



Sacral Neuromodulation System

Tined Lead Implant Manual

Model 1201, 2201 Tined Lead

Model 1801 Lead Implant Kit

Rx only

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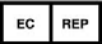








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LABEL SYMBOLS

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

Symbol	Description
	Manufacturer
	Product Model Number
	Manufacturing Date
	Conformité Européenne (European Conformity):2019. 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
	Lot number
	Do not reuse

	Sterilized using Ethylene oxide
	Use by
	Do not use if package is damaged
	Do not re-sterilize
	Authorized representative in the European community
	Open here
	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
	Curved Stylet
	Directional Guide
	Straight Stylet
	Tined Lead Test Stimulation Cable






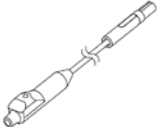

	Needle Test Stimulation Cable
	Foramen Needle
	Introducer Sheath and Dilator
	Torque Wrench
	Tunneling Tool
	Percutaneous Extension
	Magnetic Resonance (MR) Conditional

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INTRODUCTION

This manual provides information about the Axonics Sacral Neuromodulation (SNM) System tined lead (Model 1201 and 2201) and the lead implantation procedure. The tined lead can be used with the Axonics Model 1101 Neurostimulator and Model 1601 Trial Stimulator

The tined lead connects to a stimulation device, which creates a series of electrical pulses to stimulate the S3 or S4 sacral nerve. A set of accessories, including procedure-specific surgical tools, Axonics Model 1801, and stimulation cables, and a Clinician Programmer (CP) are used to implant the tined lead.

Instructions for connections to the Neurostimulator and the Trial Stimulator are found in their respective manuals.

DEVICE DESCRIPTION

The Axonics tined lead (**Figure 1**) has four cylindrical electrodes. These are designed to be implanted adjacent to one of the sacral nerve roots (most often the third sacral nerve root). All four electrodes are equal in length and spaced equidistantly along the lead.

The distal end of the lead has tines to anchor the lead in the sacrum and surrounding connective tissue. There are also markers to indicate lead depth and level of tine deployment during implantation. The proximal end of the lead has a marker to facilitate complete insertion of the lead into the Neurostimulator header. Markers B, C, and D can only be seen visually, while marker A can also be seen under fluoroscopy.

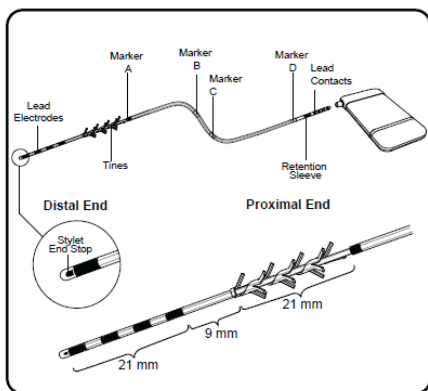


Figure 1. Axonics Tined Lead

Package contents

The **Tined Lead Kit**, Model 1201 contains the following:

- Tined lead
- Straight stylet (in situ)
- Curved stylet
- Tined lead test stimulation cable

The **Tined Lead Kit**, Model 2201 contains the following:

- Tined lead
- Straight stylet (in situ)
- Curved stylet
- Tined lead test stimulation cable
- Percutaneous extension cable

The contents of the inner packages are STERILE. The contents of the Tined Lead Kit are intended for single use only.

The **Tined Lead Implant Kit** (Axonics Model 1801) contains Lead implant tools (**Figure 2**) and Lead implant cables (**Figure 3**):

Package contents:

- Foramen needle (x2)
- Directional guide
- Introducer sheath and dilator
- Tunneling tool (including a tip and 2 sheaths)
- Torque wrench
- Needle test stimulation cable

The contents of the inner packages are STERILE. The Stimulation ground cable and pad are provided separately and are not sterile.

The contents of the Tined Lead Implant Kit are intended for single use only.

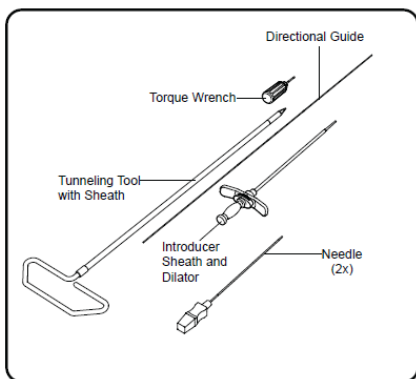


Figure 2. Lead implant tools

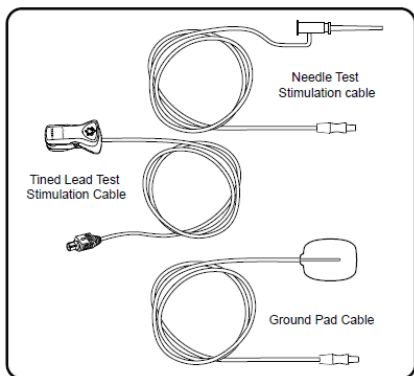


Figure 3. Lead implant cables

AXONICS SNM THERAPY FOR BOWEL CONTROL

Indications

Axonics SNM therapy for bowel control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

Contraindications

The Axonics SNM System is contraindicated for the following patients

- Patients who have not demonstrated an appropriate response to test stimulation; or
- Patients who are unable to operate the Axonics SNM System.

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. Trial stimulation with the tined lead is expected to last 14 days and should not exceed 14 days.

WARNINGS

Diathermy

Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (collectively described as diathermy) on patients implanted with the Axonics SNM System.

