Sacral Neuromodulation System

PNE Lead Implant Manual

Model 1901 PNE Lead

Model 1701 PNE Lead Implant Kit

Rx only

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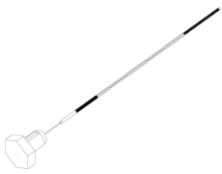
LABEL SYMBOLS

This section explains the symbols found on the product and packaging.

Symbol	Description
	Manufacturer
	Product Model Number
	Manufacturing Date
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (Notified Body reviewed) and RED 2014/53/EU (self-certified)
	Refer to instructions for use (Consult accompanying documents).
	Temperature limitation
	Humidity limitation
	Pressure limitation
	Serial number
	Lot number
	Do not reuse
	Sterilized using Ethylene oxide

	Use by
	Do not use if package is damaged
	Do not re-sterilize
EC REP	Authorized representative in the European community
	Open here
!USA Rx ONLY	For USA audiences only Caution: U.S. Federal law restricts this device for sale by or on the order of a physician
	Warning / Caution
	Product Literature
	PNE Lead

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INTRODUCTION

This manual provides information about the Axonics Sacral Neuromodulation (SNM) System PNE lead (Model 1901) and its implantation procedure. The peripheral nerve evaluation (PNE) lead is used in a basic trial with the Axonics Model 1601, external Trial Stimulator (TS). The TS is used to provide temporary electrical stimulation to the S3 or S4 sacral nerve, and this stimulation with the PNE lead is intended to not exceed 7 days.

The PNE lead connects to the Basic Trial Cable (Axonics Model 1701). This cable is then connected to the TS. The TS creates a series of electrical pulses to stimulate the sacral nerve. A set of accessories is used to implant the PNE lead. This includes procedure-specific surgical tools and stimulation cables (Axonics Model 1701) and a Clinician Programmer (CP) (Axonics Model 2501).

Instructions for connections to the TS are found in the TS manual.

Purpose of the Trial System

The Axonics SNM Trial System is used for a test period to evaluate if a subject should be treated with the Axonics SNM System.

Indications, Warnings, and Precautions

Refer to Information for Prescribers booklet for warnings, precautions, adverse events, patient selection and clinical summary.

CONTRAINDICATIONS

The Axonics SNM Trial System is contraindicated for patients who are unable to operate the Axonics SNM Trial System.

DEVICE DESCRIPTION

The Axonics PNE lead (**Figure** 1) has one cylindrical electrode area. This area is designed to be implanted adjacent to one of the sacral nerve roots (most often the third sacral nerve root).

There are also short sections of the lead that serve as markers. These markers indicate lead depth relative to the short and long foramen needles. The proximal end of the lead has a pin for insertion of the lead into the Basic Trial Cable.

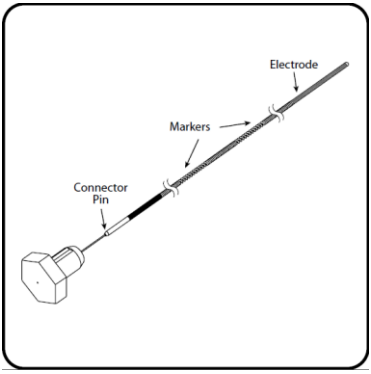

Figure 1. Axonics PNE Lead

Package contents

The **PNE Lead Kit** (Axonics Model 1701) contains the following:

- PNE lead
- Stylet (in situ)
- Needle test stimulation cable
- Short Foramen needle (x2)
- Long Foramen needle (x2)
- PNE Ground Pad and Cable
- Needle Stimulation Pad and Cable
- Basic Trial Cable
- PNE Lead Implant Manual (this document)
- PNE Lead Implant Accessories:
  - Sponge Swab Applicator Sticks
  - Ruler 6”

- Sterile Surgical Marker
- Surgical Utility Drape with Tape 15.5” x 25”
- Gauze Pads 2” x 2”
- Gauze Pads 3” x 3”
- Gauze Pads 4” x 4”
- Tegaderm 2 3/8” x 2 ¾”
- Tegaderm 4” x 4 ¾”
- Syringe 10mL
- Syringe Needle, 25 Gauge x 1.5
- Medicine Cup 2oz./60cc

- The contents of the kit (except for PNE Ground Pad and Cable, Needle Stimulation Pad and Cable, and Basic Trial Cable) are STERILE. All components are intended for single use only.

