# Neuspera Sacral Neuromodulation System

## Patient Manual

℞ only

Patent information covering this product is available at www.neuspera.com/patent-information/

# Contents

## System Description

The Neuspera Sacral Neuromodulation System, called the “Neuspera SNM System,” is made to send small electrical pulses to the sacral nerve.

The Neuspera SNM System is used to help treat urinary urge incontinence (UUI) for people who tried other options but did not find them helpful, could not handle them, or were not able to use them.

If you want to know more about how safe and effective this system is, check the Neuspera Summary of Clinical Evaluations.

### Neuspera System Components

The Neuspera SNM System includes several parts, which are explained below and shown in **Figure 1**.

A. A small device called a **neurostimulator** (similar to a wire) is placed in your lower back by your doctor. This device sends tiny pulses of energy to a nerve in your lower body, which helps control your bladder.

B. The **Wireless Transmitter (WT)** sends power to the neurostimulator without needing any wires. The neurostimulator works only when it gets power from the Wireless Transmitter. To use it, you need to wear the Wireless Transmitter in the Neuspera Undergarment during therapy. The Wireless Transmitter is

water-resistant, so you can clean it daily, and its battery can be recharged using the charging pad. The neurostimulator will only activate when the Wireless Transmitter is placed over the implant area.

C. The Wireless Transmitter comes with a **magnet** that you can use to reset it if it stops charging or is not working correctly .

D. The Neuspera Undergarment **(Undergarment)** is made to hold the Wireless Transmitter (WT) in the right spot over your implanted neurostimulator so therapy can work. The special pocket keeps the Wireless Transmitter safe and comfortable against your body. You can wear the Undergarment under regular clothes like pants, shirts, and jackets. It also works with pads and diapers. The Undergarment comes in six sizes, ranging from Extra-Small to XXX-Large, and you can choose either Men's Briefs or Women's Low-Rise Hipster styles.

E. The Wireless Transmitter **charging pad** (CHP-5 or equivalent) is used to recharge the Wireless Transmitter when it runs out of power .

F. The **Patient Controller** lets you change therapy settings to feel more comfortable and improve your symptoms. It also helps you check the battery level of the Wireless Transmitter, switch stimulation programs, and turn the Wireless Transmitter and Patient Controller communication on or off.

■ **NOTE:** Your Wireless Transmitter is made to work only with your neurostimulator and app. Someone else's Wireless Transmitter will not work with your device, and

their app will not work with your Wireless Transmitter.

All parts of the Neuspera SNM System can be used at home. Regular household items and devices should not cause problems for your system if used normally (for additional information, see **“Home Environment”**).

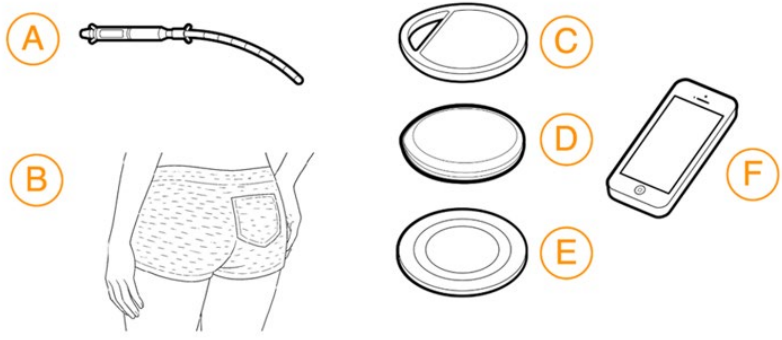



**Figure 1. Neuspera Implantable Sacral Nerve Stimulation System.**
**A. Implantable Neurostimulator, B. Undergarment, C. Magnet, D. Wireless Transmitter, E. Charging Pad, F. Patient Controller**

# Contraindications, Warnings, Precautions, Adverse Events, and Risks

## Contraindications

- Patients with sacral depth measured from the skin to the S3 foramen greater than 10 cm as confirmed by imaging.
- Patients who did not have an adequate response to test stimulation.
- Patients who are unable to operate the Neuspera SNM System.
- Men who have Benign Prostatic Hyperplasia (BPH) or patients with other blockages in their lower urinary tract that could lead to significant blockages or other issues.

After the Neurostimulator is implanted, the following contradictions apply:

- Treatments that send electrical currents into the body near the Neurostimulator, as this can permanently damage the device
- Medical treatments or procedures that use electric fields (like diathermy), unless the procedure is specifically listed as safe in the instruction manual (like MRI scans).

## Warnings

Do not take apart or change the devices, and only use the accessories mentioned in

this manual. Changing or using the equipment in the wrong way can make it unsafe or stop it from working properly. Contact your healthcare provider if you need a new device.

If you have loss of stimulation, contact your healthcare provider. Sometimes the Neurostimulator can break or move from where it is supposed to be. Your healthcare provider check for any problems with the device or its position.

Do not wear the Wireless Transmitter directly on your skin. Wearing the Wireless Transmitter directly on your skin could cause discomfort, irritation, or a burn; use the provided Undergarment instead.

Do not place the Undergarment directly on broken or healing skin, such as cuts or wounds. Follow the care instructions your doctor gives you after you get the Neuspera neurostimulator implanted. If a wound occurs after your implantation has healed, make sure that the wound is properly bandaged before using your Undergarment.

Do not use the Wireless Transmitter in very hot places (above 35°C or 95°F) or in spots where air cannot move around it, like under a blanket, thick clothing, or on a heavily cushioned chair. This could make the Wireless Transmitter too hot and cause burns or other injuries. Use the device in a chair with minimal padding or while moving around.

Do not use the Wireless Transmitter if you cannot feel heat, such as while sleeping. If the device gets too hot, it could burn or hurt you.

Electromagnetic Interference (EMI) from different devices can damage the Neurostimulator, make it stop working, or even harm you. Here are some things to watch for:

- Defibrillation or Cardioversion
  - If you have heart problems like ventricular or atrial fibrillation, doctors might use a defibrillator or cardioversion to save your life. These treatments can damage the Neurostimulator and create electric currents that may hurt you. Always let your doctor know if you are about to have or already had defibrillation or cardioversion so they can minimize the risk to you and the device and can check the device afterwards to make sure it is working safely.
- Electrocautery
  - Electrocautery tools, used to heat tissue during surgery, can cause problems if used near the Neurostimulator or its parts. They may harm the tissue close to the device, damage the Neurostimulator, or change how it works temporarily.
  - If electrocautery is needed, follow these rules:
    - Always let your doctor know if you're about to have or already had a procedure where electrocautery is used. They can minimize the risk to you and the device and can check the device afterwards to make sure it's working safely
    - Remove the Wireless Transmitter prior to any procedure with electrocautery.

        - After electrocautery, have your healthcare provider check that the device is functioning as intended.
- High-output ultrasonics or lithotripsy – Use of high-output ultrasonic devices, such as electrohydraulic lithotripters, is not recommended if you have an implanted Neurostimulator. These devices can damage the Neurostimulator, even though they won't hurt you directly. If lithotripsy must be used, inform your healthcare provided to insure that they know to minimize risk to your device.
- Radiofrequency (RF) or microwave ablation – The safety of RF or microwave ablation has not been proven for people with a Neurostimulator in patients who have an implanted Neurostimulator. These treatments could cause the Neurostimulator to heat up, which might harm nearby tissue. If these procedures must be used, inform your healthcare provided to insure that they know to minimize risk to you and your device.
- Effects of monitoring devices – For monitoring devices like an ECG, Holter Monitor, or EEG, you should take off the Wireless Transmitter. This is because the Neurostimulator's signals could show up on the test results and confuse the reading.
- Theft detectors and security screening devices (*Note*: Some theft detectors and screening devices might be hidden from view).
    - Theft detectors found in stores, libraries, and similar places, as well as security screening devices at airports or government buildings, might cause a brief

change in stimulation. If you are wearing the Wireless Transmitter, you might feel the stimulation switching on and off while passing through these devices. If your stimulation levels are low, you may feel a small change in stimulation.

- When you approach these devices, follow these steps :
  - If you can, ask to skip these devices. Security staff might use a handheld wand instead, but you should ask them not to hold it over the Neurostimulator longer than necessary. You can also ask for another type of personal search.
  - If you have to go through one of these devices, turn off or remove your Wireless Transmitter.
  - If there are two gates, walk through the middle of them at a normal pace, stay as far from each gate as you can .
  - If there is only one gate, walk as far away from it as possible.
  - Go through the device at a normal speed and do not stop or lean on it.
  - After you are done, you can turn your therapy back on .

## Precautions

(see also the EMI Precautions at the end of this manual)

- Do not use your Wireless Transmitter, Patient Controller, charging pad, or charging cables if they are damaged. Using damaged devices and cables can cause fires, electrical shocks, injuries, or more damage. Contact your healthcare provider if you need a replacement device.

- Make sure the Wireless Transmitter is not punctured or damaged to avoid battery leaks.
- If you notice a rash or other skin reaction, stop using the device and contact your healthcare provider.
- Always wear the Wireless Transmitter inside the pocket of the Neuspera Undergarment to keep you from getting burns or skin irritation. The Wireless Transmitter is not designed to touch your skin directly.
- Turn off stimulation or remove the Wireless Transmitter if it becomes uncomfortably hot.
- Avoid taking substances that may impair your ability to feel the Wireless Transmitter getting too hot. This may increase the chance of getting hurt from the Wireless Transmitter heat.
- The Wireless Transmitter may heat up while charging. Do not wear the Wireless Transmitter while it is charging since it heats up during charging and cannot provide stimulation at the same time. If you need to charge the Wireless Transmitter, you can put on a different one to keep your therapy going.
- Avoid putting too much pressure on the Wireless Transmitter, like lying on it for a long time. This can hurt you or damage the neurostimulator.
- Check with your healthcare provider before using the Wireless Transmitter on skin with wounds like blisters, burns, or cuts, or if you cannot feel heat.

- Always wear the Wireless Transmitter with the Neuspera Undergarment. This helps keep the Wireless Transmitter in the right spot over the implanted Neurostimulator so you can get proper treatment.
- Do not take the Wireless Transmitter, Patient Controller, or Clinician Programmer into any room with an MRI machine. They could get pulled into the machine and cause serious harm. Testing has shown that the Neurostimulator is safe to use under some conditions. Check the MRI Safety Information section for details.
- The Neuspera SNM System has not been tested for safety in the following people/conditions:
    - People with a BMI over 40,
    - Pregnant women,
    - Children,
    - Stimulation at two implant sites with the permanent Neuspera SNM System (stimulation at two implant sites may be used with the Trial System),
    - People with certain health conditions like neurologic causes of overactive bladder (OAB), multiple sclerosis, diabetes, or Parkinson's disease.
- The Neuspera SNM System has not been tested with other implanted medical

devices like pacemakers, drug pumps, or defibrillators. Do not use the Neuspera SNM System if you have one of these devices.

- The Neuspera SNM System has not been tested for compatibility with cardiac defibrillation. If you have been defibrillated, contact your doctor to check that your Neuspera SNM System is working properly.
- Only use items with the Neuspera SNM System that are part of the Neuspera SNM System or that are known to work with the Neuspera SNM System.
- Keep charging cords away from small children or infants to avoid accidents like strangling .
- Keep all components out of reach of children, pets and pests, that might damage the device from rough handling.

***Patient Activities***

For the **first week** following the procedure:

- Avoid sexual activity

For the **first six weeks** following the procedure:

- Avoid activities that could put too much stress on the Neurostimulator.
- Try not to do things that involve quick, strong, or repeated bending, twisting, bouncing, or stretching, as these could damage or move the device.

During the study, some patients experienced their devices moving because they did not limit their physical activities after the implant. This usually happened within six weeks of getting the device.

If the device moves or breaks, it can stop working, work off and on, cause pain, or require another surgery to fix or replace it. Activities like gymnastics, mountain biking, and sports with similar movements can cause these problems.

**After being implanted** with the Neuspera SNM System:

- Avoid strenuous physical activity that might break or move the Neurostimulator, as this could lead to it not working properly, only working sometimes, or causing pain at its location.
- Do not dive deeper than 10 meters (33 feet) underwater or enter areas with very high pressure, like hyperbaric chambers above 200kPa.
- Certain movements or changes in posture might make the stimulation feel stronger or uncomfortable. Some people feel this as a jolt or shock.
- Think about the movements in any activity you plan to do and make sure they do not put too much pressure on the Neurostimulator. For example, if you are skydiving, the sudden pull when your parachute opens could cause the Neurostimulator to move or break. This might mean you will need surgery to fix

or replace it. Talk to your healthcare provider about any hard physical activities you enjoy doing.

**While using the stimulation:**

- Do not wear the Wireless Transmitter during like driving or using dangerous tools where you or others could get hurt if you feel a sudden jolt or shock .
- Avoid taking substances that may impair your ability to feel the Wireless Transmitter getting too warm. Do not sleep or use heavy clothing or blankets while using the Wireless Transmitter. This may increase the chance of being injured if the Wireless Transmitter gets too hot.
- Avoid wearing the Wireless Transmitter while it is charging, since it might heat up during charging and won't provide therapy at the same time. If it needs to be charged, you can switch to another Wireless Transmitter to keep therapy going.
- Having metal surfaces (e.g., wall, chair back) against the Wireless Transmitter during therapy might cause an interruption in therapy.
- It is normal for the Wireless Transmitter to feel warm during therapy. If it gets too hot or feels uncomfortable, you should turn it off or take it off.

***Component Manipulation***

After getting the Neuspera SNM System implanted, don't let a chiropractor or anyone else move or press on your spine or pelvis near the Neurostimulator. This could damage the Neurostimulator, causing it to break, move out of place, or stop working properly. These problems might lead to loss of stimulation or pain where the Neurostimulator is located.

After do not push on or rub the area where the Neurostimulator was implanted. Doing this could hurt the Neurostimulator, make it move, or cause uncomfortable feelings like pain or strong stimulation.

## Adverse Events and Risks

Below is a list of the potential adverse effects (e.g. complications) that can happen when using the device. Besides the usual risks of surgery and anesthesia, these adverse events could also occur:

- Adverse change in voiding function (bowel and/or bladder function)
- 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
- Implant erosion (wearing away of skin)
- Implant fracture/failure

- Implant migration (movement)
- Electrical shock
- Heating or burn at implant site or site of Wireless Transmitter placement
- Infection
- Lack of effectiveness
- Pain or irritation at implant site
- Reoperation/Revision
- Seroma (accumulation of body fluids), hemorrhage (bleeding), and/or hematoma (accumulation of blood, or bruising)
- Nerve injury (including numbness)
- Technical device malfunction leading to an adverse event
- Transient electric shock or tingling
- Vulvovaginal pain or pelvic pain
- Unintended nerve activation (feelings of shock or tingling)

Contact your healthcare provider if any of these events occur.

# Summary of Clinical Evaluations

## Introduction

Neuspera did a study to see if the Neuspera SNM System is safe and works for treating urinary urge incontinence (UUI). The study happened at 29 clinical sites in the U.S. and 2 clinical sites in Europe. It involved patients who did not do well with or were not candidates for more conservative treatments, like pelvic floor exercises, biofeedback, or medications. A total of 128 patients got the Neuspera SNM System implant. Here is how the study was set up and what the data shows.

## Study Design

The study showed that the Neuspera SNM System was safe and worked to help reduce symptoms of urinary urge incontinence (UUI) in patients. Researchers looked at how well the system worked after six and twelve months. They figured out its success by checking if people who got the implant had fewer UUI episodes—at least 50% less—compared to before they started using the device. These people are “responders.” The study also checked the safety of the system by counting serious problems (“adverse events”) caused by the device for the twelve months after it was implanted.

To be in the study, patients needed have UUI for at least six months and have at least one UUI episode per day and at least four episodes over a three-day period. They had to be a good surgical and study candidate and be able to operate the device. The location that the implant would be in their body had to be not deeper than could be powered by the Wireless

Transmitter. They had to be 22 years of age or older with a Body Mass Index (BMI) between 18 and 40 40 kg/$m^2$. Patients had to stop taking their UUI medications long enough for the effects of the medications to wear off completely.

## Patient Disposition

At 31 sites, 242 people signed up for the study. Out of those, 130 people started the implant process, and 128 of them successfully got the implant. Figures 1 and 2 show what happened to everyone at the time of the 12-month analysis. At the time of the 12-month analysis, reasons why some people left the study include the following: 33.1% (80 out of 242) didn't meet the rules to join, 10.3% (25 out of 242) changed their minds, 3.7% (9 out of 242) were not happy with the therapy, 2.5% (6 out of 242) could not be reached, 1.7% (4 out of 242) were removed by the researcher, 1.7% (4 out of 242) left because the sites were closed by the sponsor, 1.2% (3 out of 242) had adverse events, 0.8% (2 out of 242) had an implant attempt that didn't work, 0.4% (1 out of 242) passed away, and 2.9% (7 out of 242) left for other reasons.

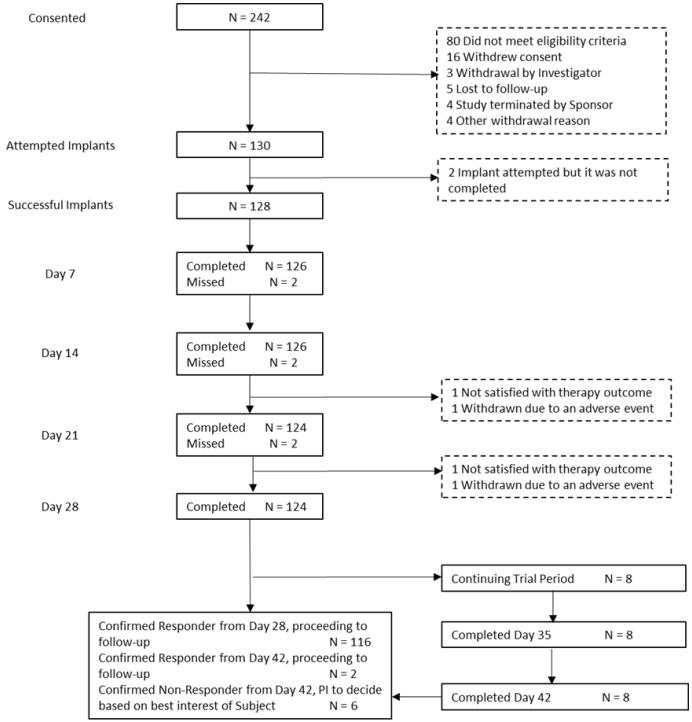



**Figure 2: Patient Disposition – Post Implant Period**

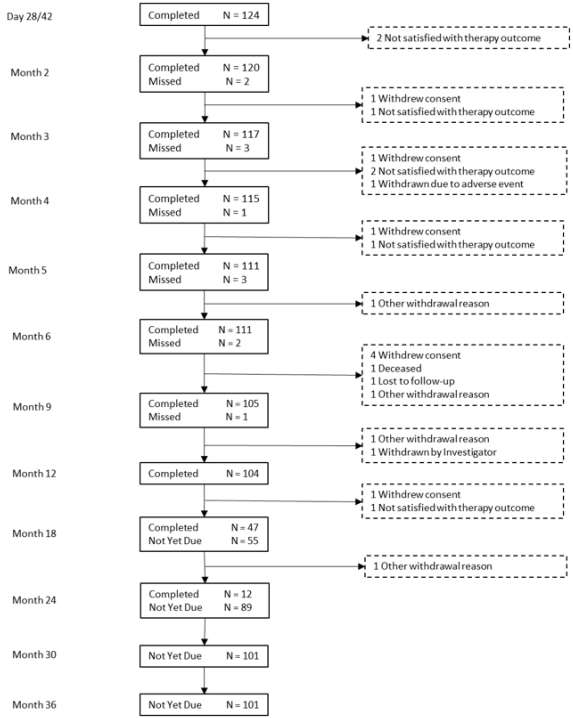



**Figure 2: Patient Disposition – Post Implant Period (continued)**

## Analysis Sets

The study included different groups for analysis, which were planned ahead of time. Here's how they were defined:

- Intent-to-Treat (ITT) Group: This group includes everyone who signed the consent form to join the study.
- Modified Intent-to-Treat (mITT) Analysis Set: This group includes all patients who had an attempt to place the implant.
- Responder Group: This group includes people who got the implant and showed good results at their check-up visits on Day 28 or Day 42 after the implant.
- Per Protocol (PP) Group: This group includes people who had the implant and didn't break any important study rules that could affect the results. Who was in this group was decided before the analysis.
- Worst Case Group: In this group, the study assumes that anyone with missing data didn't have success with the treatment.

## Patient Demographics and Baseline Characteristics

### *Demographics*

**Table 1** shows the basic information about the people in the study. For those who had the implant attempted, the average age was 60.4 years old (SD ±10.2) with an average BMI of 29.5 $kg/m^2$ (SD ±5.1).

**Table 1: Baseline Demographics**

| Baseline Characteristics | mITT (n = 130) |
|---|---|
| **Age (years)** | |
| N | 130 |
| Mean ± SD | 60.4 ± 10.2 |
| Median | 61.0 |
| Min, Max | 21.0, 83.0 |
| **BMI** | |
| N | 130 |
| Mean ± SD | 29.5 ± 5.1 |
| Median | 29.0 |
| Min, Max | 18.0, 39.0 |
| **Gender (n/N (%))** | |
| Female | 128/130 (98.5) |
| Male | 2/130 (1.5) |
| **Race (not mutually exclusive, n/N (%))** | |
| American Indian or Alaska Native | 0/130 (0.0) |
| Asian | 0/130 (0.0) |
| Black or African American | 5/130 (3.8) |
| Native Hawaiian or Other Pacific Islander | 0/130 (0.0) |
| White | 124/130 (95.4) |
| Other | 2/130 (1.5) |
| **Ethnicity (n/N (%))** | |
| Hispanic or Latino | 10/130 (7.7) |

| Baseline Characteristics | mITT (n = 130) |
|---|---|
| Not Hispanic or Latino | 120/130 (92.3) |

### *Incontinence History*

**Table 2** shows details about the incontinence history of participants at the start of the study. Among those who had the implant attempt, 93.8% were found to have overactive bladder (OAB), and 89.2% had a diagnosis of UUI at the beginning. At the same time, 38.5% of these participants had mixed incontinence, with UUI being their main issue. In addition, 10% reported having fecal incontinence, while 50.8% experienced frequent urination, and 44.6% had trouble with nighttime urination.

**Table 2: Incontinence History**

| **Incontinence History (Not mutually exclusive) n/N (%)** | **mITT (n = 130)** |
|---|---|
| Overactive bladder (OAB) | 122/130 (93.8) |
| Stress urinary incontinence (SUI) | 52/130 (40.0) |
| Urinary Urge incontinence (UUI) | 116/130 (89.2) |
| Mixed incontinence | 50/130 (38.5) |
| UUI predominates | 50/130 (38.5) |
| SUI predominates | 0/130 (0.0) |
| Other urinary incontinence | 1/130 (0.8) |
| Fecal incontinence | 13/130 (10.0) |
| Urinary Frequency | 66/130 (50.8) |
| Nocturia (Nighttime Urination) | 58/130 (44.6) |

*Note: Multiple options are allowed to be selected for the same patient. In this table, 116 mITT patients out of 130 had a diagnosis of UUI for their incontinence history. An additional eight (8) subjects had mixed incontinence with UUI predominating, indicating that they also had UUI. The remaining six (6) subjects that did not have UUI or mixed incontinence did have an OAB diagnosis; given that the subjects also had to have four UUI episodes in 72 hours, they would need to have OAB with associated UUI. Consequently, all subjects in the mITT analysis had a history of UUI.

### *UUI Treatment History*

People in the study had an average of 4.5 bladder leaks per day (± 2.5 SD). **Table 3** shows how the mITT patients were grouped based on how bad their UUI symptoms were at the start.