Diathermy can transmit energy through the implanted system. This could potentially cause tissue damage at the location of the implanted electrodes, resulting in severe injury.

Magnetic Resonance Imaging (MRI)

The implanted Axonics SNM System is an MRI **Conditional** system. Refer to the document "MRI Guidelines for the Axonics Sacral Neuromodulation System" for more information.

Warning: Patients should not undergo MRI during a trial stimulation period when using the tined lead and the Trial Stimulator.

Other Medical Procedures

Additional medical procedures that may affect the Axonics SNM System and should be avoided include:

- Lithotripsy
- Monopolar electro surgery
- Microwave and Radio-frequency (RF) ablation
- Radiation therapy over the Stimulator
- Ultrasound or scanning equipment

Electromagnetic interference (EMI)

EMI is energy that can interfere with the function of the Axonics SNM System. This energy can be generated by equipment found at home, work, or in public. The Axonics SNM System includes features that provide protection from EMI. Most electrical devices encountered in a normal day are unlikely to affect the operation of the Stimulator. While everyday electrical devices are unlikely to affect the Stimulator, there are strong sources of EMI that may temporarily affect the operation of the stimulator, including anti-theft detectors found in stores used to detect stolen merchandise. If patients encounter any of these electrical devices, they should walk as far away from the sides of the anti-theft detector when passing

through.

At the Airport, Courthouses, etc.

If patients encounter walkthrough metal detectors or security archways, they should walk-through at normal pace. These detectors should not affect the Stimulator. Hand-held security wands should be passed over the Stimulator quickly and should not affect the stimulator. Full-body security scanners (millimeter wave scanners) are used by the Transportation Security Administration (TSA) and are considered safe in patients that have a stimulator.

Additionally, patients should minimize their exposure to these devices by not lingering in the immediate area of the security systems. If patients feel poorly, they should walk away from the area and anti-theft detectors and security scanners.

Case Damage

The Stimulator contains battery chemicals that could cause severe burns if the Stimulator case were ruptured or pierced.

Effects on other implanted devices

The effect of the Axonics SNM System on the operation of other implanted devices is not known. This includes devices such as cardiac devices, other Stimulators, and implantable drug pumps. In particular, if the Axonics device is implanted close to one of these devices, they may have sensing problems and/or inappropriate device responses. Clinicians involved with both devices should investigate potential interference issues before surgery. The programming of the devices may need to be optimized to provide maximum benefit from both devices.

Stimulator interaction with implanted cardiac devices - When a patient needs both an Axonics SNM System and an implanted cardiac device, interactions between the two devices should be discussed by the patients' physicians before surgery. Such devices may include pacemakers or defibrillators. The physicians involved may include cardiologists, electrophysiologists,

urologists, and urogynecologists. To reduce potential interference, the devices should be implanted on opposite sides of the body and as far away from each other as practical.

The stimulation pulses produced by the Axonics SNM System may interact with cardiac devices that sense cardiac activity. This may lead to inappropriate behavior of the cardiac device.

PRECAUTIONS

Clinician training

Implanting clinicians should be trained on the implantation and use of the Axonics SNM System.

Prescribing clinicians should be experienced in the diagnosis and treatment of fecal incontinence and be trained on the use of the Axonics SNM System.

Use in specific populations

The safety and effectiveness of this therapy has not been established for:

- Pregnant women
- Pediatric use (patients under the age of 18)
- Patients with progressive, systemic neurological diseases
- Bilateral stimulation.

Clinician programming

Parameter adjustment – The steps below should be taken to prevent sudden stimulation changes that lead to an uncomfortable jolting or shocking feeling:

- Stimulation parameters should be changed in small increments.
- The stimulation amplitude should be allowed to ramp to full amplitude slowly.
- Before disconnecting the stimulation cable or turning the stimulation on or off, the stimulation amplitude should be decreased to 0.0 mA.

Sensitivity to stimulation – Patients who are very sensitive to stimulation, may be able to sense the telemetry signals associated with reprogramming.

Programmer interaction with a cochlear implant – Patients with cochlear implants should keep the external portion of their cochlear implant as far from the Clinician Programmer (CP) or Remote Control as possible. This will minimize unintended audible

clicks or other sounds.

Programmer interaction with flammable atmospheres – The CP is not intended to be used in the presence of a flammable gases. The consequences of using the CP in such an environment is not known.

Programmer interaction with other active implanted devices – When a patient has a Stimulator and another active implanted device the RF signal used to program any of these devices may reset or reprogram the other devices. These devices include a pacemaker, defibrillator, or another Stimulator.

Whenever the settings for these devices are changed, a clinician familiar with each device should check the program settings of each device before the patient is released (or as soon as possible). Patients should contact their physician immediately if they experience symptoms that are likely to be related to the devices or their medical condition.

Telemetry signal disruption from EMI – The Stimulator should not be programmed near equipment that may generate EMI. The equipment may interfere with the CP or Remote Control’s ability to communicate with the Stimulator. If EMI is suspected to be interrupting programming, the CP or the Remote Control and the Stimulator should be moved away from the likely source of EMI.

Interference during medical imaging – The Trial Stimulator should be turned off, disconnected, and removed prior to medical imaging (x-ray, CT). The components of the trial system may distort images or impede the ability to see certain internal structures when performing imaging tests.

Electromagnetic Interference (EMI)

Patients may encounter additional equipment that generates EMI. This equipment is unlikely to affect the Axonics SNM System if the patients follows these guidelines:

Bone growth stimulators – The external coils of bone growth stimulators should be kept at least 45 cm (18 in) away from the Axonics SNM System. Do not use a bone growth stimulator if it is not working as intended.