Caution:

- Sterile components should be discarded if their sterility is compromised. Check to ensure packaging is intact prior to opening. Do not clean and reuse or re-sterilize any sterile items that make contact outside a sterile field.
- Each component of the Axonics SNM System is designed for use only with the other components and accessories of the Axonics SNM System. The components and accessories of the Axonics SNM System should not be used with any other neuromodulation systems.

Storage and Usage Environment

Component packaging – Do not implant the component if any of the following have occurred:

- The storage package or sterile pack has been damaged, pierced, or altered. In this case, sterility cannot be guaranteed and infection may occur.
- The component itself shows any signs of damage. The component may not function properly.
- The use-by date has expired. In this case, component performance cannot be guaranteed.

Usage environment:

The following lists the appropriate temperature, humidity, and pressure condition for use of the Axonics components:

- Temperature (Lead and accessories): 5 °C to 40 °C
- Humidity (Lead and accessories): 15% to 95%
- Pressure (Lead and accessories): 70 kPa to 106 kPa

Shipping and Storage environment:

The following lists the appropriate temperature, humidity, and pressure condition for shipping and storage of Axonics components:

- Temperature (short term: 3 days, Lead and accessories): -25 °C to 70 °C
- Temperature (long term, Lead and accessories): 20 °C to 30 °C
- Humidity (short term: 3 days, Lead and accessories): 15% to 95%
- Humidity (long term, Lead and accessories): 15% to 95%
- Pressure (short term: 3 days, Lead and accessories): 57 kPa to 106 kPa
- Pressure (long term, Lead and

accessories): 70 kPa to 106 kPa

If the components were stored at temperatures outside of the operating range, do not use them until they have returned to the operating temperature range.

Sterilization

Contents* of this package have been sterilized using ethylene oxide. This device is for single use only and should not be re-sterilized.
*Non-sterile contents include the PNE Ground Pad and Cable, Needle Stimulation Pad and Cable, and the Basic Trial Cable.

SPECIFICATIONS

Table 1 shows the PNE lead specifications. For detailed descriptions and specifications for other components and accessories, refer to the product literature packaged with those devices.

Table 1. PNE Lead specifications

Physical Properties	
Lead length	41 cm
Number of electrodes	1
Electrode length	10 mm
Materials	
• Conductor wire	Stainless steel
• Proximal connector	Stainless steel
• Stimulating electrodes	Stainless steel
• Conductor wires Insulation	Fluoropolymer

Note: All dimensions are approximate.

PNE LEAD IMPLANT PROCEDURE

The following section describes the procedure for implanting the Axonics PNE lead.

Procedure supplies

In addition to the surgical tools required by the physician, the following supplies are needed for the implantation of the PNE lead:

- Axonics PNE Implant Kit (Model 1701).
- PNE lead (optional for bilateral lead implantation) (Model 1901).

Procedure preparation

1. Place the patient prone. Create an approximate 30° flexion at the hip and knees. Place a pillow underneath the patient abdomen/hips if necessary. This will help flatten the sacrum in the horizontal plane.
2. Prep the patient's lower back out laterally to the hips. Extend the prep down to the buttocks, perianal area and perineum for sterile surgery.

