Axonics

Therapy Guide



Living with Axonics™ Therapy
for Bladder or Bowel Control



Congratulations!

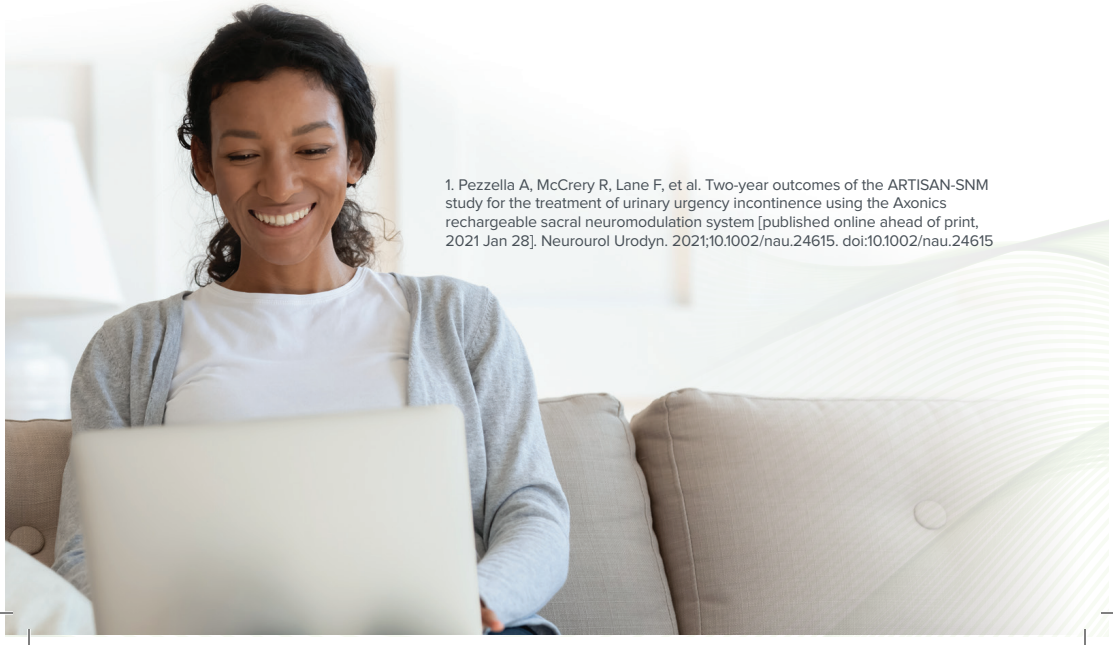
You've made the smart choice for long-lasting relief. In fact, in a recent clinical study, 94% of patients with an Axonics implant were satisfied with their therapy.[1]

You deserve the simplest therapy experience, because at Axonics, we believe relief doesn't have to be complicated.

This guide provides information on how to manage your therapy.

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1. Pezzella A, McCrery R, Lane F, et al. Two-year outcomes of the ARTISAN-SNM study for the treatment of urinary urgency incontinence using the Axonics rechargeable sacral neuromodulation system [published online ahead of print, 2021 Jan 28]. Neurourol Urodyn. 2021;10.1002/nau.24615. doi:10.1002/nau.24615

What is Axonics Therapy

Who it Helps

Sacral Neuromodulation is a therapy that can help restore normal control of the bladder and bowel. Sacral Neuromodulation is indicated as a treatment option for patients with:



Overactive Bladder



Bowel Incontinence



Urinary Retention

Note:

- Model 1101/R15 is approved for all indications listed above.
- Models 4101/F15 and 5101/R20 are only approved for Overactive Bladder and Bowel Incontinence.

The Axonics System delivers gentle stimulation to the area of the sacral nerve located near the tailbone. These mild pulses may help restore normal bladder or bowel function.

Results and experiences may vary. Stimulation may not cure your symptoms. However, most patients experience a reduction in symptoms and an improvement in their day-to-day lives.

