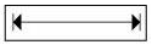
PORTED IMPLANTABLE PULSE GENERATOR AND LEADS

KIT MODEL NUMBERS: 71003, 71004, 71005, 71007, 72001, 72002, 72003, 72004, 72005, 71019, 72011, 72012

EXPLANATION OF SYMBOLS ON PRODUCT OR PACKAGE

Refer to the appropriate product for symbols that apply.

Symbol	Title	Explanation	Standard	Reference
	Manufacturer	Medical device manufacturer, as defined in EU Directive 93/42/EEC	ISO 15223-1	5.1.1
	Date of manufacture	Date when the medical device was manufactured.	ISO 15223-1	5.1.3
	Use-by date	Date after which the medical device is not to be used.	ISO 15223-1	5.1.4
	Batch code	Manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1	5.1.5
	Catalogue number	Manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1	5.1.6
	Do not use if package is damaged	Medical device should not be used if the package has been damaged or opened.	ISO 15223-1	5.2.8
	Keep away from sunlight	A medical device that needs protection from light sources.	ISO 15223-1	5.3.2
	Keep dry	A medical device that needs to be protected from moisture.	ISO 15223-1	5.3.4
	Temperature limit	The temperature limits to which the medical device can be safely exposed.	ISO 15223-1	5.3.7
	Humidity limitation	Indicates the range of humidity to which the device can be safely exposed	ISO 15223-1	5.3.8
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the device can be safely exposed	ISO 15223-1	5.3.9
	Do not re-use	A medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1	5.4.3
	Refer to instruction manual/booklet.	Indicates the instruction manual/booklet must be read. (This symbol is blue and white on the device label)	ISO 7010:2011	M002
	Caution	User to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1	5.4.4
	MR Conditional	Medical device demonstrated safety in the MR environment within defined conditions.	ASTM F2503-13	Fig. 6

	MR Unsafe	Medical device poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	ASTM F2503-13	Fig. 9
	Radio Transmitter	Device contains a radio-frequency (RF) transmitter, which may cause RF interference with other devices near this device	IEC 60601-1-2:2007	5.1.1
	Prescription use only	Caution: Law prohibits dispensing without prescription	21 CFR 801.109	N/A
	Quantity	Indicates the total number of products provided in a package.	N/A	N/A
	Serial Number	Manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1	5.1.7
	Best Before	This device is best used before this date.	N/A	N/A
	Authorized Representative in the European Community	Authorized representative in the European Community	ISO 15223-1	5.1.2
	Protected against electric shock	Device contains a type BF applied part to protect you from shock. The device is internally powered and is intended for continuous operation	IEC 60417	5333
	Protected against access to certain hazardous parts	Protected against solid objects over 12.5mm (e.g., a finger) and protected against falling drops of water, if the case is disposed at any angle up to 15 degrees from vertical	IEC 60529	N/A
	Protected from dust and temporary immersion in water	Protected from dust and against effects of immersion in water up to 1m depth for 30 mins	IEC 60529	N/A
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1	5.2.3
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1	5.2.6
	Stimulator length	Indicated the length of the device	N/A	N/A
	FCC	This symbol indicates that 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.	47 CFR 2.926	N/A
	Do not throw in the trash	This product shall not be treated as household waste. Instead it is the user's responsibility to return this product to Nalu Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact Nalu Medical.	BS EN 50419 Marking of Electrical and Electronic Equipment in Accordance with Article 11(2) of Directive 2002/96/EC (WEEE)	Fig. 1

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INTRODUCTION

The Nalu™ Neurostimulation System is a combination of sterile packaged kits consisting of implants, instruments, and accessories that are used to implant battery-free microstimulation devices. This manual describes the single-Lead and dual-Lead versions of the implantable, battery-free microstimulation devices, the implant procedure accessories, and the methods to optimally implant each device. It also provides important warnings and precautions.

INDICATIONS FOR USE

Spinal Cord Stimulation (SCS)

This system is indicated as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain.

The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

Peripheral Nerve Stimulation (PNS)

This system 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. The Nalu Neurostimulation System for PNS is not intended to treat pain in the craniofacial region.

The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

PACKAGE CONTENT DESCRIPTIONS

*NOTE: Depending on the specific configuration being deployed, not all contents listed below may apply. Not all of the items listed below and throughout the manual are applicable for both SCS and PNS Indications for Use; some items are only applicable to one Indication for Use. Please see the Nalu System Implant Kits section for clarification. Kits with SCS in the name are only applicable to SCS, kits with PNS in the name are only applicable for PNS, and kits and parts without either SCS or PNS in the name are applicable for both indications.

Implantable Pulse Generator (IPG)
The Nalu Ported Implantable Pulse Generator is a battery-free, microstimulator that comes in two 8-contact variations: 2 cm single-ported, and 2 cm dual-ported; and one 4-contact variation: 2 cm single-ported. The service life of the Implantable Pulse Generator is 18 years.

Lead (8 contact: 40 cm and 60 cm)
The stimulating portion of the neurostimulator that is inserted into the epidural space.

Tined Leads (4 contact: 25 cm and 40 cm)
The stimulating portion of the neurostimulator that is inserted subcutaneously near the target nerve.

Lead Extension (8 contact: 30 cm)
Connects to the proximal end of the Lead to extend the Lead subcutaneously or percutaneously.

Anchor(s)
A silicone overmolded device that captures the Lead and can be secured to the surrounding tissue. The tined leads do not come with an anchor.

Spoonbill Needle(s) (4.5” [11.4 cm] and 6.0” [15.2 cm])
A 14-gauge Spoonbill needle (1.71 mm inside diameter and 2.11 mm outside diameter) that is used to gain access to the epidural space for implantation of the ported Leads.

Stylet(s), Bent (45 cm)
Stiff wire(s) with a bent tip that is inserted into the Lead to aid in steering and positioning.

Stylet(s), Straight (30 cm and 45 cm)
Stiff wire(s) with a straight tip that is inserted into the Lead to aid in steering and positioning.

Tearaway Introducer(s) (10 cm and 14 cm)
A Tuohy needle (1.2 mm inside diameter, 1.47 mm outside diameter) within a 4.5F Tearaway Introducer sheath (1.5 mm inside diameter). When used in SCS it's used to gain access to the epidural space. When used in PNS it's used in the process of deploying the Tined Leads.

Pocket Tunneling Tool (10 cm)
A handheld device that is used to create a subcutaneous tunnel and/or pocket for the placement of the Implantable Pulse Generator.

Torque Wrench (6 oz-in [4.2 N-cm])
A torque limited hex driver that is used to tighten the connector set screws and the Anchor.

IPG Insertion Tool
A handheld device used to aid in advancing the IPG down the tunnel and/or pocket formed by the Pocket Tunneling Tool.

Straw Tunneller (30 cm)
A stainless steel rod with a sharp tip and a plastic sleeve that is used to create a subcutaneous pathway for the passage of the Lead or Lead Extension for certain surgical procedures (e.g. perm trials).

Electrode Interfacing Cable (EIC) (60 cm)
An electrical connector that mates with the proximal end of the Lead or the Lead Extension external to the patient and connects with a Trial Therapy Disc.

Electrode Interfacing Cable (EIC) Extension (180 cm)
Connects with the EIC and the Trial Therapy Disc to provide an extension bridging the sterile field.

SAFETY INFORMATION

Contraindications

Patients contraindicated for this therapy are those who:

- Are unable to operate the system
- Have failed trial stimulation by failing to receive effective pain relief
- Are poor surgical risks
- Are pregnant

Exposure to shortwave, microwave, or ultrasound diathermy – Diathermy should not be operated within the vicinity of a patient implanted with a Nalu Neurostimulation System or when wearing a Therapy Disc. The energy from diathermy can be transferred through the stimulator and cause tissue damage, resulting in severe injury.

Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy – Patients who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with the device. The energy in high-level areas can be transferred through the device and cause tissue damage, resulting in severe injury. Examples of environments having high level non-ionizing radiation include the following:

- 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 or Other Neurostimulation Systems—Patients who have implanted cardiac or other neurostimulation systems should not use the Nalu Neurostimulation System. Electrical pulses from the Nalu Neurostimulation System may interact with the sensing operation of an implanted cardiac or neurostimulation system, causing the system to respond inappropriately.

Warnings

Please inform your patients of these warnings when using the Nalu Neurostimulation System.

Electromagnetic Interference (EMI)—EMI is a field of energy generated by equipment found in the home, work, medical, or public environments. Very strong EMI can interfere with the System. The device includes features that provide protection from EMI. Most electrical device and magnets encountered in a normal day will not affect the operation of the System, however, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage resulting in a loss of, or change in, symptom control that might require additional surgery.
- Operational changes to the Therapy Disc. This may cause the external device to turn on, turn off, or reset to factory settings. If this occurs, the Therapy Disc needs to be reprogrammed.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation. Some patients have described a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it will not damage the device or cause direct injury to the patient. In rare cases, as a result of the unexpected changes in stimulation, patients have fallen down and been injured.

If you suspect that your Nalu Neurostimulation System is being affected by EMI, then you should:

- **For the Therapy Disc** – Remove or Turn Off
- **For the Trial Therapy Disc** – Disconnect and/or Turn Off Stimulation
- Immediately move away from the equipment or object.

Electromagnetic Equipment/ Environments—Avoidance of high electromagnetic equipment radiators or environments is highly encouraged. Examples of equipment and/or environments include the following:

- High-power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private 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, cell phone 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.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Nalu Neurostimulation System. Otherwise, performance degradation of the equipment might occur.

Machinery or Heavy Equipment—Machinery and heavy equipment (including vehicles) should not be operated while using the Nalu Neurostimulation System. Malfunction of the System could result in the loss of body control, body function, or a feeling that could render the patient incapable of controlling the equipment.

Theft Detectors and Metal Screening Devices – Certain types of antitheft devices, such as those used at the entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices may affect stimulation. If the patient is sensitive to low stimulation thresholds, patient may experience a momentary increase in perceived stimulation, which has been described as “uncomfortable” or “jolting”. Use caution when approaching such a device and request assistance to bypass the device. If patient must proceed through the device, remove the Therapy Disc and proceed with caution, but be sure to move through the detector quickly.

Your patient may seek other medical tests or treatments, please review the following warnings with the patient.

Temperature Rise During Stimulation – During prolonged use of Therapy Disc the temperature of the device may rise by 1°C above ambient temperature. If the Therapy Disc becomes uncomfortable remove the device from the clip and discontinue use.

Active Implantable or Body-Worn Medical Devices—Safety has not been established for patients who use the Nalu Neurostimulation System with other active implantable or body-worn medical devices. Malfunction and/or damage could occur to either system that could result in harm to the patient or other people nearby.

Magnetic Resonance Imaging (MRI)—MR Unsafe – For the Nalu Neurostimulation System, the only components that are allowed into the MRI system room are the 40 cm Lead (Model 12001-040), the Nalu Anchor (Model 13001), and the Nalu Implantable Pulse Generators (Model 11003-002, 11004-002).

All other components (i.e., the external component and programmer) are MR Unsafe and not permitted in the MRI system room.

Magnetic resonance imaging (MRI) – MR Conditional – Prior to conducting or recommending an MRI examination on a patient with the Nalu Neurostimulation System, it is important to read and understand the entire section entitled, “**MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION**” in the Table of Contents, which pertains to performing an MRI examination safely in a patient.

These instructions apply only to the Nalu Neurostimulation System and do not apply to other products. If you have any questions, please contact Nalu Medical or visit Nalu’s website <www.nalumed.com>.

The only Nalu Medical components that are labeled and approved as MR Conditional are the Lead (Model 12001-040), the Nalu Anchor (Model 13001) and the Nalu Implantable Pulse Generators (Model 11003-002, 11004-002). All other components are MR Unsafe.

Computed Tomography (CT) Scanning—Safety has not been established for CT scanning of patients with a Nalu Neurostimulation System. X-rays from the scan could cause unintended shocks or malfunctions of the System, and may not be immediately detectable.

1. 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:
    a. Remove the Therapy Disc from the CT scan range.
    b. Minimize X-ray exposure to the implanted device by:
    c. Using the lowest possible X-ray tube current consistent with obtaining the required image quality.
    d. Making sure that the X-ray beam is not placed over the Nalu Implantable Pulse Generator for more than a few seconds.
2. After CT scanning directly over the implanted device:
    a. Place the Therapy Disc on body/ connect the Trial Therapy Disc and turn on stimulation.
    b. Check for proper stimulation, and that indicator lights are operating as expected.
    c. Shut off the Therapy Disc if it is suspected that the device is not functioning properly.

Radiofrequency (RF) Ablation—Safety has not been established for RF ablation in patients with the device. RF ablation may result in heating and tissue damage. Do not use RF ablation anywhere near the device. If RF ablation is used, ensure that ablation is not performed over or near the device.

Medical Devices/Therapies— The following medical therapies or procedures may turn stimulation off or may cause permanent damage to the Nalu Implantable Pulse Generator particularly if used in close proximity to the device:

- Lithotripsy
- Electrocautery. Do not use monopolar cautery
- External defibrillation
- Radiation therapy
- Ultrasonic scanning
- High-output ultrasound
- Bone growth stimulators
- Dental Drills and Ultrasonic Probes
- Electrolysis
- Laser Procedures
- Radiation Therapy
- TENS (transcutaneous electrical nerve stimulation)

If the patient is required by medical necessity to undergo any of the above therapies or procedures, the procedural guidelines below must be followed. Ultimately, however, the device may need to be explanted as a result of associated failure.