**Table 3: Baseline UUI episodes per day**

| Baseline UUI episodes per day | mITT (n = 130) |
|---|---|
| Mild (<3 UUI episodes per day) | 41/130 (31.5%) |
| Moderate (3-5 UUI episodes per day) | 42/130 (32.3%) |
| Severe (>5 UUI episodes per day) | 47/130 (36.2%) |

**Table 4** shows the treatments they had tried for UUI before the study. Out of those who tried the implant, 90.8% (118 out of 130 people) had used medicines for UUI at some point. 71.5% (93 out of 130) had used antimuscarinic medicines such as tolterodine, and 43.8% (57 out of 130) had tried β3 agonist medicines, like mirabegron and vibegron. One person had used sacral nerve stimulation (0.8%), 8.5% (11 out of 130) had tried tibial nerve stimulation, and 10.8% (14 out of 130) had used Botox treatments for UUI.

**Table 4: UUI Treatment History at Baseline**

| UUI Treatment History (n/N (%)) | mITT (n = 130) |
|---|---|
| Current or previous use of any medication to treat UUI | 118/130 (90.8) |
| Use of antimuscarinics to treat UUI | 93/130 (71.5) |
| Previously Used But Discontinued | 70/130 (53.8) |
| Currently Using | 23/130 (17.7) |
| No Response Given | 0/130 (0.0) |
| Use of β3 agonist to treat UUI | 57/130 (43.8) |
| Previously Used But Discontinued | 41/130 (31.5) |
| Currently Using | 14/130 (10.8) |
| No Response Given | 2/130 (1.5) |
| Sacral Nerve Stimulation | 1/130 (0.8) |
| Tibial Nerve Stimulation | 11/130 (8.5) |
| Botulinum neurotoxin type-A (BoNT-A) | 14/130 (10.8) |

## Safety Results

Safety was checked by looking at all the adverse events people had during the study. For the 12 months after it was implanted, a total of 338 adverse events happened in 108 out of 130 people (83.1%), and there were 27 serious adverse events in 21 out of 130 people (16.2%). There were no serious adverse events caused by the device and only one of these serious adverse events might have been linked to the implant procedure.

There were 27 adverse events related to the device in 21 out of 130 people (16.2%) and 21 adverse events related to the procedure in 19 out of 130 people (14.6%). Thirteen of these

adverse events were definitely caused by the device, and one was definitely caused by the procedure.

During the study, there were 2 broken devices, 5 devices that moved out of place in 4 people, 4 devices that needed fixing, and 15 devices that were taken out by the 6-month mark. By 12 months, there had been 5 device fixes and 21 devices that were taken out, but the number of broken devices and ones that moved out of place stayed the same as at 6 months. Most of the devices that moved out of place did so in the first month after being implanted. The two breaks happened on Day 26 and Day 63. One more device breakage happened after the 12 month data analysis occurred and was thought to occur due to a chiropractic therapy.

**Table 5** shows the adverse events with devices breaking, moving, or needing fixes through the 12-month period and the actions taken to address them.

**Table 5: Fractures, Migrations, Revisions, and Explants through 12 months**

| Events | Number of events | Number of patients | Notes |
|---|---|---|---|
| Device Migration | 5 | 4 | **Action Taken:**<br>3 – Revision<br>2 – Explant |
| Device Fracture | 2 | 2 | **Action Taken:**<br>1 – Revision<br>1 – Explant |
| Revisions | 5 | 5 | **Reason for Revision:**<br>2 – Device Migration<br>1 – Device Fracture and Migration<br>2 – Loss of Stimulation |
| Explants | 21 | 21 | **Reason for Explant*:**<br>11 – Patient Request<br>7 – Other Reason<br>2 – Loss of Stimulation<br>1 – Device Migration |

*Note: Study exit required a device explant per the study protocol.

**Table 6** shows the adverse events related to the device, and **Table 7** shows the adverse events related to the procedure through 12 months after it was implanted.

**Table 6. Device-Related Adverse Events through 12 months – mITT Analysis Set (N = 130)**

| | Events<br>n | Patients<br>n/N (%)[2] |
|---|---|---|
| **Total Device-Related Adverse Events[1]** | 27 | 21/130 (16.2%) |
| Device dislocation | 5 | 4/130 (3.1%) |
| Device stimulation issue | 3 | 3/130 (2.3%) |
| Device breakage | 2 | 2/130 (1.5%) |
| Implant site pain | 2 | 2/130 (1.5%) |
| Medical device pain | 2 | 2/130 (1.5%) |
| Medical device site burn | 2 | 2/130 (1.5%) |
| Anxiety | 1 | 1/130 (0.8%) |
| Back pain | 1 | 1/130 (0.8%) |
| Defecation urgency | 1 | 1/130 (0.8%) |
| Frequent bowel movements | 1 | 1/130 (0.8%) |
| Implant site rash | 1 | 1/130 (0.8%) |
| Micturition urgency | 1 | 1/130 (0.8%) |
| Pain in extremity | 1 | 1/130 (0.8%) |
| Procedural pain | 1 | 1/130 (0.8%) |
| Radicular pain | 1 | 1/130 (0.8%) |
| Urinary tract infection | 1 | 1/130 (0.8%) |
| Vulvovaginal pain | 1 | 1/130 (0.8%) |

[1] As coded by the Clinical Events Committee chairperson.

[2] Exact 95% confidence Interval.

**Table 7 Procedure-Related Adverse Events through 12 months – mITT Analysis Set (N = 130)**

| | Events<br>n | Patients<br>n/N (%)[2] |
|---|---|---|
| **Total Procedure-Related Adverse Events[1]** | 21 | 19/130 (14.6%) |
| Device dislocation | 3 | 2/130 (1.5%) |
| Implant site rash | 2 | 2/130 (1.5%) |
| Anxiety | 1 | 1/130 (0.8%) |
| Device breakage | 1 | 1/130 (0.8%) |
| Device stimulation issue | 1 | 1/130 (0.8%) |
| Dysphagia | 1 | 1/130 (0.8%) |
| Erythema | 1 | 1/130 (0.8%) |
| Frequent bowel movements | 1 | 1/130 (0.8%) |
| Hematemesis | 1 | 1/130 (0.8%) |
| Implant site discharge | 1 | 1/130 (0.8%) |
| Implant site pain | 1 | 1/130 (0.8%) |
| Mouth ulceration | 1 | 1/130 (0.8%) |
| Pain in extremity | 1 | 1/130 (0.8%) |
| Procedural headache | 1 | 1/130 (0.8%) |
| Radicular pain | 1 | 1/130 (0.8%) |
| Respiratory failure | 1 | 1/130 (0.8%) |
| Vomiting | 1 | 1/130 (0.8%) |
| Vulvovaginal pain | 1 | 1/130 (0.8%) |

[1]As coded by the Clinical Events Committee chairperson.

[2] Exact 95% confidence Interval.

**Table 8** shows device related AEs over time after the implant surgery, up to 12 months. The procedure-related AE that happened after 366 days was linked to removing the implant.

**Table 8: Device-Related AEs Over Time (from Implant Date) – mITT Analysis Set (N = 130)**

| Device-Related Adverse Events | Day 0 | Day 1-7 | Day 8-30 | Day 31-90 | Day 91-180 | Day 181-365 | Grand Total |
|---|---|---|---|---|---|---|---|
| **Grand Total** | **4** | **4** | **8** | **7** | **3** | **1** | **27** |
| Device dislocation | | | 5 | | | | **5** |
| Device stimulation issue | | 1 | | 1 | 1 | | **3** |
| Device breakage | | | 1 | 1 | | | **2** |
| Implant site pain | 1 | | | 1 | | | **2** |
| Medical device pain | 1 | | | 1 | | | **2** |
| Medical device site burn | | | | 1 | 1 | | **2** |
| Anxiety | | 1 | | | | | **1** |
| Back pain | | | 1 | | | | **1** |
| Defecation urgency | | | | 1 | | | **1** |
| Frequent bowel movements | 1 | | | | | | **1** |
| Implant site rash | | | | | 1 | | **1** |
| Micturition urgency | 1 | | | | | | **1** |
| Pain in extremity | | 1 | | | | | **1** |

| Device-Related Adverse Events | Day 0 | Day 1-7 | Day 8-30 | Day 31-90 | Day 91-180 | Day 181-365 | Grand Total |
|---|---|---|---|---|---|---|---|
| Procedural pain | | | | 1 | | | **1** |
| Radicular pain | | | 1 | | | | **1** |
| Urinary tract infection | | | | | | 1 | **1** |
| Vulvovaginal pain | | 1 | | | | | **1** |

**Table 9** shows procedure-related AEs as a function of time after implant through the 12-month visit database lock. The procedure-related AE that occurred after 366 days was related to an explant procedure.

**Table 9: Procedure-Related AEs Over Time (from Implant Date) – mITT Analysis Set (N = 130)**

| Procedure-Related AEs | Day 0 | Day 1-7 | Day 8-30 | Day 31-90 | Day 91-180 | Day 181-365 | Day 366+ | Grand Total |
|---|---|---|---|---|---|---|---|---|
| **Grand Total** | **6** | **7** | **6** | **0** | **0** | **1** | **1** | **21** |
| Device dislocation | | | 3 | | | | | **3** |
| Implant site rash | | 1 | | | | 1 | | **2** |
| Anxiety | | 1 | | | | | | **1** |
| Device breakage | | | 1 | | | | | **1** |
| Device stimulation issue | | 1 | | | | | | **1** |
| Dysphagia | 1 | | | | | | | **1** |
| Erythema | | | | | | | 1 | **1** |
| Frequent bowel movements | 1 | | | | | | | **1** |

| Procedure-Related AEs | Day 0 | Day 1-7 | Day 8-30 | Day 31-90 | Day 91-180 | Day 181-365 | Day 366+ | Grand Total |
|---|---|---|---|---|---|---|---|---|
| Hematemesis | 1 | | | | | | | **1** |
| Implant site discharge | | | 1 | | | | | **1** |
| Implant site pain | 1 | | | | | | | **1** |
| Mouth ulceration | 1 | | | | | | | **1** |
| Pain in extremity | | 1 | | | | | | **1** |
| Procedural headache | | 1 | | | | | | **1** |
| Radicular pain | | | 1 | | | | | **1** |
| Respiratory failure | | 1 | | | | | | **1** |
| Vomiting | 1 | | | | | | | **1** |
| Vulvovaginal pain | | 1 | | | | | | **1** |

## Effectiveness Result

### *Six-Months Results (Primary Endpoint)*

For subjects with an attempted implant (N=130), 82.9% of patients at Month 6 were responders (at least 50% fewer UUI events each day compared to how many they had before the implant). The study met the 50% performance goal at 6 months, as summarized in **Table 10.**

**Table 10. Responder Rate in UUI Summary at Month 6 – mITT Analysis Set (n=130)**

| | Estimate (%) | Lower 95% CI | Upper 95% CI | P-value (2-sided) |
|---|---|---|---|---|
| Patients with ≥ 50% reduction from baseline in UUIs per day | 82.9% | 76.4% | 89.4% | <0.0001 |

The main results were also checked for other groups in the study, as shown in **Table 11** below. For all implanted participants, the responder rate was 84.2%. For those who responded within 28 or 42 days, the rate was higher at 90.5%. For the group that followed the study rules properly (Per Protocol set), the responder rate was 86.2%. For the group where missing data was treated as not successful (Worst Case group), the responder rate was 80.8%.

**Table 11. Primary Endpoint for Various Analysis Sets at Month 6**

| Patients with ≥ 50% reduction from baseline in UUIs per day | Estimate (%) | Lower 95% CI | Upper 95% CI |
|---|---|---|---|
| Implanted (N=128) | 84.2%* | 77.8% | 90.5% |
| Responder (N=118) | 90.5%* | 85.1% | 95.8% |
| Per Protocol (N=117) | 86.2%* | 80.0% | 92.5% |
| Worst Case (mITT) (N=130)[1] | 80.8%* | 74.0% | 87.5% |

* $p<0.0001$;[1] The worst case assumes all missing responses are failures.

**Table 12** shows study outcomes at 6 months for study participants based on gender, age, race, how many UUI episodes they had before the implant, and where they live.

**Table 12: Primary Endpoint Subgroup Analysis at Month 6 – mITT Analysis Set (N = 130)**

| Patients with ≥ 50% reduction from baseline in UUIs per day | Estimate (%) | Lower 95% CI | Upper 95% CI |
|---|---|---|---|
| Female (N=128) | 82.6% | 76.0% | 89.2% |
| Male (N=2) | 100.0% | 100.0% | 100.0% |
| Age <65 years (N=94) | 82.9% | 75.2% | 90.5% |
| Age ≥65 years (N=36) | 83.0% | 70.6% | 95.4% |
| White (N=123) | 82.8% | 76.2% | 89.5% |
| All other races (N=7) | 83.9% | 55.2% | 100.0% |
| Baseline UUIs <8 (N=117) | 84.4% | 77.8% | 91.0% |
| Baseline UUIs ≥8 (N=13) | 69.2% | 44.1% | 94.3% |
| US (N=124) | 82.9% | 76.2% | 89.5% |
| EU (N=6) | 83.3% | 53.5% | 100.0% |

**Table 13** gives information about how well the treatment worked for other measures of urinary problems at 6 months.

**Table 13. Secondary Effectiveness Results at Month 6 – mITT Analysis Set (N=130)**

| Effectiveness Measure (n=130) | Month 6 | p-value |
|---|---|---|
| Reduction from baseline in the mean number of UUI episodes per day | 3.28 ± 2.53 | p<0.0001 |
| Improvement from baseline in ICIQ-OABqol score | 35.24 ± 9.11 | p<0.0001 |
| Percentage of patients who experienced an improvement in ICIQ-OABqol of at least 10 points (compared to a 50% performance goal) | 91.9% | p<0.0001 |
| Reduction from baseline in Urgent Episodes | 1.21 ± 2.77 | p<0.0001 |
| Reduction in average number of daily voids in patients with at least 8 voids at baseline | 1.65 ± 5.23 | p = 0.0006 |

For the secondary effectiveness endpoints in **Table 13,** the first three endpoints supported the findings the treatment can improve UUI symptoms. The reported changes of 1.21 ± 2.77 in urgency episodes and 1.65 ± 5.23 in voids per day are not related to the UUI claim, and these data do not support safety and effectiveness of the device in treatment of urinary urgency and frequency.

### *Twelve-Months Results (Secondary Endpoint)*

For subjects who had the implant attempted (N=130), 77.7% of them at Month 12 showed improvement, with at least a 50% drop from their starting levels of daily UUIs. This is shown in **Table 14** below.

**Table 14. Responder Rate in UUI Summary at Month 12 – mITT Analysis Set (n=130)**

| | Estimate (%) | Lower 95% CI | Upper 95% CI |
|---|---|---|---|
| Patients with ≥ 50% reduction from baseline in UUIs per day | 77.7% | 70.4% | 85.0% |

This study also looked at how different groups of people responded at 12 months, as shown in **Table 15** below. For everyone who got the implant, 79.0% had at least a 50% drop in their daily UUIs. For those who were responders at 28 or 42 days, the rate was even higher—84.8%. In the Per Protocol group, which included people who followed the study rules properly, the rate was 82.1%. When researchers assumed that all missing data meant failure (Worst Case method), the response rate was 73.8%.

**Table 15. Responder Rate for Various Analysis Sets at Month 12**

| Patients with ≥ 50% reduction from baseline in UUIs per day | Estimate (%) | Lower 95% CI | Upper 95% CI |
|---|---|---|---|
| Implanted (N=128) | 79.0% | 71.7% | 86.2% |
| Responder (N=118) | 84.8% | 78.1% | 91.5% |
| Per Protocol (N=117) | 82.1% | 75.0% | 89.2% |
| Worst Case (mITT) (N=130)[1] | 73.8% | 66.3% | 81.4% |

[1] The worst case assumes all missing responses are failures.

**Table 16** shows study outcomes for study participants at 12 months based on gender, age, race, how many UUI episodes they had before the implant, and where they live.

**Table 16: Responder Rate Endpoint Subgroup Analysis at Month 12 – mITT Analysis Set (N = 130)**

| Patients with ≥ 50% reduction from baseline in UUIs per day | Estimate (%) | Lower 95% CI | Upper 95% CI |
|---|---|---|---|
| Female (N=128) | 77.4% | 70.0% | 84.8% |
| Male (N=2) | 100.0% | 100.0% | 100.0% |
| Age <65 years (N=94) | 82.1% | 74.3% | 90.0% |
| Age ≥65 years (N=36) | 66.3% | 50.4% | 82.1% |
| White (N=123) | 78.9% | 71.5% | 86.3% |
| All Other Races (N=7) | 57.1% | 20.5% | 93.8% |
| Baseline UUIs <8 (N=117) | 79.5% | 72.0% | 87.0% |
| Baseline UUIs ≥8 (N=13) | 61.5% | 35.1% | 88.0% |
| US (N=124) | 77.5% | 70.0% | 85.0% |
| EU (N=6) | 83.3% | 53.5% | 100.0% |

**Table 17** gives information about how well the treatment worked for other measures of urinary problems at 12 months.

**Table 17. Secondary Effectiveness Results at Month 12 – mITT Analysis Set (N=130)**

| Effectiveness Measure (n=130) | Month 12 |
|---|---|
| Reduction from baseline in the mean number of UUI episodes per day | 2.96 ± 2.57 |
| Improvement from baseline in ICIQ-OABqol score | 31.76 ± 22.50 |
| Percentage of patients who experienced an improvement in ICIQ-OABqol of at least 10 points (compared to a 50% performance goal) | 84.4% |
| Reduction from baseline in Urgent Episodes | 1.14 ± 2.70 |
| Reduction in average number of daily voids in patients with at least 8 voids at baseline | 1.67 ± 5.17 |

## Conclusions

### *Effectiveness Conclusions*

The clinical study shows that the Neuspera SNM System helps people who with UUI and have not had success with more conservative treatments. At 6 months, 82.9% of patients had their daily episodes of UUI cut by at least half, and by 12 months, 77.7% showed the same improvement.

Other measures in the study, like fewer UUI episodes and better scores on the ICIQ-OABqol quality of life questionnaire, also helped show that the Neuspera SNM System helps with UUI symptoms.

### *Safety Conclusions*

In the clinical study for the Neuspera SNM System, no serious device adverse events were caused by the device itself, but there was one serious issue related to the procedure. After 12 months, 27 device-related adverse events happened in 21 out of 130 people (16.2%), and 21 procedure-related adverse events happened in 19 out of 130 people (14.6%).

The most common device-related adverse events were the device moving out of place (3.1% of people), issues with device stimulation (2.3%), the device breaking (1.5%), pain at the implant site (1.5%), pain from the device (due to high levels of stimulation or after a fall; 1.5%), and a burn at the device site (when patients placed the WT directly on their skin; 1.5%). Other device-related adverse events happened in less than 1% of people. No infections at the implant site were reported.

By 12 months, there were two cases where the device broke, five cases where the device moved in four people, five surgeries to re-implant the device, and 21 devices that were removed. The majority of the devices that moved did so within the first month of being implanted, and the two devices that broke did so in the first few months. However, one additional device broke after 12-months and was attributed to chiropractic therapy.

# Getting to Know Your System

## Implantation Procedure

You will have surgery to have the neurostimulator implanted as an outpatient procedure; the procedure will happen under sedation or with local anesthesia. You will be lying face down during your surgery. A needle, fluoroscopy (which shows continuous x-ray images on a screen), and mild electrical pulses will be used to find the right place in your back for the neurostimulator. Using x-ray images as a guide, the needle will be inserted into your back, and then mild electrical pulses will be sent from the needle to the sacral nerve, which should cause some movement in your buttocks or toes when placed correctly. A small surgical cut (referred to as an incision) will be made to insert the neurostimulator in that location in your back, near the sacral nerve. Fluoroscopy images will be taken to make sure the neurostimulator is in the right location. Mild electrical pulses will be sent to the neurostimulator to make sure it is stimulating your sacral nerve. After the clinician sees that the device is in the right place and working properly your incision will be closed and covered with a bandage. You will be provided all post procedure care instructions following your procedure.

## System Setup

Your system will be set up by your clinician or clinician's assistant according to your clinician's instructions before you leave the hospital or outpatient clinic following the implantation of the neurostimulator.

Either a representative of Neuspera or the clinic will explain how each component works. The Neuspera System requires no specialized skills or knowledge for patient use.

If you have any problems using any part of the system, contact your clinician/clinic.

## Your Patient ID Card

You will receive a patient ID card (**Figure 3**) with your Neuspera System. Carry this ID card with you at all times in the event you need medical attention or are passing through a security screening. If you lose your patient ID card, request a new one by contacting your clinician/clinic.

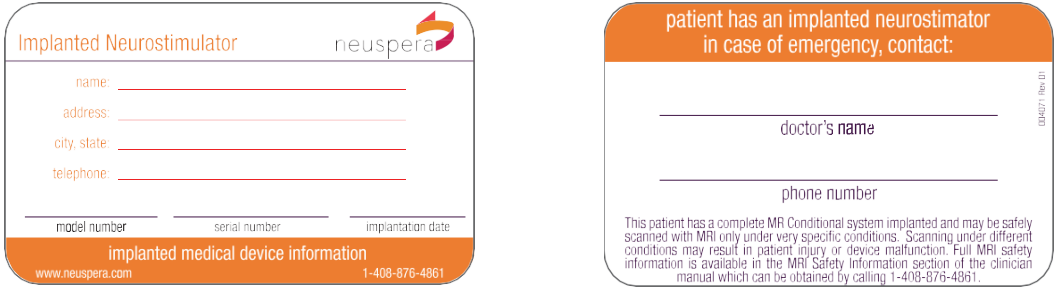



**Figure 3. Patient ID Card**

## Visiting the Clinic

Please bring your Wireless Transmitter, Charging Pad, magnet and Patient Controller with you to all follow-up visits. Important usage information will be collected. Your clinician may also need to modify the programs and/or update the software to improve therapy.

# Basic Use/Frequently Performed Tasks

Most patients see improvements in their urinary urge incontinence (UUI) symptoms with two hours of therapy a day. For additional information on the safety and effectiveness data for the Neuspera System, see the Neuspera Summary of Clinical Evaluations.

■ **NOTE:** For optimal relief of your symptoms, it is important to follow the described operating use of your Neuspera System.

■ **NOTE:** Electrical stimulation may not cure your UUI symptoms entirely. Instead, it is expected to reduce the symptoms and improve day to day life.

## Before Use

1. Inspect the Wireless Transmitter for cracks, holes, or other damage that may expose the internal circuitry or allow water inside. Do not use if there is any damage.
2. Inspect the Undergarment for:
    a. any tears or holes around the Wireless Transmitter pocket.
    b. an insulating foam spacer inside the Wireless Transmitter pocket.

Do not use if there are any tears, holes or the insulating foam is not present in the pocket.

■ **NOTE:** If your Wireless Transmitter was stored at very hot or very cold temperatures (such as in your car during cold winters or hot summers), let it reach room temperature prior to use. Depending on the storage temperature, this could take up to 5 hours. Do not use heating or cooling devices to heat or cool your Wireless Transmitter; let it come to room temperature on its own.

### *Charging the Wireless Transmitter (WT)*

The Wireless Transmitter should be charged daily prior to each use. Ensure the charging pad is plugged in and place the Wireless Transmitter on the charging pad as shown in **Figure 4**. The Wireless Transmitter can only charge if the dotted white side is facing up and the logo/label side is facing down (i.e., device is "upside-down"). You will see a light on the charging pad when charging. Leave the Wireless Transmitter on the charging pad when it is not in use for a therapy/stimulation session. If the charging pad light does not indicate the Wireless Transmitter is charging, refer to **Troubleshooting**.

■ **NOTE:** The Wireless Transmitter is unavailable for use while charging.

A. Make sure charging pad is connected to power and in the correct orientation*.

B. Place Wireless Transmitter on the charging pad with the white dotted side up and the label/Neuspera logo facing down as shown below.