Trialing the Therapy

If you and your doctor believe Axonics Therapy is right for you, a short test period allows you to see if the therapy provides satisfactory reduction of your symptoms.

The test period uses an EXTERNAL TRIAL SYSTEM, which consists of:

- A thin, flexible wire, called a “lead”, that is placed near the sacral nerve and connected to the External Stimulator
- A small External Stimulator that is worn discreetly against your body
- A Remote Control that allows you to easily monitor and adjust your therapy



Lead



Stimulator



Remote Control

The Test Period

It is important to take it easy during your test period. This ensures you have the best chance of having a positive outcome with the test stimulation. It is recommended to avoid activities that require excessive twisting, stretching and bending at the waist.

Examples of these activities include Yoga, cycling, running, weightlifting, CrossFit, Pilates and sexual activity. Walking during the trial period is okay.

During this period, it is recommended to not take baths or sit in a jacuzzi as it is important to keep the area around the external stimulator dry. Talk to your doctor for additional guidance.

Track Your Symptoms

You should fill out a symptom diary before and during your test period. The diary provides important information to you and your doctor to help decide if the Axonics Therapy is beneficial to you.

Dedicated Support For Your Care

You are not alone in your journey. The Boston Scientific team is available to help with any technical questions you may have about the therapy.

However, contact your doctor's office with any medical questions or concerns.

Your Axonics Implant

Relax. Relief is here.

After the test period, if you and your doctor decide Axonics Therapy is right for you, a permanent neurostimulator is implanted. Axonics offers three kinds of Neurostimulators:

- Axonics F15, recharge-free Neurostimulator, Model 4101, that provides therapy for 10 to 20 years depending on therapy settings.
- Axonics R15, rechargeable Neurostimulator, Model 1101, that provides therapy for 15 years or more depending on therapy settings.
- Axonics R20, rechargeable Neurostimulator, Model 5101, that provides therapy for 20 years or more depending on therapy settings.

The Implant

Your stimulator is connected to a thin flexible wire and implanted under your skin in your upper buttock. The procedure for the permanent implant is done in a surgery center or operating room. Your easy-to-use Remote Control allows you to monitor and manage your therapy.



Figure 1: Model 1101/5101 and Model 4101 Neurostimulators

Living with the Therapy

Your Stimulator is turned on when the procedure is completed or very soon thereafter. Feeling stimulation at all times is not required for symptom relief. However, if your symptoms are not improved or controlled, you should increase your stimulation level so that you gently feel sensation.

Stimulation should be on 24 hours per day, 7 days per week.

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. When cleared by your doctor, you can go back to regular activities.

If your therapy feels uncomfortable or painful, contact your doctor. If necessary, the doctor can change the stimulation setting. It may take more than one try by your doctor to find a stimulation setting that gives you both comfort and good symptom relief.

Occasionally, your physician may require a follow-up visit to check on your symptoms and Axonics Therapy. You should bring your Remote Control to your follow-up visits.

Device Materials

The Stimulator and Lead Materials are listed below and are tested to be biologically safe and there are no concerns with manufacturing residual materials.

Device	Material
Neurostimulators, 1101 & 5101	Titanium, Ceramic, Epoxy, Silicone
Neurostimulator, 4101	Titanium, Epoxy, Silicone
Tined Lead	Platinum-iridium, Polyurethane, MP35N, 35N LT, Fluoropolymer

Using Your Remote Control

Your Remote Control is designed with simplicity in mind. Easy-to-use and quick to connect, with Axonics Therapy, control is always within reach.

① Connect



Press the center “Connect” button.

The top lights on the remote will flash.

Your Remote Control is **connected** when the Program Light and Battery Status lights are on, as seen below.

② Check Status



Stimulation Level
The strength of your stimulation

Program Light
Indicates which program is active

Stimulator Battery Status
Days of therapy left

NOTE: After you connect your Remote Control, if your stimulation is Off, you will still see a light under Program 1.