- Turn off stimulation of the Nalu Implantable Pulse Generator before the procedure or therapy.

- All equipment, including ground plates and paddles, must be used as far away from the Implantable Pulse Generator as possible.
- Bipolar electrocautery is recommended. Do not use monopolar electrocautery.
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the Implantable Pulse Generator.
- If radiation therapy is required, the area over the Nalu Implantable Pulse Generator should be shielded with lead.
- Equipment should be set to the lowest energy setting clinically indicated.
- Instruct patients to confirm Implantable Pulse Generator functionality following treatment by turning on the Implantable Pulse Generator and gradually increasing stimulation to the desired level.
- Damage from these procedures to the Nalu Neurostimulation System may not be detected immediately.

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 medical device implants. Induced electrical currents can cause heating that may result in tissue damage.

Other Medical Procedures—EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps)

Painful Stimulation—If the patient experiences painful stimulation, the Therapy Disc should be disconnected and/or the amplitude of the stimulation should be decreased.

Strangulation— Entanglement in the Therapy Disc Charger cable, Electrode Interfacing Cable, or relief belt may cause a fall or strangulation.

Tampering- Do not modify or tamper with any component of the Nalu Neurostimulation System. Tampering with the device could result in harm. If the device is not working properly, visit www.nalumed.com for help.

Precautions

Clinician Training – Prescribing clinicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the Nalu Neurostimulation System. Implanting clinicians should be experienced in implantable medical device procedures and should review the procedures described in the Instructions for Use.

Sterilization – All implantable and surgical components are sterilized with ethylene oxide. Inspect the condition of the sterile package before opening the package and using the contents. Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.

- Do not use any component that shows signs of damage.
- Do not re-sterilize the package or the contents.
- Do not use if the product is past the labeled expiration date.
- All components are for single use only. Do not reuse.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

Post-Operative— During the two weeks following surgery, it is important to use extreme care so that appropriate healing will secure the implanted components and close the surgical incisions, ensure that patients are given the following guidance:

a. *Do not lift objects of more than five pounds.*

b. *Do not engage in rigorous physical activity such as twisting, bending, or climbing.*

c. *If new Leads were implanted, do not raise your arms above your head.*

Temporarily, there may be some pain in the area of the implant as the incisions heal. If discomfort continues beyond two weeks, contact your clinician.

If you notice excessive redness around the wound areas during this time, contact your clinician to check for infection and administer proper treatment. In rare cases, adverse tissue reaction to implanted materials can occur during this period.

Be sure to consult your clinician before making lifestyle changes due to decreases in pain.

Medical Tests and Procedures – Before undergoing medical tests or procedures, contact the clinician to determine if the procedure will cause damage to the patient or to the System.

Your patient may seek other medical treatments, please review the following precautions with the patient.

It is important to emphasize the proper use and care of the Therapy Disc and/or Trial Therapy Disc to the patient.

Use the Therapy Disc as Directed – Use the Therapy Disc only as explained by the clinician or as discussed in the User Manual. Using the Therapy Disc in any other manner could result in harm. Do not use any equipment or accessories that are not supplied with the Therapy Disc.

Use of Another Patient's Therapy Disc – Use of another patient's Therapy Disc will not deliver therapy. The therapy programmed is a unique prescription for each patient and their specific Nalu Implantable Pulse Generator.

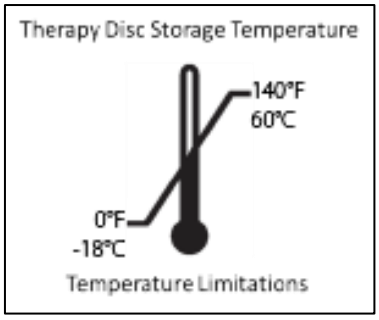
Handle the Therapy Disc with Care – The Therapy Disc is a sensitive electronic device. Avoid dropping the device onto hard surfaces. Keep the Therapy Disc out of the reach of children, pests and pets.

Keep the Trial Therapy Disc Dry – The Trial Therapy Disc is not waterproof. Keep the Trial Therapy Disc dry to avoid damage.

Avoid extended immersion with the Therapy Disc – The Therapy Disc can get wet within certain limits. It is not recommended that the Therapy Disc be used during water activities. Upon shipment, the Therapy Disc is rated IP67 (protected from total dust ingress, protected from immersion between 15 centimeters and 1 meter in depth for 30 minutes) and over time with normal wear and use, the Therapy Disc may become more susceptible to damage by immersion.

Clean the Therapy Disc – When needed, clean the outside of the Therapy Disc with a damp cloth to prevent dust and dirt.

Storage Temperatures – The Nalu Neurostimulation System should be kept within the storage temperatures listed on product packaging. Exceeding the storage temperature can affect the performance of the device.



Random Component Failure – Although unlikely, a failure of the Nalu Neurostimulation System is possible due to random component failure. If any part of your Nalu Neurostimulation System stops working or changes how it works, remove the Therapy Disc and contact your Nalu representative.

Unexpected Changes in Stimulation – Electromagnetic interference, changes in posture, and other activities can cause a perceived increase in stimulation. Some patients have described this as a jolting or shocking sensation. Before engaging in potentially unsafe activities patient should do the following:

1. **For Therapy Disc** – Remove or Turn Off
2. **For Trial Therapy Disc** – Disconnect and/or Turn Off Stimulation

Patient should discuss these activities with the clinician.

Airline policies - Follow airline policies for use of implantable medical devices and electronic equipment during flights. Refer all questions to airline personnel. Patient should carry their Patient ID card with them at all times.

Flammable or Explosive Environments – Do not use the Therapy Disc in flammable or explosive environments. Using the Therapy Disc in one of these environments could result in harm.

Activities requiring excessive twisting or stretching – Avoid activities that potentially can put undue stress on the device. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause your stimulator 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 1.48 atmospheres absolute (ATA) with the Nalu Implantable Pulse Generator. These conditions can damage the device. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with the clinician. Do not dive or enter hyperbaric chambers with the Therapy Disc.

Remote Control Interference – If interference is suspected during use of the remote control, confirm that the Bluetooth® data transmission is operating properly. If the Nalu Remote Control application is not connecting to the Therapy Disc:

a. Terminate the current stimulation program and shut down the Nalu Remote Control application.

b. Check for sources of Bluetooth interference in the surrounding area.

c. Remove or turn off the source of interference.

d. Re-establish the Bluetooth link with the Therapy Disc through pairing.

e. Reopen the Nalu Remote Control application and resume the therapy.

Adverse Environments – Any patient with a Nalu Neurostimulation System should seek medical guidance before entering environments which could adversely affect the operation of the Neurostimulation System, including areas protected by a warning against entry by patients.

ADVERSE EVENT SUMMARY

Below is a list of side effects that may occur during surgery and/or during standard spinal cord or peripheral nerve stimulation:

- Undesirable changes in stimulation sensation and/or location with or without patient movement.
- Persistent post-surgical pain at hardware implantation sites.
- Seroma or hematoma at surgery sites.
- Spinal cord injury and or compression with subsequent neurological deficits - permanent or temporary.
- Stroke.
- Lead migration, causing the electrodes to move from the intended location.
- Implantable Pulse Generator migration, which may or may not require surgical intervention.
- Fracture of the Lead(s) or failure of other system components, which may result in the loss of stimulation or untoward stimulation induced dysesthesias.

- Allergic or rejection reaction to the anaesthesia, implanted components, or external components.
- Reaction to the selected antibiotics or to the Nalu device including: rash, diarrhea, abdominal pain, nausea/vomiting, dizziness, headaches, hypersensitivity (allergic) reactions
- Undesirable skin problems such as infection, irritation, blistering, tearing or allergic reactions that may occur during the use of any wearable component of the Nalu Neurostimulation System.
- Skin irritation, including redness, itchiness, and bumpiness
- Infection at implant site that may or may not require hospitalization and require treatment with antibiotic therapy or surgical intervention
- Cerebral spinal fluid (CSF) leak inclusive of those requiring active medical intervention.
- Inadequate pain relief or increase in pain following system implantation
- Wound complications that may require medical intervention inclusive of surgical management.
- Thromboembolic events requiring medical intervention; inclusive of deep vein thrombosis and pulmonary embolism.
- Death and/or catastrophic neurological complications.
- Anesthetic complications - e.g. nausea, urinary retention.
- Headache.
- Bleeding.
- Excessive fibrotic reaction to device leading to pain and/or new pain symptoms.
- Unexpected stimulation effects including but not limited to: chest wall stimulation, muscle stimulation, tremor, dyskinesia, superficial pain, cramping, light-headedness and metallic taste.
- Weakness.
- Numbness.
- Clumsiness.
- Tissue damage.
- Nerve damage.
- Paralysis.
- Swelling.
- Sensory loss.
- Discomfort during the treatment.
- Skin erosion around the Nalu Implantable System or at the site of the Nalu wearable devices.
- Battery failure
- Lead breakage requiring replacement of the Lead.
- Electromagnetic interference causing a change in System performance.
- Loss of therapeutic effect despite a functioning system.
- Hardware malfunction requiring replacement of the neurostimulator components.
- Pain from a non-injurious stimulus to the skin (allodynia).
- An exaggerated sense of pain (hyperesthesia).
- Change in stimulation that are possibly related to tissue changes around the electrodes, shifts in electrode position, loose electrical connections, and Lead or extension fractures which have been described by some patients as uncomfortable stimulation (a jolting or shocking sensation).
- Formation of reactive tissue in the epidural space around the Lead can result in delayed spinal cord compression and paralysis, requiring surgical intervention. Time to onset can range from days to many years after implant.
- Arrhythmia.
- Cardiac arrest.
- Intracranial hypotension.
- Fracture of the lead(s) or failure of other system components.
- Loss of therapy or unpleasant paraesthesia.

Adverse effects of stimulation are usually mild and go away when stimulation is turned off. There may be changes in the level of pain control over time.

Notice: In the event of any serious incident that has occurred in relation to the Nalu Neurostimulation System, the user and/or patient should report the incident to Nalu Medical at +1.800.618.3402 or visit www.nalumed.com.

INSTRUCTIONS FOR IMPLANTATION (SCS)

The following SCS Lead Placement instructions are for the SCS procedure only. Please see INSTRUCTIONS FOR IMPLANTATION (PNS) for PNS Lead Placement Instructions.

Implanting clinicians should be experienced in procedures that gain access to the epidural space and familiar with the product labeling.

Preparing for Surgery

Before opening the Nalu Neurostimulation System component packages verify the package integrity, model number, and use-by date. This product is provided sterile. Do not use the product if the package is damaged. Do not use the product if the date has expired. Contact Nalu for any questions regarding packaging and expiration dates.

 To reduce the risk of Nalu Neurostimulation System damage that might result in intermittent or lost stimulation:

- Use only the Spoonbill Needle provided by Nalu.
- Use a shallow needle-insertion angle (45 degrees or less) when inserting or withdrawing the needle into or out of the epidural space.
- Do not handle the stimulator with an instrument that would damage it.
- Use care when replacing a Stylet.
- Use care when re-inserting Tearaway introducer to avoid potential tearing.
- The Tearaway introducer may not withstand the same manipulations that a needle would when approaching the epidural space.

SCS Lead Placement

1. Position, prep, and drape the patient in the usual accepted manner. Inject a local anesthetic at the needle insertion site.
2. Under fluoroscopic guidance, place the Spoonbill Needle into the epidural space with the bevel facing up using an angle of 45° or less.

 Use only Nalu's insertion needle. The stamped number "14" on the needle hub corresponds to the orientation of the needle bevel, which must face up. Use of other needles or turning the bevel ventral (down) may result in damage to the lead.

 The angle of the insertion needle should be 45° or less. Steep angles increase the insertion force of the Stylet and may produce a greater opportunity for the Stylet to pierce the Lead and cause tissue damage.

3. Remove the needle Stylet from the insertion needle and verify entry into the epidural space using the loss-of-resistance technique.

4. The Leads are provided with a pre-loaded bent Stylet. The Stylet should extend to the tip of the Lead. Slowly insert the Lead, with Stylet, through the insertion needle.

5. ***OPTIONAL*** If exchange of the Stylet is desired, carefully pull out the existing Stylet and insert the preferred Stylet. While inserting the Stylet into the Lead, if resistance is encountered, withdraw the Stylet approximately 3 cm, rotate the Lead and/or Stylet, and gently advance the Stylet. If resistance is still encountered, repeat the above procedure until the Stylet can be fully inserted.

⚠ Do not exchange the Stylet while the electrode array of the Lead is in the bevel of the insertion needle. If the electrode array is in the bevel area, remove the Lead from the insertion needle before exchanging the Stylet. Inserting the Stylet into the Lead while the electrode array is in the bevel of the insertion needle increases the risk of Lead and tissue damage.

⚠ If the Stylet is removed and reinserted, do not use excessive force when inserting the Stylet into the Lead. The use of instruments such as forceps to grasp the Stylet during insertion is not recommended as this could result in applying excessive force and could increase the risk of Lead and tissue damage.

6. Advance the Lead to the appropriate vertebral level under fluoroscopic guidance. A sufficient length of Lead (for example, at least 10 cm, or approximately three vertebrae) should reside in the epidural space to aid in Lead stabilization.

7. If implanting a second Lead, repeat steps 2-6 for the second Lead.

8. While holding the Lead in place, connect the Electrode Interface Cable to the proximal end of the Lead(s) by opening the hinged lid(s) on the cable and inserting the proximal end of the Lead(s) into the access port on the side of the lid. Verify that the Lead is fully inserted in the cable through the visual observation port on the top of the hinged lid(s), then close the lid until it snaps shut. If using one lead, connect lead to the bottom access port A; see figure 1. Please use caution when opening the Electrode Interface Cable. Only one side of the lid should be opened at a time and the lid opens just far enough to allow insertion of the lead. Trying to open both sides simultaneously increases the risk of breakage.

