

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

Visual learner?

We've got videos for you.

For a quick introduction to Axonics Therapy, visit intro.axonics.com

For videos on how to manage your Axonics Therapy, visit howto.axonics.com

How to:

- Use the Remote Control
- Change your Stimulation Program during the Trial period
- Use the Charging System
(for a Rechargeable Stimulator Only)

Just point the camera on your mobile device to this code to watch the videos



howto.axonics.com



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

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.

Trial 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



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 Axonics 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.

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.



Living with the Therapy

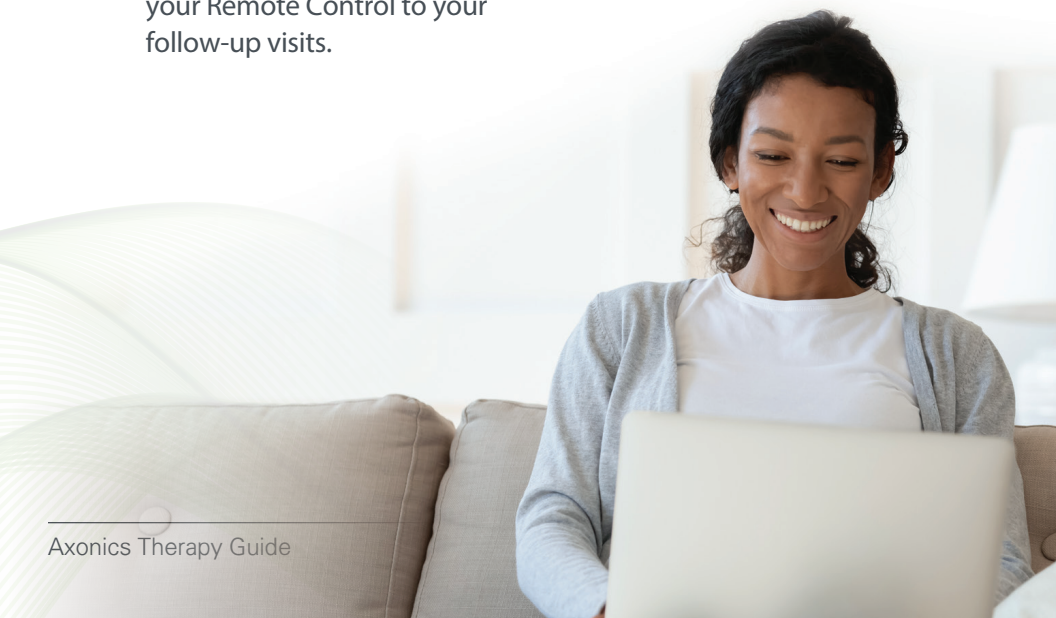
Your Stimulator is turned on when the procedure is completed or very soon thereafter. Feeling stimulation at all times is not required for symptom relief. However, if your symptoms are not improved or controlled, you should increase your stimulation level so that you gently feel sensation.

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.



Using Your Remote

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



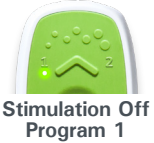
Stimulation Level
The strength of your stimulation

Program Light
Indicates which program is active

Stimulator Battery Status
Time of therapy left



Stimulation On
Level 3, Program 1



Stimulation Off
Program 1

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)

Stimulator Battery Status Light

Trial Stimulator & Rechargeable Stimulator:



Solid green:

Stimulator battery will last 4 or more days

Flashing green (Rechargeable only):

Stimulator battery is charging



Solid orange:

Stimulator battery will last 2 to 4 days

Flashing orange:

Stimulator battery will last 2 days or less

Recharge-Free Stimulator:



Solid green: Stimulator battery level is not low



Solid orange:

Stimulator battery level is low.

The battery may provide therapy for several months before the system shuts off.

(Talk to your doctor about replacing your Stimulator)

Flashing orange:

Stimulator battery level is very low. Your therapy will turn off soon, possibly within a few months.

(Talk to your doctor about replacing your Stimulator)

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



Using your Charger

(Rechargeable Stimulator 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

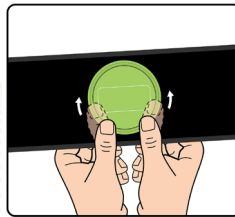
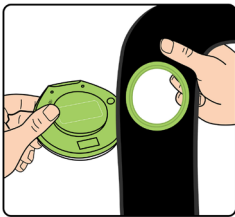


Remove the Charger from the dock when ready to charge your Stimulator

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.

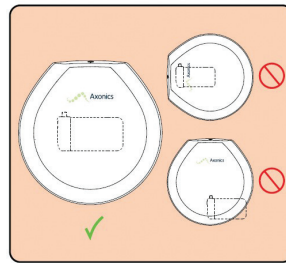
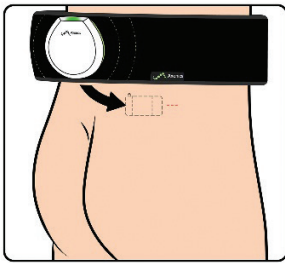
Strap the belt around your waist.



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.



Patient Identification Card

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

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

Axonics is here to support you

Questions? Give us a call. We're here in Irvine, CA (USA) and happy to help to answer questions about your Axonics Therapy.

+ 1-877-929-6642

Hours: M-F, 6:00am – 6:00pm (Pacific Time)

Please note that Axonics can only answer technical questions about your therapy and cannot talk about your medical conditions.

Contact your doctor if you have questions about your health or medical conditions.

IMPORTANT SAFETY INFORMATION:

Indications:

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.

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.

Warnings:

This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture. Implantation and use of the Axonics System incurs risk 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.

Precautions:

The safety and effectiveness of the Axonics System has not been established for use in women who are pregnant or in delivery; for pediatric patients (under the age of 18 years for fecal incontinence and under the age of 16 years for overactive bladder and urinary retention); for patients with neurological disease origins, such as multiple sclerosis or diabetes, or for bilateral stimulation.

Caution:

U.S. federal law restricts this device to sale and use by, or on the order of, a physician.



Experience the Difference.
EXPERIENCE AXONICS.®

Axonics, Inc.

26 Technology Drive
Irvine, CA 92618 (USA)
Tel: +1-877-929-6642
Fax: +1-949 396-6321

www.axonics.com