Dental drills and ultrasonic probes –The drill or probe should be kept 15 cm (6 in) away from the Stimulator.

The Stimulator should be turned off.

Electrolysis – The electrolysis wand should be kept at least 15 cm (6 in) away from the Stimulator. The Stimulator should be turned off.

Electromagnetic field devices – The following equipment or environments should be avoided or patients should exercise caution around:

- Antenna of citizens band (CB) radio or ham radio
- Electric arc welding equipment
- Electric induction heaters such as those used in industry to bend plastic
- Electric steel furnaces
- High-power amateur transmitters
- High-voltage areas (generally safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment
- Magnets or other equipment that generates strong magnetic fields
- Microwave communication transmitters (generally safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio transmitting towers (generally safe if outside the fenced area)

Laser procedures – The laser should not be directed at the Stimulator. The Stimulator should be turned off.

Psychotherapeutic procedures – Equipment used for psychotherapeutic procedures may induce electrical currents which may cause heating at the lead electrodes and could result in tissue damage. Equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) during psychotherapeutic procedures have not been established as safe to operate in a patient with a Stimulator. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Radiation therapy – Stimulator operation may be affected by high-radiation exposure. Sources of high-radiation should not be directed at the Stimulator. Stimulator damage due to high-radiation exposure may not be immediately evident, and exposure should be limited using appropriate measures, including shielding and adjusting the beam angle to avoid exposure to the Stimulator.

Transcutaneous electrical nerve stimulation (TENS) – TENS electrodes should not be placed in locations where the TENS current passes over any component of the Axonics SNM System. Discontinue using TENS if it starts

affecting the performance of the Axonics SNM System.

If a patient thinks that an EMI generating equipment or environment is affecting the function of their Axonics SNM System, the patient should:

1. Move away from the equipment or object.
2. Turn off the equipment or object. (if possible)
3. Use the patient Remote Control to adjust stimulation if necessary and to confirm the system is functioning appropriately.

If the patient is unable to eliminate the interference or believes the interference has altered the effectiveness of their therapy, the patient should contact their clinician.

Sources of strong EMI can result in the following:

- **Serious patient injury**, resulting from heating of the Stimulator and/or leads. This may damage the surrounding tissue.
- **System damage**, which may require surgical replacement due to change in symptom control.
- **Operational changes to the Stimulator**, causing it to turn on or off or to reset the settings, resulting in unexpected changes of stimulation and return of symptoms. Reprogramming by the clinician may be needed.

Unexpected changes in stimulation, leading to a sudden increase or change in stimulation, which may be experienced as a jolting or shocking sensation. While the sensation may be uncomfortable, the device would not be damaged nor would it cause direct injury to the patient. In rare cases, the change in stimulation may cause the patient to fall and be injured.

Patient activities

Activities requiring excessive twisting or stretching – Patient should avoid activities that may strain the implanted components of the Axonics SNM System. For example, movements that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching may cause migration or breakage of the SNM leads.

Lead breakage or migration may cause loss of stimulation, intermittent stimulation, or stimulation at the fracture site. Additional surgery may be required to replace or reposition the component. Activities that typically involve these movements include gymnastics, mountain biking, and other vigorous sports. Clinicians should ask their patients about the activities in which they participate and inform them of the need for restricted activities.

Charging use – If swelling or redness occurs near the Charger attachment site, the patient should contact their clinician before using the Charger again. Swelling or redness may indicate an infection or an allergic reaction to the Charger adhesive.

Component manipulation by patient (Twiddler’s syndrome) – Clinicians should advise patients to refrain from manipulating the Axonics SNM System through the skin. Manipulation may cause device damage, lead migration, skin erosion, or uncomfortable stimulation.

Scuba diving or hyperbaric chambers – Pressures below 10 meters (33 feet) of water (or above 200 kPa) could damage the Axonics SNM System. Diving below 10 meters (33 feet) of water or entering hyperbaric chambers above 200 kPa should be avoided. Patients should discuss the effects of high pressure with their physician before diving or using a hyperbaric chamber.

Skydiving, skiing, or hiking in the mountains – High altitudes should not affect the Neurostimulator. Nevertheless, patients should be cautious with high altitude activities. These may cause movements that may put stress on the implanted components. For example, the sudden jerk that occurs when a parachute opens while skydiving may cause lead breakage or migration. This may require surgery to remove or replace the lead.

Unexpected changes in stimulation – EMI, postural changes, and other activities may cause a perceived increase in stimulation. Some patients may find this uncomfortable (a jolting or shocking feeling). Before engaging in activities that receiving a jolt would be unsafe

for the patient or those around them, patients should lower the stimulation amplitude to the lowest setting and turn off the Stimulator. Patients should also discuss these activities with their clinician.

Showering and bathing during the trial stimulation period –

Patients should not expose the Trial Stimulator (TS) to water during the trial stimulation period. They may take sponge baths during the trial stimulation period. However patients will have to remove the TS and keep their lead implant site and their surgical dressings dry. Patients should be advised on avoiding showers and baths by their physician.

Patient programming and Remote Control

Patient access to Remote Control – Patients should carry their Remote Control with them at all times. This will allow them to adjust the stimulation amplitude and/or turn on/off the Stimulator.

Remote Control may affect other implanted devices – Patients should avoid placing the Remote Control over or near other active implanted medical devices (for example pacemaker, defibrillator and other stimulators).