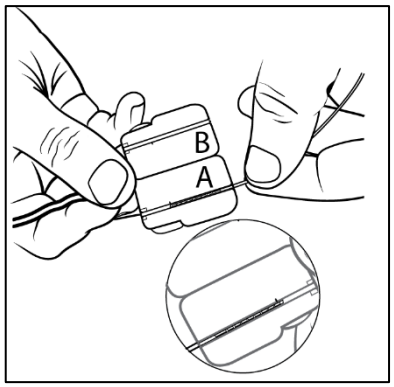


Figure 1 Connecting to the lead(s)

9. ***OPTIONAL*** Connect the larger female end of the Electrode Interface Cable Extension to the male micro-HDMI connector end of the cable. Extending the Cable or Extension outside of the sterile field, connect the smaller male end of the Electrode Interface Cable or Extension to the female micro-HDMI connector of the Trial Therapy Disc.

10. Check the connections with an impedance measurement using the Clinician Programmer. If the impedance is satisfactory proceed to Step 11. If not, check to make sure that all components are connected properly and try again.

11. If paresthesia coverage is desired, then identify the most appropriate stimulation parameters, beginning at a medium pulse width and frequency range. Increase the amplitude while asking the patient close-ended questions to identify the perception threshold, the discomfort threshold, and the area of paresthesia coverage.

12. **OPTIONAL** Capture a fluoroscopic image of the Lead placement on the Clinician Programmer to record the final placement of the Lead electrodes.

13. If performing a staged trial (using a permanent Lead during the trial phase), remove the Electrode Interface Cable from the Lead and proceed to the sections, “ANCHORING THE LEAD” and “CONNECTING THE LEAD EXTENSION,” and/or “TUNNELING THE LEAD AND LEAD EXTENSION.” If performing a temporary trial using a short term temporary implanted Lead, coil the excess Lead and cover the Lead and Cable with gauze and dressing. If performing a permanent implantation proceed to the sections “ANCHORING THE LEAD,” “CONNECTING THE LEAD EXTENSION” and/or “IMPLANTABLE PULSE GENERATOR IMPLANTATION.”

Anchoring the Lead

1. Carefully remove the Stylet using fluoroscopy to ensure that the Lead position does not change.
2. Make a small midline incision at the Lead entry site.
3. Place an Anchor over the Lead and down to the supraspinous ligament or down to the deep fascial tissue. Ensure the long tip of the Anchor is pushed into the ligamentous tissue.
4. Suture to the supraspinous ligament or deep fascia, then thread through and tie off the suture to the proximal eyelet of the Anchor. After suturing to the proximal eyelet, tighten the set screw of the Anchor using the provided Torque Wrench, while stabilizing the screw block with a pair of forceps.

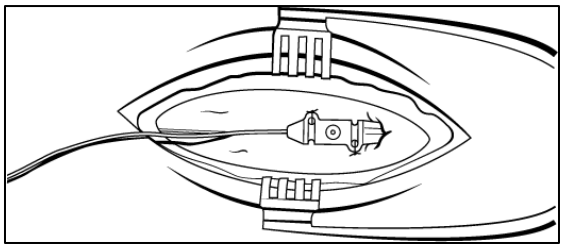


Figure 2 Lead Anchor at incision site

Note: *The Anchor set screw is captured and does not advance downward towards the Lead as the set screw is tightened. Tighten the set screw in a clockwise direction until a ‘click’ sound is heard, indicating that the Anchor is locked. It is not necessary to push down on the Torque Wrench during tightening or to overtighten resulting in multiple clicks.*

5. After tightening the setscrew, suture the distal eyelet to the supraspinous ligament or deep fascia in manner similar to the proximal eyelet
6. Ensure that the Anchor has secured the Lead.
7. Ensure that the Lead has not moved by performing test stimulation and using fluoroscopic imaging as necessary. If the Lead has migrated, loosen the set screw, reposition the Lead, and re-tighten the set screw.
8. Repeat steps 1-7 for the second Lead if applicable.

Connecting the Lead Extension

1. Wipe clean the proximal end of the Lead with gauze, then insert the proximal end into the Lead Extension connector until it is fully inserted inside the boot and the set screw ring (long ring) is directly under the set screw.

Note: *If there appears to be an obstruction when inserting the Lead into the Lead Extension connector, use the Torque Wrench to loosen (counterclockwise) the set screw until a ‘click’ is heard and/or gently rotate the Lead to help advance the proximal end.*

⚠ *Excessive unscrewing of the set screws may result in disengagement from the block. If this occurs, apply a small amount of downward force while twisting clockwise to reengage.*

2. Ensure that the Lead is fully inserted before tightening the set screw to prevent Lead damage.
3. Using the supplied Torque Wrench, turn the Extension connector set screw clockwise until a ‘click’ is heard, indicating that the connector is locked. Once the set screw is locked in place, it will not move.

Note: *Ensure the Torque Wrench is fully seated in the set screw prior to tightening. The Torque Wrench is torque limited and cannot be overtightened.*

4. Repeat steps 1 – 3 for the second Lead Extension, if applicable.
5. Connect the Electrode Interference Cable to the Lead Extension(s). Perform test stimulation and verify the desired system response.
6. If performing a staged trial using a permanent Lead, a small suture may be used to close the exit wound of the Extension. Place and tape a stress relief loop and dress the wound.
7. Close the midline incision and cover with gauze and dressing. Coil the Lead Extension Cable(s) and cover with gauze and dressing at the exit wound.

Ported Implantable Pulse Generator Implantation

1. If a staged trial was performed using a permanent Lead implanted and the patient is proceeding to a permanent implant, perform steps 2-4, if not proceed to step 5.
2. Cut the Lead Extension proximal to the connector using scissors. Pull the remaining portion of the Lead Extension out through the exit wound site and discard.
3. Using the supplied Torque Wrench, turn the Extension connector set screw counter-clockwise to loosen the set screw in the Lead Extension connector boot. Remove and discard the connector boot portion of the Lead Extension.
4. Repeat steps 2-3 for the second Lead, if applicable.
5. Locate the final Implantable Pulse Generator pocket site at the desired location. With the Therapy Disc in a sterile bag, center the Disc over the desired implanted Pulse Generator final pocket site and trace the outline of the Therapy Disc with surgical marker.

Note: *The final implanted Pulse Generator pocket site should be pre-determined through consultation with the patient prior to the surgery.*

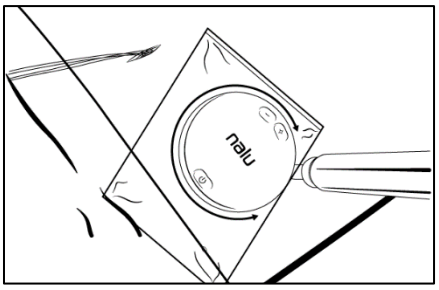


Figure 3 Trace outline of the Therapy Disc

6. Create a subcutaneous pocket and tunnel the Leads and/or Extensions.

⚠ To use the nonsterile Therapy Disc components in a sterile field, place sterile barrier between the patient and system components to prevent infection.

Creating a Subcutaneous Pocket

Note: *Ensure that the distance from the incision site to the center of the desired implanted Pulse Generator final pocket site allows for the length of the system to be implanted (e.g. ported connector length of 7 cm.)*

Note: *The Pocket and Tunnelling Tool can create a subcutaneous pocket up to 10 cm in length and at a depth of 1 cm.*

1. Create an incision for a subcutaneous pocket.
2. Create a subcutaneous pocket the size of the Implantable Pulse Generator outline at a depth of up to 1 cm.
3. Perform hemostasis, if required.

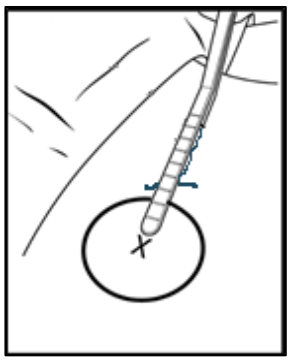


Figure 4 Pocket and Tunneling Tool

Note: *The marks on the top portion of the Pocket Tunneller are spaced 1 cm apart and can be used to measure the distance from the incision site to the end of the pocket site.*

Note: *Keep the Pocket Tunneller shallow while tunneling, without puncturing the skin.*

Note: *The pocket may be irrigated with sterile saline solution or antibiotic solution.*

⚠ The Pocket Tunneller helps ensure that the Implantable Pulse Generator can be placed below the skin at a consistent depth and approximately parallel to the skin. If the Implantable Pulse Generator is too deep or is severely tilted relative to the skin, connection with the Therapy Disc may be suboptimal or unsuccessful.

Tunneling the Lead or Lead Extension

The Straw Tunneller and/or the Pocket Tunneling Tool may be used for tunneling.

1. Administer the appropriate local anesthetic along the tunneling path.
2. **OPTIONAL** If necessary, bend the Straw Tunneller tool shaft to conform to the patient's body.
3. Create a subcutaneous tunnel between the lead(s) incision site and the IPG pocket or lead exit site until the straw or the Pocket and Tunneling Tool tip is visible and accessible at the exit point.
4. If using the Pocket Tunneling Tool, using the tool as a template, lay the Pocket Tunneller on the skin and trace the path of the top portion of the tool from the incision to the center of the outline of the Therapy Disc.
5. If using the Straw Tunneller:
    a. Grasp the handle of the tool with one hand while grasping the tip of the straw with the other. Pull the tool shaft out through the straw.
    b. Pull the lead(s) or extension(s) through the straw, then withdraw the straw.
6. Place a small loop in the Lead for slack.
7. Pass the free end of the Lead or Lead Extension through the straw until it emerges from the exit site. Carefully remove excess slack by gently pulling the Lead or Extension from the exit wound.

Connecting the Lead(s) or Lead Extension(s) to the Implantable Pulse Generator

1. Wipe clean the proximal end of the Lead, then insert the proximal end into the Ported Implantable Pulse Generator connector until it is fully inserted inside the boot and the set screw ring (long ring) is directly under the set screw.

Note: *If there appears to be an obstruction when inserting the Lead into the Implantable Pulse Generator connector, use Nalu's Torque Wrench to loosen (counterclockwise) the set screw and/or gently rotate the Lead to help advance the proximal end.*

⚠ Use only Nalu's Torque Wrench. Other Torque Wrenches may damage the Nalu Lead.

2. Ensure that the Lead is fully inserted before tightening the set screw to prevent Lead damage.
3. Using Nalu's Torque Wrench, turn the Ported Implantable Pulse Generator connector set screw clockwise until a 'click' is heard, indicating that the connector is locked.

Note: *Ensure the Torque Wrench is fully seated in the set screw prior to tightening. The Torque Wrench is torque limited and cannot be overtightened.*

4. Repeat above steps for the second Lead, if applicable.
5. With the Therapy Disc in a sterile bag, place the Therapy Disc over the implanted Pulse Generator and perform test stimulation. Verify the desired physiologic response.

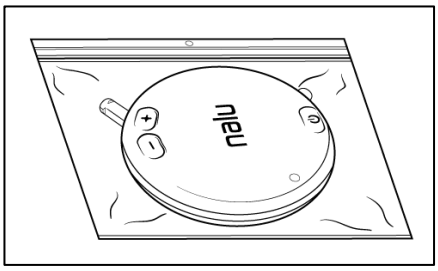


Figure 5 Therapy Disc in sterile bag

Note: *Ensure that the Therapy Disc buttons are facing away from the implanted Pulse Generator when performing test stimulation.*

Inserting the Implantable Pulse Generator

1. Insert the tip of the Implantable Pulse Generator Insertion tool into the receptacle in the Implantable Pulse Generator where the connector leads protrude from the body of the IPG device. Friction will retain the implanted Pulse Generator to the Pulse Generator Insertion tool.

Note: *When loading the implantable Pulse Generator onto the Pulse Generator Insertion tool in preparation for insertion, remember that the Nalu logo should be skin-side before advancement into the tunnel.*

2. Using the Pocket and Tunneling Tool tip or forceps to maintain the pocket opening, ensure the Implantable Pulse Generator has the Nalu logo facing skin-side. Advance the Implantable Pulse Generator with a pushing motion along the subcutaneous tissue path until the Implantable Pulse Generator is located at the center of the Therapy Disc outline. Verify using palpation the presence of the Implantable Pulse Generator at the desired final pocket site.

3. While applying slight percutaneous pressure to the Implantable Pulse Generator, remove the Implantable Pulse Generator Insertion tool, leaving the implanted Pulse Generator in place.

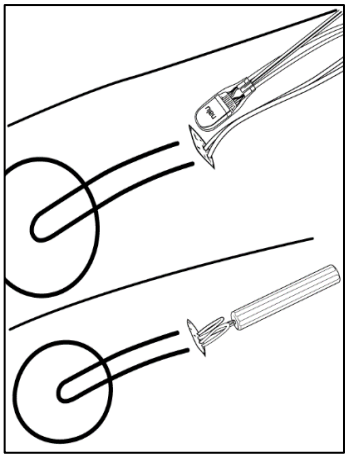


Figure 6 Using the Implantable Pulse Generator Insertion tool to advance the Implantable Pulse Generator

Note: *If excessive resistance is encountered upon initial insertion of the Implantable Pulse Generator into the pocket and/or tunnel, ensure that the implanted pulse generator is connected to the insertion tool and that the IPG is following the subcutaneous pathway. If the Implantable Pulse Generator Insertion tool is disconnected from the Implantable Pulse Generator, gently pull back on the lead(s) to remove the Implantable Pulse Generator.*

If excessive resistance inserting the Implantable Pulse Generator is still encountered after multiple attempts, alternative tools, such as forceps, may be used. Proper care should be given in how and where the IPG is gripped to avoid damaging the system.