3. Administer local anesthesia in the area of the targeted sacral foramen. Inject anesthesia down to the sacrum.
4. Affix the stimulation ground pad (non-sterile) to the skin.
    a. Clean and dry skin area where ground pad is to be affixed (trimming hair from area is often helpful).
    b. Open the pouch of the ground pad.
    c. Peel the plastic packing off the ground pad.
    d. Apply ground pad to the skin area. Hold in place for 15 seconds.
    e. Insert the black plug into the CP ground (⏚) next to Needle Test Stimulation Cable (**Figure** 2).
5. Remove the needle test stimulation cable from the packaging.
6. Ensure that the stimulation amplitude on the CP is set to zero.
7. Insert the black plug of the needle test stimulation cable into the CP outside the sterile field (**Figure** 2). Keep the clip end of the cable in the sterile field.

Note: Ensure all cable connections are secure.

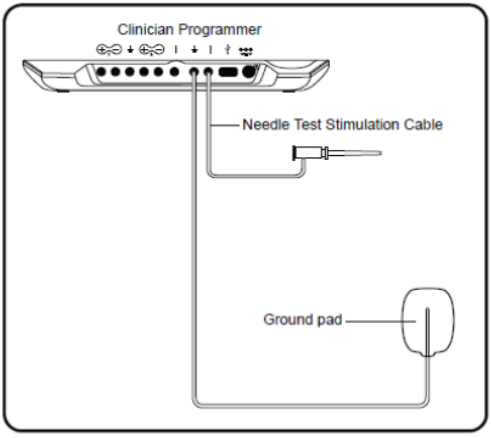

Figure 2. Clinician Programmer cable connections for the lead implant procedure.

8. Arrange sterile drapes to allow visualization

of the pelvic floor. This will help verify an appropriate motor response to stimulation.

9. Ensure that the motor response of the toes and/or soles of the feet can also be observed.

Needle placement and test stimulation

Needle placement adjacent to the sacral nerve is assisted by anatomical landmarks and/or fluoroscopy. The placement can be confirmed using test stimulation.

Note: For instructions on using the CP, refer to the Axonics Clinician Programmer Manual.

1. Using bony landmarks and/or fluoroscopy to guide placement, insert a foramen needle into the sacral foramen. Keep an approximate 60-degree insertion angle relative to the skin. The nerve lies along the superior-medial aspect of the foramen. (Figure 3)

Notes: The foramen needle has depth markings to aid in needle placement. The depth markings are 1 cm apart.

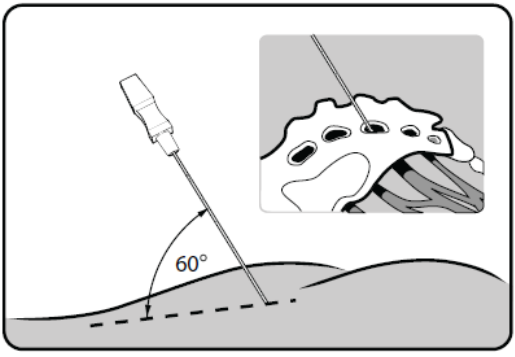

Figure 3. Insert the foramen needle at a 60-degree angle.

Caution: The number of needle insertions into the foramen and the implant depth should be limited. Stop the needle insertion at the point where the desired stimulation response usually occurs. This is usually at about 2.5 to 4.0 cm (1.0 to 1.5 in) in depth. The needle tip should be at the anterior surface of the sacral foramen for initial stimulation. A low opening threshold of less than 2 mA indicates close proximity to the nerve. This threshold should be the goal for initial needle placement.

2. Attach the clip end of the needle test stimulation cable to the non-insulated section of the foramen needle (just below hub and above the triple dash mark on the foramen needle) (**Figure** 4).

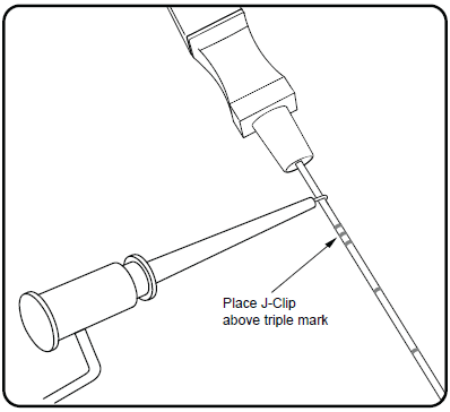

Figure 4. Connect needle test stimulation cable to the foramen needle.

