PATIENT INFORMATION SHEET

This leaflet is intended to assist you in determining whether the treatment is suitable for you. Please read this leaflet carefully before you undergo this treatment. For a spare copy, please contact Axonics Inc. (contact details on page 6).

Before undergoing this treatment, you must have undergone a trial stimulation with either a temporary lead for up to 7 days, or a permanent lead for up to 14 days, and have experienced a 50% reduction in symptoms. Please contact your doctor for more information.

MR Conditions

People with an Axonics SNM System can have a full-body MRI scan under certain conditions. Your healthcare provider will determine whether you meet those conditions when you are implanted. See MRI Guidelines for patients for more information.

1.0 Device Identification

This information sheet contains important summary information about your Axonics Sacral Neuromodulation System, specifically the **implantable neurostimulator** component model number 1101. Refer to your Axonics SNM System Patient Therapy Guide for more detailed information relating to all system components.

2.0 Intended Purpose and Intended Performance

Axonics SNM therapy is intended to improve one or more of the following symptoms in patients who have failed or could not tolerate more conservative treatments;

- Urinary urgency-frequency – a sudden need to urinate that happens eight (8) or more times a day
- Urinary urge incontinence – involuntary leakage of urine with a sudden, strong need to urinate
- Urinary retention – the inability to completely empty the bladder
- Fecal or bowel incontinence – the inability to control bowel movements, causing unexpected stool (feces) leaks or frequent bowel movements

Note: This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture. The safety and effectiveness of this therapy has not been established for pregnant women, pediatric patients under the age of 18 years for fecal incontinence and under the age of 16 years for overactive bladder and urinary retention, patients with neurological disease origins, such as multiple sclerosis or diabetes, or bilateral stimulation.

3.0 Device Description

You may be eligible for an implantation with the Axonics Sacral Neurostimulator (SNM) System Neurostimulator (Model 1101), which is part of the Axonics SNM System. The Neurostimulator is a programmable device that is connected to the Axonics Tined Lead, which conducts stimulation pulses to the sacral nerve.

4.0 Safe Use of Your Device / Special Operating Instructions

Before undergoing this treatment, you must have undergone a trial stimulation. Contact your doctor to confirm.

Your doctor will implant, and if required, explant, your tined lead. Your stimulation must be on 24 hours

per day and 7 days per week. Do not turn off stimulation unless you are feeling persistent pain or are directed to do so by your doctor. Body position may affect stimulation intensity or where you feel the sensation. You may feel a small amount of stimulation, but it should not be bothersome or painful. If you are doing well and not feeling the stimulation, there is no need to increase the stimulation. However, in the first month or so, you may need to adjust stimulation levels to achieve symptom control. You do not have to feel stimulation at all times if your symptoms are controlled. If your symptoms are not improved or controlled, you should increase the level, so you feel sensation.

In the first few weeks after your procedure, limit your activities. This helps ensure that the lead remains in place and that therapy will be effective. Avoid strenuous activities with repetitive bending, twisting, bouncing, or stretching (like cycling, running, weightlifting, CrossFit, Pilates, and yoga). Do not lift heavy objects. Avoid sexual activity. A small amount of pain at the incision site is normal. Follow your doctor's instructions regarding bathing to ensure proper incision healing. Follow your doctor's instructions on when to return to work. Contact your doctor if you have increasing pain, redness, discomfort, or increased drainage from the site of your implant. When cleared by your doctor, you can go back to regular activities.

After your implantation, the doctor will train you on how to operate your neurostimulator using the Patient Remote Control and how to use the Charger provided to you. For detailed instructions, refer to the Patient Remote Control User Manual and Charging System User Manual that comes with your Patient Remote Control and Charger. Alternatively, the Patient Remote Control Manual and Charging System Manual can also be found on the Axonics website under patient resources.

Note: If you experience changed device performance and/or worsening discomfort or pain over time contact your doctor immediately.

5.0 Warnings

Once implanted with an Axonics SNM System, you should be aware that there are certain medical procedures that should not /cannot be performed. The effect of the Axonics SNM System on the operation of other implanted devices such as cardiac devices, other stimulators, and implantable drug pumps is not known. Your healthcare provider will determine those risks. Examples of prohibited medical procedures include:

Diathermy

Shortwave diathermy or microwave diathermy CANNOT be performed on patients implanted with the Axonics SNM System. Diathermy can transmit energy through the implanted system, potentially causing tissue damage at the accessory location or the implanted electrodes, resulting in severe injury.

Microwave ablation

Microwave ablation uses a thin probe that emits microwave energy to heat and destroy unwanted tissue. Microwave ablation CANNOT be performed on the Axonics SNM System as safety has not been established. Microwave ablation may interact with the Axonics SNM System, which can result in unintended tissue damage, device malfunction, or device damage.

Patients should consult their doctor prior to conducting other procedures.

Electromagnetic Interference (EMI)
Electromagnetic interference is energy generated by equipment found at home, work, or in public that can interfere with the function of the Axonics SNM System. The Axonics SNM System includes features that provide protection from EMI so that most electrical devices encountered in a normal day are unlikely to affect the operation of the Neurostimulator. While everyday electrical devices are unlikely to affect the Neurostimulator, there are strong sources of EMI that may temporarily affect the operation of your Neurostimulator, 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 a normal pace. These detectors should not affect the Neurostimulator. Hand-held security wands should be passed over the Neurostimulator quickly and should not affect the Neurostimulator. Full-body security scanners (millimeter wave scanners) are used by the Transportation Security Administration (TSA) and are considered safe in patients that have a Neurostimulator.