Remote Control handling – To avoid damaging the Remote Control, patients should avoid immersing it in liquid and should clean it with water and a soft cloth. Patients should avoid dropping the device or mishandling it in any way that may damage it.

Remote Control use – Patients should avoid operating the Remote Control when near flammable or explosive gases.

Storage and Usage Environment

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

- The storage package or sterile pack has been damaged, pierced, or altered. In this case the sterility cannot be guaranteed, which may lead to infection.
- The component itself shows any signs of damage. The component may not function properly.
- The use-by date has expired. In this case, component sterility cannot be guaranteed and infection may occur.
- The sterile component was dropped onto a non-sterile surface. In this case, the sterility cannot be guaranteed and infection may occur.

Usage environment:

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

- Temperature (leads): 20 °C to 45 °C
- Temperature (accessories): 5 °C to 40 °C
- Humidity (accessories): 15% to 95%
- Pressure (accessories): 70 kPa to 106 kPa
- Pressure (leads): The Leads should function at up to 10 m (33 feet) underwater (200 kPa) and at altitudes up to 3000 m (10,000 feet) associated with activities like hiking and skydiving (as low as 70 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):
-10 °C to 55 °C
- Temperature (short term: 3 days, 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): 30% to 85%
- 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 are exposed to extreme temperatures, they may be permanently damaged and should not be used, even if they returned to a temperature that is within the specified operating range.

Sterilization

The contents of this package have been sterilized using ethylene oxide. This device is for single use only and should not be resterilized.

System implant

Compatibility – For proper therapy, use only Axonics SNM components. The use of non-Axonics components with the Axonics SNM System may result in damage to Axonics components, loss of stimulation, or patient injury.

Use of non-Axonics components voids Axonics warranty coverage.

Component failures – The components of the Axonics SNM System may fail at any time. The tined lead should provide at least 15 years of service, unless unexpected stress, strain, or impact causes earlier failure. Such failures, such as electrical shorts, open circuits, and insulation breaches are unpredictable. Also, the Neurostimulator battery will eventually fail to recharge.

Component handling – The components of the Axonics SNM System must be handled with extreme care. They may be damaged by excessive force or sharp instruments. Such damage can lead to intermittent stimulation or loss of stimulation altogether and may require surgery to replace. Do not use saline or other

ionic fluids at connections, which could result in a short circuit.

POTENTIAL ADVERSE EVENTS SUMMARY

Implantation and use of the Axonics SNM System incurs risk beyond those normally associated with surgery. Some risks may necessitate surgical intervention. These risks include, but are not limited to the following:

- Adverse change in voiding function (bowel and/or bladder)
- Allergic or immune system response to the implanted materials that could result in device rejections
- Change in sensation or magnitude of stimulation which has been described as uncomfortable (jolting or shocking) by some patients
- Device fracture/failure
- Device migration
- Electrical shock
- Infection
- Pain or irritation at Stimulator and/or lead site
- Seroma, hemorrhage, and/or hematoma
- Suspected lead or Neurostimulator migration or erosion
- Suspected nerve injury (including numbness)
- Suspected technical device malfunctions
- Transient electric shock or tingling
- Unintended nerve activation
- Heating or burn at Stimulator site
- Lack of efficacy
- Reoperation/Revision
- Undesirable change in pelvic function

INDIVIDUALIZATION OF

TREATMENT

Fully inform patients about the risks and benefits of SNM therapy. This includes risks of the surgical procedure, follow-up responsibilities, and self-care requirements. In order to achieve optimal benefits from the therapy, the Axonics SNM System requires a long-term commitment to post-surgical management.

Patient selection – Select the patients carefully to ensure they meet the following criteria:

- The patient is an appropriate surgical candidate. Give special consideration for the lead length, implant depth, and ability to successfully implant the lead and route the lead to the Stimulator.
- The patient can properly operate the Axonics SNM System. This includes the ability to use the Remote Control, to detect alignment of the Charger, and to understand when charging is complete.
- If the patient underwent a test stimulation period, he/she received satisfactory results.
- The patient does not have a history of sensitivity to stimulation.

PATIENT COUNSELING INFORMATION

Clinicians should provide the following:

- Information about the components of the Axonics SNM System.
- Instructions for using the Remote Control and Charge System.

Also, the clinician should provide each patient with a copy of the Axonics SNM System Patient Therapy Guide and, when appropriate, the Trial Guide.

Clinicians should also instruct their patients as follows:

- Patients should tell their healthcare professionals, including their primary

doctor and dentist, that they have a neuromodulation system. Patients should bring their Patient Therapy Guide to all medical and dental appointments. This will help resolve any questions that their healthcare profession may have regarding any precautions to take to avoid potential device problems.

- Patients should always carry their Remote Control. This will allow them to change the stimulation amplitude and/or turn the Stimulator on or off.
- Patients should always bring their Remote Control to appointments related to their Axonics SNM System, including all programming sessions.
- Patients should contact their physician if they have any unusual signs or symptoms.

COMPONENT DISPOSAL

The following steps should be taken when the Axonics SNM System is explanted (for example, due to replacement, cessation of therapy, or after patient death) or when disposing of accessories:

- If possible, the explanted component should be returned to Axonics along with completed paperwork for analysis and disposal.
- The device should not be autoclaved or exposed to ultrasonic cleaners to allow it to be analyzed by Axonics.
- Any components not returned to Axonics should be disposed of according to local regulations. Any potentially contaminated materials should be treated as biohazardous waste.