4. Check the connections with an impedance measurement. If the impedance is satisfactory proceed to the next Step. If not, check to make sure that all components are connected properly and try again.

Note: *Ensure that the Therapy Disc buttons are facing away from the skin when performing the impedance check.*

5. Loop and tuck any excess Lead into the initial incision site.

Note: *Ensure that all of the excess lead(s) length is pulled back towards the initial incision. There should be no lead loops underneath where the Therapy Disc will be placed. Lead loops under the Therapy Disc may cause communication issues.*

Please see Device Explant for device replacement or explant.

INSTRUCTIONS FOR IMPLANTATION (PNS)

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

Common Peripheral Nerve Targets

Common peripheral nerves treated with PNS include the suprascapular, brachial plexus, intercostals, ulnar, median, radial, cluneal, femoral, ilioinguinal, sacral, scrotal, genitofemoral, iliohypogastric, pudendal, sciatic, peroneal, sural, and tibial nerves.

Preparing for Surgery

Before opening the Nalu Neurostimulation System component packages verify the package integrity, model number, and use-by date. This product is provided sterile. Do not use the product if the package is damaged. Do

not use the product if the date has expired. Contact Nalu for any questions regarding packaging and expiration dates.

To reduce the risk of Nalu Neurostimulation System damage that might result in intermittent or lost stimulation:

- *Use only the Spoonbill needle and Tearaway Introducer sheath supplied in the kit.*
- *The Tearaway Introducer sheath supplied is only available for kits with tined leads.*
- *Do not handle the stimulator with an instrument that would damage it*
- *Use care when replacing a Stylet.*

PNS Lead Placement

1. Position, prep, and drape the patient in the usual accepted manner.
2. Map the area of the patient's peripheral nerve and mark on the skin the planned trajectory of the receiver stimulator.

Notes:

- *The Anchor(s) must be placed on the Lead prior to advancing the Leads into the introducer.*
- *Use ONLY the introducer and needle provided in the device kit. Do not remove the dilator from the introducer assembly when driving into the tissue.*
- *Physician may use ultrasound or a nerve conduction technique to identify the location of the peripheral nerve.*
- *If the Nalu Implantable Pulse Generator is using one lead, a single integrated device will be used.*
- *Plan the needle entry site so that it is far enough away from the target nerve so that the device may be fully implanted. Measurements and skin marking may be performed before the procedure.*
- *Use care when re-inserting Tearaway introducer to avoid potential tearing.*
- *The Tearaway introducer may not withstand the same manipulations that a needle would when approaching the epidural space.*
- *4 Contact Tined Lead kits ONLY include and are compatible with the Introducer.*

3. Inject a local anesthetic at the needle insertion site.
4. If necessary, make a puncture incision before inserting the needle.
5. Advance needle or introducer through the incision in the direction of the peripheral nerve.
6. If using the needle, remove the stylet and leave the needle in place. If using the introducer, remove the needle and leave the sheath in place.
7. The 8 Contact Leads are provided with a pre-loaded bent Stylet. 4 Contact Tined Leads are provided with a pre-loaded straight Stylet. The Stylet should extend to the tip of the Lead. Slowly insert the Lead, with Stylet, through the insertion needle or sheath.
8. ***OPTIONAL*** If exchange of the Stylet is desired, carefully pull out the existing Stylet and insert the preferred Stylet. While inserting the Stylet into the Lead, if resistance is encountered, withdraw the Stylet approximately 3 cm, rotate the Lead and/or Stylet, and gently advance the Stylet. If resistance is still encountered, repeat the above procedure until the Stylet can be fully inserted.

⚠ Do not exchange the Stylet while the electrode array of the Lead is in the bevel of the insertion needle. If the electrode array is in the bevel area, remove the Lead from the insertion needle before exchanging the Stylet. Inserting the Stylet into the Lead while the electrode array is in the bevel of the insertion needle increases the risk of Lead and tissue damage.

⚠ If the Stylet is removed and reinserted, do not use excessive force when inserting the Stylet into the Lead. The use of instruments such as forceps to grasp the Stylet during insertion is not recommended as this could result in applying excessive force and could increase the risk of Lead and tissue damage.

9. If implanting a second Lead, repeat steps 2-9 for the second Lead.
10. While holding the lead in place, pull back on the needle or sheath to expose the lead's contacts.
11. While holding the Lead in place, connect the Electrode Interface Cable to the proximal end of the Lead(s) by opening the hinged lid(s) on the cable and inserting the proximal end of the Lead(s) into the access port on the side of the lid. Verify that the Lead is fully inserted in the cable through the visual observation port on the top of the hinged lid(s), then close the lid until it snaps shut. If using one lead, connect lead to the bottom access port A; see figure 7. Please use caution when opening the Electrode Interface Cable. Only one side of the lid should be opened at a time and the lid opens just far enough to allow insertion of the lead. Trying to open both sides simultaneously increases the risk of breakage.

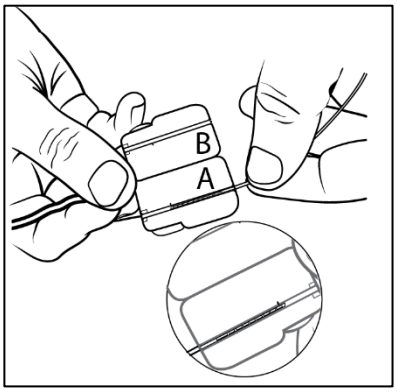


Figure 7 Connecting to the lead(s)

12. ***OPTIONAL*** Connect the larger female end of the Electrode Interface Cable Extension to the male micro-HDMI connector end of the cable. Extending the Cable or Extension outside of the sterile field, connect the smaller male end of the Electrode Interface Cable or Extension to the female micro-HDMI connector of the Trial Therapy Disc.
13. Check the connections with an impedance measurement using the Clinician Programmer. If the impedance is satisfactory proceed to next Step. If not, check to make sure that all components are connected properly and try again.
14. If paresthesia coverage is desired, then identify the most appropriate stimulation parameters, beginning at a medium pulse width and frequency range. Increase the amplitude while asking the patient close-ended questions to identify the perception threshold, the discomfort threshold, and the area of paresthesia coverage.
15. **OPTIONAL** Capture a fluoroscopic image of the Lead placement on the Clinician Programmer to record the final placement of the Lead electrodes.
16. If performing a staged trial (using a permanent Lead during the trial phase), remove the Electrode Interface Cable from the Lead and proceed to the sections, "ANCHORING THE LEAD" (8 Contact Lead) or "DEPLOYING LEAD TINES" (4 Contact Tined Lead) and "CONNECTING THE LEAD EXTENSION." If performing a temporary trial using a short term temporary implanted Lead, coil the excess Lead and cover the Lead and Cable with gauze and dressing. If performing a permanent implantation using proceed to the

sections “ANCHORING THE LEAD,” “CONNECTING THE LEAD EXTENSION” and/or “IMPLANTABLE PULSE GENERATOR IMPLANTATION.”

Deploying Lead Tines

Note: *The Tined Lead features two white marker bands, which are each indicators used for Tine Deployment. The distal marker band is used in conjunction with the 10 cm Tearaway Introducer. The proximal marker band is used in conjunction with the 14cm Tearaway Introducer.*

⚠ *During the deployment process the Lead and Stylet will be passed through the Introducer. When the appropriate white Marker Band slides completely inside the corresponding Introducer and disappears from sight, the first Lead Tine will begin to deploy.*

Note*: Do not remove the Stylet until the Tearaway Introducer Sheath has been removed and the lead is in its final position.*

1. Grasp the Tined Lead and secure it in a fixed position. Slowly pull back on the Introducer until the Introducer approaches the corresponding marker band.
2. Begin deploying the first Lead Tine by carefully pulling the Introducer backward so that the white marker band disappears into the Introducer. Continue to pull backward until a drop in resistance is felt.

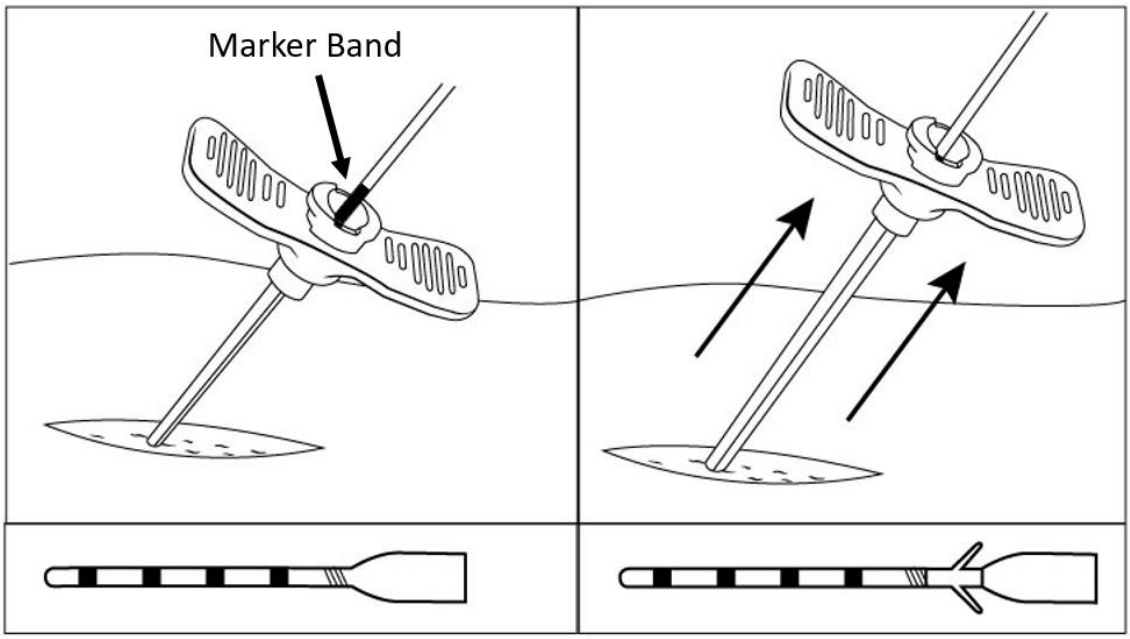


Figure 3 Tine deployment in tissue

Ensure that the Lead has not moved by performing test stimulation and using fluoroscopic and/or ultrasonic imaging as necessary. If the Lead has migrated, reposition the Lead before deploying the remaining Tines.

3. Continue deploying the remaining Tines using the following technique: Immobilize the Lead by holding it stationary against the surface of the patient. While holding the lead stationary, deploy the remaining Tines by peeling the Tearaway Introducer sheath.
4. Carefully remove the Stylet using fluoroscopy or ultrasound as necessary to ensure that the Lead position does not change.

Device Explant

1. Locate the initial incision/Lead entry site. This can be done by palpation, observation of existing surgical artifacts (i.e., previous sites as indicated by scarring), patient interviews, and by using fluoroscopy.
2. Make a small midline incision at the original initial incision/Lead entry site.
3. Cut and remove the sutures from the Anchor(s).
4. Uncoil the lead and gently pull on the slack end(s) of the Lead loop(s) until the distal tip of the Lead(s) emerges from the epidural space.
5. Once the distal end of the Lead(s) has(have) been removed from the epidural or peripheral nerve space, gently pull on the remaining slack in the Lead(s) in order to dislodge and remove the Implantable Pulse Generator(s).
6. After the device has been removed, verify that all components are intact and that all implanted materials are accounted for.
7. Close the midline incision and cover with gauze and dressing.

Tined Device Explant

1. Make a small incision at the original initial incision/Lead entry site.
2. Use hemostats to blunt dissect tissue down to the location where Tined Lead section is deployed.
3. Under direct visualization grasp the lead with hemostats to loosen tines from tissue. Once loosened, grasp the Lead with hemostats and gently pull on the Lead until the distal tip of the Lead emerges from the peripheral nerve space.
4. Once the distal end of the Lead(s) has (have) been removed from the peripheral nerve space, gently pull on the remaining slack in the Lead(s) in order to dislodge and remove the Implantable Pulse Generator.
5. After the device has been removed, verify that all components are intact and that all implanted materials are accounted for.
6. Close the incision and cover with gauze and dressing.

Device Disposal

1. Explanted devices are not to be re-sterilized or re-implanted.
2. Explanted devices are to be disposed of per local regulatory requirements.