③ Adjust Stimulation



To change your stimulation

Press: Turn up stimulation one level.
Press + Hold: Turn on stimulation (if off).

Press: Turn down stimulation one level.
Press + Hold: Turn off stimulation (if on).

Check Your Battery Status



	Axonics R15™ **Legacy Rechargeable** Model 1101	Axonics R20™ **Rechargeable** Model 5101	Axonics F15™ **Recharge-Free** Model 4101
Solid Green	4 or more days	30 or more days	Stimulator has plenty of charge
Solid Orange	2 to 4 days	7 to 30 days	Typically, several months*
Flashing Orange	2 days or less	7 days or less	Therapy will soon turn off*
Flashing Green	Stimulator is charging	Stimulator is charging	N/A

* Talk to your physician about replacing your Stimulator

Note: If you see a Red Error Light on your Remote Control, contact your doctor.



Using Your Charger

(Rechargeable Stimulators 1101 & 5101 Only)

① Connect



Plug the Power Supply into the dock and a wall outlet.



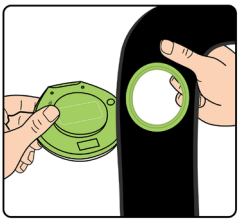
Place the Charger into the dock and charge until its light is green.

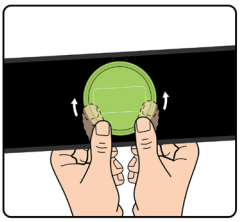


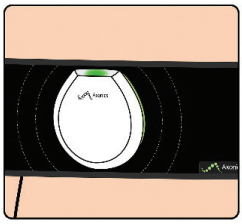
Remove the Charger from the dock when ready to charge your Stimulator.

② Use the Charger Belt

- Snap the Charger on the belt. The Axonics logo on the Charger and the logo on the belt should be on the same side.
- Strap the belt around your waist.

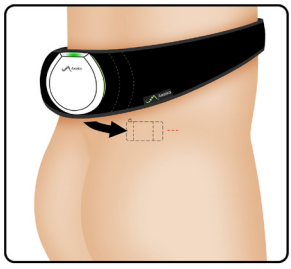


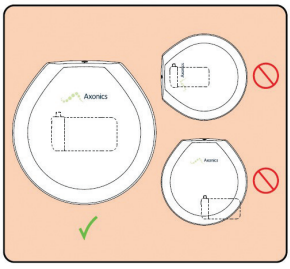




3 Align the Charger

- Hold the Charger near your Stimulator.
- You will hear one long tone when the Charger is over the Stimulator. Tighten the belt.





4 Charge

- You can perform basic tasks while charging.
- If you hear three beeps and feel the Charger vibrate, you need to realign the Charger with the Stimulator.

5 Remove the Charger

- When charging is complete, you will hear three rising tones.
- Store the belt for your next charge. Return the Charger to the dock.

Note: If you have to charge your Stimulator more often, contact your doctor to discuss the change in your Stimulator battery life.



Precautions

The safety and effectiveness of the Axonics System has not been established for:

- use in women who are pregnant or in delivery
- pediatric patients (under the age of 18 years)
- patients with neurological diseases, such as multiple sclerosis; or for bilateral stimulation

Physical Activity Precautions

It is very important to avoid activities that would affect your trial or implanted system. It is especially critical to take it easy during the test period. This will ensure you get a fair assessment of your response to the test stimulation.

For trial system, follow these precautions:

- Avoid scuba diving or use of hyperbaric chambers.
- Avoid skiing or hiking.
- A perceived increase in stimulation may be caused by electro-magnetic 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 those around you, lower the stimulation amplitude to the lowest setting and turn off the Stimulator.
- Watch for signs of infection. Call your doctor if you see any redness or swelling where your lead is implanted. Keep your lead implant site dry and clean to prevent infection.
- Keep your Stimulator dry. If you need to clean your Stimulator, use a cloth lightly dampened with water and then wipe dry with a dry cloth.
- Do not expose the test stimulation system to extreme temperatures. For example, do not place an electric blanket or heating pad near or over any part of the test stimulation system.
- DO not expose your trial system to water. Your physician should advise you on avoiding showers and baths. You may take sponge baths, but you will have to remove the trial stimulator and keep the lead implant site and surgical dressings dry.