Light on the edge of the charging pad indicates Wireless Transmitter is charging.


Incorrect orientation - Wireless Transmitter will not charge if the label/Neuspera logo is facing up.

C. Confirm charging pad status light* indicates charging has started.

D. If charging has not started or there is an error indicated by the charging pad status light*, refer to the troubleshooting section.

**If needed, refer to instructions for charging pad provided by manufacturer*

**Figure 4. Charging the Wireless Transmitter**

If the battery is fully drained, it may take up to 5 hours to fully charge your Wireless Transmitter. A fully charged battery should provide enough power for at least 2 hours of use.

■ **NOTE:** Your Wireless Transmitter will turn on as soon as it is removed from its charging pad. If you are not putting it on immediately, use your App to turn it off (see **"Stopping/Starting Stimulation with the App"**) to ensure that it has enough battery power when you need it.

## Putting on the Wireless Transmitter

■ **NOTE:** Your Wireless Transmitter must be worn in the pocket of your Neuspera Undergarment. This is to protect you from the heat of the Wireless Transmitter and to position it correctly to power your neurostimulator.

■ **NOTE:** It is normal for the Wireless Transmitter to become warm during use as it is delivering power to your neurostimulator. If it becomes uncomfortably warm, turn it off (**Figure 15**), take off your Undergarment and contact your clinician/clinic. The Wireless Transmitter will automatically turn off if it senses that it is too hot. If the Wireless Transmitter fails to turn off due to malfunction, remove the Wireless Transmitter.

**Undergarment**

A. Remove the Wireless Transmitter from the charging pad and insert it into the pocket of your Neuspera Undergarment as shown in **Figure 5A**. Be sure to insert it so the white, dotted side will be against your body (against the foam side of the pocket) and the logo/label side will be facing out from your body.

B. Put on the Undergarment as shown in **Figure 5B**. The Undergarment label should be on the inside. The Undergarment can be worn by itself or over pads or diapers.

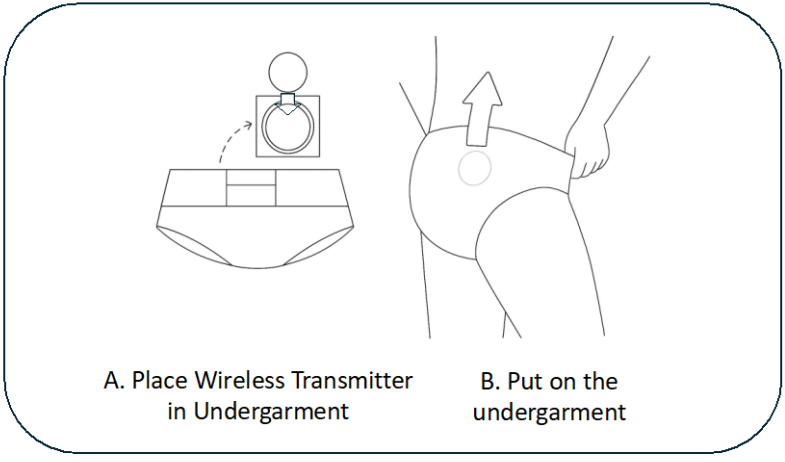



**Figure 5. Put the Wireless Transmitter in the specially designed pocket in the Undergarments**

■ **NOTE:** When the Wireless Transmitter is in the correct position, it will connect automatically to the neurostimulator to begin treatment. You should feel a slight "tingling" or "pulling" sensation.

■ **NOTE:** If you do not feel the tingling/pulling, check that the Wireless Transmitter is inserted correctly into the pocket of the Undergarment with the dotted white side

facing your body.

a. If you still do not feel the tingling/pulling, check your App to confirm that the Wireless Transmitter battery is charged (**Figure 9**), stimulation is on (**Figure 10**), and communication is on (**Figure 11**).

b. If you still do not feel the tingling/pulling, use your App to increase the stimulation until you can feel it - see **"Changing Stimulation Settings"**.

## Removing the Wireless Transmitter/Ending a Therapy Session

**CAUTION:** The Wireless Transmitter will become warm during use. If it is too hot to handle, turn stimulation off to let it cool down or remove the Wireless Transmitter by taking off your Undergarment. The Wireless Transmitter may interrupt therapy if an elevated temperature is detected. Programmed therapy will resume after the Wireless Transmitter temperature has sufficiently decreased.

Stimulation stops when the Wireless Transmitter is removed from the area over your neurostimulator. Removing your Undergarment and Wireless Transmitter or removing the Wireless Transmitter from the Undergarment pocket will stop stimulation. Place the Wireless Transmitter on the charging pad, after removal to ensure it is charged for its next use.

■ **NOTE:** You may also stop therapy from your App - see **"Stopping/Starting Stimulation with the App"**.

## Your Patient Controller and Neuspera Application

The Neuspera Application (“App”) is a simple tool you and your doctor can use to adjust your therapy, monitor your Wireless Transmitter battery level, view your program use history, and adjust your Wireless Transmitter for airplane and international travel. The App runs on an iPhone SE, “Patient Controller,” see **Figure 6** below).

■ **NOTE:** Keep your Patient Controller at least 10 centimeters (4 inches) away from your Wireless Transmitter while you are wearing it during a therapy session. Your Patient Controller may interfere with the communication between your Wireless Transmitter and neurostimulator.

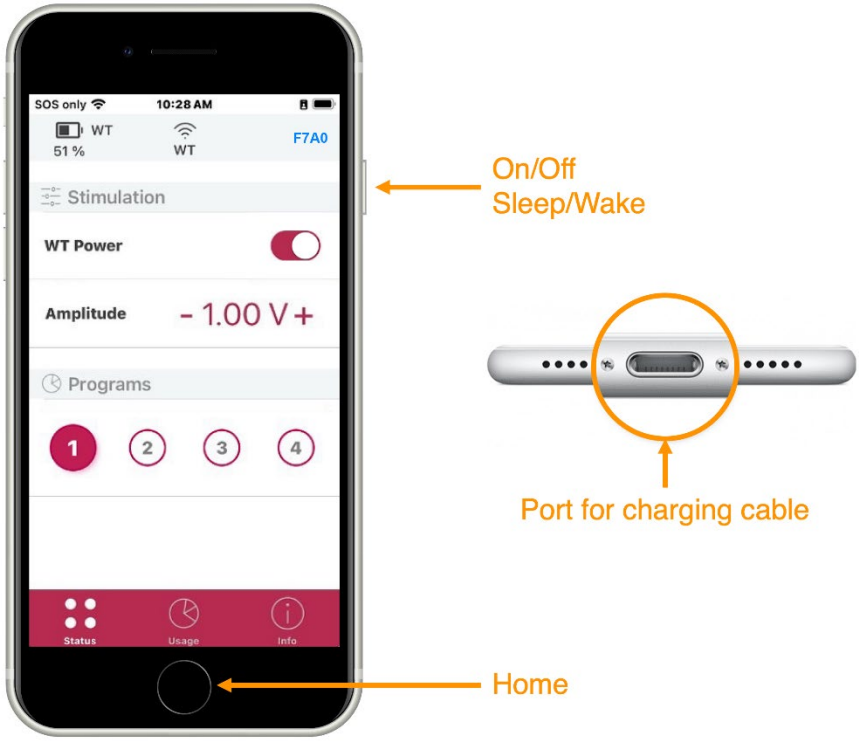



**Figure 6. Patient Controller**

## Charging Your Patient Controller

1. Plug charging cable into a USB outlet.
2. Insert charging cable into the bottom of the Patient Controller.
3. You should see a lightning bolt in the battery icon if the device is charging.

## Turning on Your App and Connecting to Your Wireless Transmitter

1. Press the center “Home” button on the Patient Controller to turn on the display. If the Patient Controller is off, press and hold the top button to turn it on (see **Figure 6** above).
2. Your App should automatically connect to your Wireless Transmitter when it is within 1 meter (3 feet). When the App is connected to your Wireless Transmitter, the Wireless Transmitter ID will appear in blue in the upper right corner of the App display (see **Figure 7** below).

■ **NOTE:** You do not need to turn on the App to connect your Wireless Transmitter to your neurostimulator or to receive therapy.

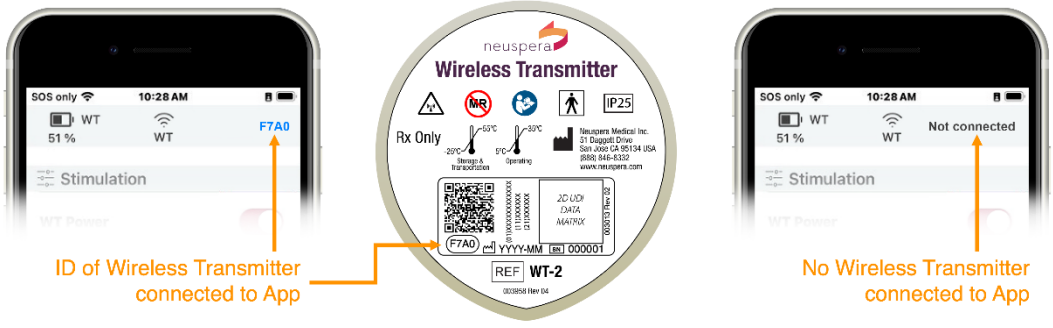



**Figure 7. App screen - Connected Wireless Transmitter identification. Your Wireless Transmitter ID is found on the label, under the square barcode. If your App is not connected to any Wireless Transmitter, the ID will display as "Not Connected" (right image).**

3. If the App shows that it is connected to a Wireless Transmitter other than the one you are wearing, tap the Wireless Transmitter ID in the upper right corner and select the correct Wireless Transmitter (WT, see **Figure 8**).

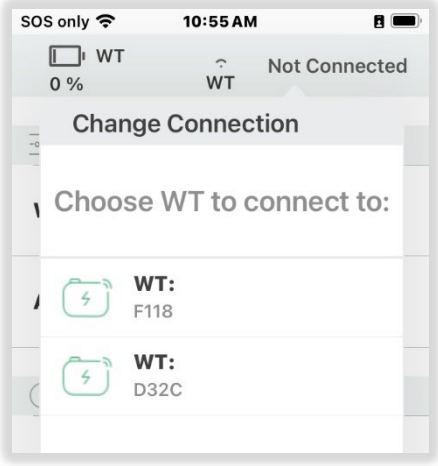



**Figure 8. Choosing a Wireless Transmitter to connect**

## Checking Wireless Transmitter and Patient Controller Battery Levels

You can check the battery level of your Wireless Transmitter and Patient Controller from any screen on your App. The Wireless Transmitter battery level is in the upper left corner. The Patient Controller battery level is in the upper right corner (see **Figure 9**).

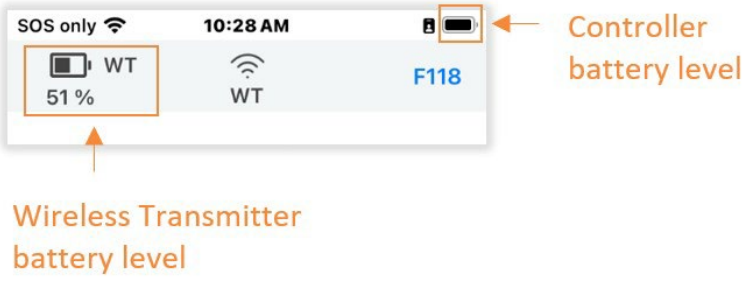



**Figure 9. Checking battery levels**

## Changing Stimulation Settings

From the Status screen on your App, you can adjust your stimulation (see **Figure 10**).

1. You should change the stimulation level if:
    a. Therapy is painful - decrease Amplitude (tap the minus "–") until it is no longer painful.
    b. You do not feel any "tingling" - increase Amplitude (tap the plus "+") until you begin to feel the tingling.

2. You may also switch to a different program that your clinician has set up for you. Turn stimulation off (see next section **"Stopping/Starting Stimulation with the App"**), select a different program (number), and turn stimulation back on. Consult with your clinician for instructions on when to switch programs.

   ■ **NOTE:** You cannot switch programs when the stimulation is on. You must turn stimulation off before changing programs.

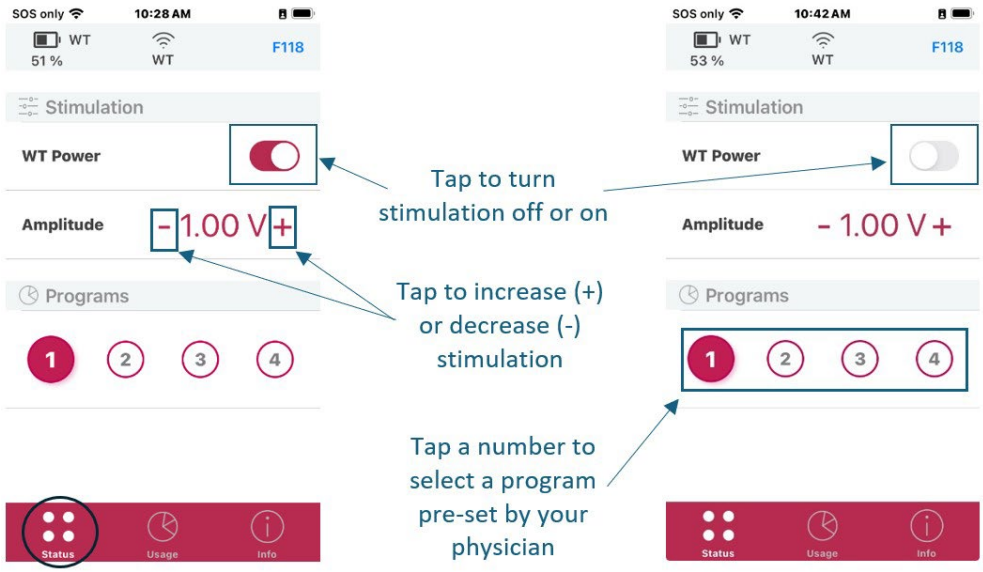



**Figure 10. App Status screen - Adjusting stimulation settings and stopping stimulation. Left image: Stimulation on. Right image: Stimulation off.**

## Stopping/Starting Stimulation with the App

You can stop stimulation on the App by tapping the Power "switch" to move it to the off position (right image, see **Figure 10**).

■ **NOTE:** If you turn stimulation off with your App, it will automatically turn back on the next time your Wireless Transmitter is removed from the charging pad.

You can start stimulation by removing your Wireless Transmitter from the charging pad and tilting it. If your Wireless Transmitter does not turn on automatically, you can manually turn it on through the App on your Patient Controller.

## Adjusting Your Wireless Transmitter and Patient Controller for Travel

■ **NOTE:** See also **"TSA and Other Security Screening"** for information on going through airport security.

If you are traveling on an airplane or traveling to another continent, you may have to adjust your Wireless Transmitter.

### *Turning Wireless Communication Off*

If your cell phone must be in airplane mode, communications from your Wireless Transmitter and App should be turned off. Place the magnet on the Wireless Transmitter to turn it off. You can also go to the Info screen on your App and tap the Communication "switch" so it is in the off position (see **Figure 11**).

■ **NOTE:** When communication is turned off, your Wireless Transmitter will

not power your neurostimulator. You must turn communication back on to restart stimulation.

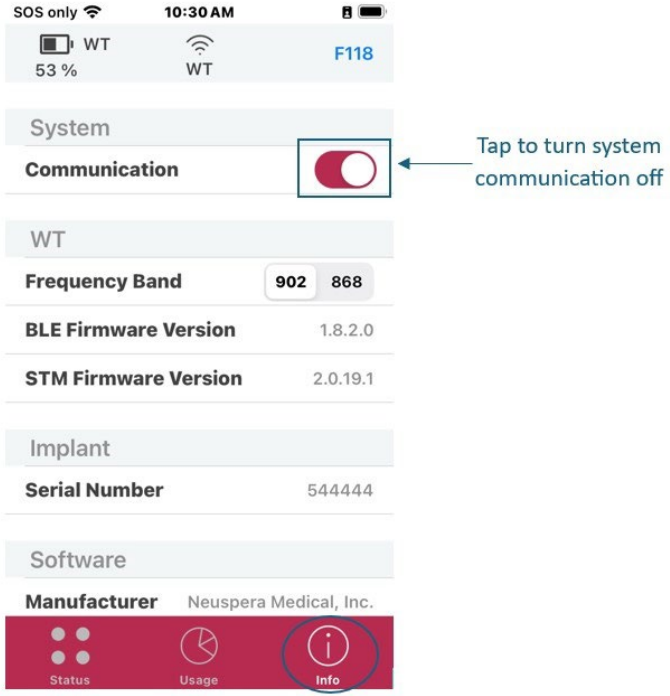



**Figure 11. App Info screen – Making adjustments for travel**

## Viewing Your Program Usage History

From the Usage screen on your App, you can see the relative amount of time that you have used the different programs and a history of your therapy sessions. You can change the time frame that is displayed by changing the start/end dates or choosing a pre-defined range (see **Figure 12** below).

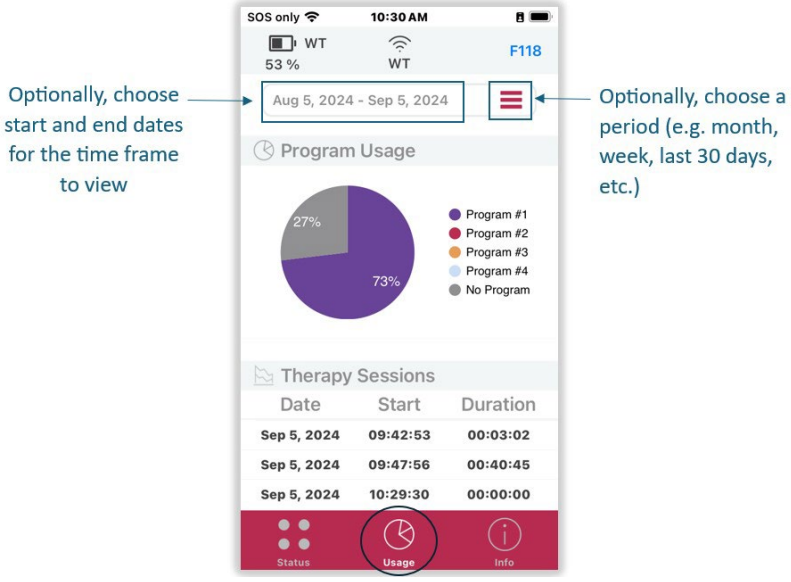



**Figure 12. Viewing program and therapy history on the Usage screen**

# Care of Your System

## Cleaning the Wireless Transmitter

**CAUTION:** The Wireless Transmitter is water-resistant but should not be submerged. Submerging it in water or other cleaning liquids may cause it to malfunction.

**CAUTION:** Do not use harsh cleaning chemicals to clean the Wireless Transmitter since they may damage the case.

For your safety and hygiene, it is recommended that you inspect your Wireless Transmitter for damage and clean your Wireless Transmitter daily. Look for any signs of damage such as cracking or holes that may expose the internal circuitry or allow water to get inside. To clean your Wireless Transmitter, use a damp cloth and mild soap (such as liquid dish soap).

## Cleaning the Neuspera Undergarments

**CAUTION:** Ensure your Wireless Transmitter is removed prior to washing the Undergarment.

You will receive multiple pairs of Undergarments. For proper hygiene, it is recommended to wash the Undergarments between uses. The Undergarments are designed to be washed like normal undergarments. For best results, it is recommended to machine wash in warm water and lay flat to dry. Machine drying,

use of chlorine bleach, ironing, or dry cleaning is not recommended. If you need more Undergarments, contact your clinician/clinic.

## Cleaning the Magnet, Charging Pad and Patient Controller

Use a soft, dry, lint-free cloth to clean the magnet, charging pad and Patient Controller as needed. Avoid getting liquid in any openings.

## Monitoring System Performance

Periodically monitor the activity of the Wireless Transmitter and App. Turn on the App and check for any messages or prompts.

## Software Updates

You may receive a notification to update the App software or Wireless Transmitter. These updates may be done at home or during a follow-up visit with your clinician.

# Troubleshooting

Common problems and their resolutions are listed below. If these actions do not solve the problem, please contact your clinician/clinic.

## Troubleshooting, Causes, and Resolutions

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| Wireless Transmitter is not charging (light is not solid and the correct color)<br>*NOTE: The light is dim and may not be visible in bright lighting. | Charging pad is not plugged in | Check that the charging pad cable is plugged into a powered outlet and plugged into the charging pad. |
| | Charging pad is not placed with the correct side facing up | Check that correct side of charging pad is face up (Wireless Transmitter will be placed on this side of the pad). |

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| *(Cont.)*<br>Wireless Transmitter is not charging (light is not solid and the correct color) | Wireless Transmitter is not placed with the correct side down on charging pad | Make sure the dotted, white side of the Wireless Transmitter is facing up and logo/label side is on the bottom (see **Figure 4**). |
| | Wireless Transmitter is not centered correctly on charging pad | Remove Wireless Transmitter from charging pad and set down in the center of the charging pad. |
| | Wireless Transmitter was too warm when placed on charging pad | Remove Wireless Transmitter from the charger and replace it back on the charging pad and confirm charging status indicated in **Figure 4**. |
| | Wireless Transmitter has been damaged (by physical shock, extreme temperatures, and/or water has leaked into device) | Contact your clinician for a replacement Wireless Transmitter. |

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| *(Cont.)*<br>Wireless Transmitter is not charging (light is not solid and the correct color) | Wireless Transmitter has become inoperative | Wireless Transmitter needs to be reset.<br>Place the Wireless Transmitter correctly on the charging pad (dotted side face up). Place the label side of the magnet (bottom of magnet) against the dotted side of the Wireless Transmitter for 5-10 seconds to perform reset. The teardrop point of the magnet should be aligned with the teardrop point of the Wireless Transmitter (see **Figure 13**). |

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| *(Cont.)*<br>Wireless Transmitter is not charging (light is not solid and the correct color) | | Confirm reset was successful by observing the following:<br>1. Confirming the green light on the Wireless Transmitter is blinking.<br>2. Waiting 30 seconds and |

| | | |
|---|---|---|
| | | observing that the status light of the charging pad has initiated. |
| Patient Controller is not charging | Charging cable not plugged in | Check that the charging cable is properly plugged into a powered outlet and into the Patient Controller. |
| Patient Controller display doesn't turn on | Patient Controller is turned off | Turn Patient Controller on by pressing button on top edge of device (see **Figure 6**). |
| | Patient Controller battery is extremely low | Charge Patient Controller for at least 2 minutes and while still plugged in, turn Patient Controller on by pressing button on top edge of device. |

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| App is not connecting to Wireless Transmitter | Wireless Transmitter and Patient Controller are not close enough | Check that the Wireless Transmitter is within 1 meter (3 feet) of the Patient Controller. |
| | Patient Controller battery is too low | Check battery level on your App (see **Figure 9**) and charge if needed. |
| | Wireless Transmitter battery is too low | Charge Wireless Transmitter and try again. |
| | Wireless Transmitter has been unlinked from your App | Contact your clinician/clinic to link your Wireless Transmitter to your App. |
| App is connected to the wrong Wireless Transmitter | Another Wireless Transmitter is within range of your Patient Controller | If there is another Wireless Transmitter nearby, place the magnet on the unused Wireless Transmitter, click on the Wireless Transmitter "ID" and select the desired Wireless Transmitter (WT; see **Figure 8**). |

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| Wireless Transmitter stops working | Wireless Transmitter battery is not charged or was not fully charged at the start of therapy | Check Wireless Transmitter battery level from the App (see **Figure 9**). Charge Wireless Transmitter if battery level is low. Always leave the Wireless Transmitter on the charging pad when not in use. |
| | Wireless Transmitter has overheated | Remove the Wireless Transmitter from the Undergarment and place it on the charger. This will turn the Wireless transmitter off which will allow it to cool down. Once it has cooled down to room temperature, remove the Wireless Transmitter from the charger and then place it back on the charger. The Wireless Transmitter will then begin charging. |