NALU SYSTEM IMPLANT KITS

Table 1 – Model numbers and kit components

Model No.	Description	Quantity	Model No.
71003	**Nalu IPG Kit (Ported, Single 8)**		
	IPG (Ported, Single 8, 2 cm)	1	11003-002
	Pocket Tunneller (10 cm)	1	23004
	Torque Wrench	1	23005
	IPG Insertion Tool	1	23006
71004	**Nalu IPG Kit (Ported, Dual 8)**		
	IPG (Ported, Dual 8, 2 cm)	1	11004-002
	Pocket Tunneller (10 cm)	1	23004
	Torque Wrench	1	23005
	IPG Insertion Tool	1	23006
71005	**Nalu Neurostimulation SCS Kit (Ported, Dual 8, 40 cm)**		
	IPG (Dual 8 Contact)	1	11004-002
	Lead (8 contact, 40 cm)	2	12001-040
	Anchor	2	13001
	14 GA Spoonbill Needle, 4.5" (11.4 cm)	2	23001-045
	Bent Stylet (45 cm)	2	23002-045
	Pocket Tunneller (10 cm)	1	23004
	Torque Wrench	1	23005
	IPG Insertion Tool	1	23006
71007	**PNS Single Connector PNS Kit (4 contact)**		
	IPG (Ported, Single 4, 2 cm)	1	11006-002
	Torque Wrench	1	23005
	Pocket Tunneler (10 cm)	1	23004
	IPG Insertion Tool	1	23006
72001	**SCS Lead Kit (8 contact, 40 cm)**		
	Lead (8 contact, 40 cm)	1	12001-040
	Anchor	1	13001
	14 GA Spoonbill Needle, 4.5" (11.4 cm)	1	23001-045
	Bent Stylet (45 cm)	1	23002-045
	Torque Wrench	1	23005
72002	**SCS Lead Kit (8 contact, 60 cm**)		
	Lead (8 contact, 60 cm)	1	12001-060
	Anchor	1	13001
	14 GA Spoonbill Needle, 4.5" (11.4 cm)	1	23001-045
	Bent Stylet (65 cm)	1	23002-065
	Torque Wrench	1	23005
72003	**Trial Lead Kit (8 contact, 60 cm)**		
	Trial Lead (8 contact, 60 cm, Trial)	1	12006-060
	14 GA Spoonbill Needle, 4.5” (11.4 cm)	1	23001-045
	Bent Stylet (65 cm)	1	23002-065

Model No.	Description	Quantity	Model No.
72004	**Extension 8 Kit**		
	Extension Cable (8 Contact)	1	12002-030
	Torque Wrench	1	23005
	Straw Tunneller (30 cm)	1	23007
72005	**Extension 4 PNS Kit**		
	Extension Cable (4 Contact)	1	12003-035
	Torque Wrench	1	23005
	Straw Tunneler (30 cm)	1	23007
72006	**Tined Lead PNS Kit (4 contact, 25cm)**		
	Tined Lead (4 contact, 25cm)	1	12005-025
	Tearaway Introducer (14 cm Sheath)	1	23003-060
	Straight Stylet (30 cm)	1	23012-030
72007	**Tined Lead PNS Kit (4 contact, 40cm)**		
	Tined Lead (4 contact, 40cm)	1	12005-040
	Tearaway Introducer (14 cm Sheath)	1	23003-060
	Straight Stylet (45 cm)	1	23012-045
71019	**Nalu Neurostimulation PNS Kit (Ported, Dual 8, 40 cm)**		
	IPG (Dual 8 Contact)	1	11004-002
	Lead (8 contact, 40 cm)	2	12007-040
	Anchor	2	13001
	14 GA Spoonbill Needle, 4.5" (11.4 cm)	2	23001-045
	Bent Stylet (45 cm)	2	23002-045
	Pocket Tunneller (10 cm)	1	23004
	Torque Wrench	1	23005
	IPG Insertion Tool	1	23006
72011	**PNS Lead Kit (8 contact, 40 cm)**		
	Lead (8 contact, 40 cm)	1	12007-040
	Anchor	1	13001
	14 GA Spoonbill Needle, 4.5" (11.4 cm)	1	23001-045
	Bent Stylet (45 cm)	1	23002-045
	Torque Wrench	1	23005
72012	**PNS Lead Kit (8 contact, 60 cm**)		
	Lead (8 contact, 60 cm)	1	12007-060
	Anchor	1	13001
	14 GA Spoonbill Needle, 4.5" (11.4 cm)	1	23001-045
	Bent Stylet (65 cm)	1	23002-065
	Torque Wrench	1	23005

A La Carte

Straight Stylet (30 cm)	1	23012-030
Straight Stylet (45 cm)	1	23012-045
Straight Stylet (65 cm)	1	23012-065
Bent Stylet (45 cm)	1	23012-045
14 GA Spoonbill Needle, 6" (15.2 cm)	1	23001-060
Tearaway Introducer (14 cm Sheath)	1	23003-060
Tearaway Introducer (10 cm Sheath)	1	23003-0645

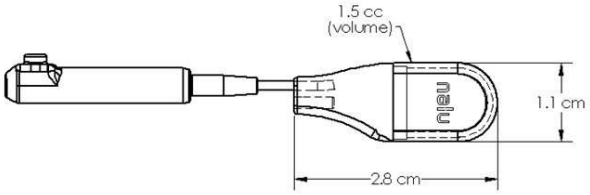
DEVICE SPECIFICATIONS

The Nalu Neurostimulation System is intended for both trial and permanent stimulation. Table 2 details the specifications of the Nalu System implants. Table 3 lists the component materials and materials in contact with human tissue for the implants and surgical accessories. Table 4 lists the radiofrequency (RF) and wireless data parameters for the device.

Table 2 – Specifications of Nalu System implants

Model No.	Description

11003-002 **Implantable Pulse Generator (Ported, Single 8)**



Pulse Generator:

Length: 2.8 cm

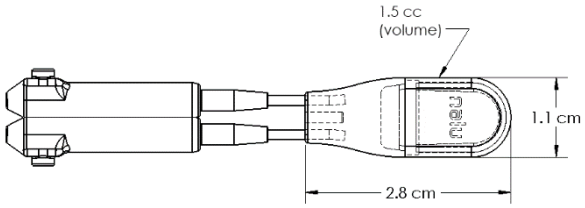
Thickness: 4.9 mm

Number of contacts: 8

Width: 1.1 cm

Volume: 1.5 cc

11004-002 **Implantable Pulse Generator (Ported, Dual 8)**



Pulse Generator:

Length: 2.8 cm

Thickness: 4.9 mm

Number of contacts: 16

Width: 1.1 cm

Volume: 1.5 cc

12001-040 **Lead (8 contact, 40 cm)** **12001-060** **Lead (8 contact, 60 cm)**

12006-060 **Trial Lead (8 contact, 60 cm, Trial)**

12007-040 **PNS Lead (8 contact, 40 cm)** **12007-060** **PNS Lead (8 contact, 60 cm)**

Stimulator(s):

Length(s): 40 cm, 60 cm

Diameter: 1.3 mm

Electrode(s):

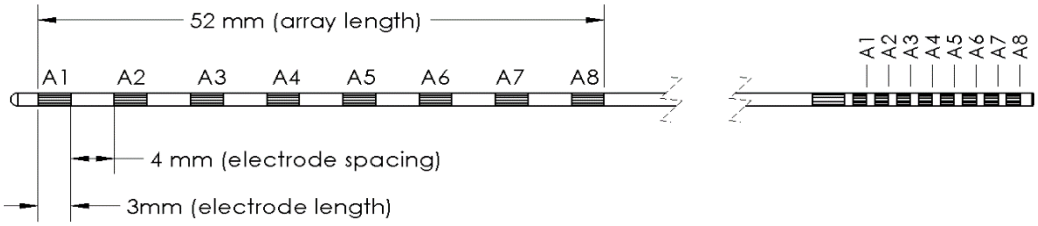
Number: 8

Shape: Cylindrical

Length: 3 mm

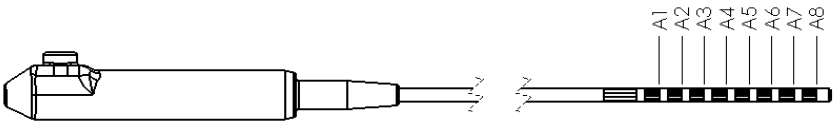
Spacing: 4 mm

Array Length: 52 mm

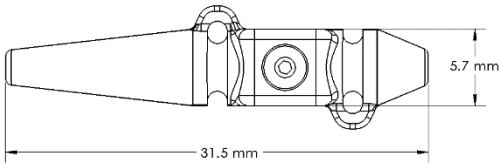


12002-030 **Lead Extension (8 contact, 30 cm)**

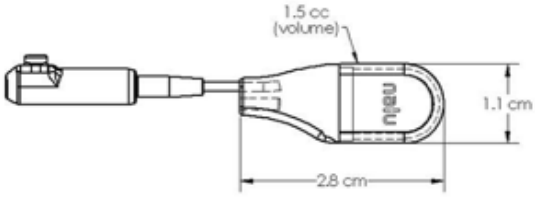
No. of contacts: 8 Length: 30 cm



Model No.	Description
13001	**Anchor**



11006-002 **Implantable Pulse Generator (Ported, Single 4)**



Pulse Generator:

Length: 2.8 cm Width: 1.1 cm

Thickness: 4.9 mm Volume: 1.5 cc

Number of contacts: 4

Model No.	Description
12005-025	**Tined Lead (4 contact, 25 cm)**
12005-040	**Tined Lead (4 contact, 40 cm)**

Stimulator(s):

Length(s): 25 cm, 40 cm

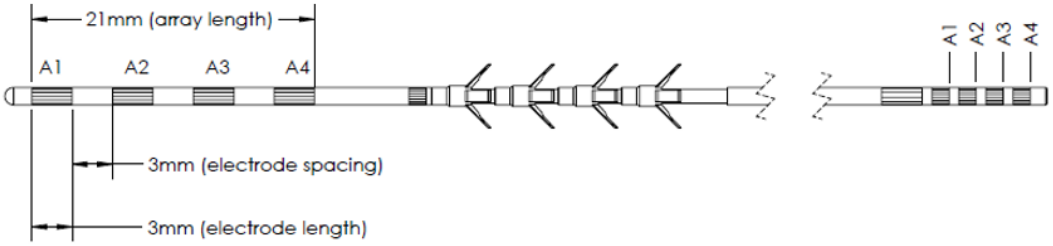
Diameter: 1.3 mm

Electrode(s):

Number: 4

Shape: Cylindrical Spacing: 3 mm

Length: 3 mm Array Length: 21 mm



12003-035 **Lead Extension (4 contact, 35 cm)**

No. of contacts: 4 Length = 35mm

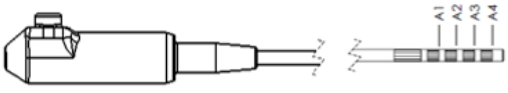


Table 3 – Materials

Component	Material	Human tissue contact (Y/N)
Nalu Implantable Pulse Generator(s)		
Enclosure (case)	Ceramic/Titanium	No
Case cover	Silicone	Yes
Lead body	Polyurethane	Yes
Contact	Platinum Alloy	Yes
Lead		
Lead body	Polyurethane	Yes
Contact	Platinum Alloy	Yes
Set screw ring	Nickel Alloy	Yes
Tine	Polyurethane	Yes
Extension		
Extension body	Polyurethane	Yes
Contact	Platinum Alloy	No
Connector boot	Silicone	Yes
Set screw ring	Nickel Alloy	Yes
Anchor		
Securement device	Titanium	Yes
Anchor covering	Silicone	Yes
Spoonbill Needle		
Needle	Stainless Steel	Yes
Needle stylet	Stainless Steel	Yes
Stylet	PolyTetraFluoroEthylene (PTFE)	
Mandrel	coated stainless steel	No
Tearaway Introducer		
Tearaway sheath	PTFE	Yes
Tuohy needle / stylet	Stainless Steel	Yes
Pocket Tunneller		
Body	Acrylonitrile butadiene styrene (ABS)	Yes
IPG Insertion Tool	Fluorinated ethylene propylene (FEP)	Yes
Shaft	Stainless Steel	Yes

Proximity to Other Wireless Products and Minimum Separation Distance

Recommended separation distances between portable and mobile radio frequency (RF) communications equipment and the Nalu Neurostimulation System			
The Nalu Neurostimulation System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Nalu Neurostimulation System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12m	0.12m	0.45 m
0.1	0.37m	0.37m	1.41 m
1	1.17m	1.17m	4.47 m
10	3.70m	3.70m	14.12 m
100	11.70m	11.70m	44.65 m

Table 4 – RF and Wireless Data Parameters

Bluetooth Low Energy (BLE) – Clinician Programmer, Remote Control, Therapy Disc
Industrial, Scientific, & Medical (ISM) – Therapy Disc, Nalu Implantable Pulse Generator

Parameter	Band	Description
Frequency	BLE	2.402-2.480 GHz (data)
	ISM	40.66-40.70 MHz (power and data transfer)
Bandwidth	BLE	2MHz
	ISM	1 MHz (low-depth amplitude modulation)
Power	BLE	4.6dBm max EIRP
	ISM	-14.1dBm max EIRP (330 mW max conducted)
Data transfer	BLE	1000-2000 kbps, 6ms latency, CRC, encryption
	ISM	250kbps, 32-bit CRC protection
Effective Range	BLE	<3 meters
	ISM	<3 cm

FCC ID	
Therapy Disc	FCC ID: 2AMB3-34001-001 Contains FCC ID: 2AAQS-ISP1507
Trail Therapy Disc	Contains FCC ID: 2AAQS-ISP1507

Classification per IEC 60601-1: Therapy Disc and Trial Therapy Disc	
In use	Type BF
Charging	Class II

GUIDANCE AND MANUFACTURER'S DECLARATION		
Electromagnetic Emissions		
The Nalu Neurostimulation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Nalu Neurostimulation System should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic Environment- Guidance**
RF Emissions 1	Group 2	The Nalu Neurostimulation System must emit electromagnetic energy in order to perform its intended function. Nearby equipment may be affected.
RF Emissions CISPR 11	Class B	The Nalu Neurostimulation 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	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
CISPR 14-1	Complies	The Therapy Disc is not intended to be connected to other equipment except the Charger. The Trial Therapy Disc is not intended to be connected to other equipment except the Electrode Interference Cable and Charger.