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

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

Effects on Other Implanted Devices
The effect of the Axonics SNM System on the operation of other implanted devices, such as cardiac devices, other Neurostimulators, and implantable drug pumps, is not known. In particular, if the Axonics device is implanted close to one of these devices, they may have sensing problems and/or inappropriate device responses. Potential interference issues should be investigated before surgery by clinicians involved with both devices. The programming of the devices may need to be optimized to provide maximum benefit from both devices.

Neurostimulator Interaction with Implanted Cardiac Devices
When a patient needs both an Axonics SNM System and an implanted cardiac device (for example, a pacemaker or defibrillator), potential interactions between the two devices should be discussed by the patients' doctors involved with both devices (such as the cardiologist, electrophysiologist, urologist, and urogynecologist) before surgery. 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, leading to inappropriate behavior of the cardiac device**.**

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.

Unauthorized Modifications
No modification of any component of the Axonics SNM System is allowed. Modification may result in more risks and hazards.

6.0 Undesirable Risks and Potential Benefits
There are risks associated with all surgically implanted devices including your tined lead. Procedural risks include, for example, fluid build-up (seroma), bleeding (hemorrhaging), bruising (hematoma), swelling, and infection. Device related risks include, for example, pain or irritation at the implant site, suspected device movement or erosion, suspected nerve injury (including numbness), unintended nerve action, suspected technical device malfunctions, heating or burning at the implant site, unwanted change in bowel and/or bladder function, allergic or immune system response to implanted material, device rejection and jolting, shocking or tingling. Surgical intervention may be required to remove your implanted tined lead. Please discuss all concerns with your doctor.

A potential benefit of your tined lead is improved control of urinary and bowel function.

7.0 Residual Risks
There are no known residual risks that could arise due to shortcoming in the protective measures implemented for your implanted tined lead.

8.0 Precautions and Other Measures to be Taken by Patient or a Health Care Professional

Activities Requiring Excessive Twisting or Stretching
After implantation, it is important that you refrain from 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 Axonics 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. Ask your doctor about the safety requirements around any activity that you participate in.

Component Manipulation by Patient (Twiddler's Syndrome)
You should refrain from manipulating the Axonics SNM System through the skin. Manipulating the device may cause damage, lead migration, skin erosion, or uncomfortable stimulation.

Scuba Diving or Hyperbaric Chambers
For implanted system: Pressures below 30 meters (100 feet) of water (or above 403 kPa, total pressure) could damage the implanted Axonics SNM System. Diving below 30 meters (100 feet) of water or entering hyperbaric chambers above 403 kPa (total pressure) should be avoided. You should discuss the effects of high pressure with your doctor before diving or using a hyperbaric chamber.
For trial system: *you should not scuba dive or use a hyperbaric chamber during your trial stimulation period.*

Skydiving, Skiing, or Hiking in the Mountains
For implanted system: High altitudes should not affect the Neurostimulator. Nevertheless, you should be cautious with high altitude activities due to the potential for 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, which may require surgery to replace or remove the lead.
For trial system: *You should not sky-dive, ski or go hiking during the trial stimulation period.*

Unexpected Changes in Stimulation
A perceived increase in stimulation may be caused by electromagnetic interference, postural changes, and other activities. You may find this uncomfortable (a jolting or shocking feeling). Before engaging in activities that receiving a jolt would be unsafe for, you or someone around you should lower the stimulation amplitude to the lowest setting and turn off the Stimulator. You should also discuss these activities with your clinician.

Showering and bathing during the trial stimulation period
You should not expose the Trial Stimulator to water during the trial stimulation period. You may take sponge baths during the trial stimulation period. However, you will have to remove the Trial Stimulator and keep your lead implant site and your surgical dressings dry. For the safety of you and the Trial Stimulator, showers and baths should be avoided for the trial stimulation period.

Device Malfunction or Damage
Device malfunction or damage is highly unlikely. If device malfunction or damage were to occur, it could cause discomfort, unintended stimulation, painful stimulation, or direct current stimulation which may result in nerve damage and other associated problems. Contact your doctor immediately for further evaluation.

Note: If you experience changed device performance and/or worsening discomfort or pain over time, contact your doctor immediately.

9.0 Regular and Preventive Examination, Monitoring and Maintenance
Your prescribing doctor will contact you for regular health checkups to ensure the system and treatment you receive are working as intended. Your neurostimulator requires recharging approximately every 6 weeks.

Note: If you experience changed device performance and/or worsening discomfort or pain over time contact your doctor immediately.

10.0 Expected Device Lifetime
The expected device lifetime of the neurostimulator is 15 years. As per sequence 4.0, you should avoid activities with repetitive bending twisting, bouncing, or stretching (like cycling, running, weightlifting, CrossFit, Pilates, and yoga). Do not lift heavy objects.

Depending on the therapy settings programmed by your doctor, the lifetime of your neurostimulator can vary. High amplitude settings will result in a shorter lifespan for the neurostimulator. Likewise, a lower amplitude setting will lengthen the neurostimulator's lifespan.

Note: If you experience changed device performance and/or worsening discomfort or pain over time contact your doctor immediately.

11.0 Materials, Substances and Manufacturing Residuals

Your neurostimulator does not contain unknown materials, substances or manufacturing residuals that could pose a risk to you. The below listed materials and/or substances come into direct contact with patient tissue. The post sterilization ethylene oxide (EO) residuals are within the permissible industry standard limits, as per ISO 10993-7.

- Titanium
- Ceramic
- Epoxy
- Silicone

12.0 Reporting Device Problems

Report all serious incidents that occur with your Axonics SNM System, including your Neurostimulator, to your doctor, to Axonics Modulation Technologies, 26 Technology Drive, Irvine CA 92618, USA, **phone** +61 1800 954 009, **e-mail** customersupport@axonics.com, and to the Therapeutic Goods Administration via https://www.tga.gov.au.

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