Note that in some countries, explanting a battery-operated implantable device is mandatory.



Cautions:

- Components that are explanted or that have come into contact with bodily fluids should be handled with appropriate biohazard controls. Such

components should only be returned to Axonics in packaging supplied by Axonics.

- The Neurostimulator may explode if subjected to high temperatures; therefore the Neurostimulator should not be incinerated and should be explanted before patient cremation.
 - Implantable devices should not be reused after exposure to body tissues or fluids because the sterility and functionality of these devices cannot be assured.
-

SPECIFICATIONS

Table 1 shows the Tined lead specifications. **Table 2** shows the Percutaneous Extension specifications. For detailed descriptions and specifications for other components and accessories, refer to the product literature packaged with those devices.

Table 1. Tined lead specifications

Physical and Electrical Properties

Lead length	30 cm
Lead diameter	1.3 mm
Connector	In-line
Number of electrodes	4
Electrode shape	Cylindrical
Electrode length	3 mm
Electrode spacing	3 mm
Number of conductor wires	4
Conductor resistance	135 Ohms (maximum)

Materials

• Conductor wires	35N LT
• Proximal connector	Platinum-iridium
• Stimulating electrodes	Platinum-iridium
• Tines/Anchor	Polyurethane
• Retention sleeve	MP35N
• Conductor wires Insulation	Fluoropolymer
• Jacket tubing	Polyurethane

Note: All dimensions are approximate.

Table 2. Percutaneous Extension specifications (for Model 2201 only)

<i>Physical Properties</i>	
Length	96 cm
Number of electrodes	4

Note: All dimensions are approximate.

LEAD IMPLANT PROCEDURE

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

Procedure supplies

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

- Axonics Tined Lead Kit (Model 1201 or 2201)
- Axonics Clinician Programmer (CP) (Model 1501 or 2501).

Note: When connecting the tined lead to a Trial Stimulator, use CP Model 2501. When connecting the tined lead to an implanted Neurostimulator, use CP Model 1501.

- Axonics Lead Implant Kit (Model 1801)
- Medical images from previous test or permanent lead implants to be used to inform correct lead placement (if applicable).

Procedure preparation

1. Place the patient prone with an approximate 30° flexion at the hip and knees. Place a pillow underneath the patient abdomen/hips if necessary to flatten the sacrum in the horizontal plane.
2. Prep the patient's lower back out laterally to the hips and extending the prep down to the buttocks, perianal area and perineum for sterile surgery.
3. Administer local anesthesia or general anesthesia/sedation, if applicable. **Note:** Do not use muscle relaxants or paralytic agents. Use of muscle relaxants or paralytic agents during anesthesia will diminish or eliminate muscle response to stimulation.

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.

Insert the black plug into the CP ground (⚡) next to Needle Test Stimulation Cable (**Figure 4**).

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 4**). Keep the clip end of the cable in the sterile field.
8. Remove the tined lead test stimulation cable from the packaging.
9. Insert the grey plug of the tined lead test stimulation cable into the CP outside the sterile field (**Figure 4**). Keep the clip end of the cable in the sterile field.

Note: Ensure all cable connections are secure

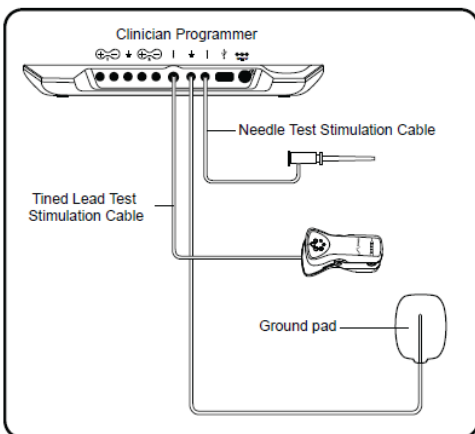


Figure 4. Clinician Programmer cable connections for the lead implant procedure.

10. Arrange sterile drapes to allow visualization of the pelvic floor to verify an appropriate motor response to stimulation.
11. 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 and 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 with an approximate 60-degree insertion angle relative to the skin.

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

2. Place the needle into the foramen at an approximate 60-degree angle to the bony surface. The nerve lies along the superior-medial aspect of the foramen. (Figure 5)

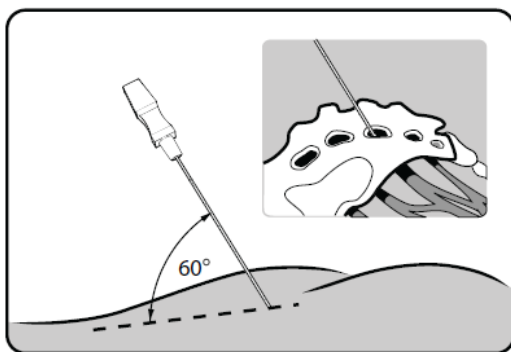


Figure 5. Insert the foramen needle at a 60-degree angle



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, usually 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 and this threshold should be the goal for initial needle placement.

3. 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 6**).