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| *(Cont.)*<br>Wireless Transmitter stops working | Wireless Transmitter damaged by dropping or water or excessive moisture | Contact your clinician/clinic for a new Wireless Transmitter. |
| | Wireless Transmitter is inoperative | Wireless Transmitter needs to be reset.<br><br>Place the Wireless Transmitter correctly on the charging pad (dotted side face up). Place the label side of the magnet (bottom of magnet) against the dotted side of the Wireless Transmitter for 5-10 seconds to perform reset. The teardrop point of the magnet should be aligned with the teardrop point of the Wireless Transmitter (see **Figure 13**). Ensure that the green light has stopped blinking when the magnet is placed on the Wireless Transmitter. |

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| *(Cont.)*<br>Wireless Transmitter stops working | | After 5-10 seconds, remove magnet from Wireless Transmitter. Do not leave magnet on Wireless Transmitter while it is charging.<br>Confirm reset was successful by observing the following:<br>1. Confirming the green light on the Wireless Transmitter is blinking.<br>2. Waiting 30 seconds and observing that the status light of the charging pad has initiated. |
| Wireless Transmitter enclosure is cracked | Wireless Transmitter damaged by dropping or exposure to extremely high or low temperatures or pressure | Discontinue use. Contact your clinician/clinic for a new Wireless Transmitter. |

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| Skin irritation develops | Sensitivity to Undergarment material | Take off Undergarment and discontinue use of system. Contact your clinician. |
| Undergarment is uncomfortable | Incorrect size or worn incorrectly | Check that the garment label is on the inside and it is at the back. If the garment is still uncomfortable, contact your clinician/clinic for other sizes. |
| Therapy is uncomfortable | Stimulation too high | Decrease amplitude or change programs (see **"Changing Stimulation Settings"**). If this does not resolve your discomfort, contact your clinician/ clinic. |

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| Therapy is not felt | Stimulation too low | Increase amplitude or change programs (see **"Changing Stimulation Settings"**). |
| | Wireless Transmitter is not connecting to your neurostimulator | See below. |
| Wireless Transmitter is not connecting to your neurostimulator | Wireless Transmitter is not worn in correct position | Wireless Transmitter must be worn on your lower back in order to connect to your neurostimulator. Ensure the Wireless Transmitter is in the pocket of your Neuspera Undergarment. Put on the Undergarment so the Wireless Transmitter is positioned over your implanted neurostimulator (see **Figure 5**). |

| Problem | Potential Cause | Recommended Action |
|---|---|---|
| *(Cont.)*<br>Wireless Transmitter is not connecting to your neurostimulator | Wireless Transmitter is not in Undergarment pocket correctly | Check that dotted white side is against your body. The logo/label should be away from your body. |
| | Wireless Transmitter battery is too low | Check battery level from your App (see **Figure 9**). Charge Wireless Transmitter if battery is low. |
| | Stimulation has been turned off | Check the Status screen on your App and confirm Stimulation Power is set to "On" (see **Figure 10**). Tap the switch to turn on, if necessary. |
| | Wireless Transmitter has been damaged (by physical shock, extreme temperatures, and/or water has leaked into device) | Contact your clinician/clinic for a replacement Wireless Transmitter. |

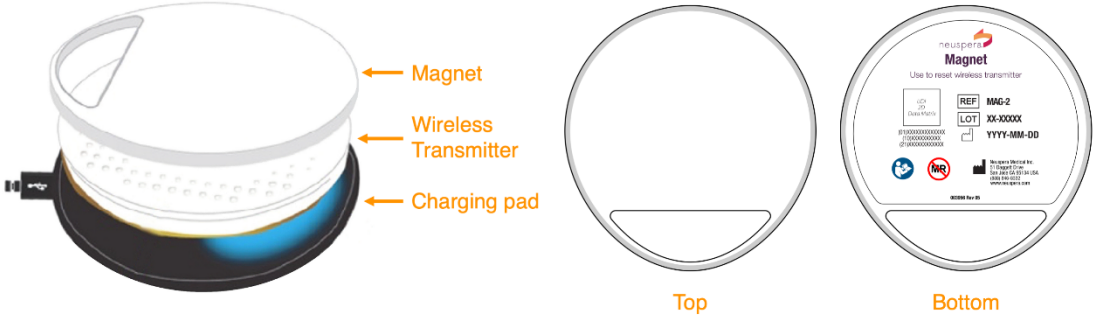



**Figure 13. Resetting the Wireless Transmitter. Place the label side of the magnet (bottom of magnet) on the Wireless Transmitter for 5-10 seconds. The top of the magnet is visible during correct placement. Remove magnet after reset is completed. Do not leave magnet on Wireless Transmitter while it is charging.**

## App Messages, Causes, and Resolutions

| System Message | Cause | Resolution |
|---|---|---|
| **Action Not Available**<br>Cannot change settings while Therapy is active. | User tried to change program while Wireless Transmitter is powering neurostimulator | Tap “OK” to close message. Turn Stimulation Power off, change program, and turn Stimulation Power on (see **Figure 10**). |
| **Therapy Error**<br>Please flip over the WT to clear error. | User tried to turn on WT Power while communication has been turned off<br>or<br>User tried to turn on WT Power after removing WT from charger without flipping WT over. | Tap “OK” to close message.<br>Go to Info page and turn on Communication.<br>or<br>If the WT was just removed from charger, flip over the WT to turn on WT Power. |
| **WT Alert**<br>Battery level below 10% | WT battery is getting low | Tap “OK” to close message.<br>Return Wireless Transmitter to the charging pad. |

| System Message | Cause | Resolution |
|---|---|---|
| **Connection Failed** Connecting to the WT failed, please ensure that the WT is in range and tap yes to try to connect again. | Patient Controller does not detect Wireless Transmitter signal | Ensure Wireless Transmitter and Patient Controller are within 1 meter (3 feet) of each other. Tap "Yes" to try to connect again. If the issue continues, put Wireless Transmitter on charging pad for a few minutes. Remove Wireless Transmitter from charging pad and try again. If the issue continues, close the App, after a few minutes, restart App and try again. |
| **Connection Failed** Please ensure the WT is powered on, Bluetooth advertising, and try again | Patient Controller does not detect Wireless Transmitter signal (2nd message if still cannot connect after above message) | Check battery level from your App (see **Figure 9**).<br>Charge Wireless Transmitter if battery is low. |

| System Message | Cause | Resolution |
|---|---|---|
| **WT Alert**<br>WT temperature algorithm is non-functional | Wireless Transmitter temperature control is not working | Tap “OK” to close message. Discontinue use. Contact your clinician/clinic for a new Wireless Transmitter. |
| **Disconnected**<br>The connection to the WT was lost, would you like to reconnect? | Wireless Transmitter completely drained, turned off due to contact with a magnet, or moved out of range | Ensure Wireless Transmitter is:<br>• Not near a magnet<br>• Charged<br>• Within range (1 meter or 3 feet) of the Patient Controller<br>Click “Yes” to reconnect.<br>If the issue continues, close the App, after a few minutes, restart App and try again. |
| **Retrieval Failure**<br>Log file retrieval encountered an error. Data shown may not have been updated. | Communication between App and Wireless Transmitter interrupted | Tap “OK” to close message. Ensure App is connected to the Wireless Transmitter. Switch to the Status screen and then switch back to the Usage screen to update data. |

| System Message | Cause | Resolution |
|---|---|---|
| **Confirm Delete**<br>Are you sure you want to delete all registered WT's? | User has selected "Delete All Connections" | Tap "No" to exit the message.<br>**NOTE:** Only your clinician or clinic representative, at your clinician's direction, should delete the Wireless Transmitter from your App. |
|  | No Wireless Transmitters are linked to your App | Contact your clinician/clinic. |

# Other Information

## MRI Safety Information

Patients with a Neuspera neurostimulator may have an MRI (magnetic resonance imaging) under certain conditions (referred to as “MR Conditional”). The neurostimulator does **not** need to be programmed to a special mode to undergo an MRI. Consult with your clinician prior to undergoing an MRI.

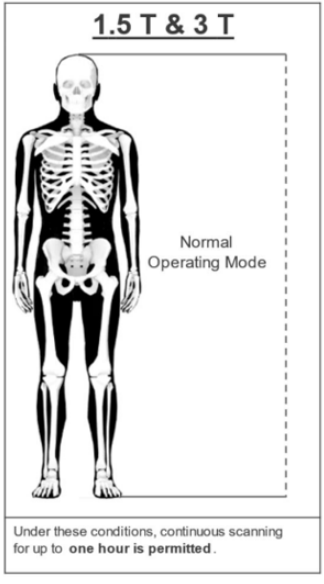
If you need to undergo an MRI, make sure to inform the relevant MRI medical professionals about your implant when you make the appointment for the MR exam and also upon arrival at the MRI facility for the exam. Make sure to present your Patient ID card and inform your clinician or radiologist that the MRI safety information is available in the MRI Safety Information section of the Clinician Manual which can be obtained by calling (888) 846-8332.

Remove all external components before scanning. The Undergarment, Patient Controller, and accessory components including Wireless Transmitter have not been evaluated for safety in MRI and should be considered to be MR Unsafe. Do not bring them into the MR scanner room.

Patients with this device can be safely scanned in an MR system meeting the following conditions:

| Scanner Parameters | Parameter Set |
|---|---|
| Scanner Type | Horizontal Cylindrical Bore |
| Static Magnetic Field Strength (B0) | 1.5T or 3T |
| Maximum Spatial Field Gradient | 2000 G/cm (20 T/m) |
| Operating Mode | Normal Mode |
| Scan Regions | Full Body. Any Landmark is acceptable. |
| Scan Duration | Up to 1 hour of continuous scanning without a cooling period |
| MR Artifact | In non-clinical testing, the image artifact caused by the implanted stimulator extends radially approximately 2.5 cm from the device when imaged in a 3 T MRI system. |

## Predicted Heating Zone Summary




If information about a specific parameter is not included, there are no conditions associated with the parameter.

## Electromagnetic Interference (EMI) Precautions

Electromagnetic interference (EMI) is a disruption caused by fields generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with Neuspera SNM System function. Neurostimulators include features that provide protection from electromagnetic interference. Most electrical devices encountered in a normal day are unlikely to affect the operation of the Neuspera SNM System. However, sources of strong EMI can result in the following:

- System damage, resulting in a loss of or change in symptom control and requiring surgical replacement.
- Operational changes to the system causing the Neuspera SNM System to not turn on or off as expected. The Neurostimulator can always be turned off by removing the Wireless Transmitter.

Removing the interference source or moving away from it should return the Neuspera SNM System to normal operation.

Examples of EMI sources are:

- Switching mode power supplies
- Power substations
- MR imagers
- Cardiac devices
- Strong permanent magnets
- Defibrillators
- Radiation therapy
- Arc welders
- Theft detections/screening devices
- Plasma cutters

Seek medical guidance prior to entering environments which may adversely affect the operation of the Neuspera SNM System, including areas protected by a warning preventing entry to the area by patients with implanted medical devices.

***EMC-Related Precautions***

You should take precautions to protect your Neurostimulator from electromagnetic interference (EMI). (see **"Locations with Electromagnetic Interference (EMI)"**).

- Avoid or move away from sources of electromagnetic interference (EMI) to prevent device malfunction (see **"Locations with Electromagnetic Interference (EMI)"**).
- Remove the Wireless Transmitter during other medical procedures and treatments to avoid potential interference with other medical equipment.
- Inform your healthcare professional about your implanted neurostimulator prior to any medical procedure, including the following
  - procedures that might use electrocautery as this may damage the implant
  - diathermy (shortwave, microwave, or therapeutic ultrasound) and radiofrequency ablation in the vicinity of the neurostimulator. These procedures have not been evaluated to be safe and effective for patients with the Neurostimulator.

- therapeutic ultrasound in the area of the sacral nerve neurostimulator. The device can inadvertently concentrate the ultrasound field and cause harm.
- laser procedures. Remove the Wireless Transmitter. Keep the laser directed away from the neurostimulation system.
- magnetoencephalography (MEG), Computerized axial tomography (CT or CAT) scans, Positron emission tomography (PET) scans. Remove the Wireless Transmitter
- transcutaneous electrical nerve stimulation (TENS). Do not place TENS electrodes so that the TENS current passes over any part of the Neurostimulator. If the TENS seems to be interfering with the implanted Neurostimulator, discontinue using the TENS and contact your clinician.

- Do not use therapeutic ionizing radiation, psychotherapeutic procedures, high-output ultrasonics, or lithotripsy as these procedures can damage the electrical components of the neurostimulator, and any damage may not be immediately detectable.
- Effects of monitoring devices – When using diagnostic monitoring devices such as an electrocardiogram (ECG), Holter Monitor, or electroencephalogram (EEG), remove the Wireless Transmitter as pulses from the Neurostimulator may be detected as an electrical signal.
- The Wireless Transmitter should be removed if the following equipment is used. If it cannot be removed, to ensure the Neuspera SNM System is not affected by EMI adhere to the following guidelines:

- Bone growth stimulators – Keep external magnetic field bone growth stimulator coils 45 cm (18 in) away from the Wireless Transmitter. When using either an implantable or external bone growth stimulator, ensure that both the bone stimulator and Neurostimulator are working as intended.
- Dental drills and ultrasonic probes – Keep the drill or probe 15 cm (6 in) away from the Wireless Transmitter.
- Electrolysis –Keep the electrolysis wand at least 15 cm (6 in) away from the Wireless Transmitter.

- Electromagnetic field devices – You should exercise care or avoid the following equipment or environments when wearing the Wireless Transmitter:

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

- Microwave communication transmitters (generally safe if outside the fenced area)
- Television and radio transmitting towers (generally safe if outside the fenced area)

*Note*: If you suspect that equipment is interfering with Wireless Transmitter function, you should do the following:

- Move away from the equipment or object.
- If possible, turn off the equipment or object.
- Then, if necessary, use the Patient Controller App to return the Wireless Transmitter to the desired on or off state and amplitude.
- Inform the equipment owner or operator of the occurrence.

*Note: If the above actions do not resolve the effects of the interference, or you suspect that their therapy is not effective after exposure to EMI, you should contact their clinician/clinic.*

- Avoid psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have an implanted Neurostimulator. Induced electrical currents may cause heating of the Neurostimulator resulting in tissue damage.

- Radiation therapy – High-radiation sources should not be directed at the Neurostimulator. High-radiation exposure may temporarily interfere with Neurostimulator operation and may damage the Neurostimulator. Damage may not be immediately apparent. To limit device exposure, use appropriate shielding or other measures, such as making beam angle adjustments to avoid the device.

### *Considerations for Locations and Environments*

#### *Home Environment*

**CAUTION:** Keep away from lint, dust, or directed sunlight, otherwise Wireless Transmitter may not function as specified.

This Neuspera system has been designed for use in the home environment. Patients use their devices primarily at home or at work; some do therapy during daily activities. Most household appliances and equipment that are working properly and grounded properly will not interfere with your Neuspera System. Metal surfaces (e.g., wall, chair back) against your Wireless Transmitter may temporarily interrupt therapy (stimulation). If you notice an interruption in therapy move away from the metal surface.

The following equipment is generally safe if you follow these guidelines:

- Portable RF communications or wireless power equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables

specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Stereo speakers and radios for the home or car: Do not lift or carry speakers or radios near the Wireless Transmitter.

- Induction range (a glass stovetop with burners under the surface): Keep the Wireless Transmitter away from the burners while they are turned on.
- Power tools: Keep the motors away from the Wireless Transmitter.
- Avoid close proximity to high power wireless power transfer equipment such laying between Electric Vehicle (EV) wireless chargers and the vehicle

The Wireless Transmitter and Patient Controller generate and radiate radio-frequency energy that may, in some instances, interfere with radio communications from other devices. If you suspect that your system is causing interference with other devices, move your Wireless Transmitter and Patient Controller away or turn off system communications using your App (see **Figure 11**).

### *Locations with Electromagnetic Interference (EMI)*

**CAUTION:** If your Wireless Transmitter is damaged by EMI, you may experience excessive heating of the device and/or the area of your back near the Wireless Transmitter.

**CAUTION:** Your Wireless Transmitter, Patient Controller, and charging pad emit EM. Use of these devices near other EM equipment may affect equipment performance. If use of your Neuspera System near EM equipment is necessary,

check that both your system and the equipment are operating normally.

**CAUTION:** Portable radio communications or wireless power equipment (including accessories such as antenna cables and external antennas) should be used no closer than 30 centimeters (12 inches) to any part of your Neuspera System when the Wireless Transmitter or Patient Controller are turned on. When used closer, the performance of the radio equipment may be affected.

Equipment that emits large amounts of electromagnetic radiation (EM) may interfere with the proper functioning of your Neuspera System. Examples of such equipment are:

- Switching mode power supplies
- Power substations
- MRI equipment
- Cardiac device
- Defibrillators
- Radiation equipment
- Arc welders
- Strong permanent magnets

***Essential Performance***

The device has essential performance, as defined by IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed 3.2), of stimulation output charge balance and charge density. Performance of the device was maintained during electromagnetic disturbance testing.

### *Recognized EMC Standards*

The device complies with the requirements for medical devices contained in

- IEC 60601-1-2:2014, 4th ed
- CISPR11:2015+AMD1:2016
- ANSI IEEE C63.27:2017
- IEC 60601-1-11:2015, 2nd ed.
- IEC /TR 60601-4-2:2016, 1st ed.
- ISO 14708-3:2017, 2nd ed.

### *Electromagnetic Emissions and Environment*

The Neuspera SNM System is intended for use in the electromagnetic environment specified below. The user of the Neuspera SNM System should make sure it is used in such an environment.

**Table 18. Guidance and manufacturer's declaration – electromagnetic emissions**

| Emissions Test | Compliance | Electromagnetic Environment-Guidance |
|---|---|---|
| RF Emissions<br>CISPR 11 Group 1 | Class B | The external stimulator uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause interference in nearby electronic equipment. |
| RF Emissions<br>CISPR 11 Group 2 | Class B | The Wireless Transmitter must emit electro-magnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |

**Table 19. Guidance and manufacturer's declaration electromagnetic immunity**

| Test and Method | Test Levels | Compliance level | Electromagnetic environment – guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV and ±15 kV air | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV and ±15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m at 50Hz/60Hz | 30 A/m at 50Hz/60Hz | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or professional healthcare environment. |
| Radiated RF IEC 61000-4-3 | 10 V/m<br>80 MHz to 2.7 GHz<br><br>Refer to Table 3 for wireless proximity RF field test levels | 10 V/m<br>80 MHz to 2.7 GHz<br><br>Refer to Table 3 for wireless proximity RF field test levels | |
| Radiated Fields in Close Proximity | 8 A/m CW | 8 A/m CW | |

| | | | |
|---|---|---|---|
| IEC 61000-4-39 | 65 A/m, Pulse modulation 2.1 kHz<br>7.5 A/m, Pulse modulation 50 kHz | 65 A/m, Pulse modulation 2.1 kHz<br>7.5 A/m, Pulse modulation 50 kHz | |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Neuspera SNM System is used exceeds the applicable RF compliance level above, the Neuspera SNM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Neuspera SNM System. | | | |

**Table 20. Guidance and manufacturer's declaration electromagnetic immunity**

| Test Frequency (MHz) | Band (MHz) | Service | Modulation | Immunity Test Level (V/m) | Compliance Level (V/m) |
|---|---|---|---|---|---|
| 385 | 380 - 390 | TETRA 400 | Pulse Modulation 18Hz | 27 | 27 |
| 450 | 430-470 | GMRS 460<br>FRS 460 | FM ± 5kHz deviation<br>1kHz Sine Wave | 28 | 28 |
| 710<br>745<br>780 | 704 - 787 | LTE Band 13 & 17 | Pulse Modulation 217 Hz | 9 | 9 |
| 810<br>870<br>930 | 800 - 960 | GSM 800/900<br>TETRA 800<br>iDEN 820<br>CDMA 850<br>LTE Band 5 | Pulse Modulation 18Hz | 28 | 28 |
| 1720<br>1845<br>1970 | 1700-1990 | GSM 1800<br>CDMA 1900<br>DECT<br>LTE Band | Pulse Modulation 217 Hz | 28 | 28 |

| **Test Frequency (MHz)** | **Band (MHz)** | **Service** | **Modulation** | **Immunity Test Level (V/m)** | **Compliance Level (V/m)** |
|---|---|---|---|---|---|
| | | 1,3,4,25, UMTS | | | |
| 2450 | 2400-2570 | Bluetooth<br>WLAN<br>802.11b/g/n<br>RFID 2450<br>LTE Band 7 | Pulse Modulation<br>217 Hz | 28 | 28 |
| 5240<br>5500<br>5785 | 5100 -5800 | WLAN 802.11 a/n | Pulse Modulation<br>217 Hz | 9 | 9 |

## Electronic Article Surveillance

Electronic Article Surveillance/Anti-theft systems such as those at the point of sale and entrances/exits of stores, libraries, banks, etc., emit signals that may interact with your Neuspera System. It is very unlikely that these systems will interact significantly. The most likely effect is the WT may turn off momentary and therapy may need to be reinitiated through the app (See **Figure 10**). To minimize the possibility of interaction, however, walk through these areas at a normal pace and avoid lingering near or leaning on these systems.

## TSA and Other Security Screening

Remove all external accessories prior to walking through a metal detector or other security screening. You may need to provide the officer with your patient ID card or the TSA (transportation security administration) notification card* to describe your condition. You may need to undergo a manual ("pat-down") screening. If you go through security screening with the system active, the WT may turn off momentarily and therapy may need to be reinitiated through the app (See **Figure 10**).

*The TSA notification card template can be found on their website: https://www.tsa.gov/sites/default/files/disability_notification_card_508.pdf.

It is recommended to fill this out by stating you have an internal medical device. Bring the card with you to security.

## Technical Details

### *Neurostimulator*

The Neuspera Sacral Nerve neurostimulator is an implantable device that is like a short wire with 4 electrodes. Electrical impulses are delivered through these electrodes. The electrical impulses are voltage driven, may vary in amplitude (0.2–4.8 V), pulse width (105–945 µs), and pulse frequency (5–100 Hz). Your clinician will determine the appropriate settings for you.

### *Wireless Transmitter*

The Wireless Transmitter communicates wirelessly with the implanted neurostimulator and the Patient Controller. The Wireless Transmitter contains two antennae. One antenna connects to the implanted neurostimulator to transmit power using mid- field powering technology developed by Neuspera. This antenna must be directly over (within 3 cm) the neurostimulator to deliver power. The other antenna connects to the App using Bluetooth® technology. The Wireless Transmitter is powered by a rechargeable lithium-ion battery that is recharged on a wireless charging pad.

| | |
|---|---|
| Battery capacity | ≥2000 mAh |
| Battery capacity (therapy time) | Minimum 2 hours (will vary with therapy) |
| Time for full recharge | ≤5 hours |
| Maximum operating temperature (surface of Wireless Transmitter) | <60°C (140°F)* |
| Frequency range (implant powering) | 902–928 MHz (ISM compliant) |
| Frequency range (Bluetooth) | 2.4–2.5 GHz |
| Water resistance | IP25 (Protected from touch by fingers and objects greater than 12 millimeters. Protected from low pressure water jets from any direction) |
| Diameter | 8 cm (3.1 inches) |
| Thickness | 15 mm (0.6 inches) |
| Weight | 103 g |

**If the Wireless Transmitter reaches 60°C, it will stop stimulation until it cools down.*

***Power Transmission Frequency Range***

Your Wireless Transmitter communicates best with your neurostimulator in the 902 - 928 MHz industrial, scientific, and medical (ISM) frequency band specifically allocated for use by medical devices in North America.

***Undergarments***

The Neuspera Undergarment is specially designed to hold and position the Wireless Transmitter over the sacrum. The Wireless Transmitter is placed in a padded and insulated pocket sewn into the waistband of the Undergarment to hold the Wireless Transmitter against your body comfortability. The Undergarments are provided in sizes from Extra Small to XXX-Large. The Undergarments are made from standard garment material (spandex, nylon, polyester, and polyurethane).