After your test period you will be able to resume certain physical activities over time.

For permanent implant, follow these precautions:

- Avoid rubbing the implanted Stimulator through the skin and activities that require excessive or repetitive twisting, bending, bouncing or stretching. These activities can damage the implanted system resulting in loss of symptom relief and additional surgery. Examples of activities to avoid are gymnastics, mountain biking, and sky diving, skiing and other vigorious sports. Less extreme activities should not impact your system, like running, jogging, road biking, swimming, and sexual activity.
- Scuba diving below 30 meters (100 feet) of water (or above 403 kPa total pressure) entering hyperbaric chambers above 200kPa should be avoided.
- 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 those around you, lower the stimulation amplitude to the lowest setting and turn off the Stimulator.

Consult your doctor if you have any questions or concerns about physical activities.

Adverse Events

Implantation and use of the Axonics System incurs risks beyond those normally associated with surgery, some of which may necessitate surgical intervention. These risks include, but are not limited to adverse change in voiding function (bowel and/or bladder), infection, pain or irritation at the implant site, lead or device migration, electrical shock, change in sensation or magnitude of stimulation which has been described as uncomfortable (jolting or shocking) by some patients, and heating or burns at the device site.

Results and experiences may vary and are unique to each patient. No promise or guarantee is made about specific results or experiences. Talk to your doctor about whether the Axonics System is right for you and to discuss the potential risks and benefits.

For more information about safety and potential risks, go to: **www.axonics.com/isi**

Adverse Event Reporting

In case of any serious incident related to the product, please report to Axonics **(+61 1800 954 009)** as well as Therapeutic Goods Administration's at: **www.tga.gov.au**

Patient Implant Card

You will be given a patient implant card that contains basic information about you and your System. Your patient implant card shows that you have an implanted Stimulator if you have an emergency.

If you lose your patient implant card, please contact Axonics for a new card.

You're not alone on your journey. Boston Scientific is committed to supporting you at every stage of your therapy journey.

Local Support Team

Once your procedure has been scheduled by your doctor, you're welcome to contact your local Boston Scientific representative for any questions related to your therapy. For any medical concerns or clinical advice, please reach out directly to your doctor's office.

Boston Scientific patient assistance line: 0483 911 810

IMPORTANT SAFETY INFORMATION:

Indications (for Model 1101):

Axonics SNM Therapy for urinary control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence (leakage) and significant symptoms of urgency-frequency, either alone or in combination, in patients who have failed or could not tolerate more conservative treatments. Axonics SNM Therapy for bowel control is indicated for the treatment of chronic fecal incontinence. The therapy should only be used in patients who have failed or are not candidates for more conservative treatments.

Indications (for Models 4101 & 5101):

Axonics SNM Therapy for urinary control is indicated for the treatment of the symptoms of overactive bladder, including urinary urge incontinence (leakage) and significant symptoms of urgency-frequency, either alone or in combination, in patients who have failed or could not tolerate more conservative treatments. Axonics SNM Therapy for bowel control is indicated for the treatment of chronic fecal incontinence. The therapy should only be used in patients who have failed or are not candidates for more conservative treatments.

Contraindications

The Axonics SNM System is contraindicated for patients who have not demonstrated an appropriate response to test stimulation or patients who are unable to operate the Axonics SNM System.

Warning

This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

Talk to your doctor about whether the Axonics System is right for you and to discuss the potential risks and benefits.

For more information about safety and potential risks, refer to Information for Prescribers and Patients at **www.axonics.com/eIFU**.

Caution

This device is required to be sold and used by, or on the order of, a physician only. Indications, contraindications, warnings, and instructions for use can be found at **www.Axonics.com/eIFU**

Experience the Difference.

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