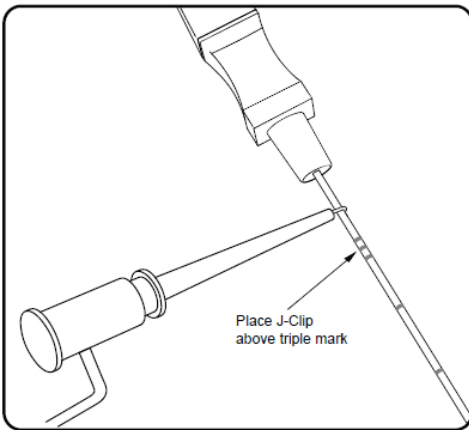


Figure 6. Connect needle test stimulation cable to the foramen needle

4. 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

Nerve	Motor response		Sensory response
	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

5. Observe the patient's motor responses to stimulation.
6. Look for the desired gross motor responses in the buttocks/perineum and leg/foot.
7. If the patient is awake, ask the patient to describe the sensation of the stimulation including the location (pelvic floor, vagina, testes, rectum/anus, bladder, scrotum, etc.) and quality (pulling, tapping, etc.) of the sensation.
8. Use the CP to reduce the stimulation amplitude to zero once appropriate responses are noted.
9. 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.

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

Tined lead placement

1. Make a small incision on the lateral side of the foramen needle (in the direction where the tunneling will occur towards the Neurostimulator pocket).
2. Remove the stylet from the foramen needle (**Figure 7**).

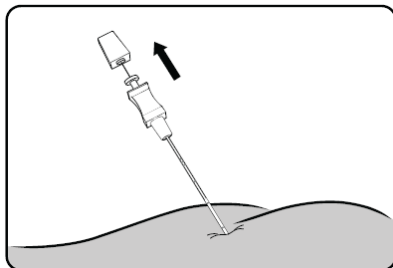


Figure 7. Remove the stylet from the foramen needle

3. Insert the directional guide into the foramen needle, aligning the appropriate depth marker on the directional guide with the top of the foramen needle (**Figure 8**).

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

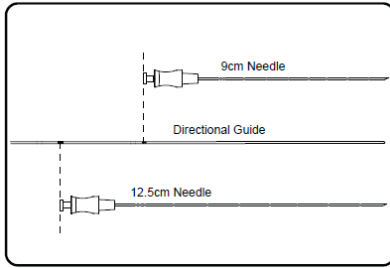


Figure 8. Insert the directional guide until the appropriate depth marker is aligned with the hub of the foramen needle

4. While keeping the directional guide in place, gently slide the foramen needle out of the foramen over the directional guide, leaving the guide in place (Figure 9).

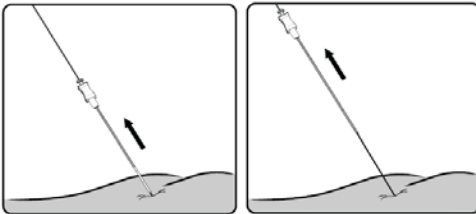


Figure 9. Remove the foramen needle

5. Hold the directional guide in place at the incision. Place the dilator and introducer sheath over the directional guide and advance them into the foramen. The third most proximal depth marker on the directional guide should be aligned with the top of the dilator (**Figure 10**). If available, confirm with fluoroscopy that the introducer sheath radiopaque marker is 1/2-2/3rd the way through the sacral plate

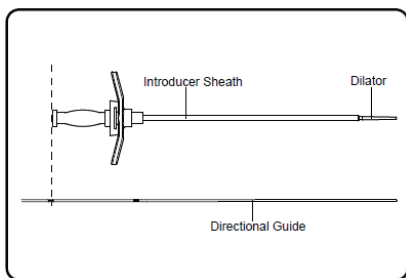


Figure 10. Align the dilator sheath hub with the appropriate mark on the directional guide

6. Rotate the dilator 90 degrees to unlock it from the introducer sheath (**Figure 11**). Being careful to leave the introducer sheath in place, remove the directional guide and dilator (**Figure 12**).

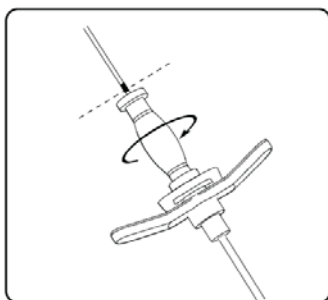


Figure 11. Unlock dilator from introducer sheath

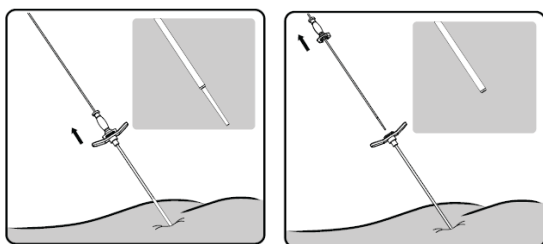


Figure 12. Remove the directional guide and dilator.

7. The tined lead is provided with the straight stylet. If desired, remove the straight stylet from the lead and replace with the curved stylet.

- Carefully insert the tined lead (with stylet) into the introducer sheath until visual marker B on the tined lead is aligned with the top of the introducer sheath handle. Confirm with fluoroscopy that all electrodes on the lead are proximal to the distal tip of the sheath (**Figure 13**).

Notes:

- Use the tined lead markers to determine at what point the tines will be deployed. Refer to Figure 1 on page 16.
- The stylet supplied is 5mm longer than the tined lead and should not be forced into the lead.
- Sterile water can be used as a lubricant if necessary to insert the tined lead into the introducer sheath.

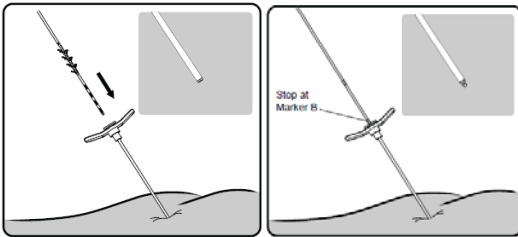


Figure 13. Insert the lead through the introducer sheath.

