

# Therapy Guide



**Living with Axonics® Therapy**  
for Bladder Control

**AxonicsR20™**



# 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.<sup>1</sup>

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.



## What's inside this guide?

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What is Axonics Therapy?.....	5
Trialling the Therapy.....	6
Your Axonics Implant.....	8
Living with the Therapy .....	9
Using your Remote Control.....	10
Using your Charger .....	12
Important Safety Information .....	14
Patient Identification Card .....	17

# Visual learner?

## We've got videos for you.

For a quick introduction to Axonics Therapy, visit:

**[intro.axonics.com](https://intro.axonics.com)**

For videos on how to manage your Axonics Therapy, visit:

**[howto.axonics.com](https://howto.axonics.com)**

### How to:

- Use the Remote Control
- Change your Stimulation Program during the Trial
- 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](https://howto.axonics.com)**



# What is Axonics Therapy?

## Who it Helps

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



### Overactive Bladder

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 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.

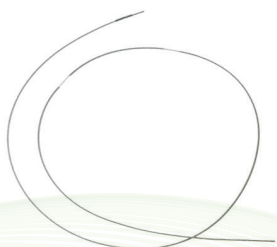


# Trialling the Therapy

If you and your doctor believe Axonics Therapy is right for you, a short test period allows you both to see if the therapy provides a 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

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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, weight-lifting, 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

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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

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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.

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After the test period, if you and your doctor decide Axonics Therapy is right for you, a permanent neurostimulator is implanted.

## The Implant

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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 centre or operating room. Your easy-to-use Remote Control allows you to monitor and manage your therapy.





# Living with the Therapy

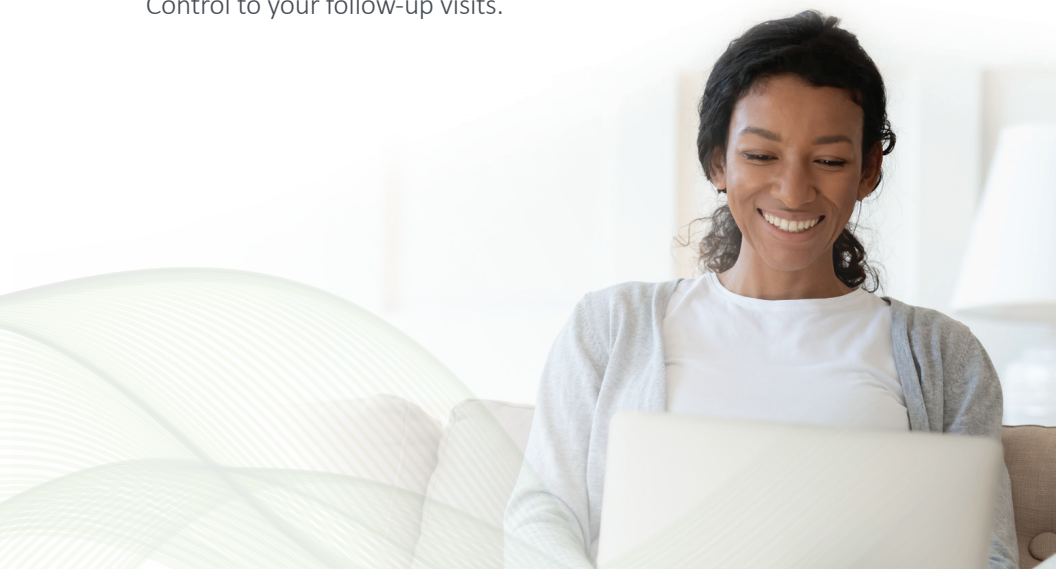
Your Stimulator is turned on when the procedure is completed or very soon thereafter. Feeling stimulation at all times is not required for symptom relief. However, if your symptoms are not improved or controlled, you should increase your stimulation level so that you gently feel sensation.

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 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



**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).

## Check Your Battery Status



<b>Trial Stimulator</b>	<b>Solid green:</b> Stimulator battery will last for 4 or more days.	<b>Solid orange:</b> Stimulator battery will last for 2 to 4 days. <b>Flashing orange:</b> Stimulator battery will last for 2 days or less.
<b>Rechargeable Stimulator</b>	<b>Solid green:</b> Stimulator battery will last for 30 or more days. <b>Flashing green:</b> Stimulator battery is charging.	<b>Solid orange:</b> Stimulator battery will last for 7 to 30 days. <b>Flashing orange:</b> Stimulator battery will last for 7 days or less.

**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.

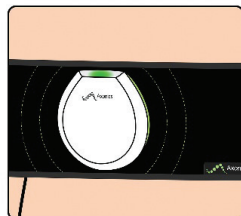
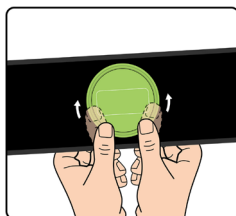
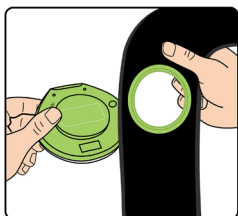


Remove the Charger from the dock when ready to charge your Stimulator.

## 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.

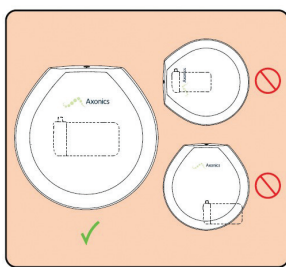
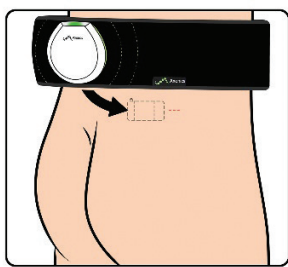
Strap the belt around your waist.



### 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.



## IMPORTANT SAFETY INFORMATION

**Indications:** 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.

**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.

For a complete list of warnings refer to [www.axonics.com/isi](http://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 16 years for overactive bladder)
- patients with neurological disease origins, such as multiple sclerosis or diabetes
- 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 a hyperbaric chamber.
- Avoid skiing or hiking.
- 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.
- 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.



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 sports. Less extreme activities should not impact your system, like running, jogging, road biking, swimming, and sexual activity.
- Scuba diving below 10 meters (33 feet) of water or 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.

**Caution:** This device can be sold and used by, or on the order of, a physician only.

For Summary of Safety and Clinical Performance (SSCP), refer to: <https://ec.europa.eu/tools/eudamed/#/screen/home>

## **Adverse Events**

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 of 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](http://www.axonics.com/isi).

## **Adverse Event Reporting**

In case of any serious incident related to the product, please report to Axonics as well as the competent authority of your state, which can be found here:

<https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human>

# 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**

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**Questions?** Send us an email. We're happy to help to answer questions about your Axonics Therapy.

**[customersupport@axonics.com](mailto:customersupport@axonics.com)**

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.

Experience the Difference.  
**EXPERIENCE AXONICS®.**



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