***Charging pad and Patient Controller***

The charging pad and Patient Controller hardware (iPhone) are standard consumer electronics. See manufacturer's manuals for additional information on these devices. Both of these devices may be charged from USB (2.0 or 3.0 ports) or 120V and 240V power mains (standard wall outlet).

The iPhone (“Patient Controller”) has been specially configured to maintain security of the Neuspera patient software application (“App”) used to control your Wireless Transmitter. Your App can only communicate with your Wireless Transmitter.

### *System Compliance to Standards*

| | |
|---|---|
| Neurostimulator | ISO 14708-3 (active implantable devices - neurostimulators) IEC 60601-1<br>ISO 10993 (permanent tissue contact) |
| Wireless Transmitter | IEC 60601-1 (Type BF Applied Part)<br>IEC 60601-1-6<br>IEC 60601-1-11<br>IEC 62133-2 (battery) |
| Patient Controller | IEC 60950-1 |
| Charging pad | FCC Part 15 Subpart C 15.209 |

## Service Life/Ordering Replacements

When used as intended, the estimated service life for your Neuspera System components is as follows:

| Component | Service Life | Signs it should be replaced |
|---|---|---|
| Neurostimulator | 3 years | Does not provide expected stimulation |
| Undergarment | 1 year | Worn out/won't hold Wireless Transmitter in correct position |

*To order replacement components, contact your clinician /clinic.*

## Safe Disposal

All components of your system (Wireless Transmitter, Patient Controller, magnet and charging pad) should be returned to your clinician/clinic for disposal. Your data will be extracted for your patient record and all personal information will be erased.

## Operating, Storage and Transportation Conditions

The Wireless Transmitter and Patient Controller both run on lithium-ion batteries. These devices are designed to be used and stored in the following conditions:

| | Operating Temperature Range | Storage and Transportation Temperature Range |
|---|---|---|
| Wireless Transmitter | 5°C to 35°C (41°F to 95°F)* | -25°C to 55°C (-13°F to 131°F)** |
| Patient Controller | 0°C to 35°C (32°F to 95°F) | -20°C to 45°C (-4°F to 113°F) |

**NOTE:* *The operating conditions of the Wireless Transmitter are within a relative humidity range of 15% to 90% non-condensing but not requiring a water vapor partial pressure greater than 50 hPa, and an atmospheric pressure range of 700 hPha to 1,060 hPa.*

***NOTE:* *The Wireless Transmitter may be exposed to temperatures as low as –30°C (–22°F) for up to 24 hours and may be stored at temperatures as high as 55°C (131°F) for up to one (1) month. Prior to using, the Wireless Transmitter should be allowed to come to room temperature (this may take up to 5 hours).*

The devices may be damaged and battery life shortened if used or stored outside these temperature ranges. Avoid exposing the devices to dramatic changes in temperature or humidity. Avoid leaving the Wireless Transmitter or Patient Controller in the car where temperatures can be extreme.

Avoid leaving the Wireless Transmitter and Patient Controller in wet areas (sinks, showers, tubs) or near sources of heat (stove, fireplace, radiant heaters). The Undergarment, magnet and charging pad do not have restrictions on use or storage temperatures.

## Technical Maintenance

**WARNING:** No modification of the equipment is allowed. Modifying the equipment may make it unsafe.

**CAUTION:** Do not attempt to remove or replace the batteries in the Wireless Transmitter or Patient Controller.

No technical maintenance is required on any of the Neuspera System components. See **“Care of Your System”** for general care of the components.

The Neuspera System components are not repairable by service personnel.

## Quality of Service and Security for Wireless Technology

### *Quality of Service*

The Neuspera System uses wireless communication between the Neurostimulator and Wireless Transmitter, and between the Wireless Transmitter and Patient Controller and Clinician Programmer.

The wireless service between the neurostimulator and the Wireless Transmitter is in the 902-928MHz ISM band. The Wireless Transmitter should be placed directly over the implant within the Undergarment. All communication is verified for accuracy. Any communication containing uncorrectable errors are rejected and communication is retried automatically.

The wireless service between the Patient Controller or Clinical Programmer to the WT is in the 2.4-2.5 GHz ISM band utilizing the 802.15.4 standard. The typical communication range between the Patient Controller or Clinical Programmer and the Wireless Transmitter is 3 feet. Any communication containing uncorrectable errors are rejected and communication is retried automatically. The user is notified if the wireless link is dropped.

See troubleshooting section for additional information on addressing issues that may arise.

### *System Security*

After the Neurostimulator is implanted, the Wireless Transmitter will be uniquely paired to your implant and the Clinician and Patient Apps (see **Figure 14**).

The Wireless Transmitter communicates with the Patient Controller App in the Patient iOS device over a Bluetooth LE (BLE) link. The data over this BLE link is also encrypted and authenticated. The Patient Controller App is downloaded onto the Patient iOS device over WiFi.

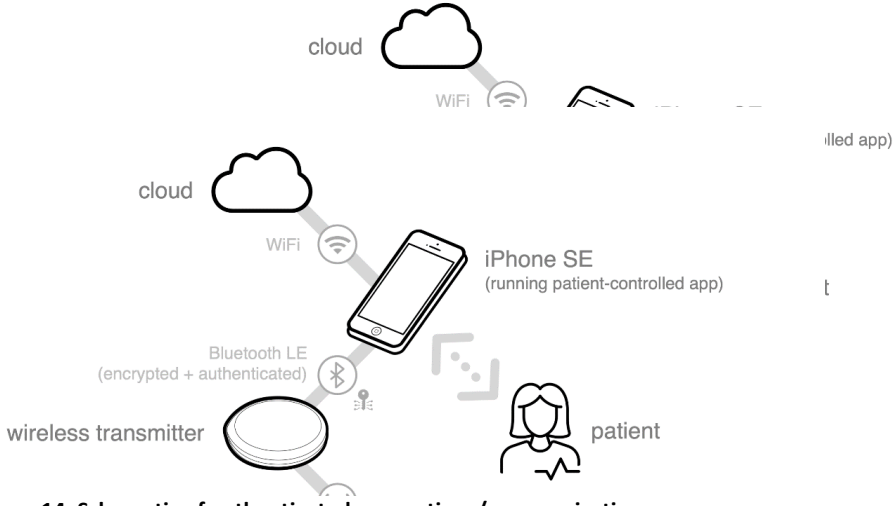



**Figure 14. Schematic of authenticated connections/communications**

### *Device Features*

The Wireless Transmitter receives selected preprogrammed therapy configuration parameters from the Patient Controller. The Wireless Transmitter also receives complete therapy configuration from the Clinician Programmer. The Wireless Transmitter delivers power and therapy configuration to the Neurostimulator. Wireless Transmitter firmware updates are made wirelessly from the Clinician Programmer.

The Neurostimulator is only powered when energy is received from the Wireless Transmitter. When the Wireless Transmitter is removed, power is lost in the Neurostimulator, and it stops functioning. The Neurostimulator does not retain any operating configuration or data when power has been removed. Powering of the Neurostimulator is unique and cannot be accomplished with existing off the shelf components. Additionally, the mid-field powering technology used to power the Neurostimulator has a limited range of operation (within centimeters), thereby mitigating in a physical manner any unapproved device trying to communicate with the Neurostimulator.

### *User Configurable Cybersecurity Controls*

There are no installable or user alterable security controls.

### *Secure Configuration*

An advanced cryptographically secure process is used to uniquely pair your Neurostimulator to your Wireless Transmitter and the Wireless Transmitter to the Patient Controller App. The Wireless Transmitter will only communicate with an authenticated paired Patient Controller. Only a single Patient Controller App may be authenticated to link to a Wireless Transmitter. Only a single Wireless Transmitter may be paired to an App at a time.

Data integrity checks are performed by the Neurostimulator to ensure it only responds to the paired Wireless Transmitter.

### *Hardware, Software, Infrastructure Requirements*

The Neuspera SNM System is only supported on the hardware and software provided by Neuspera.

### *Password Requirements*

The user is recommended to set up a password through the iOS operating system for the Patient Controller.

### *Authentication*

The system is designed to ask for an encrypted message to be sent and received prior

system operation to ensure that both the sender and receiver of system information are authorized. The Patient Controller will each pair through a different workflow of authorization. The Patient Controller must scan a generated barcode from a Clinician Programmer to pair to the Wireless Transmitter.

***Network Ports***

There are no network ports except the WiFi connections in the Patient Controller.

***Software Bill of Materials (SBOM)***

Contact the manufacturer by phone or email provided to access the human readable SBOM.

***Updating of Application and Device Firmware***

When an update or a patch is available for the Patient Controller App, a notification is sent to the patient about the availability along with a link to download. The patient can then download the Patient Controller App.

***Backup and Restore***

No backup or restore function is provided.

### *Retention/Recovery of Device Configuration*

The Neuspera SNM System retains a log of therapy information within the Wireless Transmitter. Recovery of this information is not supported with loss of data.

### *Log Files*

The general log contains errors from various security functions, including authentication for troubleshooting and product investigations.

### *End of Support*

The Neuspera SNM System will continue to function to the end of the service life (see **“Service Life/Ordering Replacements”**).

### *Decommissioning*

Data may be removed from the Patient Controller by uninstalling the Neuspera App and deleting the files. Data may be removed from the Wireless Transmitter by leaving the Wireless Transmitter off the charger on for several sessions such that all data is overwritten.

## Contact Your Clinician/Clinic

For assistance in setting up, using, or maintaining your Wireless Transmitter or system or to report unexpected operation or events, contact your clinician/clinic.

For questions regarding the Neuspera SNM System, contact our Customer Support Center toll-free at (888) 846-8332.

## Symbols

Explanation of symbols used on product or package labeling.

| Symbol | Description |
|---|---|
|  | Catalog number |
|  | Serial number |
|  | Wireless transmitter identification number |
|  | Manufacturer |
|  | Refer to instruction manual |
|  | Magnetic Resonance (MR) Conditional |
|  | Magnetic Resonance (MR) Unsafe |

| Symbol | Description |
| --- | --- |
|  | Upper limit of temperature |
|  | Temperature limit |
|  | Humidity limitation |
| IP25 | Protected from touch by fingers and objects greater than 12 millimeters.<br>Protected from low pressure water jets from any direction. |
| Rx only | Requires prescription in the United States |
|  | Non-ionizing electromagnetic radiation |
|  | Battery charge level |
|  | Wireless signal strength |
|  | Do not dispose of this product in the unsorted municipal waste |

| Symbol | Description |
| --- | --- |
|  | Type BF applied part |
|  | Machine wash warm |
|  | Non chlorine bleach |
|  | Tumble dry low |
|  | Iron low heat |

## Glossary of Terms

Explanation of terms used on product or package labeling.

| Acronym/ Abbreviation | Term |
|---|---|
| EM / EMI | Electromagnetic / Electromagnetic Interference |
| g | Grams |
| IT | Information Technology |
| mA / µA | Milliamperes / Microamperes |
| MR / MRI | Magnetic Resonance / Magnetic Resonance Imaging |
| RF / RFID | Radiofrequency / Radiofrequency Identification |
| SNS | Sacral Nerve Stimulation |
| UUI | Urinary Urge Incontinence |
| USB | Universal Serial Bus |
| V | Volts |
| WT | Wireless Transmitter |

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# Neuspera Trial System

## Patient Manual

℞ only

Patent information covering this product is available at www.neuspera.com/patent-information/

# Contents

# Getting to Know Your System

The Neuspera Sacral Neuromodulation System ("Neuspera SNM System") is intended to deliver electrical stimulation to the sacral nerve.

Neuspera SNM System is indicated for the treatment of urinary urge incontinence in patients who have failed, could not tolerate, or were not a candidate for more conservative treatments.

## Neuspera System Components

The Neuspera System is composed of several components, described below and shown in **Figure 1** and **Figure 2**.

A. A small **Trial Lead** (similar to a wire) is implanted in your lower back by your clinician.

B. The **External Stimulator** is connected to the temporary lead and delivers pulses of energy to the sacral nerve that helps control the bladder. The External Stimulator will continue to stimulate as programmed as long as the Orange U-Clip remains in the closed (flush) position. **Note: If stimulation is uncomfortable at any time, the Orange U-Clip on the External Stimulator can be pulled back to immediately stop stimulation** (see **Figure 3**)**.**

C. A **Wireless Transmitter (WT)** is used to allow communication between the External Stimulator and Patient Controller. Your Wireless Transmitter must be placed

against the External Stimulator to facilitate communication. This device is water-resistant to allow for cleaning. The device is powered by a rechargeable battery that is recharged on a wireless charging pad.

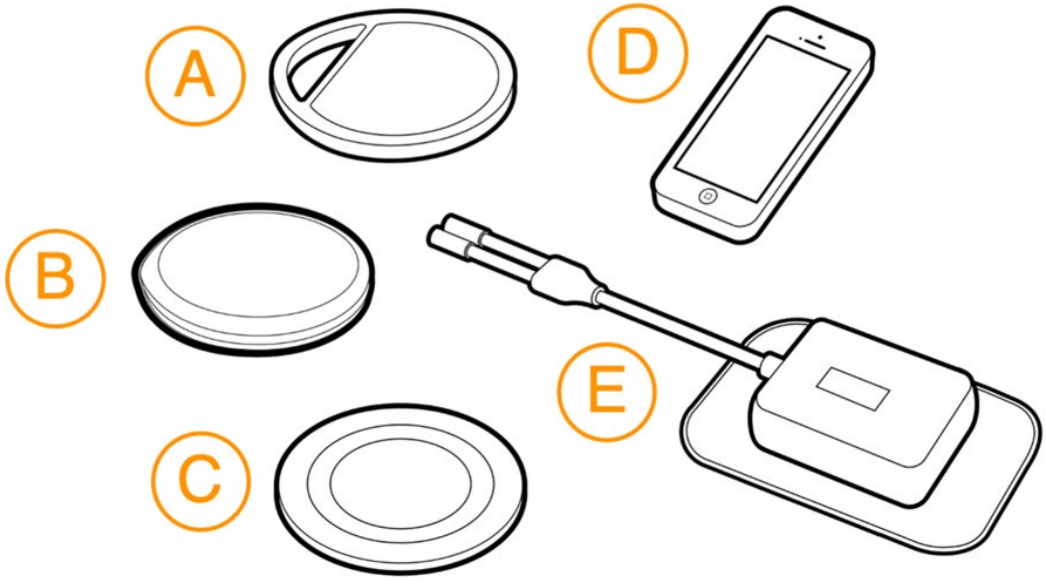
D. The Wireless Transmitter will be provided with a **magnet**, which is used to reset the Wireless Transmitter and to turn the Wireless Transmitter off to preserve battery life.

E. The Wireless Transmitter **charging pad** is used to recharge the Wireless Transmitter.

F. The **Patient Controller** adjusts therapy settings to optimize comfort and symptom relief. The Patient Controller also allows you to monitor battery levels of the Wireless Transmitter, change stimulation programs, and turn communications from your Wireless Transmitter and Patient Controller on/off.

■ **NOTE:** Your Wireless Transmitter is specific to your External Stimulator and your Patient Controller. Another person's Wireless Transmitter will not work with your External Stimulator. Another person's Patient Controller will not work with your Wireless Transmitter.

All parts of the Neuspera system are suitable for use at home. Your system should not be affected by standard household appliances or devices under normal use (for additional information, see **“Home Environment”** ).




**NOTE:** Images not to scale.

**Figure 1. The Neuspera Trial System**

**A. Magnet, B. Wireless Transmitter (WT), C. Charging Pad; D. Patient Controller, E. External Stimulator with Ground Pad**

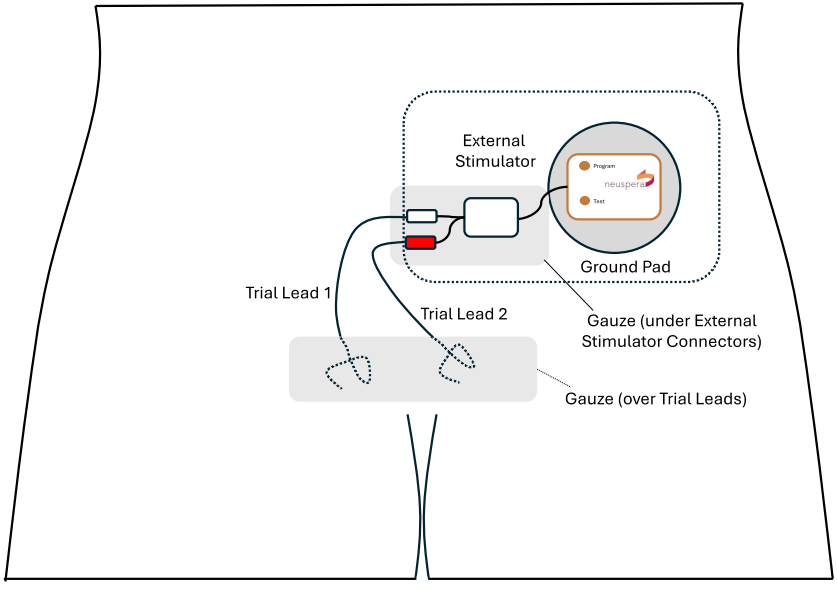



**Figure 2. Placement of Neuspera Trial System.**

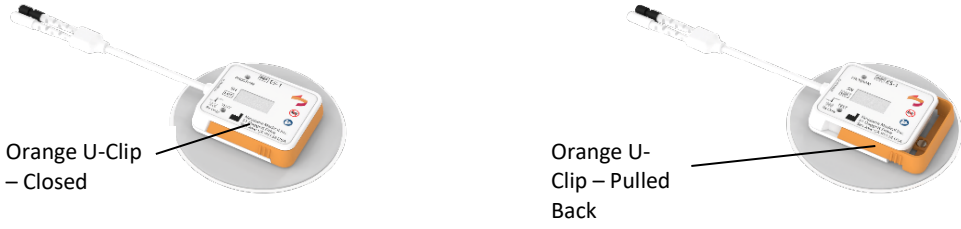



**Figure 3. External Stimulator with Orange U-Clip. Closed (Left); Pulled Back (Right)**

# Contraindications, Warnings, Precautions, Adverse Events, and Risks

## Contraindications

- Patients with sacral depth measured from the skin to the S3 foramen greater than 10 cm as confirmed by imaging.
- Patients who did not have adequate response to test stimulation.
- Patients who are unable to operate the Neuspera Trial System.
- Men who have Benign Prostatic Hyperplasia (BPH) or patients with other blockages in their lower urinary tract that could lead to significant blockages or

other issues.

After the Trial System is implanted, the following contradictions apply:

- Treatments that send electrical currents into the body near the Neurostimulator, as this can permanently damage the device
- Medical treatments or procedures that use electric fields (like diathermy), unless the procedure is specifically listed as safe in the instruction manual (like MRI scans).

## Warnings

Do not take apart or change the devices, and only use the accessories mentioned in this manual. Changing or using the equipment in the wrong way can make it unsafe or stop it from working properly. Contact your healthcare provider if you need a new device.

If you have loss of stimulation, contact your healthcare provider. Sometimes the Neurostimulator can break or move from where it is supposed to be. Your healthcare provider check for any problems with the device or its position.

Do not wear the Wireless Transmitter directly on your skin. Wearing the Wireless Transmitter directly on your skin could cause discomfort, irritation, or a burn.

Do not use the Wireless Transmitter in very hot places (above 35°C or 95°F) or in spots where air cannot move around it, like under a blanket, thick clothing, or on a heavily

cushioned chair. This could make the Wireless Transmitter too hot and cause burns or other injuries. Use the device in a chair with minimal padding or while moving around.

Do not use the Wireless Transmitter if you cannot feel heat, such as while sleeping. If the device gets too hot, it could burn or hurt you.

Electromagnetic Interference (EMI) from different devices can damage the Trial System, make it stop working, or even harm you. Here are some things to watch for:

- Defibrillation or Cardioversion
  - If you have heart problems like ventricular or atrial fibrillation, doctors might use a defibrillator or cardioversion to save your life. These treatments can damage the Trial System and create electric currents that may hurt you. Always let your doctor know if you are about to have or already had defibrillation or cardioversion so they can minimize the risk to you and the device and can check the device afterwards to make sure it is working safely.
- Electrocautery
  - Electrocautery tools, used to heat tissue during surgery, can cause problems if used near the Trial System or its parts. They may harm the tissue close to the device, damage the Trial System, or change how it works temporarily.
  - If electrocautery is needed, follow these rules:
    - Always let your doctor know if you're about to have or already had a procedure where electrocautery is used. They can minimize the risk to

you and the device and can check the device afterwards to make sure it's working safely
    - Remove the Wireless Transmitter and External Stimulator prior to any procedure with electrocautery.
    - After electrocautery, have your healthcare provider check that the device is functioning as intended.
- High-output ultrasonics or lithotripsy – Use of high-output ultrasonic devices, such as electrohydraulic lithotripters, is not recommended if you are undergoing a stimulation trial. You should wait until after your trial procedure is done and the Trial System is removed before having these procedures.
- Radiofrequency (RF) or microwave ablation – The safety has not been established for RF or microwave ablation in patients who have the Trial System. Induced electrical currents may cause heating of the Trial Lead resulting in tissue damage. You should wait until after their trial procedure is done and the Trial System is removed before having these procedures.
- Effects of monitoring devices – Avoid using diagnostic monitoring devices such as an electrocardiogram (ECG), Holter Monitor, or electroencephalogram (EEG) if you are undergoing a sacral nerve stimulation trial procedure with the Neuspera trial systems as pulses from the External Stimulator may be detected as an electrical signal. You should wait until after your trial procedure is done and the Trial System is removed before having these procedures.

- Theft detectors and security screening devices (*Note*: Some theft detectors and screening devices might be hidden from view).
    - Theft detectors found in stores, libraries, and similar places, as well as security screening devices at airports or government buildings might cause a brief change in stimulation. When passing through these devices while undergoing a trial procedure with the Neuspera Trial System, you might feel the stimulation switching on and off while passing through these devices. If your stimulation levels are low, you may feel a small change in stimulation.
    - When you approach these devices, follow these steps:
        - If you can, ask to skip these devices. Security staff might use a handheld wand instead, but you should ask them not to hold it over the Trial System longer than necessary. You can also ask for another type of personal search.
        - If you have to go through one of these devices, use your Patient Controller and Wireless Transmitter to turn off your External Stimulator.
        - If there are two gates, walk through the middle of them at a normal pace, stay as far from each gate as you can.
        - If there is only one gate, walk as far away from it as possible.
        - Go through the device at a normal speed and do not stop or lean on it.
        - After you are done, you can turn your therapy back on.

## Precautions

(see also the EMI Precautions at the end of this manual)

- Do not use your Wireless Transmitter, Patient Controller, charging pad, or charging cables if they are damaged. Using damaged devices and cables may cause fires, electrical shocks, injuries, or more damage. Contact your healthcare provided if you need a replacement device.
- Make sure the Wireless Transmitter is not punctured or damaged to avoid battery leaks.
- If you notice a rash or other skin reaction, stop using the device and contact your healthcare provider.
- The Wireless Transmitter is not intended for direct skin contact.
- Turn off stimulation or remove the Wireless Transmitter if any of the components becomes uncomfortably hot.
- The Wireless Transmitter may heat up while charging. Do not wear the WT while it is charging since it heats up during charging. The Wireless Transmitter cannot communicate while charging.
- Inform your healthcare professional about your Trial System prior to any medical procedure.
- The External Stimulator should not be placed in areas with broken or blistered skin or with poor circulation.