3. Using the CP (outside the sterile field), gradually increase the stimulation amplitude to obtain appropriate S3 motor and/or sensory response (**Table** 2).

Table 2. Motor and sensory responses to sacral nerve stimulation

	Motor response		**Sensory response**
Nerve	**Pelvic Floor**	**Leg/Foot**	
S2	Potential clamp response (anterior-posterior contraction of the perineal structures; a clamp-like contraction of the anal sphincter, and in males, a retraction of the penis base).	Rotation of the leg/hip rotation, rotation of the heel, calf contraction.	Generally none or may have a sensation in the buttocks.
S3	Bellows (flattening and deepening of the buttock groove due to the lifting and dropping of the pelvic floor).	Flexing great toe, occasionally flexing of other toes.	Pulling in rectum, extending forward to scrotum or labia.
S4	Bellows	None	Pulling in rectum.

4. Observe the patient's motor responses to stimulation.
5. Ask the patient to describe the sensation of the stimulation. Also include the location (pelvic floor, vagina, testes, rectum/anus, bladder, scrotum, etc.) and quality (pulling, tapping, etc.) of the sensation.
6. Use the CP to reduce the stimulation amplitude to zero once appropriate responses are noted.
7. If the desired responses are not seen, reposition the needle higher and more medially in the foramen and/or change the angle of the needle as deemed appropriate. If the response is still not as desired, test at one foramen level above or below. Testing the contralateral side should also be

considered as this may also improve the response.

Note: Due to anatomical variations in nerve location, the appropriate nerve responses may be seen at different foramen levels.

8. When testing is complete, decrease the stimulation amplitude to zero and disconnect the needle test stimulation cable from the needle.

PNE lead placement

1. Remove the stylet from the foramen needle (**Figure** 5).

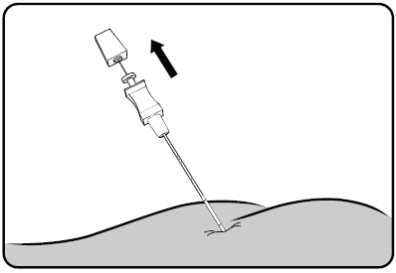

Figure 5. Remove the stylet from the foramen needle.

2. Insert the PNE lead into the foramen needle. Align the appropriate depth marker on the PNE lead with the top of the foramen needle (Figure 6). The distal electrode of the PNE lead will extend from the needle tip when the lead marker is aligned with the needle.

Note: The more distal depth marker should be used for alignment with the shorter foramen needle (9.0 cm or 3.5 in). The more proximal marker should be used with the longer foramen needle (12.5 cm or 5 in).

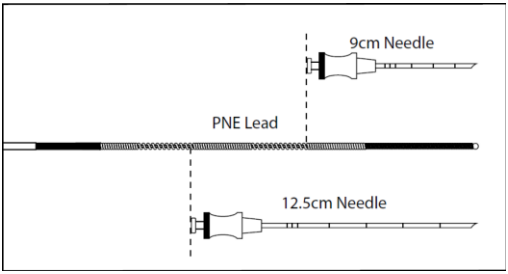

Figure 6. Insert the PNE lead until the appropriate depth marker is aligned with the hub of the foramen needle.

Caution:
Do not remove the lead stylet until the lead position has been tested and the desired response to test stimulation is observed. The lead position cannot be adjusted once the stylet is removed.

3. Attach the stim clip to the distal connector of the PNE lead.
4. Test the PNE lead placement by stimulating and observing patient motor and/or sensory responses (**Table** 2). If necessary, reposition the lead within the foramen if optimal responses are not obtained.