GUIDANCE AND MANUFACTURER'S DECLARATION			
Electromagnetic Immunity			
The Nalu Neurostimulation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Nalu Neurostimulation System should assure that it is used in such an environment			
Immunity Test	**IEC 60601 Test Level**	**Compliance**	**Electromagnetic Environment- Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of Spinal Modulation Neurostimulator System, than 0.2 meter, based on transmitters of 80 MHz to 2.5 GHz.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Interference may occur in the vicinity of equipment marked with the following symbol: 
Electrostatic discharge (ESD)	IEC 61000-4-2	± 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	Pass	Mains power quality should be that of a typical commercial or home environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth		Mains power quality should be that of a typical commercial or home environment
Voltage dips, short interruptions and voltage variations on power supply	input lines IEC 61000-4-11 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 95% dip in UT) for 5 s NOTE UT is the a.c. mains voltage prior to application of the test level.		Mains power quality should be that of a typical commercial or home environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital, or home environment.

Statement of FCC Compliance

The Nalu's Therapy Disc 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, uses, and can radiate radiofrequency 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 that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION (SCS)

All of the components of the Nalu Neurostimulation System are MR Unsafe except for the following:

- *Nalu Implantable Pulse Generators (Dual Integrated Model 11002-040, Single Integrated Model 11001-040)*
- *Nalu Implantable Pulse Generators (Dual Ported Model 11004-002 connected to two 40 cm Nalu Lead Model 12001-040, Single Ported Model 11003-002 connected to a 40 cm Nalu Lead Model 12001-040)*
- *Nalu Anchor (Model 13001).*

WARNING
Do not bring MR Unsafe components of the Nalu Neurostimulation System into the MRI system room.

It is important to read this entire section prior to conducting or recommending an MRI examination on a user implanted with the Nalu Neurostimulation System. These instructions only apply to the Nalu Neurostimulation System and do not apply to other products. If you have any questions, please contact Nalu Medical or visit www.nalumed.com.

SCS Head and Extremities scan using a transmit/receive head and extremities coil – See page 34

SCS Scan using a whole-body RF transmit coil – See page 40

PNS Head and Extremities scan using a transmit/receive head and extremities coil – See page 44

SCS Head and Extremities scan using a transmit/receive head and extremities

MRI Safety Information

MR Conditional

Nonclinical testing demonstrated that the Nalu Neurostimulation System (i.e., the pulse generator and leads) is MR Conditional. The implanted components of the Nalu Neurostimulation System that are MR Conditional are, as follows: Pulse Generators (11003-002, 11004-002), 40 cm Lead (12001-040, 12007-040) and Anchor (13001).

A patient with an implantable pulse generator, leads, and anchor can be scanned safety in an MRI system under the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3.0 T, only.
- Maximum spatial field gradient of 2,000 gauss/cm (20 T/m).
- 15 minutes of continuous scanning in First level controlled mode for Transmit-receive and extremity and head coils (Partial body SAR of the exposed body part of 10 W/kg and Head SAR of 3.2 W/kg).No external components of the Nalu Neurostimulation system are permitted the MRI system room.
- Do not perform MRI using a transmit RF body coil with a receive-only extremity coil at 3 T
- Do not perform MRI using a transmit RF body coil with a receive-only extremity coil at 1.5 T unless fully adhering to Full Body conditions (see page 40)
- For head/brain MRI examinations, only the transmit/receive RF head coil is permitted for use. **No parts of the implanted Nalu Neurostimulation System may be within the transmit/receive RF head coil.**

- For extremity MRI examinations, only use a transmit/receive RF coil that includes a knee, foot/ankle, or wrist transmit/receive RF coil. **No part of the implanted Nalu Neurostimulation System may be within one of these transmit/receive RF coils.**

Under the scan conditions defined above, the Nalu Neurostimulation System is expected to produce a maximum temperature rise of 2.5ºC after 15 minutes of continuous scanning (i.e., per pulse sequence) when using one of the above types of transmit/receive RF coils at a maximum, whole body averaged SAR of 2 W/kg.

In non-clinical testing, the image artifact caused by the Nalu Neurostimulation System extends approximately 10 mm from this implant when imaged using a gradient echo pulse sequence and a 3 T MRI system.

Important Note: An MRI examination performed outside these guidelines may result in the electromagnetic fields used with MRI technology to interact adversely with an implanted Nalu Neurostimulation System potentially injuring the patient and/or damaging the device. Due to the risks of using MRI in a patient with an active implanted device, it is important to read, understand, and comply with all instructions to prevent potential harm or injury to the patient and/or damage to the device.

Acceptable 1.5 T/64-MHz or 3 T/128 MHz MRI Scenarios

Note the position of the implantable pulse generator (IPG) and leads relative to the transmitted RF energy

for each respective transmit/receive RF coil.

Head/Brain MRI Examination

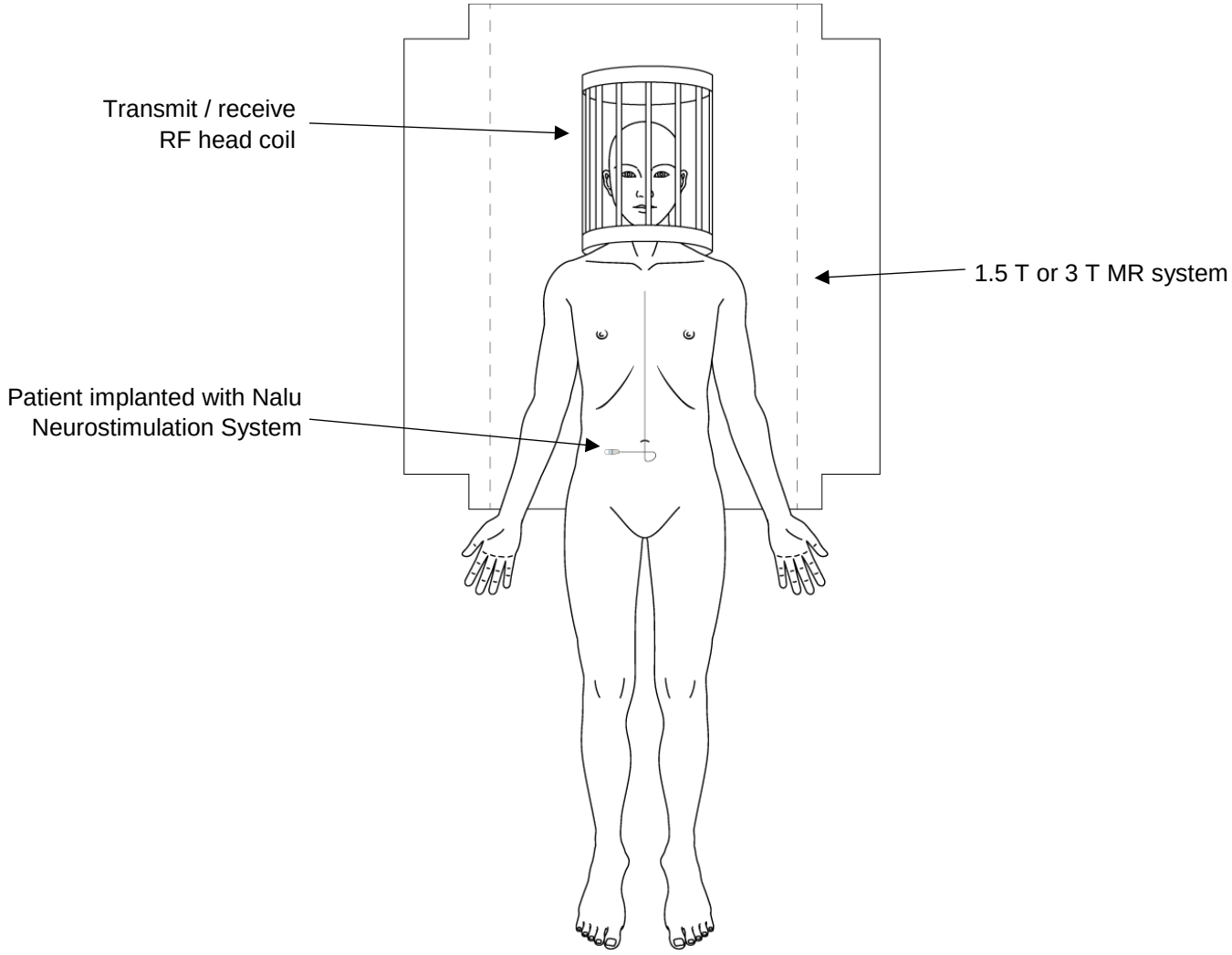


***Figure 1**. Head/brain MRI examinations are permitted using a 1.5 T or 3 T MRI system and a transmit/receive RF head coil. No part of the implanted Nalu Neurostimulation System may be within the transmit/receive RF head coil. All other aforementioned conditions must be carefully followed.*