- Do not take the Wireless Transmitter, Patient Controller, and Clinician Programmer into any room with an MRI machine. They could be drawn into the machine and cause serious harm. The Neuspera Trial Lead and External Stimulator are MR Unsafe. Check the MRI Safety Information section for details.
- The safety and performance of the Neuspera System has not been evaluated for the following:
    - People with a BMI over 40,
    - Pregnant women,
    - Children,
    - Stimulation at two implant sites with the permanent Neuspera SNM System (stimulation at two implant sites may be used with the Trial System),
    - People with certain health conditions like neurologic causes of overactive bladder (OAB), multiple sclerosis, diabetes, or Parkinson's disease.
- The Neuspera System has not been tested for compatibility with other active implantable medical device such as neurostimulators, drug pumps, pacemakers, or internal defibrillators. Do not use the System with an active implantable device.
- The Neuspera System has not been tested for compatibility with cardiac

defibrillation. If you have been defibrillated, contact your clinician to check the performance of your Neuspera System.

- Only use items with the Neuspera System that have been specified as part of the system or that have been specified as being compatible with the system.
- Keep all charger cables away from small children or infants for risk of strangulation.
- Keep all components out of reach of children, pets and pests, which may damage the device from rough handling.

### *Patient Activities*

During the trial procedure, limit physical activities that may put stress on the External Stimulator and Trial Lead. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional procedures to replace or reposition the component.

You should avoid the following activities:

- Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching.
- Sexual activity during the trial period.
- Activities such as gymnastics, mountain biking, and other sports or equipment that involve the movements described above.
- Chiropractic manipulation

- Activities that could be unsafe for yourself or others (e.g., driving or the use of dangerous equipment) if they were to receive an unexpected jolt or shock.
- Baths, swimming and hot tubs. Sponge baths are allowed during the trial phase. Showers may be allowed during the trial period if water-proof bandages are used; check with your physician to determine if showering is allowed.

Use caution with normal activities such as getting dressed and putting on shoes. Postural changes, and other activities may result in you noticing an increase in stimulation which may be uncomfortable; it can be a jolting or shocking sensation.

Do not remove the bandages. If dressing becomes soiled, wet, or loose, apply new dressings over the top of the old dressings. A small amount of blood is normal.

Turn the test stimulator OFF while driving (it may remain on if you are a passenger). A sudden jolt or bump could cause the Trial Lead electrode to move closer to the nerve resulting in uncomfortable or painful stimulation. If you were driving at the time, the sudden discomfort or pain could cause you to lose control of the vehicle resulting in significant injury or death.

### *Component Manipulation*

Refrain from receiving any form of spinal or pelvic manipulation in the area of the Trial System by chiropractors. This manipulation may result in implant fracture or dislodgement, which may result in loss of stimulation, intermittent stimulation, or pain at the implant site.

Refrain from manipulating the External Stimulator. Pushing on or rubbing the Trial System components may cause damage, dislodgement, uncomfortable stimulation, or pain at the implant site.

## Adverse Events and Risks

Below is a list of the potential adverse effects (e.g. complications) associated with the use of the device. In addition to the risks normally associated with surgery and anesthesia, the following adverse events may occur:

- Adverse change in voiding function (bowel and/or bladder function)
- 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
- Implant erosion (wearing away of skin)
- Implant fracture/failure
- Implant migration (movement)
- Electrical shock
- Heating or burn at implant site or site of Wireless Transmitter placement
- Infection
- Lack of effectiveness
- Pain or irritation at implant site
- Reoperation/Revision

- Seroma (accumulation of body fluids), hemorrhage (bleeding), and/or hematoma (accumulation of blood, or bruising)
- Nerve injury (including numbness)
- Technical device malfunction leading to an adverse event
- Transient electric shock or tingling
- Vulvovaginal pain or pelvic pain
- Unintended nerve activation (feelings of shock or tingling)

Contact your clinician if any of these events occur.

# Summary of Clinical Evaluations

## Introduction

Neuspera did a study to see if the Neuspera SNM System is safe and works for treating urinary urge incontinence (UUI). The study happened at 29 clinical sites in the U.S. and 2 clinical sites in Europe. It involved patients who did not do well with or were not candidates for more conservative treatments, like pelvic floor exercises, biofeedback, or medications. A total of 128 patients got the Neuspera SNM System implant. Here is how the study was set up and what the data shows.

## Study Design

The study showed that the Neuspera SNM System was safe and worked to help reduce symptoms of urinary urge incontinence (UUI) in patients. Researchers looked at how well the system worked after six and twelve months. They figured out its success by checking if people who got the implant had fewer UUI episodes—at least 50% less—compared to before they started using the device. These people are “responders.” The study also checked the safety of the system by counting serious problems (“adverse events”) caused by the device for the twelve months after it was implanted.

To be in the study, patients needed have UUI for at least six months and have at least one UUI episode per day and at least four episodes over a three-day period. They had to be a good surgical and study candidate and be able to operate the device. The location that the implant would be in their body had to be not deeper than could be powered by the Wireless

Transmitter. They had to be 22 years of age or older with a Body Mass Index (BMI) between 18 and 40 40 kg/$m^2$. Patients had to stop taking their UUI medications long enough for the effects of the medications to wear off completely.

## Patient Disposition

At 31 sites, 242 people signed up for the study. Out of those, 130 people started the implant process, and 128 of them successfully got the implant. **Figure 4** shows what happened to everyone at the time of the 12-month analysis. At the time of the 12-month analysis, reasons why some people left the study include the following: 33.1% (80 out of 242) didn't meet the rules to join, 10.3% (25 out of 242) changed their minds, 3.7% (9 out of 242) were not happy with the therapy, 2.5% (6 out of 242) could not be reached, 1.7% (4 out of 242) were removed by the researcher, 1.7% (4 out of 242) left because the sites were closed by the sponsor, 1.2% (3 out of 242) had adverse events, 0.8% (2 out of 242) had an implant attempt that didn't work, 0.4% (1 out of 242) passed away, and 2.9% (7 out of 242) left for other reasons.

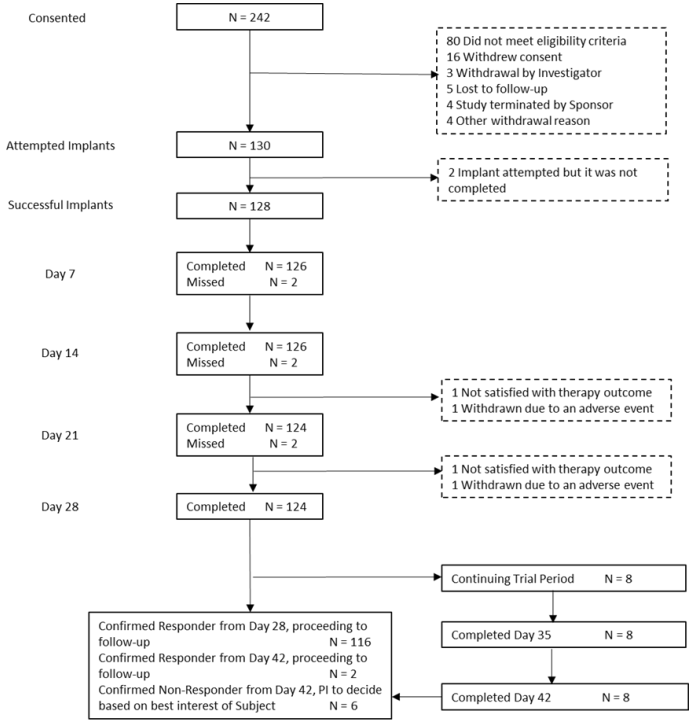



**Figure 4: Patient Disposition – Post Implant Period**

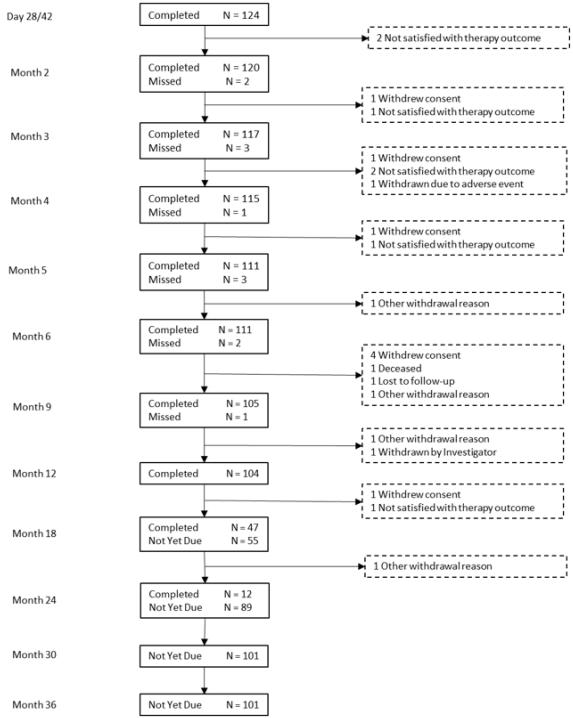



**Figure 4: Patient Disposition – Post Implant Period (continued)**

## Analysis Sets

The study included different groups for analysis, which were planned ahead of time. Here's how they were defined:

- Intent-to-Treat (ITT) Group: This group includes everyone who signed the consent form to join the study.
- Modified Intent-to-Treat (mITT) Analysis Set: This group includes all patients who had an attempt to place the implant.
- Responder Group: This group includes people who got the implant and showed good results at their check-up visits on Day 28 or Day 42 after the implant.
- Per Protocol (PP) Group: This group includes people who had the implant and didn't break any important study rules that could affect the results. Who was in this group was decided before the analysis.
- Worst Case Group: In this group, the study assumes that anyone with missing data didn't have success with the treatment.

## Patient Demographics and Baseline Characteristics

### *Demographics*

**Table 1** shows the basic information about the people in the study. For those who had the implant attempted, the average age was 60.4 years old (SD ±10.2) with an average BMI of 29.5 $kg/m^2$ (SD ±5.1).

**Table 1: Baseline Demographics**

| Baseline Characteristics | mITT (n = 130) |
|---|---|
| **Age (years)** | |
| N | 130 |
| Mean ± SD | 60.4 ± 10.2 |
| Median | 61.0 |
| Min, Max | 21.0, 83.0 |
| **BMI** | |
| N | 130 |
| Mean ± SD | 29.5 ± 5.1 |
| Median | 29.0 |
| Min, Max | 18.0, 39.0 |
| **Gender (n/N (%))** | |
| Female | 128/130 (98.5) |
| Male | 2/130 (1.5) |
| **Race (not mutually exclusive, n/N (%))** | |
| American Indian or Alaska Native | 0/130 (0.0) |
| Asian | 0/130 (0.0) |
| Black or African American | 5/130 (3.8) |
| Native Hawaiian or Other Pacific Islander | 0/130 (0.0) |
| White | 124/130 (95.4) |
| Other | 2/130 (1.5) |
| **Ethnicity (n/N (%))** | |
| Hispanic or Latino | 10/130 (7.7) |

| Baseline Characteristics | mITT (n = 130) |
|---|---|
| Not Hispanic or Latino | 120/130 (92.3) |

### *Incontinence History*

**Table 2** shows details about the incontinence history of participants at the start of the study. Among those who had the implant attempt, 93.8% were found to have overactive bladder (OAB), and 89.2% had a diagnosis of UUI at the beginning. At the same time, 38.5% of these participants had mixed incontinence, with UUI being their main issue. In addition, 10% reported having fecal incontinence, while 50.8% experienced frequent urination, and 44.6% had trouble with nighttime urination.

**Table 2: Incontinence History**

| Incontinence History (Not mutually exclusive) n/N (%) | mITT (n = 130) |
|---|---|
| Overactive bladder (OAB) | 122/130 (93.8) |
| Stress urinary incontinence (SUI) | 52/130 (40.0) |
| Urinary Urge incontinence (UUI) | 116/130 (89.2) |
| Mixed incontinence | 50/130 (38.5) |
| UUI predominates | 50/130 (38.5) |
| SUI predominates | 0/130 (0.0) |
| Other urinary incontinence | 1/130 (0.8) |
| Fecal incontinence | 13/130 (10.0) |
| Urinary Frequency | 66/130 (50.8) |
| Nocturia (Nighttime Urination) | 58/130 (44.6) |

*Note: Multiple options are allowed to be selected for the same patient. In this table, 116 mITT patients out of 130 had a diagnosis of UUI for their incontinence history. An additional eight (8) subjects had mixed incontinence with UUI predominating, indicating that they also had UUI. The remaining six (6) subjects that did not have UUI or mixed incontinence did have an OAB diagnosis; given that the subjects also had to have four UUI episodes in 72 hours, they would need to have OAB with associated UUI. Consequently, all subjects in the mITT analysis had a history of UUI.

### *UUI Treatment History*

People in the study had an average of 4.5 bladder leaks per day (± 2.5 SD). **Table 3** shows how the mITT patients were grouped based on how bad their UUI symptoms were at the start.

**Table 3: Baseline UUI episodes per day**

| **Baseline UUI episodes per day** | **mITT (n = 130)** |
|---|---|
| Mild (<3 UUI episodes per day) | 41/130 (31.5%) |
| Moderate (3-5 UUI episodes per day) | 42/130 (32.3%) |
| Severe (>5 UUI episodes per day) | 47/130 (36.2%) |

**Table 4** shows the treatments they had tried for UUI before the study. Out of those who tried the implant, 90.8% (118 out of 130 people) had used medicines for UUI at some point. 71.5% (93 out of 130) had used antimuscarinic medicines such as tolterodine, and 43.8% (57 out of 130) had tried β3 agonist medicines, like mirabegron and vibegron. One person had used sacral nerve stimulation (0.8%), 8.5% (11 out of 130) had tried tibial nerve stimulation, and 10.8% (14 out of 130) had used Botox treatments for UUI.

**Table 4: UUI Treatment History at Baseline**

| UUI Treatment History (n/N (%)) | Enrolled (n = 242) | mITT (n = 130) |
|---|---|---|
| Current or previous use of any medication to treat UUI | 187/242 (77.3) | 118/130 (90.8) |
| Use of antimuscarinics to treat UUI | 149/242 (61.6) | 93/130 (71.5) |
| Previously Used But Discontinued | 112/242 (46.3) | 70/130 (53.8) |
| Currently Using | 34/242 (14.0) | 23/130 (17.7) |
| No Response Given | 3/242 (1.2) | 0/130 (0.0) |
| Use of β3 agonist to treat UUI | 99/242 (40.9) | 57/130 (43.8) |
| Previously Used But Discontinued | 76/242 (31.4) | 41/130 (31.5) |
| Currently Using | 19/242 (7.9) | 14/130 (10.8) |
| No Response Given | 4/242 (1.7) | 2/130 (1.5) |
| Sacral Nerve Stimulation | 1/242 (0.4) | 1/130 (0.8) |
| Tibial Nerve Stimulation | 16/242 (6.6) | 11/130 (8.5) |
| Botulinum neurotoxin type-A (BoNT-A) | 19/242 (7.9) | 14/130 (10.8) |

## Safety Results

Safety was checked by looking at all the adverse events people had during the study. For the 12 months after it was implanted, a total of 338 adverse events happened in 108 out of 130 people (83.1%), and there were 27 serious adverse events in 21 out of 130 people (16.2%). There were no serious adverse events caused by the device and only one of these serious adverse events might have been linked to the implant procedure.

There were 27 adverse events related to the device in 21 out of 130 people (16.2%) and 21 adverse events related to the procedure in 19 out of 130 people (14.6%). Thirteen of these adverse events were definitely caused by the device, and one was definitely caused by the procedure.

During the study, there were 2 broken devices, 5 devices that moved out of place in 4 people, 4 devices that needed fixing, and 15 devices that were taken out by the 6-month mark. By 12 months, there had been 5 device fixes and 21 devices that were taken out, but the number of broken devices and ones that moved out of place stayed the same as at 6 months. Most of the devices that moved out of place did so in the first month after being implanted. The two breaks happened on Day 26 and Day 63. One more device breakage happened after the 12 month data analysis occurred and was thought to occur due to a chiropractic therapy.

**Table 5** shows the adverse events with devices breaking, moving, or needing fixes through the 12-month period and the actions taken to address them.

**Table 5: Fractures, Migrations, and Revisions through 12 months**

| Events | Number of events | Number of patients | Notes |
|---|---|---|---|
| Device Migration | 5 | 4 | **Action Taken:**<br>3 – Revision<br>2 – Explant |
| Device Fracture | 2 | 2 | **Action Taken:**<br>1 – Revision<br>1 – Explant |
| Revisions | 5 | 5 | **Reason for Revision:**<br>2 – Device Migration<br>1 – Device Fracture and Migration<br>2 – Loss of Stimulation |
| Explants | 21 | 21 | **Reason for Explant*:**<br>11 – Patient Request<br>7 – Other Reason<br>2 – Loss of Stimulation<br>1 – Device Migration |

*Note: Study exit required a device explant per the study protocol.

**Table 6** shows the adverse events related to the device, and **Table 7** shows the adverse events related to the procedure through 12 months after it was implanted.

**Table 6. Device-Related Adverse Events through 12 months – mITT Analysis Set (N = 130)**

| | Events<br>n | Patients<br>n/N (%)[2] |
|---|---|---|
| **Total Device-Related Adverse Events[1]** | 27 | 21/130 (16.2%) |
| Device dislocation | 5 | 4/130 (3.1%) |
| Device stimulation issue | 3 | 3/130 (2.3%) |
| Device breakage | 2 | 2/130 (1.5%) |
| Implant site pain | 2 | 2/130 (1.5%) |
| Medical device pain | 2 | 2/130 (1.5%) |
| Medical device site burn | 2 | 2/130 (1.5%) |
| Anxiety | 1 | 1/130 (0.8%) |
| Back pain | 1 | 1/130 (0.8%) |
| Defecation urgency | 1 | 1/130 (0.8%) |
| Frequent bowel movements | 1 | 1/130 (0.8%) |
| Implant site rash | 1 | 1/130 (0.8%) |
| Micturition urgency | 1 | 1/130 (0.8%) |
| Pain in extremity | 1 | 1/130 (0.8%) |
| Procedural pain | 1 | 1/130 (0.8%) |
| Radicular pain | 1 | 1/130 (0.8%) |
| Urinary tract infection | 1 | 1/130 (0.8%) |
| Vulvovaginal pain | 1 | 1/130 (0.8%) |

[1] As coded by the Clinical Events Committee chairperson.

[2] Exact 95% confidence Interval.

**Table 7 Procedure-Related Adverse Events through 12 months – mITT Analysis Set (N = 130)**

| | Events<br>n | Patients<br>n/N (%)[2] |
|---|---|---|
| **Total Procedure-Related Adverse Events[1]** | 21 | 19/130 (14.6%) |
| Device dislocation | 3 | 2/130 (1.5%) |
| Implant site rash | 2 | 2/130 (1.5%) |
| Anxiety | 1 | 1/130 (0.8%) |
| Device breakage | 1 | 1/130 (0.8%) |
| Device stimulation issue | 1 | 1/130 (0.8%) |
| Dysphagia | 1 | 1/130 (0.8%) |
| Erythema | 1 | 1/130 (0.8%) |
| Frequent bowel movements | 1 | 1/130 (0.8%) |
| Hematemesis | 1 | 1/130 (0.8%) |
| Implant site discharge | 1 | 1/130 (0.8%) |
| Implant site pain | 1 | 1/130 (0.8%) |
| Mouth ulceration | 1 | 1/130 (0.8%) |
| Pain in extremity | 1 | 1/130 (0.8%) |
| Procedural headache | 1 | 1/130 (0.8%) |
| Radicular pain | 1 | 1/130 (0.8%) |
| Respiratory failure | 1 | 1/130 (0.8%) |
| Vomiting | 1 | 1/130 (0.8%) |
| Vulvovaginal pain | 1 | 1/130 (0.8%) |

[1]As coded by the Clinical Events Committee chairperson.

[2] Exact 95% confidence Interval.

**Table 8** shows device- and procedure-related AEs over time after the implant surgery, up to 12 months. The procedure-related AE that happened after 366 days was linked to removing the implant.

**Table 8: Device-Related AEs Over Time (from Implant Date) – mITT Analysis Set (N = 130)**

| Device-Related Adverse Events | Day 0 | Day 1-7 | Day 8-30 | Day 31-90 | Day 91-180 | Day 181-365 | Grand Total |
|---|---|---|---|---|---|---|---|
| **Grand Total** | **4** | **4** | **8** | **7** | **3** | **1** | **27** |
| Device dislocation | | | 5 | | | | **5** |
| Device stimulation issue | | 1 | | 1 | 1 | | **3** |
| Device breakage | | | 1 | 1 | | | **2** |
| Implant site pain | 1 | | | 1 | | | **2** |
| Medical device pain | 1 | | | 1 | | | **2** |
| Medical device site burn | | | | 1 | 1 | | **2** |
| Anxiety | | 1 | | | | | **1** |
| Back pain | | | 1 | | | | **1** |
| Defecation urgency | | | | 1 | | | **1** |
| Frequent bowel movements | 1 | | | | | | **1** |
| Implant site rash | | | | | 1 | | **1** |
| Micturition urgency | 1 | | | | | | **1** |
| Pain in extremity | | 1 | | | | | **1** |
| Procedural pain | | | | 1 | | | **1** |

| Device-Related Adverse Events | Day 0 | Day 1-7 | Day 8-30 | Day 31-90 | Day 91-180 | Day 181-365 | Grand Total |
|---|---|---|---|---|---|---|---|
| Radicular pain | | | 1 | | | | **1** |
| Urinary tract infection | | | | | | 1 | **1** |
| Vulvovaginal pain | | 1 | | | | | **1** |

**Table 9** shows procedure-related AEs as a function of time after implant through the 12-month visit database lock. The procedure-related AE that occurred after 366 days was related to an explant procedure.

**Table 9: Procedure-Related AEs Over Time (from Implant Date) – mITT Analysis Set (N = 130)**

| Procedure-Related AEs | Day 0 | Day 1-7 | Day 8-30 | Day 31-90 | Day 91-180 | Day 181-365 | Day 366+ | Grand Total |
|---|---|---|---|---|---|---|---|---|
| **Grand Total** | **6** | **7** | **6** | **0** | **0** | **1** | **1** | **21** |
| Device dislocation | | | 3 | | | | | **3** |
| Implant site rash | | 1 | | | | 1 | | **2** |
| Anxiety | | 1 | | | | | | **1** |
| Device breakage | | | 1 | | | | | **1** |
| Device stimulation issue | | 1 | | | | | | **1** |
| Dysphagia | 1 | | | | | | | **1** |
| Erythema | | | | | | | 1 | **1** |
| Frequent bowel movements | 1 | | | | | | | **1** |
| Hematemesis | 1 | | | | | | | **1** |
| Implant site discharge | | | 1 | | | | | **1** |
| Implant site pain | 1 | | | | | | | **1** |

| Procedure-Related AEs | Day 0 | Day 1-7 | Day 8-30 | Day 31-90 | Day 91-180 | Day 181-365 | Day 366+ | Grand Total |
|---|---|---|---|---|---|---|---|---|
| Mouth ulceration | 1 | | | | | | | **1** |
| Pain in extremity | | 1 | | | | | | **1** |
| Procedural headache | | 1 | | | | | | **1** |
| Radicular pain | | | 1 | | | | | **1** |
| Respiratory failure | | 1 | | | | | | **1** |
| Vomiting | 1 | | | | | | | **1** |
| Vulvovaginal pain | | 1 | | | | | | **1** |

## Effectiveness Result

### *Six-Months Results (Primary Endpoint)*

For subjects with an attempted implant (N=130), 82.9% of patients at Month 6 were responders (at least 50% fewer UUI events each day compared to how many they had before the implant). The study met the 50% performance goal at 6 months, as summarized in **Table 10.**

**Table 10. Responder Rate in UUI Summary at Month 6 – mITT Analysis Set (n=130)**

| | Estimate (%) | Lower 95% CI | Upper 95% CI | P-value (2-sided) |
|---|---|---|---|---|
| Patients with ≥ 50% reduction from baseline in UUIs per day | 82.9% | 76.4% | 89.4% | <0.0001 |

The main results were also checked for other groups in the study, as shown in **Table 11** below. For all implanted participants, the responder rate was 84.2%. For those who responded within 28 or 42 days, the rate was higher at 90.5%. For the group that followed the study rules properly (Per Protocol set), the responder rate was 86.2%. For the group where missing data was treated as not successful (Worst Case group), the responder rate was 80.8%.