- Advance the lead further through the introducer sheath until visual marker C is aligned with the introducer sheath handle while holding the introducer sheath in place. Use fluoroscopy to confirm that the distal tip of the sheath is proximal to the electrodes (**Figure 14**).

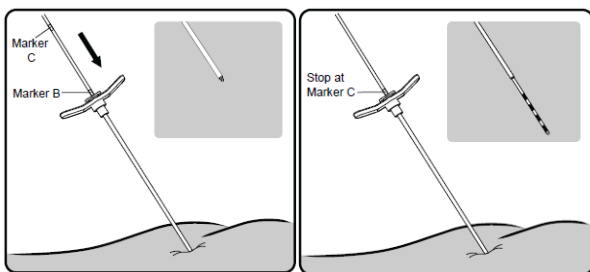


Figure 14. Advance the lead into the introducer sheath to expose the electrodes.

10. Connect the tined lead test stimulation cable to the lead (**Figure 15**). Using the CP, ensure electrical connections are made with all 4 contacts.

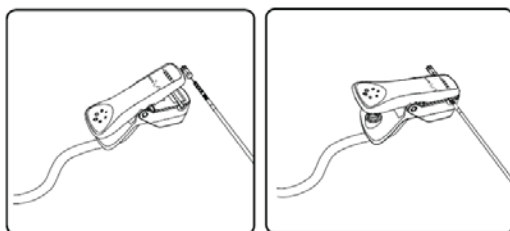


Figure 15. Connect the lead stimulation cable to the tined lead

11. Test the tined 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. If repositioning the lead using the curved stylet, retract the lead so the electrodes are in the introducer sheath before rotating the curved stylet, then reintroduce the electrodes into the tissue

Notes:

- For instructions on how to use the CP for test stimulation of the tined lead placement, refer to the Clinician Programmer Manual.
- Hold sheath and lead together when

adjusting lead position.

 **Caution:**

Optimal motor responses should be observed intraoperatively at ≤ 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 long-term therapy. Consider repositioning the lead to achieve the desired range.

12. When the tined lead is in its final location, remove the tined lead stimulation cable then carefully withdraw the introducer sheath and lead stylet under fluoroscopic guidance while holding the tined lead in place (**Figure 16**).

Note: Withdrawing the introducer sheath deploys the tines, anchoring the tined lead in place.

 **Cautions:**

Be careful to not displace the tined lead when removing the sheath and stylet.

Do not deploy the tines until the tined lead is in the correct position.

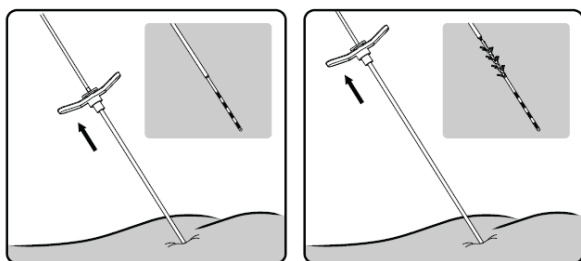


Figure 16. Grasp the tined lead to hold it in place. Withdraw the introducer sheath and lead stylet. Tines are deployed as the sheath is removed.

13. Reconnect the tined lead test stimulation cable to the lead and test stimulation with each electrode to confirm the previous responses.

Notes:

- To advance the lead after the tines are deployed, reinsert the lead stylet and gently adjust the lead position.
- To retract the lead after the tines are deployed, remove the lead completely using gentle traction and replace the lead.

Tined lead tunneling

For instructions on creating a Neurostimulator pocket, refer to the Neurostimulator Implant Manual.

1. Screw the tunneling tip to the tunneling tool and remove the tunneling tip protector. Make sure the clear tunneling sheath is in place over the tunneling tool when performing the tunneling part of the procedure.
2. If necessary, bend the tunneling tool to conform to the patient's body.
3. Create a subcutaneous tunnel from the lead to the Neurostimulator pocket.

Note: Deep tunneling is not desirable.

4. Leaving the tunneling sheath in the tunnel, remove the tunneling tool.
5. Gently insert the lead through the sheath.
6. Leaving the lead in position, gently remove the sheath from the tunnel.
7. Close the lead implant incision and dress the wound appropriately.

Connecting to the percutaneous extension (for model 2201 only)

For trial stimulation with the Trial Stimulator (model 1601), the tined lead should be connected to the percutaneous extension cable.



Cautions:

- The site where the percutaneous extension is connected should be irrigated with antibiotic solution, and it is recommended that IV antibiotics be administered perioperatively. Do not soak the percutaneous extension in antibiotic solution as this may affect lead connections.
 - The percutaneous extension has been sterilized. The percutaneous extension should not be placed on any non-sterile surface. The percutaneous extension should not be placed on skin. An infection may require surgical removal of the trial system.
-

1. The components should be wiped and dried to remove any fluids before making the connections. If necessary, use sterile water or a non-ionic antibiotic solution, then wipe dry.
-



Caution: Failure to completely dry the components could lead to undesired stimulation, intermittent stimulation, or loss of therapy.

2. Ensure that the percutaneous extension connector block is dry and clean.
3. Use the torque wrench to turn the setscrew counterclockwise to back up the setscrew. Do not remove the setscrew from the connector block (**Figure 17**)

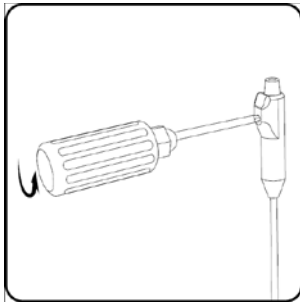


Figure 17: Use the torque wrench to turn the setscrew counterclockwise to **back up** the percutaneous extension setscrew and allow for insertion of the lead.