Extremity MRI Examinations

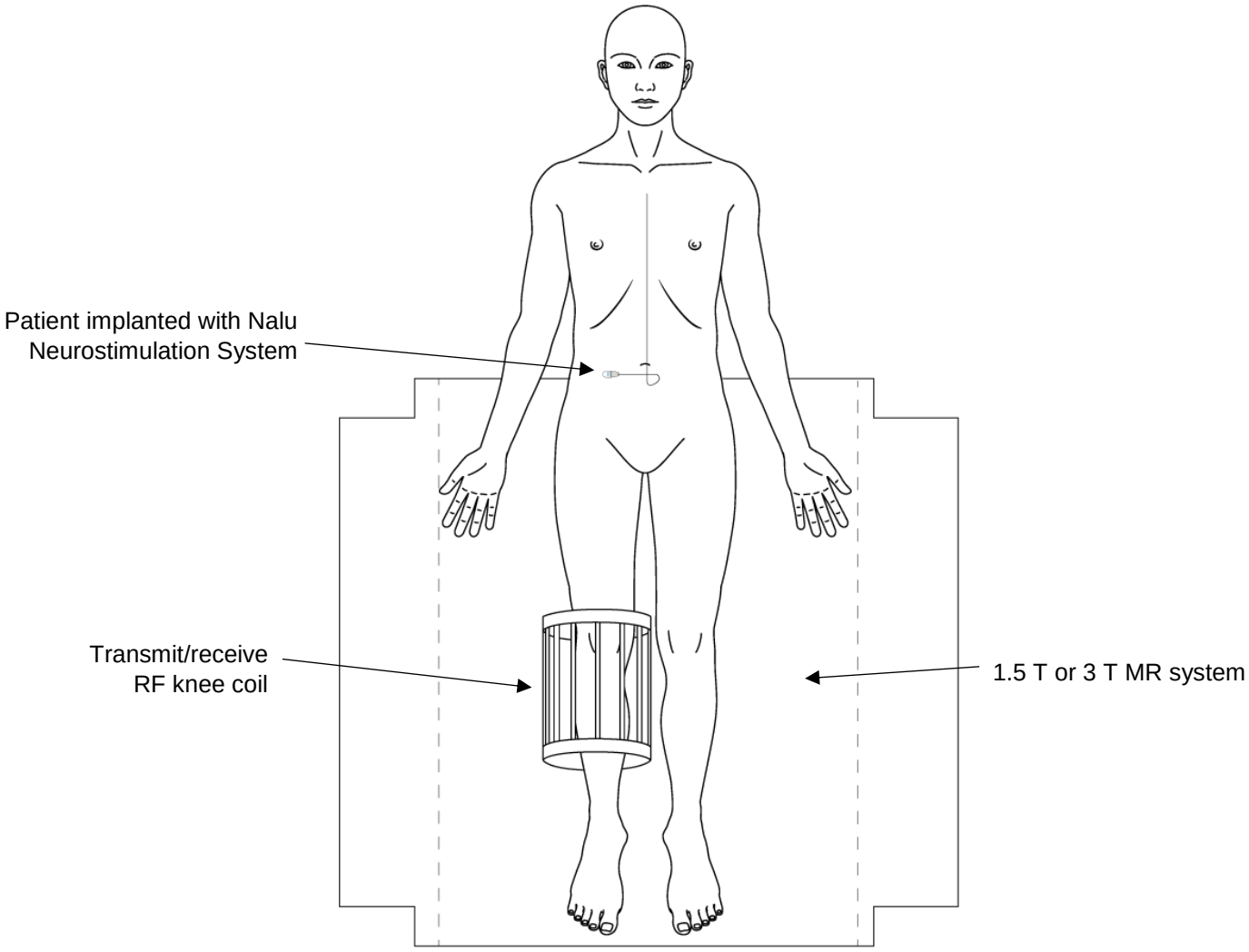


Figure 2a

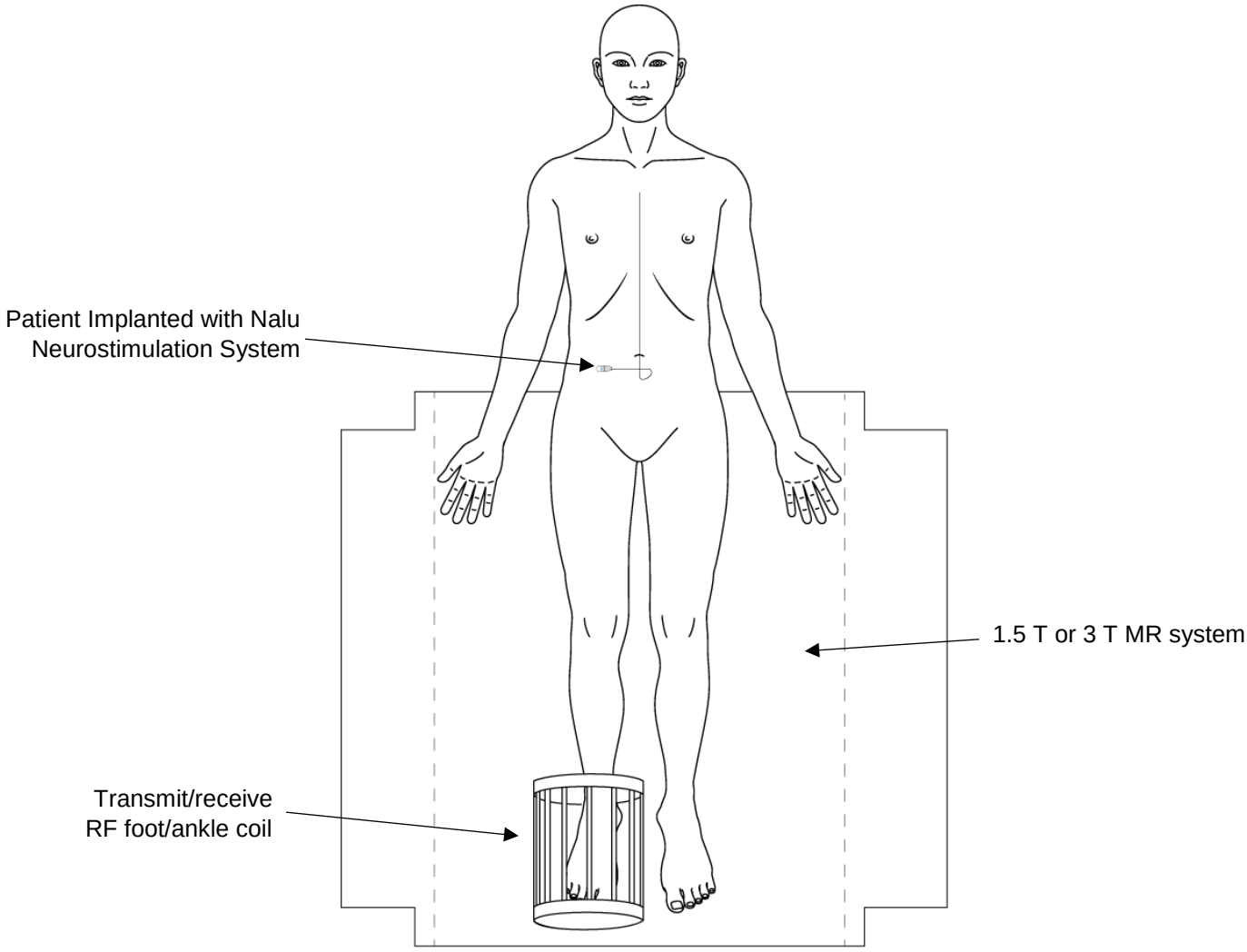

Patient Implanted with Nalu Neurostimulation System
1.5 T or 3 T MR system
Transmit/receive RF foot/ankle coil

Figure 2b

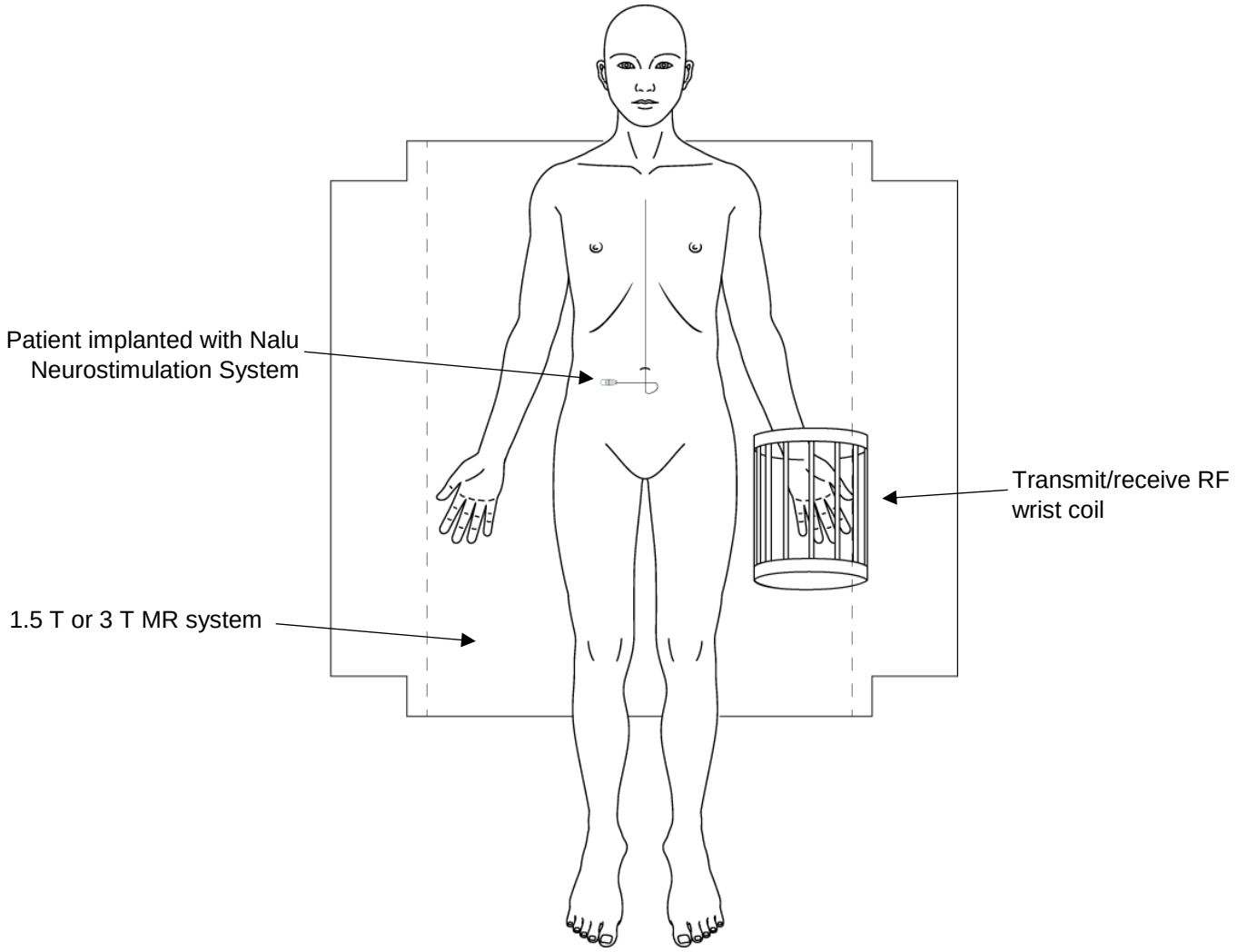


Figure 2c

Figure 2. *Extremity MRI examinations are permitted using a 1.5 T or 3 T MRI system and a transmit/receive RF extremity coil (e.g., knee, foot/ankle, wrist). No part of the implanted Nalu Neurostimulation System may be within the transmit/receive RF extremity coil. All other aforementioned conditions must be carefully followed.* ***(a)*** *Represents an MRI of the knee using a transmit/receive RF knee coil.* ***(b)*** *Represents an MRI of the foot or ankle using a transmit/receive RF foot/ankle coil. (c) Represents an MRI of wrist using a transmit/receive RF wrist coil.*

SCS Scan using a whole body RF transmit coil

MRI Safety Information

MR Conditional

Nonclinical testing demonstrated that the Nalu Neurostimulation System (i.e., the pulse generator and leads) is MR Conditional. The implanted components of the Nalu Neurostimulation System that are MR Conditional are, as follows: Pulse Generators (11001-040, 11002-040, 11003-002, 11004-002), 40 cm Lead (12001-040), and Anchor (13001). Patient has implanted a Nalu IPG laterally pocketed from the vicinity of vertebrae L2 with 40cm leads in epidural space with stimulating contacts in the vicinity of T8-T10 (per Figure 3); anchors (Model 13001) may be present.

A patient with an implantable pulse generator, leads, and anchor can be scanned safety in an MRI system under the following conditions:

- Static magnetic field of 1.5 Tesla (T).
- Maximum spatial field gradient of 2,000 gauss/cm (20 T/m).
- Up to 15-minute exposure to whole-body continuous scanning with a SAR value of 1.0 W/kg so that the temperature rise would be less than 6 degrees Celsius.No external components of the Nalu Neurostimulation system are permitted in the MRI system room.
- Patient has implanted a Nalu IPG laterally pocketed from the vicinity of vertebrae L2 with 40cm leads in epidural space with stimulating contacts in the vicinity of T8-T10 (per Figure 3); anchors (Model 13001) may be present.

Under the scan conditions defined above, the Nalu Neurostimulation System is expected to produce a maximum temperature rise of 6°C after 15 minutes of continuous scanning (i.e., per pulse sequence) when using one of the above types of transmit/receive RF coils at a maximum, whole body averaged SAR of 1.0 W/kg.

In non-clinical testing, the image artifact caused by the Nalu Neurostimulation System extends approximately 10 mm from this implant when imaged using a gradient echo pulse sequence and a 3 T MRI system.

Important Note: An MRI examination performed outside these guidelines may cause the electromagnetic fields used with MRI technology to interact adversely with an implanted Nalu Neurostimulation System potentially injuring the patient and/or damaging the device. Due to the risks of using MRI in a patient with an active implanted device, it is important to read, understand, and comply with all instructions to prevent potential harm or injury to the patient and/or damage to the device.

Acceptable MRI Scenarios for Full Body Transmit Coil Use

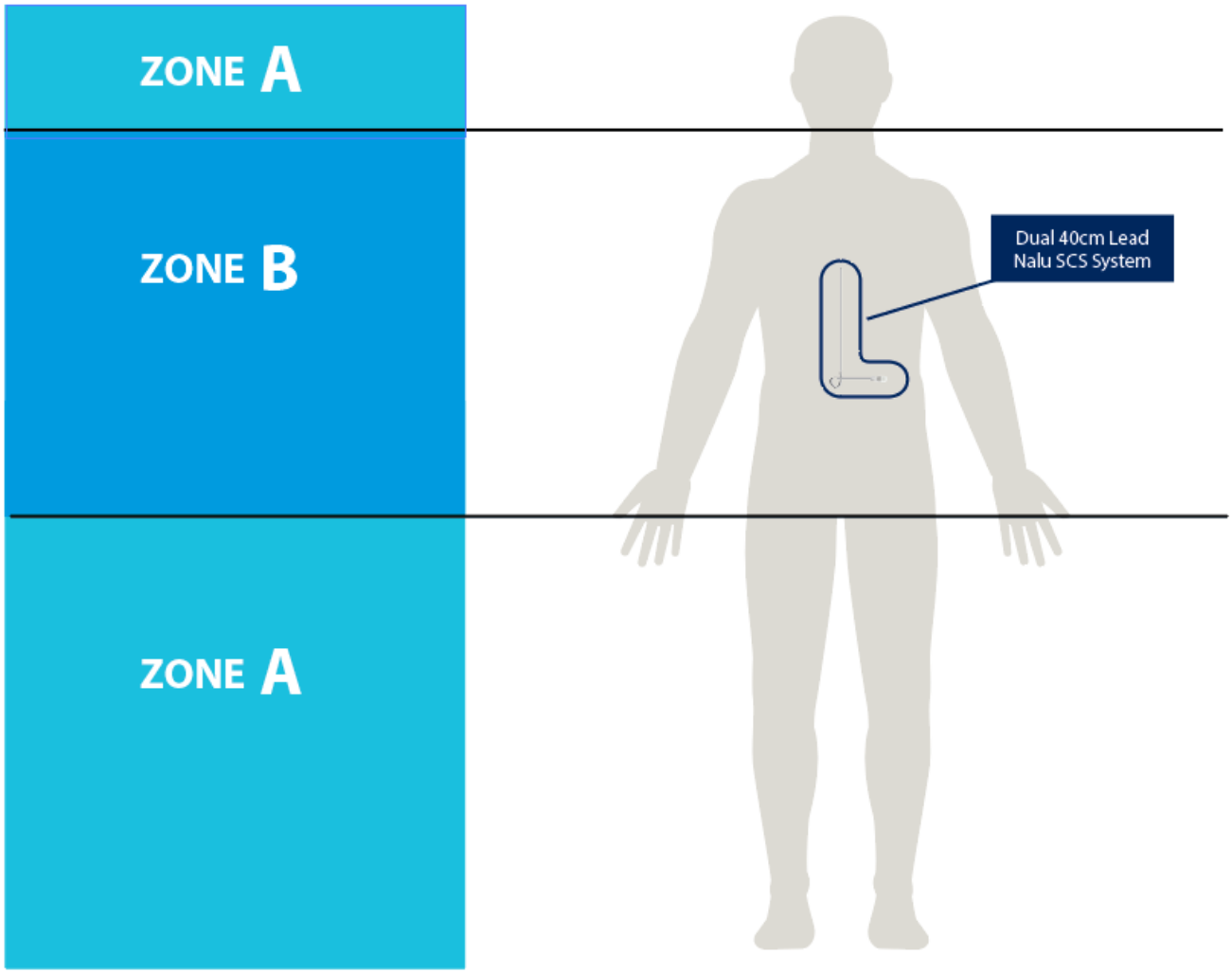
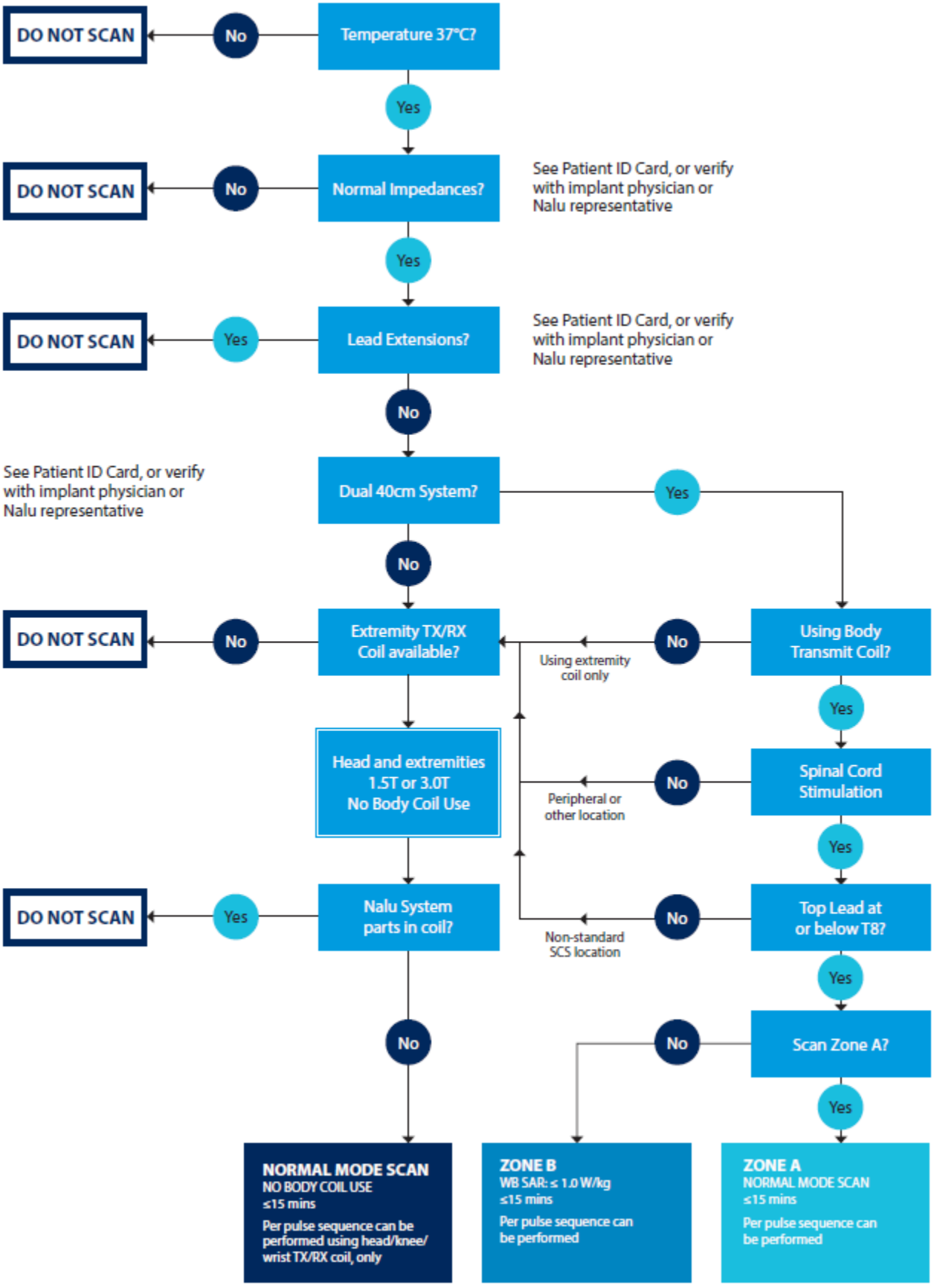