Caution:

Optimal motor responses should be observed intraoperatively at $\leq$ 3 mA during test stimulation of the lead. If the amplitude required to obtain a motor response is larger than 3.0 mA, the lead may not allow for optimal trial therapy. Consider repositioning the lead to achieve the desired range.

5. When the PNE lead is in the desired location, carefully withdraw the foramen needle over the PNE lead. Then remove the lead stylet with the PNE lead in place.

Cautions:

Be careful to not displace the PNE lead when removing the needle and lead stylet.

Be careful to not stretch the PNE lead while removing the stylet.

6. Reconnect the test stimulation cable to the lead. Test stimulation to confirm the lead placement.

Connecting the Basic Trial Cable

1. Place the ground pad on the lower back. Connect its cable to the ground connector on the Basic trial cable (if using the ground pad) (**Figure** 7).

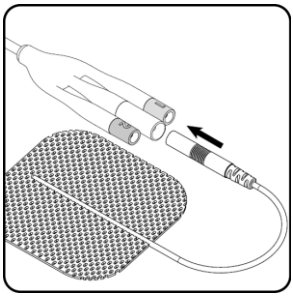

Figure 7. Insert the ground pad connector into the center, white connector of the Basic Trial Cable.

2. Connect the lead to the desired connector on the Basic Trial Cable (**Figure** 8).

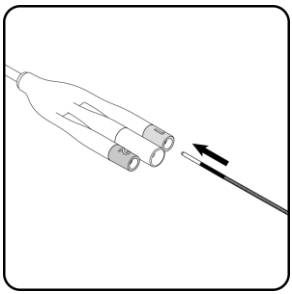

Figure 8. Insert the pin of the PNE lead into the Basic Trial Cable connector labeled “1” or “2”.

3. (optional) For a bilateral PNE trial, connect the second PNE Lead to the remaining connector of the Basic Trial Cable.

   NOTE: When programming for a bilateral PNE trial, only one lead can be an active lead (cathode) at a given time. The contralateral lead can be programmed to be inactive (if using a ground pad) or ground (anode).

4. Connect the basic trial cable to the External Trial Stimulation (**Figure** 9).

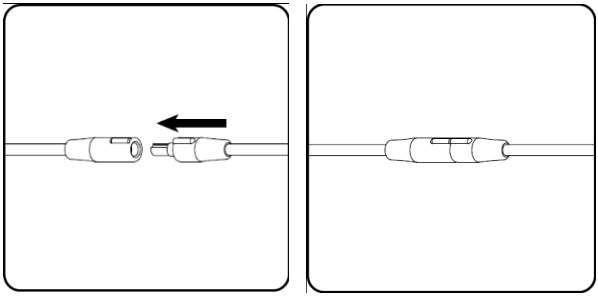

Figure 9. Align the raised grey bar on the Trial Stimulator with the raised bar on the Basic Trial Cable (left).

Note: The basic trial cable can be cleaned with sterile water or isopropyl alcohol as needed.

5. Check the impedances of the connections between the PNE lead(s), the ground pad (if present), and the TS using the Clinician Programmer. Resolve any impedance issues before proceeding.
6. Dress the PNE implant site with gauze and place gauze under the PNE connectors of the Basic Trial Cable. Coil excess length of the Basic Trial Cable to provide strain relief and minimize the unsecured cable length. Use Tegaderm to cover the PNE lead implant site and the connection to the Basic Trial Cable.

PNE lead removal

At the end of trial stimulation period, the PNE lead should be removed.

1. Turn off TS stimulation. Disconnect all cables. Refer to the TS manual for instructions on turning off the TS.
2. Gentle traction can be used to remove the lead.
3. Follow the appropriate protocol for disposal of biohazardous waste. For e.g. to dispose of the PNE lead, the trial cables, and surgical dressings.

CUSTOMER SERVICE

For questions regarding the Axonics SNM System, call our Customer Support Center toll-free at +1-877-929-6642.

Additional information and product manuals can be found at our website: www.axonics.com

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