4. Insert the lead into the percutaneous extension connector block until fully seated and the lead cannot be inserted further. Marker D on the lead should be inside the percutaneous extension strain relief (**Figure 18**). The retention sleeve on the tined lead should be positioned under the percutaneous extension setscrew.

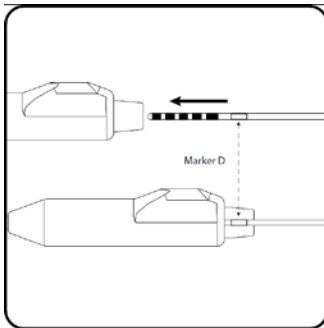


Figure 18: Insert lead fully into the Percutaneous extension connector block.



Cautions:

- Avoid pulling the lead body taut when implanted.
- Do not attempt to insert the lead into the Percutaneous extension if the setscrew is not sufficiently retracted. Doing so may cause damage to the lead and/or cause the lead to not seat fully into the connector block.
- Ensure that the setscrew tightens on the retention sleeve, not an electrode. Tightening the setscrew onto the contact could damage the

contact, leading to lack of therapy.

5. Fully insert the torque wrench into the hole of the percutaneous extension connector block. Tighten the setscrew by turning the torque wrench clockwise until it clicks (**Figure 19**).

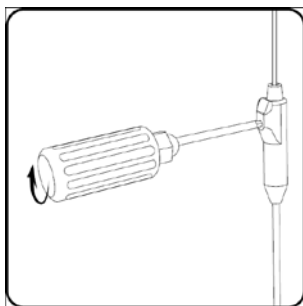


Figure 19: Secure the lead by tightening the setscrew clockwise onto the retention sleeve.



Cautions:

- Ensure that the torque wrench is fully inserted into the setscrew. Otherwise the setscrew may be damaged. This can result in intermittent or loss of stimulation.
- The torque wrench is designed for single use only and cannot be assured to work appropriately if used for multiple surgeries. Discard the torque wrench after use.

-
6. Screw the tunneling tip to the tunneling tool. Make sure the clear tunneling sheath is in place over the tunneling tool when performing the tunneling.
 7. If necessary, bend the tunneling tool to conform to the patient's body.
 8. Create a subcutaneous tunnel from the lead connection site that exits the skin at least 10 cm away from the connection site.
Note: Deep tunneling is not desirable.
 9. Leaving the tunneling sheath in the tunnel, remove the tunneling tool.
 10. Gently insert the percutaneous extension through the sheath.

Note: The stopper tube on the percutaneous extension

should be visible outside the sheath.

11. Leaving the percutaneous extension in position, gently remove the sheath from the tunnel.

Note: The stopper tube on the percutaneous extension should be outside the body.

Note: No aspect of the tined lead should be outside the body.

Note: Avoid sharp bends or kinks in the lead and percutaneous extension when positioning the connection within the pocket.

12. Close and dress the wound appropriately.
13. To connect the percutaneous extension to the Trial Stimulator refer to the Trial Stimulator manual.

Removing the Percutaneous Extension

1. Carefully open the pocket site where the percutaneous extension connects to the tined lead.
2. Fully insert the torque wrench into the hole of the percutaneous extension connector block. Loosen the setscrew by turning the torque wrench counterclockwise.

NOTE: Do not fully remove the setscrew.

3. Gently remove the lead from the percutaneous extension connector block.

NOTE: If significant resistance is encountered while removing the lead, further loosen the setscrew with the torque wrench.

Inspect the lead for any signs of damage if there was difficulty in the removal process.

4. Cut off the percutaneous extension connector block at the lead body region and discard the connector block.
5. Remove the Percutaneous extension by pulling it out from the exit site where it was previously tunneled out of the body.

Note: Do not pull the percutaneous extension out from the Neurostimulator site. Doing so will increase the risk of infection.

6. Close and dress the percutaneous extension exit site appropriately if the patient is not proceeding to a Neurostimulator implant.

Connecting to the Neurostimulator (permanent implant)

For the steps to connect the lead to the Axonics Model 1101 Neurostimulator, refer to the Neurostimulator manual.

Completing a lead implant procedure

1. Close and dress all incisions.
2. Give the patient the Remote Control and patient ID card prior to discharge.



Caution:

The patient must carry the Remote Control at all times to be able to adjust or turn off the Stimulator.

3. Complete the patient and system registration paperwork and return to Axonics.
4. Train the patient on the use of the Remote Control and, if a Neurostimulator was implanted, the Charger.
5. Schedule the patient's follow-up visits at regular intervals to ensure that the stimulation is programmed optimally.

Post-surgery treatment

Administer prophylactic antibiotics for 24 hours.

Post-surgery lead removal

At the end of the useful life of the product, all implanted components should be removed. If the tined lead needs to be removed, make a small incision at the lead insertion site. Use sharp and blunt dissection to access and release lead tines from surrounding tissue. Gentle traction can be used in conjunction with dissection to remove the lead.



Caution:

Do not use excessive force to remove the tined lead. A force larger than gentle traction may cause lead breakage. This can result in device fragments left in the patient's body.

If resistance occurs during lead removal, additional dissection may be needed to release the lead tines and remove the entire lead.

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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