**Table 11. Primary Endpoint for Various Analysis Sets at Month 6**

| Patients with ≥ 50% reduction from baseline in UUIs per day | Estimate (%) | Lower 95% CI | Upper 95% CI |
|---|---|---|---|
| Implanted (N=128) | 84.2%* | 77.8% | 90.5% |
| Responder (N=118) | 90.5%* | 85.1% | 95.8% |
| Per Protocol (N=117) | 86.2%* | 80.0% | 92.5% |
| Worst Case (mITT) (N=130)[1] | 80.8%* | 74.0% | 87.5% |

* $p<0.0001$;[1] The worst case assumes all missing responses are failures.

**Table 12** shows study outcomes at 6 months for study participants based on gender, age, race, how many UUI episodes they had before the implant, and where they live.

**Table 12: Primary Endpoint Subgroup Analysis at Month 6 – mITT Analysis Set (N = 130)**

| Patients with ≥ 50% reduction from baseline in UUIs per day | Estimate (%) | Lower 95% CI | Upper 95% CI |
|---|---|---|---|
| Female (N=128) | 82.6% | 76.0% | 89.2% |
| Male (N=2) | 100.0% | 100.0% | 100.0% |
| Age <65 years (N=94) | 82.9% | 75.2% | 90.5% |
| Age ≥65 years (N=36) | 83.0% | 70.6% | 95.4% |
| White (N=123) | 82.8% | 76.2% | 89.5% |
| All other races (N=7) | 83.9% | 55.2% | 100.0% |
| Baseline UUIs <8 (N=117) | 84.4% | 77.8% | 91.0% |
| Baseline UUIs ≥8 (N=13) | 69.2% | 44.1% | 94.3% |
| US (N=124) | 82.9% | 76.2% | 89.5% |
| EU[1] (N=6) | 83.3% | 53.5% | 100.0% |

**Table 13** gives information about how well the treatment worked for other measures of urinary problems at 6 months.

**Table 13. Secondary Effectiveness Results at Month 6 – mITT Analysis Set (N=130)**

| Effectiveness Measure (n=130) | Month 6 | p-value |
|---|---|---|
| Reduction from baseline in the mean number of UUI episodes per day | 3.28 ± 2.53 | p<0.0001 |
| Improvement from baseline in ICIQ-OABqol score | 35.24 ± 9.11 | p<0.0001 |
| Percentage of patients who experienced an improvement in ICIQ-OABqol of at least 10 points (compared to a 50% performance goal) | 91.9% | p<0.0001 |
| Reduction from baseline in Urgent Episodes | 1.21 ± 2.77 | p<0.0001 |
| Reduction in average number of daily voids in patients with at least 8 voids at baseline | 1.65 ± 5.23 | p = 0.0006 |

For the secondary effectiveness endpoints in **Table 13,** the first three endpoints supported the findings the treatment can improve UUI symptoms. The reported changes of 1.21 ± 2.77 in urgency episodes and 1.65 ± 5.23 in voids per day are not related to the UUI claim, and these data do not support safety and effectiveness of the device in treatment of urinary urgency and frequency.

### *Twelve-Months Results (Secondary Endpoint)*

For subjects who had the implant attempted (N=130), 77.7% of them at Month 12 showed improvement, with at least a 50% drop from their starting levels of daily UUIs. This is shown in **Table 14** below.

**Table 14. Responder Rate in UUI Summary at Month 12 – mITT Analysis Set (n=130)**

| | Estimate (%) | Lower 95% CI | Upper 95% CI |
|---|---|---|---|
| Patients with ≥ 50% reduction from baseline in UUIs per day | 77.7% | 70.4% | 85.0% |

This study also looked at how different groups of people responded at 12 months, as shown in **Table 15** below. For everyone who got the implant, 79.0% had at least a 50% drop in their daily UUIs. For those who were responders at 28 or 42 days, the rate was even higher—84.8%. In the Per Protocol group, which included people who followed the study rules properly, the rate was 82.1%. When researchers assumed that all missing data meant failure (Worst Case method), the response rate was 73.8%.

**Table 15. Responder Rate for Various Analysis Sets at Month 12**

| Patients with ≥ 50% reduction from baseline in UUIs per day | Estimate (%) | Lower 95% CI | Upper 95% CI |
|---|---|---|---|
| Implanted (N=128) | 79.0% | 71.7% | 86.2% |
| Responder (N=118) | 84.8% | 78.1% | 91.5% |
| Per Protocol (N=117) | 82.1% | 75.0% | 89.2% |
| Worst Case (mITT) (N=130)[1] | 73.8% | 66.3% | 81.4% |

[1] The worst case assumes all missing responses are failures.

**Table 16** shows study outcomes for study participants at 12 months based on gender, age, race, how many UUI episodes they had before the implant, and where they live.

**Table 16: Responder Rate Endpoint Subgroup Analysis at Month 12 – mITT Analysis Set (N = 130)**

| Patients with ≥ 50% reduction from baseline in UUIs per day | Estimate (%) | Lower 95% CI | Upper 95% CI |
|---|---|---|---|
| Female (N=128) | 77.4% | 70.0% | 84.8% |
| Male (N=2) | 100.0% | 100.0% | 100.0% |
| Age <65 years (N=94) | 82.1% | 74.3% | 90.0% |
| Age ≥65 years (N=36) | 66.3% | 50.4% | 82.1% |
| White (N=123) | 78.9% | 71.5% | 86.3% |
| All Other Races (N=7) | 57.1% | 20.5% | 93.8% |
| Baseline UUIs <8 (N=117) | 79.5% | 72.0% | 87.0% |
| Baseline UUIs ≥8 (N=13) | 61.5% | 35.1% | 88.0% |
| US (N=124) | 77.5% | 70.0% | 85.0% |
| EU (N=6) | 83.3% | 53.5% | 100.0% |

**Table 17** gives information about how well the treatment worked for other measures of urinary problems at 12 months.

**Table 17. Secondary Effectiveness Results at Month 12 – mITT Analysis Set (N=130)**

| Effectiveness Measure (n=130) | Month 12 |
|---|---|
| Reduction from baseline in the mean number of UUI episodes per day | 2.96 ± 2.57 |
| Improvement from baseline in ICIQ-OABqol score | 31.76 ± 22.50 |
| Percentage of patients who experienced an improvement in ICIQ-OABqol of at least 10 points (compared to a 50% performance goal) | 84.4% |
| Reduction from baseline in Urgent Episodes | 1.14 ± 2.70 |
| Reduction in average number of daily voids in patients with at least 8 voids at baseline | 1.67 ± 5.17 |

## Conclusions

### *Effectiveness Conclusions*

The clinical study shows that the Neuspera SNM System helps people who with UUI and have not had success with more conservative treatments. At 6 months, 82.9% of patients had their daily episodes of UUI cut by at least half, and by 12 months, 77.7% showed the same improvement.

Other measures in the study, like fewer UUI episodes and better scores on the ICIQ-OABqol quality of life questionnaire, also helped show that the Neuspera SNM System helps with UUI symptoms.

### *Safety Conclusions*

In the clinical study for the Neuspera SNM System, no serious device adverse events were caused by the device itself, but there was one serious issue related to the procedure. After 12 months, 27 device-related adverse events happened in 21 out of 130 people (16.2%), and 21 procedure-related adverse events happened in 19 out of 130 people (14.6%).

The most common device-related adverse events were the device moving out of place (3.1% of people), issues with device stimulation (2.3%), the device breaking (1.5%), pain at the implant site (1.5%), pain from the device (due to high levels of stimulation or after a fall; 1.5%), and a burn at the device site (when patients placed the WT directly on their skin; 1.5%). Other device-related adverse events happened in less than 1% of people. No infections at the implant site were reported.

By 12 months, there were two cases where the device broke, five cases where the device moved in four people, five surgeries to re-implant the device, and 21 devices that were removed. The majority of the devices that moved did so within the first month of being implanted, and the two devices that broke did so in the first few months. However, one additional device broke after 12-months and was attributed to chiropractic therapy.

## Trial System Implantation Procedure

The Neuspera Trial System may be implanted in office or in the operating room. You will be given local anesthesia in the area of skin over the targeted area. You will be lying face down during your surgery. A needle and mild electrical pulses will be used to find the right place in your back for the neurostimulator; fluoroscopy may also be used to help find the right device placement. The needle will be inserted into your back, and then mild electrical pulses will be sent from the needle to the sacral nerve, which should cause some movement in your buttocks or toes when placed correctly. Once the optimum sacral nerve stimulation location has been identified, a Trial Lead is placed at the sacral nerve site, and an External Stimulator is connected. Appropriate Trial Lead placement is again verified by observing the appropriate patient responses. A second Trial Lead may be placed on the opposite side in the same manner, to determine which side leads to the best improvement in your UUI symptoms. After the clinician sees that the device is in the right place and working properly your incision will be closed and covered with a bandage. You will be provided all post procedure care instructions following your procedure.

## System Setup

Your system will be set up by your clinician or clinician's assistant according to your clinician's instructions before you leave the hospital or outpatient clinic following the placement of the trial lead(s) and the External Stimulator.

After pairing the External Stimulator to the Wireless Transmitter, pairing is

confirmed by checking the Blue “TEST” light and the green “PROGRAM” light. The green “PROGRAM” light indicates that the Wireless Transmitter is transmitting to the External Stimulator while the blue “TEST” light signals when the External Stimulator is receiving and responding to the communication from the Wireless Transmitter.

Either a representative of Neuspera or the clinic will explain how each component works. The Neuspera System requires no specialized skills or knowledge for patient use.

If you have any problems using any part of the system, contact your clinician/clinic.

### Visiting the Clinic

Please bring your Wireless Transmitter, Charging Pad, magnet, and Patient Controller with you to all follow-up visits. Your clinician may also need to modify the programs and/or update the software to improve therapy.

## Trial System Use

The Trial System is intended to be used continuously during the stimulation trial. If the trial stimulation is successful, you can choose to proceed to receive a permanent system.

With the permanent system, most patients see improvements in their urinary urge

incontinence symptoms with two hours of therapy a day. For additional information on the safety and effectiveness data for the Neuspera System, see the Neuspera Summary of Clinical Evaluations.

- **NOTE:** Electrical stimulation may not cure patients' urinary urge incontinence symptoms entirely. Instead, it is expected to reduce the symptoms and improve day to day life.
- **NOTE:** For the best evaluation of SNM therapy, it is important to follow the described operating use of your Neuspera System.
- **NOTE:** If your Wireless Transmitter was stored at very hot or very cold temperatures (such as in your car during cold winters or hot summers), let it reach room temperature prior to use. Depending on the storage temperature, this could take up to 5 hours. Do not use heating or cooling devices to heat or cool your Wireless Transmitter; let it come to room temperature on its own.

## Before Use

Inspect the Wireless Transmitter for cracks, holes, or other damage that may expose the internal circuitry or allow water inside. Do not use if there is any damage.

### *Charging the Wireless Transmitter (WT)*

Ensure the charging pad is plugged in and place the Wireless Transmitter on the

charging pad as shown in **Figure 5**. The Wireless Transmitter can only charge if the dotted white side is facing up and the logo/label side is facing down (i.e., device is “upside-down”). You will see a light on the charging pad when charging. Leave the Wireless Transmitter on the charging pad when it is not in use If the charging pad light does not indicate the Wireless Transmitter is charging, contact your clinician for assistance.

- **NOTE:** The Wireless Transmitter is unavailable for use while charging.

A. Make sure charging pad is connected to power and in the correct orientation*.

B. Place Wireless Transmitter on the charging pad with the white dotted side up and the label/Neuspera logo facing down as shown below.

Light on the edge of the charging pad indicates Wireless Transmitter is charging.

Incorrect orientation - Wireless Transmitter will not charge if the label/Neuspera logo is facing up.

C. Confirm charging pad status light* indicates charging has started.

D. If charging has not started or there is an error indicated by the charging pad status light*, refer to the troubleshooting section.

**If needed, refer to instructions for charging pad provided by manufacturer*

**Figure 5. Charging the Wireless Transmitter**

■ **NOTE:** Your Wireless Transmitter will turn on as soon as it is removed from its charging pad. If you are not putting it on immediately, use your Patient Controller to turn it off (see **"Stopping/Starting Stimulation"** ) or use the magnet to turn it off. Keeping it turned off until you are ready to use it will ensure that it has enough battery power when you need it.

## Patient Controller

The Patient Controller (see **Figure 6** and **Figure 7** below) is a handheld device you and your doctor can use to adjust your therapy.

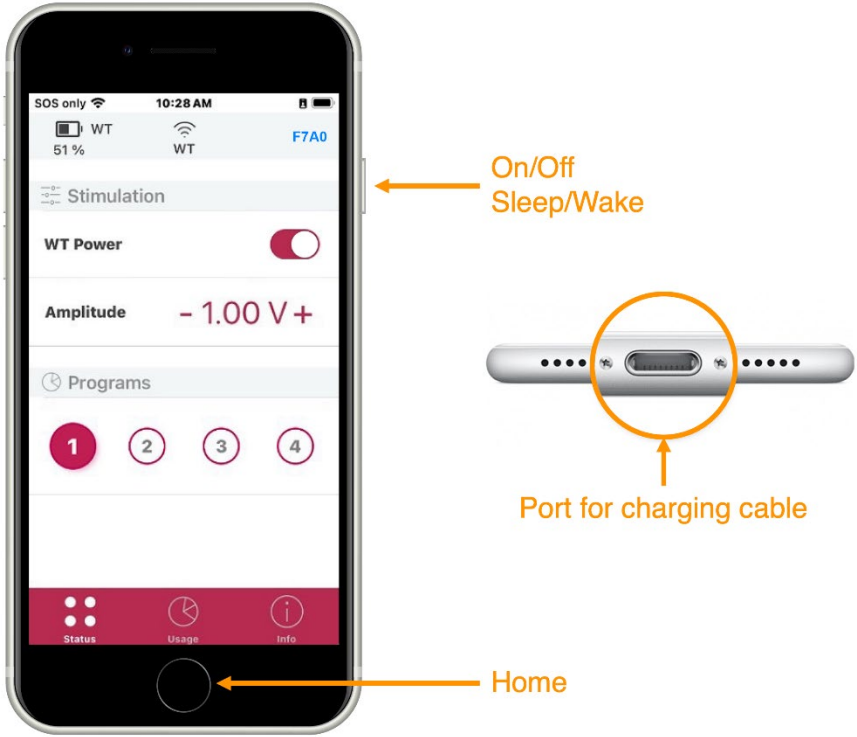



**Figure 6. Patient Controller**

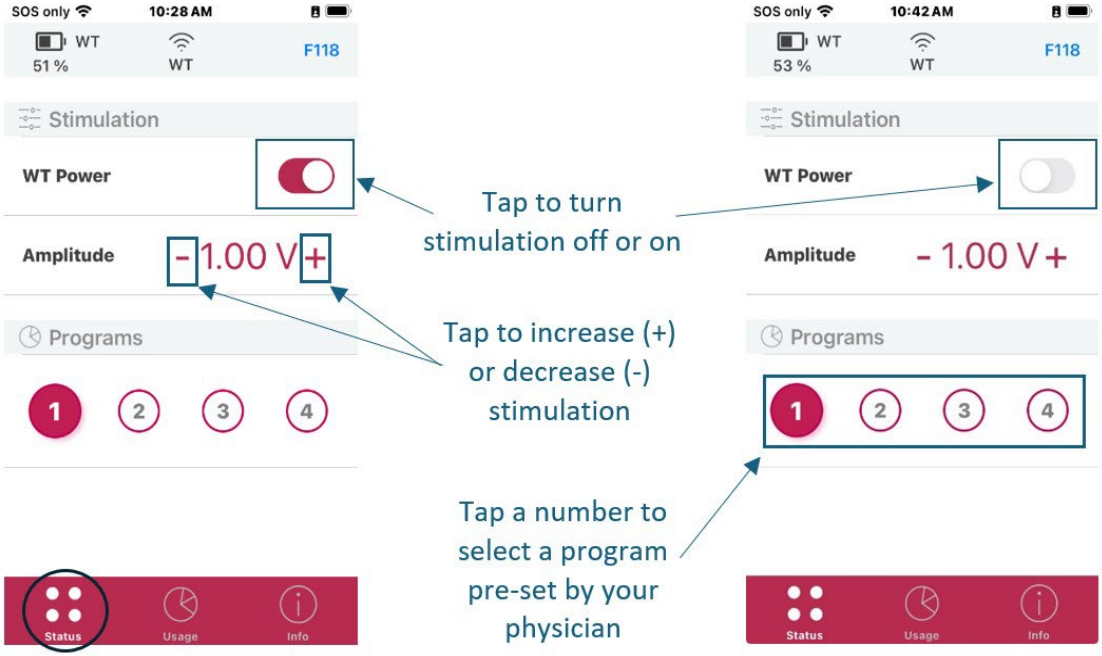



**Figure 7. Patient Controller Screen - Adjusting stimulation settings and stopping stimulation. Left image: Stimulation on. Right image: Stimulation off.**

## Stopping/Starting Stimulation

The trial stimulation is intended to be continuous and does not require the Wireless Transmitter to be in place for the stimulation. You may need to stop or start stimulation if you become uncomfortable with the continuous stimulation or need to make adjustments and this will require use of the Wireless Transmitter.

If you need to stop or start stimulation, follow these steps:

- Place your Wireless Transmitter over your External Stimulator. Make sure that the Wireless Transmitter is charged and that the magnet is removed prior to placing the Wireless Transmitter over the External Stimulator.
- Turn on your Patient Controller.
- Ensure that the Wireless Transmitter is ON.
- You can stop stimulation with the Patient Controller by tapping the Power "switch" to move it to the off position (right image, see **Figure 7**).
- Turn off the Patient Controller.

■ **NOTE: If stimulation is uncomfortable at any time and needs to be stopped immediately, the Orange U-Clip on the External Stimulator can be pulled back to immediately stop stimulation. However, because this action may cause the Trial Lead to be dislodged, use this method only in urgent cases.**

■ **NOTE:** There are no sensors in the External Stimulator. If a cable attached to the External Stimulator is broken, contact your clinician and use the other side, if

available.

■ **NOTE:** You do not need to keep your WT over your External Simulator for stimulation to continue.

## Changing Stimulation Amplitude

You should change the stimulation level if:

- Therapy is painful – decrease stimulation level
- You do not feel any "tingling" – increase stimulation level until you begin to feel the tingling.

To change stimulation levels, follow these steps:

- Place your Wireless Transmitter over your External Stimulator. Make sure that the Wireless Transmitter is charged and that the magnet is removed prior to placing the Wireless Transmitter over the External Stimulator.
- Turn on your Patient Controller.
- Ensure that the Wireless Transmitter is ON.
- Adjust your stimulation level (see **Figure 7**) from the Status screen on your Patient Controller.
    - Click the (-) button to decrease stimulation
    - Click the (+) button to increase stimulation
- Once the stimulation is at a comfortable level, either replace the magnet on the

Wireless Transmitter, or place the Wireless Transmitter back on the charging pad. Stimulation will continue with the Wireless Transmitter removed.

- Turn off the Patient Controller.

■ **NOTE:** Keep your Patient Controller at least 10 centimeters (4 inches) away from your Wireless Transmitter when in use. Your Patient Controller may interfere with the communication between your Wireless Transmitter and External Stimulator.

## Changing Stimulation Programs

You should change the stimulation programs as directed by your clinician.

To change stimulation programs, follow these steps:

- Place your Wireless Transmitter over your External Stimulator. Make sure that the Wireless Transmitter is charged and that the magnet is removed prior to placing the Wireless Transmitter over the External Stimulator.
- Turn on your Patient Controller.
- Ensure that the Wireless Transmitter is OFF to ensure that the change of program does not cause unwanted jolting sensations.
- Select a new Program (see **Figure 7**) from the Status screen on your Patient Controller.
- Turn on the External Stimulator using the Wireless Transmitter and Clinician Programmer.

- Adjust the Amplitude level to comfortably feel stimulation.
- Once the stimulation is at a comfortable level, either replace the magnet on the Wireless Transmitter, or place the Wireless Transmitter back on the charging pad. Stimulation will continue with the Wireless Transmitter removed.
- Turn off the Patient Controller.

## Charging Your Patient Controller

1. Plug charging cable into a USB outlet.
2. Insert charging cable into the bottom of the Patient Controller.
3. You should see a lightning bolt in the battery icon if the device is charging.

## Checking Wireless Transmitter and Patient Controller Battery Levels

You can check the battery level of your Wireless Transmitter and Patient Controller from any screen on your Patient Controller. The Wireless Transmitter battery level is in the upper left corner. The Patient Controller battery level is in the upper right corner (see **Figure 8**).

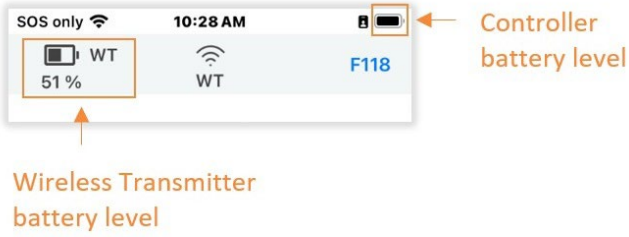



**Figure 8. Checking battery levels**

# Care of Your System

## Cleaning the Wireless Transmitter

**CAUTION:** The Wireless Transmitter is water-resistant but should not be submerged. Submerging it in water or other cleaning liquids may cause it to malfunction.

**CAUTION:** Do not use harsh cleaning chemicals to clean the Wireless Transmitter since they may damage the case.

For your safety and hygiene, it is recommended that you inspect your Wireless Transmitter for damage prior to use. Look for any signs of damage such as cracking or holes that may expose the internal circuitry or allow water to get inside. To clean your Wireless Transmitter, use a damp cloth and mild soap (such as liquid dish soap).

## Cleaning the Magnet, Charging Pad and Patient Controller

Use a soft, dry, lint-free cloth to clean the magnet, charging pad and Patient Controller as needed. Avoid getting liquid in any openings.

# Troubleshooting

If you have difficulty with your Trial System, please contact your clinician right away.

# Other Information

## Electronic Article Surveillance

Electronic article surveillance/anti-theft systems such as those at the point of sale and entrances/exits of stores, libraries, banks, etc., emit signals that may interact with your Neuspera Trial System. It is very unlikely that these systems will interact significantly. The most likely effect is the WT or External Stimulator may turn off momentary and therapy may need to be reinitiated through the app (see Figure 6). To minimize the possibility of interaction, however, walk through these areas at a normal pace and avoid lingering near or leaning on these systems.

## TSA and Other Security Screening

You should not be screened by a walk-through metal detector with the Trial System.

Inform the security officer that you have an internal medical device and ask to bypass the metal detector. You may need to undergo a manual ("pat-down") screening. If you must walk through the security system, turn off system communications using your Patient Controller.

*The TSA notification card template can be found on their website: https://www.tsa.gov/sites/default/files/disability_notification_card_508.pdf.

It is recommended to fill this out by stating you have an internal medical device. Bring the card with you to security.

## Technical Details

### *External Stimulator*

The External Stimulator is a single-use, non-rechargeable, external device, that provides electrical pulses to stimulate the sacral nerve root by the Trial Lead for up to 7 days. The External Stimulator is placed on an adhesive ground pad on the patient's back for the trialing period (up to 7 days). The External Stimulator may also be covered with a transparent adhesive to ensure that it is secured and protected during the stimulation trial.