Figure 3a:

The location of the IPG in figure 3a is laterally pocketed from the vicinity of vertebrae L2 with 40cm leads in epidural space with stimulating contacts in the vicinity of T8-T10 (per Figure 3); anchors (Model 13001) may be present.

ZONE A	The center of the bore is below the bottom of the buttocks or above the bottom of the skull.	Normal operating mode (whole body average SAR ≤ 2.0 W/kg and head average SAR ≤ 3.2W/kg) can be used for scanning.
ZONE B	The center of bore is between the bottom of the skull and bottom of the buttocks.	Enforce whole body average SAR restriction of 1.0 W/kg.

Acceptable MRI Scenarios Chart



Additional conditions for all MRI Examinations

- Do not perform an MRI if the patient has a device or device component lead(s), extension, etc. attached to the Nalu Implantable Pulse Generator or leads from a different manufacturer attached to the Nalu Implantable Pulse Generator. The risk of performing an MRI examination under those circumstances has not been evaluated and, thus, may cause harm to the patient and/or the components.
- Nalu Neurostimulation System external components are not allowed in MRI system room. These components include Therapy Discs (Model 34001 or Model 34002), the iOS or Android device with the Nalu Remote Control application, Charger, Clinician Programmer and Belts, surgical instruments or accessories. All such parts are **MR Unsafe** and are not be permitted in the MRI system room.
- Do not perform MRI on a patient undergoing the trial phase of the Nalu Implantable Pulse Generator (i.e. the patient has a percutaneously implanted lead and an external Trial Therapy Disc (Model 34002).
- Do not perform MRI on a patient that has any other active medical implants.

Preparation of the Patient Prior to the MRI Examination

- Inform the patient of the risks associated with undergoing an MRI examination: an MRI exam performed outside recommended guidelines may result in the electromagnetic fields used with MRI technology interacting adversely with an implanted Nalu Neurostimulation System, potentially injuring the patient and/or damaging the device.
- A trained healthcare professional with the proper knowledge of MRI technology such as an MRI safety-trained radiologist, MRI technologist, MRI nurse, or MRI physicist must ensure that the MRI examination will be conducted according to the information presented in this document.
- Perform an impedance check. Do not perform an MRI if the impedance is greater than 10 kΩ.
- Remove the Therapy Disc from the patient before entering the MRI system room.
- Do not conduct an MRI examination if the 40 cm implanted lead(s) are not connected to the Nalu Implantable Pulse Generator.
- Do not sedate or anesthetize the patient so that the patient can inform the MRI system operator of any unusual sensations or problems associated with the MRI examination.
- Instruct the patient to immediately inform the MRI system operator if any discomfort, stimulation, shocking, or heating is experienced during MRI.

Considerations during the MRI Examination

- Similar to other MRI examinations, carefully monitor the patient throughout the MRI procedure both visually and audibly. Immediately discontinue the MRI examination if the patient reports any problems or unusual sensations.

Considerations after the MRI Examination

- After the patient leaves the MRI system room, turn the Therapy Disc on and verify connection to the Implantable Pulse Generator.
- Perform an impedance check.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION (PNS)

PNS Head and Extremities scan using a transmit/receive head and extremities

All of the components of the Nalu Neurostimulation System are MR Unsafe except for the following:

- *Nalu Implantable Pulse Generators (Dual Ported Model 11004-002 connected to two 40 cm Nalu Lead Model 12001-040 or 12007-040, Single Ported Model 11003-002 connected to a 40 cm Nalu Lead Model 12001-040 or 12007-040, Single 4-Contact Ported Model 11006-002 connected to a 25 cm Nalu Tined Lead Model 12005-025 or a 40 cm Nalu Tined Lead Model 12005-040).*
- *Nalu Anchor (Model 13001).*

WARNING
Do not bring MR Unsafe components of the Nalu Neurostimulation System into the MRI system room.

It is important to read this entire section prior to conducting or recommending an MRI examination on a user implanted with the Nalu Neurostimulation System. These instructions only apply to the Nalu Neurostimulation System and do not apply to other products. If you have any questions, please contact Nalu Medical or visit www.nalumed.com.

SCS Head and Extremities scan using a transmit/receive head and extremities coil – See page 34

SCS Scan using a whole-body RF transmit coil – See page 40

PNS Head and Extremities scan using a transmit/receive head and extremities coil – See page 44

MRI Safety Information

For Complete instructions, please visit www.nalumed.com and refer to the Nalu MRI Checklist.

MR Conditional

Nonclinical testing demonstrated that the Nalu Neurostimulation System (i.e., the pulse generator and leads) is MR Conditional. The implanted components of the Nalu Neurostimulation System that are MR Conditional are, as follows: Pulse Generators (11003-002, 11004-002, 11006-002), 40 cm Lead (12001-040, 12007-040), 25 cm Tined Lead (12005-025), 40 cm Tined Lead (12005-040) and Anchor (13001).

A patient with an implantable pulse generator, leads, and anchor can be scanned safety in an MRI system under the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3.0 T, only.
- Maximum spatial field gradient of 2,000 gauss/cm (20 T/m).
- 15 minutes of continuous scanning in First level controlled mode for Transmit-receive and extremity and head coils (Partial body SAR of the exposed body part of 10 W/kg and Head SAR of 3.2 W/kg).
- No external components of the Nalu Neurostimulation system are permitted the MRI system room.
- Do not perform MRI using the transmit/receive RF body coil of the transmit RF body coil with a receive-only coil at 1.5 T or 3 T.

- For head/brain MRI examinations, only the transmit/receive RF head coil is permitted for use. No parts of the implanted Nalu Neurostimulation System may be within the transmit/receive RF head coil.
- For extremity MRI examinations, only use a transmit/receive RF coil that includes a knee, foot/ankle, or wrist transmit/receive RF coil. **No part of the implanted Nalu Neurostimulation System may be within these transmit/receive RF coils.**

Under the scan conditions defined above, the Nalu Neurostimulation System is expected to produce a maximum temperature rise of 2.5ºC after 15 minutes of continuous scanning (i.e., per pulse sequence) when using one of the above types of transmit/receive RF coils at a maximum, whole body averaged SAR of 2 W/kg.

In non-clinical testing, the image artifact caused by the Nalu Neurostimulation System extends approximately 10 mm from this implant when imaged using a gradient echo pulse sequence and a 3 T MRI system.

Important Note: An MRI examination performed outside these guidelines may result in the electromagnetic fields used with MRI technology to interact adversely with an implanted Nalu Neurostimulation System potentially injuring the patient and/or damaging the device. Due to the risks of using MRI in a patient with an active implanted device, it is important to read, understand, and comply with all instructions to prevent potential harm or injury to the patient and/or damage to the device.

Additional conditions for all MRI Examinations

- Do not perform an MRI if the patient has a device or device component lead(s), extension, etc. attached to the Nalu Implantable Pulse Generator or leads from a different manufacturer attached to the Nalu Implantable Pulse Generator. The risk of performing an MRI examination under those circumstances has not been evaluated and, thus, may cause harm to the patient and/or the components.
- A patient implanted with a Model 12001-040 or Model 12007-040 40 cm lead(s) connected to a Model 11003-002 or Model 11004-002 Ported IPG; or a Model 12005-025 25 cm tined lead or Model 12005-040 40 cm tined lead connected to a Model 11006-002 4-Contact Ported IPG can undergo an MRI examination under the specified conditions. Do not perform an MRI if the leads have been disconnected from the IPG.
- MRI is only permitted using an MRI system operating at 1.5 T/64 MHz or 3 T/128 MHz.
- Use only a transmit/receive RF head coil or transmit/receive RF extremity coil (e.g., head/brain, knee, foot/ankle, wrist). The risk of using other types of RF coils has not been evaluated for the Nalu Neurostimulation System.
- Nalu Neurostimulation System external components are not allowed in MRI system room. These components include Therapy Discs (Model 34001 or Model 34002), the iOS or Android device with the Nalu Remote Control application, Charger, Clinician Programmer and Belts, surgical instruments or accessories. All such parts are **MR Unsafe** and are not be permitted in the MRI system room.
- Do not perform MRI on a patient undergoing the trial phase of the Nalu Implantable Pulse Generator (i.e. the patient has a percutaneously implanted lead and an external Trial Therapy Disc (Model 34002).
- Do not perform MRI on a patient that has any other active medical implants.
- **No parts of the implanted Nalu Neurostimulation System may be within the transmit/receive RF head coil.**

Preparation of the Patient Prior to the MRI Examination

- Inform the patient of the risks associated with undergoing an MRI examination: an MRI exam performed outside recommended guidelines may result in the electromagnetic fields used with MRI technology interacting adversely with an implanted Nalu Neurostimulation System, potentially injuring the patient and/or damaging the device.
- A trained healthcare professional with the proper knowledge of MRI technology such as an MRI safety-trained radiologist, MRI technologist, MRI nurse, or MRI physicist must ensure that the MRI examination will be conducted according to the information presented in this document.
- Document the patient's programming parameters.
- Perform an impedance check. Do not perform an MRI if the impedance is greater than 10 kΩ.
- Remove the Therapy Disc from the patient before entering the MRI system room.

- Do not conduct an MRI examination if the 40 cm implanted lead(s) are not connected to the Nalu Implantable Pulse Generator.
- If possible, do not sedate or anesthetize the patient so that the patient can inform the MRI system operator of any unusual sensations or problems associated with the MRI examination.
- Instruct the patient to immediately inform the MRI system operator if any discomfort, stimulation, shocking, or heating is experienced during MRI.

Considerations during the MRI Examination

- Similar to other MRI examinations, carefully monitor the patient throughout the MRI procedure both visually and audibly. Immediately discontinue the MRI examination if the patient reports any problems or unusual sensations.

Considerations after the MRI Examination

- After the patient leaves the MRI system room, turn the Therapy Disc on and verify connection to the Implantable Pulse Generator.
- Perform an impedance check.

CONTACT INFORMATION

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This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

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

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