The External Stimulator meets the following specifications:

| Stimulation Parameter | Neurostimulator Specification |
|---|---|
| Control mode | Voltage-driven |
| Amplitude | 0.2-4.8 V |
| Pulse width duration | 105-945 microseconds |
| Pulse frequency | 5-100 Hz |
| Mode | Continuous or Cycling |
| **Water resistance** | IP56 (Protected from limited dust ingress. Protected from high pressure water jets from any direction) |

### *Trial Lead*

The Trial Lead is a temporary trial lead with a single electrode that allows the electrical pulses from the External Stimulator to be delivered to the sacral nerve. The Trial Lead is placed percutaneously through a needle. The Trial Lead is 34 cm long and has a diameter of 0.84 mm. The contact is 7.4 mm in length. The electrode is placed through the sacral foramina to stimulate the sacral nerve root; the remainder of the Trial Lead exits the skin to be connected to the Neuspera External Stimulator. A second Trial Lead may be placed on the contralateral side, and both Trial Leads may be connected to one Neuspera External Stimulator.

### *Wireless Transmitter (WT)*

The Wireless Transmitter communicates wirelessly with the External Stimulator and the Patient Controller. The Wireless Transmitter contains two antennae. One antenna allows communication to the External Stimulator. This antenna must be directly over (within 3 cm) the External Stimulator to communicate. The other antenna connects to the Patient Controller using Bluetooth® technology. The Wireless Transmitter is powered by a rechargeable lithium-ion battery that is recharged on a wireless charging pad.

| | |
|---|---|
| Battery capacity | ≥2000 mAh |
| Battery capacity (therapy time) | Minimum 2 hours (will vary with therapy) |
| Time for full recharge | ≤5 hours |
| Maximum operating temperature (surface of Wireless Transmitter) | <60°C (140°F)* |
| Frequency range (implant powering) | 902–928 MHz (ISM compliant) |
| Frequency range (Bluetooth) | 2.4–2.5 GHz |
| Water resistance | IP25 (Protected from touch by fingers and objects greater than 12 millimeters. Protected from low pressure water jets from any direction) |
| Diameter | 8 cm (3.1 inches) |
| Thickness | 15 mm (0.6 inches) |
| Weight | 103 g |

**If the Wireless Transmitter reaches 60°C, it will stop transmission until it cools down.*

### *Power Transmission Frequency Range*

Your Wireless Transmitter communicates best with your External Stimulator in the 902 - 928 MHz industrial, scientific, and medical (ISM) frequency band specifically allocated for use by medical devices in North America.

### *Charging Pad and Patient Controller*

The charging pad and Patient Controller hardware (iPhone) are standard consumer electronics. See manufacturer's manuals for additional information on these devices. Both of these devices may be charged from USB (2.0 or 3.0 ports) or 120V and 240V power mains (standard wall outlet).

The iPhone (“Patient Controller”) has been specially configured to maintain security of the Neuspera patient software application (“App”) used to control your Wireless Transmitter. Your Patient Controller can only communicate with your Wireless Transmitter.

### *System Compliance to Standards*

| | |
|---|---|
| External Stimulator | IEC 60601-1 (Type BF Applied Part)<br>IEC 60601-1-6<br>IEC 60601-1-11 |
| Wireless Transmitter | IEC 60601-1 (Type BF Applied Part)<br>IEC 60601-1-6<br>IEC 60601-1-11<br>IEC 62133-2 (battery) |
| Patient Controller | IEC 60950-1 |
| Charging pad | FCC Part 15 Subpart C 15.209 |

## Service Life

The components of the Neuspera Trial System are expected to last 7 days. If the trial is successful, some of the components, such as the Wireless Transmitter and Patient Controller, may also be used by the same patient for the permanent Neuspera SNM System. Refer to the permanent Neuspera SNM System manuals for information on the shelf life of these components.

## Safe Disposal

All components of your system (Wireless Transmitter, Patient Controller, magnet and charging pad) should be returned to your clinician/clinic for disposal. Your data will be extracted for your patient record, and all personal information will be erased.

## Operating, Storage, and Transportation Conditions

The Wireless Transmitter and Patient Controller both run on lithium-ion batteries. These devices are designed to be used and stored in the following conditions:

| Operating Temperature Range | | Storage and Transportation Temperature Range |
|---|---|---|
| Wireless Transmitter | 5°C to 35°C (41°F to 95°F)* | -25°C to 55°C (-13°F to 131°F)** |
| Patient Controller | 0°C to 35°C (32°F to 95°F) | -20°C to 45°C (-4°F to 113°F) |
| External Stimulator | 5°C to 40°C (41°F to 104°F)* | -25°C to 55°C (-13°F to 131°F)** |

***NOTE:** The operating conditions of the Wireless Transmitter and External Stimulator are within a relative humidity range of 15% to 90%, non-condensing, but not requirement a water vapor partial pressure greater than 50 hPa, and an atmospheric pressure range of 700 hPa to 1,060 hPa.*

***NOTE:** The Wireless Transmitter may be exposed to temperatures as low as -30°C (–22°F) for up to 24 hours and may be stored at temperatures as high as 55°C (131°F) for up to one (1) month. Prior to using, the Wireless Transmitter should be allowed to come to room temperature (this may take up to 5 hours). The storage conditions of the External Stimulator are -25°C to +5°C, +5°C to +35°C at a relative humidity up to 90%, non-condensing, or +35°C to +55°C at a water vapor pressure up to 50hPa.*

The devices may be damaged and battery life shortened if used or stored outside these temperature ranges. Avoid exposing the devices to dramatic changes in temperature or humidity. Avoid leaving the Wireless Transmitter or Patient Controller in the car where temperatures can be extreme.

Avoid leaving the Wireless Transmitter and Patient Controller in wet areas (sinks, showers, tubs) or near sources of heat (stove, fireplace, radiant heaters).

The magnet and charging pad do not have restrictions on use or storage temperatures.

## Technical Maintenance

**WARNING:** No modification of the equipment is allowed. Modifying the equipment may make it unsafe.

**CAUTION:** Do not attempt to remove or replace the batteries in the Wireless Transmitter or Patient Controller.

No technical maintenance is required on any of the Neuspera Trial System components. See **"Care of Your System"** for general care of the components.

The Neuspera System components are not repairable by service personnel.

## Quality of Service and Security for Wireless Technology

### *Quality of Service*

The Neuspera System uses wireless communication between the External Stimulator and Wireless Transmitter, and between the Wireless Transmitter and Patient Controller and Clinician Programmer. The wireless service between the External

Stimulator and the Wireless Transmitter is in the 902-928MHz ISM band. The Wireless Transmitter should be placed directly over the External Stimulator within about an inch. All communication is verified for accuracy. Any communication containing uncorrectable errors are rejected and communication is retried automatically.

The wireless service between the Patient Controller or Clinical Programmer to the WT is in the 2.4-2.5 GHz ISM band utilizing the 802.15.4 standard. The typical communication range between the Patient Controller or Clinical Programmer and the Wireless Transmitter is 3 feet. Any communication containing uncorrectable errors are rejected and communication is retried automatically. The user is notified if the wireless link is dropped.

See troubleshooting section for additional information on addressing issues that may arise.

### *System Security*

After the Trial Lead is implanted and External Stimulator is placed, the Wireless Transmitter will be uniquely paired to your External Stimulator and Patient Controller (see **Figure 9**).

The Wireless Transmitter communicates with the Patient Controller App in the Patient iOS device over a Bluetooth LE (BLE) link. The data over this BLE link is also encrypted and authenticated. The Patient Controller App is downloaded onto the Patient iOS device over WiFi.

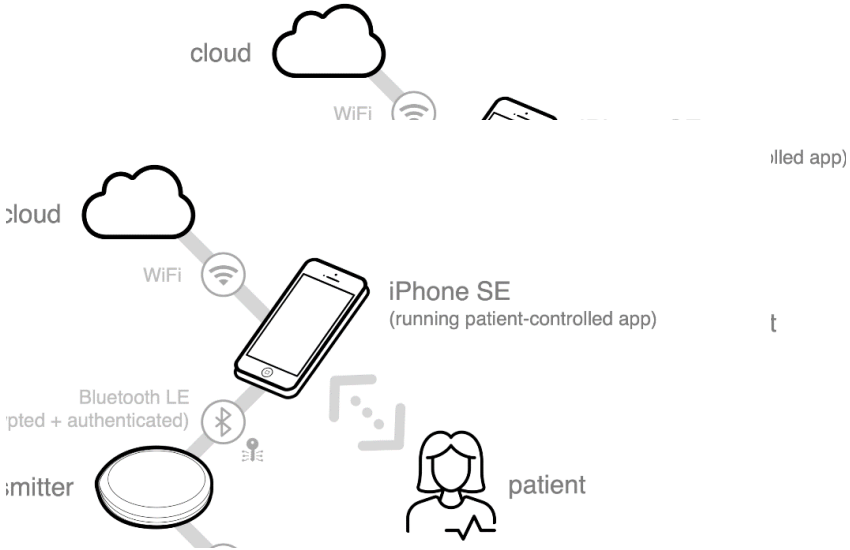



**Figure 9. Schematic of authenticated connections/communications**

### *Device Features*

The Wireless Transmitter receives selected preprogrammed therapy configuration parameters from the Patient Controller. The Wireless Transmitter also receives complete therapy configuration from the Clinician Programmer. The Wireless Transmitter delivers power and therapy configuration to the External Stimulator.

Wireless Transmitter firmware updates are made wirelessly from the Clinician Programmer.

Powering of the External Stimulator is unique and cannot be accomplished with existing off the shelf components.

### *User Configurable Cybersecurity Controls*

There are no installable or user alterable security controls.

### *Secure Configuration*

An advanced cryptographically secure process is used to uniquely pair your External Stimulator to your Wireless Transmitter and the Wireless Transmitter to the Patient Controller. The Wireless Transmitter will only communicate with an authenticated paired Patient Controller. Only a single Patient Controller may be authenticated to link to a Wireless Transmitter. Only a single Wireless Transmitter may be paired to an Patient Controller at a time.

Data integrity checks are performed by the External Stimulator to ensure it only responds to the paired Wireless Transmitter.

### *Hardware, Software, Infrastructure Requirements*

The Neuspera SNM System is only supported on the hardware and software provided by Neuspera.

### *Password Requirements*

The user is recommended to set up a password through the iOS operating system for the Patient Controller.

### *Authentication*

A strong cryptographic challenge-response mechanism using symmetric cryptography has been implemented to authenticate each party. The Patient Controller will each pair through a different workflow of authorization. The Patient Controller must scan a generated barcode from a Clinician Programmer to pair to the Wireless Transmitter.

### *Network Ports*

There are no network ports except the WiFi connections in the Patient Controller.

### *Software Bill of Materials (SBOM)*

Contact the manufacturer by phone or email provided to access the human readable SBOM.

### *Updating of Application and Device Firmware*

When an update or patch is available for the Patient Controller App, a notification is sent to the patient about the availability along with a link to download. The patient can then download the Patient Controller App.

### *Backup and Restore*

No backup or restore function is provided.

### *Retention/Recovery of Device Configuration*

The Neuspera Trial System retains a log of therapy information within the Wireless Transmitter. Recovery of this information is not supported with loss of data.

### *Log Files*

The general log contains errors from various security functions, including authentication for troubleshooting and product investigations.

### *End of Support*

The Neuspera SNM System will continue to function to the end of the service life (see **“Service Life”**).

### *Decommissioning*

Data may be removed from the Patient Controller by uninstalling the Neuspera App and deleting the files. Data may be removed from the Wireless Transmitter by leaving the Wireless Transmitter off the charger for several sessions such that all data is overwritten.

## MRI Safety Information

Remove any Trial Leads and Trial System components from the patient before undergoing any MRI procedure. No Trial System components should enter the MRI room with the patient. The Clinician Programmer and Patient Controller, and accessory components including the External Nerve Stimulator Kit, foramen needles, and Wireless Transmitter have not been evaluated for safety in MRI and should be considered to be MR Unsafe. Do not bring them into the MR scanner room. ***Note****: See also the EMI Warnings and Precautions Section of this manual.*

## Electromagnetic Interference (EMI) Precautions

Electromagnetic interference (EMI) is a disruption caused by fields generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with Trial System function. Neurostimulators include features that provide protection from electromagnetic interference. Most electrical devices encountered in a normal day are unlikely to affect the operation of the Trial System. However, sources of strong EMI can result in the following:

- System damage, resulting in a loss of or change in symptom control and requiring Trial System replacement.
- Operational changes to the system causing the Neuspera Trial System to not turn on or off as expected. The Trial System can be turned on with the Patient Controller.

Removing the interference source or moving away from it should return the Neuspera

Trial System to normal operation.

Examples of EMI sources are:

- Switching mode power supplies
- Power substations
- MR imagers
- Cardiac devices
- Strong permanent magnets
- Defibrillators
- PET therapy
- Arc welders
- Theft detections/screening devices
- Plasma cutters

Seek medical guidance prior to entering environments which may adversely affect the operation of the Neuspera Trial System, including areas protected by a warning preventing entry to the area by patients with implanted medical devices.

### *EMC-Related Precautions*

Patients should wait until after their trial procedure is done and the Trial System is removed before having these procedures:

- Bone growth stimulators
- Dental drills and ultrasonic probes
- Electrolysis

Electromagnetic field devices – Patients should exercise care or avoid the following equipment or environments when undergoing a trial stimulation procedure with the

Neuspera Trial System:

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

*Note*: If patients suspect that equipment is interfering with trial system function, they should do the following:

- Move away from the equipment or object.
- If possible, turn off the equipment or object.
- Then, if necessary, use the Patient Controller App to return the Wireless Transmitter to the desired on or off state and amplitude.

- Inform the equipment owner or operator of the occurrence.

*Note*: If the above actions do not resolve the effects of the interference, or the patients suspect that their therapy is not effective after exposure to EMI, they should contact their clinician/clinic.

Patients should wait until after their trial procedure is done and the Trial System is removed before having these procedures:

- Laser procedures
- Psychotherapeutic procedures
- Radiation
- Transcutaneous electrical nerve stimulation (TENS)

- Avoid or move away from sources of electromagnetic interference (EMI) to prevent device malfunction (see **"Considerations for Locations with Electromagnetic Interference**" below).
- Diathermy (shortwave, microwave, or therapeutic ultrasound) and radiofrequency ablation should not be used with the Trial System in place because these procedures have not been evaluated to be safe and effective for patients with the Neurostimulator.
- Therapeutic ultrasound should not be used with the Trial System in place as the device can inadvertently concentrate the ultrasound field and cause harm.
- Therapeutic ionizing radiation can damage the electrical components of the Trial

System and any damage may not be immediately detectable.

- The Trialing System should be removed from the patient for all of the following procedures:
  - Computerized axial tomography (CT or CAT) scans.
  - External pressure used during some medical procedures may damage the External Stimulator which may require surgery to replace the device. During x-ray procedures that require external compression around the Trial Lead and External Stimulator, the x-ray equipment should be adjusted to limit the amount of pressure exerted on the External Stimulator.
  - Any procedure involving electrocautery
  - Magnetoencephalography (MEG)
  - Positron emission tomography (PET) scans
  - Diagnostic ultrasound
  - Transcutaneous electrical stimulation (TENS)
  - Psychotherapeutic procedures
  - Laser procedures
  - High-output ultrasonics or lithotripsy
- Avoid using diagnostic monitoring devices such as an electrocardiogram (ECG), Holter Monitor, or electroencephalogram (EEG) on patients undergoing a sacral nerve stimulation trial procedure with the Neuspera trial systems pulses from the

External Stimulator may be detected as an electrical signal. Wait until after their trial procedure is done and the Trial System is removed before having these procedures.

- The Neuspera System has not been tested for compatibility with other active implantable medical device such as neurostimulators, drug pumps, pacemakers, or internal defibrillators. Do not use the System with an active implantable device.
- The Neuspera System has not been tested for compatibility with cardiac defibrillation. If you have been defibrillated, contact your clinician to check the performance of your Neuspera System.
- Only use items with the Neuspera System that have been specified as part of the system or that have been specified as being compatible with the system.

### *Considerations for Locations and Environments*

#### *Home Environment*

**CAUTION:** Keep away from lint, dust, or directed sunlight, otherwise the Trial System may not function as specified.

This Neuspera system has been designed for use in the home environment. Patients use their devices primarily at home or at work; some do therapy during daily activities. Most household appliances and equipment that are working properly and grounded properly will not interfere with your Neuspera System.

The following equipment is generally safe if you follow these guidelines:

- Portable radio communications or wireless power transfer equipment (including accessories such as antenna cables and external antennas) should be used no closer than 30 centimeters (12 inches) to any part of your Neuspera Trial System when the Wireless Transmitter or Patient Controller are turned on. When used closer, the performance of the radio equipment may be affected
- Stereo speakers and radios for the home or car: Do not lift or carry speakers or radios near the Trial System.
- Induction range (a glass stovetop with burners under the surface): Keep the Trial System away from the burners while they are turned on.
- Power tools: Keep the motors away from the Trial System.
- Avoid close proximity to high power wireless power transfer equipment such laying between Electric Vehicle (EV) wireless chargers and the vehicle

The Trial System generates and radiate radio-frequency energy that may, in some instances, interfere with radio communications from other devices. If you suspect that your system is causing interference with other devices, turn off system communications using your Patient Controller.

### *Locations with Electromagnetic Interference (EMI)*

 **CAUTION:** If your Wireless Transmitter is damaged by EMI, you may experience excessive heating of the device and/or the area of your back near the Wireless Transmitter.

 **CAUTION:** Your Wireless Transmitter, Patient Controller, and charging pad emit EM. Use of these devices near other EM equipment may affect equipment performance. If use of your Neuspera Trial System near EM equipment is necessary, check that both your system and the equipment are operating normally.

 **CAUTION:** Portable radio communications or wireless power transfer equipment (including accessories such as antenna cables and external antennas) should be used no closer than 30 centimeters (12 inches) to any part of your Neuspera Trial System when the Wireless Transmitter or Patient Controller are turned on. When used closer, the performance of the radio equipment may be affected.

Equipment that emits large amounts of electromagnetic radiation (EM) may interfere with the proper functioning of your Neuspera Trial System. Examples of such equipment are:

- Switching mode power supplies
- Power substations
- MRI equipment

- Cardiac device
- Defibrillators
- Radiation equipment
- Arc welders
- Strong permanent magnets

### *Essential Performance*

The device has essential performance, as defined by IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed 3.2), of stimulation output charge balance and charge density. Performance of the device was maintained during electromagnetic disturbance testing.

### *Recognized EMC Standards*

The device complies with the requirements for medical devices contained in

- IEC 60601-1-2:2014, 4th ed
- CISPR11:2015+AMD1:2016
- ANSI IEEE C63.27:2017
- IEC 60601-1-11:2015, 2nd ed.
- IEC /TR 60601-4-2:2016, 1st ed.
- ISO 14708-3:2017, 2nd ed.

### *Electromagnetic Emissions and Environment*

The Neuspera Trial System is intended for use in the electromagnetic environment specified below. The user of the Neuspera Trial System should make sure it is used in such an environment.

**Table 18. Guidance and manufacturer's declaration – electromagnetic emissions**

| **Emissions Test** | **Compliance** | **Electromagnetic Environment-Guidance** |
|---|---|---|
| RF Emissions<br>CISPR 11 Group 1 | Class B | The external stimulator uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause interference in nearby electronic equipment. |
| RF Emissions<br>CISPR 11 Group 2 | Class B | The Wireless Transmitter must emit electro-magnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |

**Table 19. Guidance and manufacturer's declaration electromagnetic immunity**

| Test and Method | Test Levels | Compliance level | Electromagnetic environment – guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV and ±15 kV air | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV and ±15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m at 50Hz/60Hz | 30 A/m at 50Hz/60Hz | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or professional healthcare environment. |
| Radiated RF IEC 61000-4-3 | 10 V/m<br>80 MHz to 2.7 GHz<br><br>Refer to table 3 for wireless proximity RF field test levels | 10 V/m<br>80 MHz to 2.7 GHz<br><br>Refer to table 3 for wireless proximity RF field test levels | |
| Radiated Fields in Close Proximity | 8 A/m CW<br>65 A/m, Pulse modulation 2.1 kHz | 8 A/m CW<br>65 A/m, Pulse modulation 2.1 kHz | |

| | | | |
|---|---|---|---|
| IEC 61000-4-39 | 7.5 A/m, Pulse modulation 50 kHz | 7.5 A/m, Pulse modulation 50 kHz | |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Neuspera SNM System is used exceeds the applicable RF compliance level above, the Neuspera SNM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Neuspera SNM System.

**Table 20. Guidance and manufacturer's declaration electromagnetic immunity**

| Test Frequency (MHz) | Band (MHz) | Service | Modulation | Immunity Test Level (V/m) | Compliance Level (V/m) |
|---|---|---|---|---|---|
| 385 | 380 - 390 | TETRA 400 | Pulse Modulation 18Hz | 27 | 27 |
| 450 | 430-470 | GMRS 460<br>FRS 460 | FM ± 5kHz deviation 1kHz Sine Wave | 28 | 28 |
| 710<br>745<br>780 | 704 - 787 | LTE Band 13 & 17 | Pulse Modulation 217 Hz | 9 | 9 |
| 810<br>870<br>930 | 800 - 960 | GSM 800/900<br>TETRA 800<br>iDEN 820<br>CDMA 850<br>LTE Band 5 | Pulse Modulation 18Hz | 28 | 28 |
| 1720<br>1845<br>1970 | 1700-1990 | GSM 1800<br>CDMA 1900<br>DECT<br>LTE Band 1,3,4,25, UMTS | Pulse Modulation 217 Hz | 28 | 28 |

| Test Frequency (MHz) | Band (MHz) | Service | Modulation | Immunity Test Level (V/m) | Compliance Level (V/m) |
|---|---|---|---|---|---|
| 2450 | 2400-2570 | Bluetooth<br>WLAN<br>802.11b/g/n<br>RFID 2450<br>LTE Band 7 | Pulse Modulation<br>217 Hz | 28 | 28 |
| 5240<br>5500<br>5785 | 5100 -5800 | WLAN 802.11 a/n | Pulse Modulation<br>217 Hz | 9 | 9 |

## Contact Your Clinician/Clinic

For assistance in setting up, using, or maintaining your Neuspera Trial system or to report unexpected operation or events, contact your clinician/clinic.

For questions regarding the Neuspera Trial System, contact our Customer Support Center toll-free at (888) 846-8332.

## Symbols

Explanation of symbols used on product or package labeling.

| Symbol | Description |
|---|---|
| REF | Catalog number |
| SN | Serial number |
| 1234 | Wireless transmitter identification number |
|  | Manufacturer |
|  | Refer to instruction manual |
|  | Magnetic Resonance (MR) Unsafe |
|  | Upper limit of temperature |
|  | Temperature limit |

| Symbol | Description |
| --- | --- |
|  | Humidity limitation |
| IP25 | Protected from touch by fingers and objects greater than 12 millimeters. Protected from low pressure water jets from any direction. |
| IP56 | Protected from limited dust ingress. Protected from high pressure water jets from any direction. |
| Rx only | Requires prescription in the United States |
|  | Non-ionizing electromagnetic radiation |
|  | Battery charge level |
|  | Wireless signal strength |
|  | Do not dispose of this product in the unsorted municipal waste |
|  | Type BF applied part |

## Glossary of Terms

Explanation of terms used on product or package labeling.

| Acronym/ Abbreviation | Term |
|---|---|
| EM / EMI | Electromagnetic / Electromagnetic Interference |
| IT | Information Technology |
| mA / µA | Milliamperes / Microamperes |
| MR / MRI | Magnetic Resonance / Magnetic Resonance Imaging |
| RF / RFID | Radiofrequency / Radiofrequency Identification |
| SNM | Sacral Neuromodulation |
| UUI | Urinary Urge Incontinence |
| USB | Universal Serial Bus |
| V | Volts |
| WT | Wireless Transmitter |

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